Smokers' Attempts at 'Harm Reduction'; Their Effectiveness and Associations With Cessation

Emma Victoria Beard

Department of Epidemiology and Public Health

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Declaration

The following work was carried out at the Department of Epidemiology and Public Health, University College London, under the supervision of Professor Robert West, Professor Ann McNeill and Professor Susan Michie. Chapter VI, with amendments, is under review for publication (Beard, Aveyard, McNeill, Michie & West, under review); Chapter VII, with amendments, has been published (Beard, McNeill, Aveyard, Fidler, Michie & West, 2011); Chapter VIII, with amendments, is under preparation for submission (Beard & West, unpublished); Chapter X, with amendments, has been published (Beard, McNeill, Aveyard, Fidler, Michie & West, in press); Chapter XI, with amendments, is under review for publication (Beard, McNeill, Aveyard, Fidler, Michie & West, under review); Chapter XII, with amendments, has been published (Beard, Fidler & West, 2011); Chapter XIII, with amendments, is under review for publication (Beard, Michie, Fidler & West, under review); Chapter XIV, with amendments, has been published (Beard, Vangeli, Michie & West, in press); Chapter XV, with amendments, has been published (Beard, McDermott, McEwen & West, in press). See Appendix K for copies of the papers which have been published. The results from Chapters VII, X and XI, have also been presented at the Division of Health Psychology Annual Conference (2009, 2010), the UK National Smoking Cessation Conference (2010, 2011), the Society for Research on Nicotine and Tobacco Conference (2010) and the European Conference on Tobacco or Health (2011).

This dissertation is my own work and contains nothing which is the outcome of work done in collaboration with others, except as specified above, where co-authors have been noted. Further collaborations include Belinda Iringe-Koko, who acted as a second coder for the review paper (see Chapter 5) and the interview study (Beard, Vangeli, Michie & West, in press), and Professor Paul Aveyard, who ensured that the meta-analyses and mediation analyses (see Chapters 6 & 11) were conducted accurately. Any auxiliary support is noted in the acknowledgements. My work was supported by the UK Centre for Tobacco Control Studies, a UKCRC Public Health Research Centre of Excellence.

Correspondence concerning this dissertation should be addressed to Emma Beard, emmavbeard@yahoo.co.uk

Signed: ………………………………………………………….

Printed name: Emma Victoria Beard

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Abstract

Interest has grown in the concept of using Nicotine Replacement Therapy (NRT) during attempts at smoking reduction (SR) and temporary abstinence (TA). This is partially due to data from clinical trials showing that the concurrent use of NRT and cigarettes can result in significant reductions in cigarette consumption, and increases the propensity of smokers to quit. However, it is not clear whether similar findings will emerge outside of that structured setting. Data are also limited on the acceptability among smokers of using NRT in these ways, and whether healthcare professionals will be opposed to offering such a strategy. This thesis aimed to address these issues using three methodologies: population-based surveys of English smokers; in-depth telephone interviews with smokers; and surveys of stop smoking practitioners and managers. More than 1/10th of smokers in England were found to be using NRT for SR and/or TA. Prevalence did not appear to have changed since 2007. The use of NRT for SR and/or TA was associated with greater probability of reporting a quit attempt and of subsequently stopping smoking, but any reduction in concurrent cigarette consumption was very small. Nicotine intake was similar whether smokers were or were not using NRT whilst smoking. This suggests that smokers may have instead been compensating for the additional nicotine attained from NRT by adapting the way they smoked their cigarettes. The interview study indicated a number of factors which may account for the lack of reductions in cigarette intake, including smokers' failure to set specific goals. A significant proportion of those working in stop smoking services did not agree with offering NRT for SR. Overall, the research reported in this thesis supports the idea that the use of NRT for SR and/or TA may promote cessation in the general population, but in itself is currently conferring little health benefit. Future research should examine the range of methods smokers use to reduce smoke exposure, and whether interventions which promote clear goal setting and monitoring of intake, such as through the use of expired carbon monoxide readings, can lead to effective SR.

Table of Contents

Declaration 2
Acknowledgements 4
Abstract 5
Preface 13
Chapter 1: General Introduction 23

Development of the Smoking Epidemic 23
Smoking and Health 24
Underlying Pathology of Nicotine Dependence 26
Theories of Dependence 28
Dependence as Loss of Control 28
Dependence as Rational Choice 31
Dependence as Non-Rational Choice 33
Dependence as a Learned Phenomenon 37
Dependence as Environmental 40
A Synthetic Theory of Dependence 41
Current Approaches to Tobacco Control 44
Influencing the Behaviour of Current Smokers or Potential Smokers 44
Limiting the Activities of the Tobacco Industry 47
The Need for a New Approach: Harm Reduction 49
Aims and Objectives of the Current Thesis 50

Chapter 2: History of Tobacco Harm Reduction and Defining Concepts 52

Defining Harm Reduction 52
The Emergence of a Harm Reduction Approach in Society 54
The Beginnings of Tobacco Harm Reduction 56
Taxonomy of Tobacco Harm Reduction Approaches 59
Producers as the Target 60
Others as the Target 64
Users as the Target 66

Chapter 3: A Potential Approach to Harm Reduction: Smoking Reduction and Temporary Abstinence 69

Estimates of Prevalence 69
Associated Characteristics 71
Extent of Reductions in Cigarette Consumption 74
Maintenance of Reductions in Cigarette Consumption 75
Reductions in Disease risk 76
Association With Attempts to Quit Smoking 79
Undermining Smoking Cessation 79
Promoting Smoking Cessation 82
Evidence to Date 84

Effect on Continuing Smokers and Non-Smokers 87

Chapter 4: Improving Smokers' Success of Attempts at Smoking Reduction and Temporary Abstinence: The Utility of Behavioural Support and Nicotine Replacement Therapy 88

Behavioural Interventions 88

Use of Nicotine Replacement Therapy 91

History of Nicotine Replacement Therapy 92

Licensing of Nicotine Replacement Therapy for Harm Reduction Purposes 93

Reductions in Cigarette Intake and the Association With Smoking Cessation 94

Chapter 5: Efficacy of Using Nicotine Replacement Therapy for Smoking Reduction and During Periods of Temporary Abstinence: A Meta-Analysis 98

Introduction 98

Methods 99

Search Strategies 99

Selection 100

Data Abstraction and Outcomes 100

Quality Assessment 101

Statistical Analysis 101

Results 103

Recruitment and Methodology 103

Participant Selection Criteria 110

Choice of Nicotine Replacement Therapy and Adherence 110

Percentage Reduction in Cigarette Consumption from Baseline 111

Point-Prevalence Reduction of 50% in Cigarette Consumption 111

Sustained Reduction of 50% in Cigarette Consumption 113

Reductions in Biomarkers 114

Quit Attempts 115

Seven-day Point Prevalence Cessation 115

Sustained Abstinence 116

Motivation to Quit 117

Rate of Reduction and Smoking Cessation 118

Nicotine Withdrawal/Urges to smoke 119

Quality of Life 119

Adverse Events 119

Views About Smoking Reduction and Nicotine Replacement Therapy 120

Excluded Studies 120

Discussion 122

Conclusion 130

Chapter 6: Effectiveness of Using Nicotine Replacement Therapy for Smoking Reduction and During Periods of Temporary Abstinence: A Systematic Review 131

Introduction 131

Methods 133

Search Strategies 133
Selection 134
Data Abstraction and Outcomes 134
Quality Assessment 135
Statistical Analysis 136
Results 136
Study Characteristics 136
Prevalence of Nicotine Replacement Therapy use 137
Extent and Stability of Nicotine Replacement Therapy use 142
Views About Smoking Reduction and Nicotine Replacement Therapy 142
Cigarette Consumption 142
Attempts to Quit Smoking and Smoking Cessation 143
Discussion 144
Conclusion 150
Chapter 7: The use of Nicotine Replacement for Smoking Reduction and During Periods of Temporary Abstinence: A National Survey of English Smokers 151
Introduction 151
Methods 158
Study Design and Sampling 158
Ethical Approval 159
Measures 159
Analysis 160
Parametric Assumptions 160
Statistical Analysis 162
Power 163
Results 164
Discussion 174
Conclusion 185
Chapter 8: The Combined use of Nicotine Replacement Therapy for Smoking Reduction and During Periods of Temporary Abstinence: A Re-Analysis of a National Survey of English Smokers 187
Introduction 187
Methods 192
Study Design and Sampling 192
Ethical Approval 192
Measures 192
Analysis 193
Parametric Assumptions 193
Statistical Analysis 194
Power 196
Results 196

Discussion 201

Conclusion 207

Chapter 9: A 'Split-ballot' Approach to Assess the Influence of Question Wording on Reports of Attempts at Smoking Reduction: A National Survey of English Smokers 208

Introduction 208

Methods 214

Study Design and Sampling 214

Ethical Approval 214

Measures 214

Analysis 215

Parametric Assumptions 215

Statistical Analysis 217

Power 218

Results 218

Discussion 224

Conclusion 229

Chapter 10: The use of Nicotine Replacement Therapy for Smoking Reduction and During Periods of Temporary abstinence: A Prospective National Survey of English Smokers 231

Introduction 231

Methods 236

Study Design and Sampling 236

Ethical Approval 236

Measures 236

Analysis 238

Parametric Assumptions 238

Statistical Analysis 239

Power 241

Results 241

Discussion 246

Conclusion 251

Chapter 11: Analysis of Mediating Variables in the Association Between the use of Nicotine Replacement Therapy for Harm Reduction and Attempts to Quit Smoking: A National Survey of English Smokers 252

Introduction 252

Increased Motivation to Quit 253

Increased Self-Efficacy 256

Decreased Rewarding Effects of Cigarettes 258

Methods 259

Study Design and Sampling 259

Ethical Approval 259

Measures 260

Analysis 261
Power 264
Results 264
Discussion 269
Conclusion 276
Chapter 12: The Association Between the use of Nicotine Replacement for Harm Reduction and Cotinine Levels: A National Survey of English Smokers 277
Introduction 277
Methods 281
Study Design and Sampling 281
Ethical Approval 281
Measures 281
Analysis 283
Parametric Assumptions 283
Statistical Analysis 285
Power 286
Results 286
Discussion 290
Conclusion 294
Chapter 13: Association Between the use of Nicotine Replacement Therapy During Various Periods of Temporary Abstinence and Attempts to Quit Smoking: A National Survey of English Smokers 295
Introduction 295
Methods 300
Study Design and Sampling 300
Ethical Approval 300
Measures 301
Analysis 302
Parametric Assumptions 302
Statistical Analysis 303
Power 305
Results 305
Discussion 311
Conclusion 316
Chapter 14: The use of Nicotine Replacement Therapy for Smoking Reduction and During Periods of Temporary Abstinence: An Interview Study 317
Introduction 317
Methods 319
Design and Procedure 319
Ethical Approval 320
Participants 320

Data Analysis 321
Reflexivity 322
Results 322
Themes 322
Additional Themes 340
Synthesis of the Major Themes 341
Discussion 344
Reductions in Cigarette Consumption 344
Preference for the Nicotine Patch 350
Other Themes 354
Limitations 356
Conclusion 357
Chapter 15: Beliefs of Stop Smoking Practitioners and Managers in England on the use of Nicotine Replacement Therapy for Smoking Reduction: A National Survey 358
Introduction 358
Methods 363
Study Design and Sampling 363
Ethical Approval 364
Measures 364
Analysis 366
Parametric Assumptions 366
Statistical Analysis 368
Power 368
Results 369
Discussion 378
Conclusion 385
Chapter 16: General Discussion 386
Summary of the Findings 386
Implications and Future Considerations 390
References 400
Appendix A 457
Appendix B 485
Appendix C 493
Appendix D 504
Appendix E 512
Appendix F 518
Appendix G 532
Appendix H 541
Appendix I 547
Appendix J 559
Appendix K 572

‘‘This year, the tobacco epidemic will kill nearly 6 million people. More than 5 million of them will be users and ex-users of smoked and smokeless tobacco and more than 600,000 will be non-smokers who were exposed to tobacco smoke. By 2030, the epidemic could kill 8 million’’

(World Health Organisation, 2011)

New ways in which to tackle the tobacco epidemic require consideration . . . is harm reduction a possible approach?

Preface

Tobacco control strategies have traditionally focussed on the prevention of uptake and abrupt cessation among smokers. However, in recent years recognition has grown regarding the need for newer approaches in order to tackle the worldwide tobacco issue. Numerous suggestions have been made, with the United Kingdom (UK) taking possibly one of the largest leaps forward, through the modification of the licensing of Nicotine Replacement Therapy (NRT). The UK now affords smokers who may be unwilling or unable to stop smoking the opportunity to use NRT for harm reduction purposes, which includes as a means to reduce cigarette consumption and simply to tide them over when they are unable to smoke. This decision was based largely on the findings from randomised controlled trials that the use of NRT as part of a smoking reduction programme increases the propensity of smokers to quit, and induces significant reductions in cigarette consumption. Proposals have also been put in place to extend English stop smoking services, which are currently based on the cessation only model, to additionally offer harm reduction strategies as a route to quit.

Although other countries are following suit, with many having already adopted the indication of NRT for periods of temporary abstinence, others appear to be largely opposed to such an approach. Even before the change in licensing of NRT so that it could be used for harm reduction purposes in the UK, opponents from around the world raised concerns. A pivotal one being, that similar findings to the randomised controlled trials may not emerge at a population level, where the provision of NRT is not usually free of charge, adherence may be lower, and little behavioural support is provided. A further concern was whether healthcare professionals, who have traditionally been provided with ‘abrupt cessation only’ messages, would be accepting of such an approach. This is of particular importance if stop smoking services offer NRT for smoking reduction and/or temporary abstinence to smokers as a treatment option. Failure to recommend tobacco harm reduction strategies in a suitable manner to those who are unwilling or unable to quit smoking, would not only come at a huge economic cost, since the financial bill incurred from a complete overhaul of the current treatment of tobacco dependence in the UK would likely be large; but if the use of NRT for smoking reduction and or during periods of temporary abstinence is proved to be effective, it could represent a missed opportunity to capitalise on the medical encounter. An additional concern was that few smokers would be inclined to opt to cut down or to temporarily abstain with NRT, and that those enticed to do so, would be those smokers interested in achieving cessation abruptly in the absence of a harm reduction strategy. If this were the case, public health benefits may not be realised, with the aim of any new tobacco control measure to target smokers who have become discontented with current treatment options.

This thesis attempted to address these concerns using three methodologies: 1) population-based surveys of English smokers to assess a) the prevalence of NRT use for smoking reduction and/or temporary abstinence, b) the socio-demographic and smoking characteristics associated with the use of NRT in these ways, and c) the association between the use of NRT for harm reduction with attempts to quit smoking and cigarette consumption; 2) an interview based study to determine smokers' beliefs and views on the use of NRT for smoking reduction and/or temporary abstinence, and to assess in what ways smokers are using NRT to reduce harm; and 3) surveys of stop smoking practitioners and managers to assess their beliefs about using NRT for smoking reduction and whether these beliefs are related to clinical practice, job and personal characteristics.

Study 1 (Chapter 7), using population-based cross-sectional data, investigated the prevalence of the use of NRT for smoking reduction and/or temporary abstinence; the association between the use of NRT in these ways with socio-demographic characteristics and nicotine dependence; the association between the use of NRT for harm reduction purposes with cigarette consumption and/or attempts to quit smoking; and whether these relationships, if they existed, differed as a function of the NRT product which was used. It was established that less than 15% of smokers were using NRT for harm reduction purposes in England, with a substantial overlap in the use of NRT for smoking reduction and the use of NRT for temporary abstinence. Although the prevalence of NRT use did not appear to have changed since 2007, prevalence was found to vary as a function of smokers demographic characteristics. The use of NRT for smoking reduction was more common amongst those of higher nicotine dependency, while the use of NRT for temporary abstinence was more common among younger female smokers and those who were more reliant on cigarettes. Interestingly, smokers demonstrated a preference for the nicotine patch, followed by the nicotine gum. In line with the previous clinical trials, higher odds of previous attempts to quit smoking were reported amongst those using NRT for smoking reduction and/or temporary abstinence. In contrast, while those using NRT for smoking reduction reported higher cigarette consumption than those cutting down without NRT, those using NRT for temporary abstinence reported similar cigarette consumption to other smokers generally. Both attempts to quit smoking and cigarette consumption varied as a function of the NRT product which was used. For example, the nicotine gum was associated with the lowest cigarette intake and one of the lowest odds of a previous quit attempt. These findings point towards the possibility that the spontaneous use of NRT for harm reduction purposes may increase smokers' motivation to stop smoking, but that it may not result in sizeable reductions in cigarette intake. However, the cross-sectional nature of this study clearly limits the conclusions that can be drawn. For example, another explanation for these findings is that quit attempts and the use of NRT both materialise from a general tendency to try and mitigate the harmful effects of smoking.

Study 2 (Chapter 8), following the finding of a substantial overlap in harm reduction activities, aimed to determine whether those using NRT both during attempts to cut down and during periods of temporary abstinence, differed to those using NRT for only one of these purposes; and secondly, whether the associations reported previously between the use of NRT for smoking reduction or temporary abstinence with attempts to quit smoking, cigarette consumption, and socio-demographic characteristics, were affected when those reporting the use of NRT for both reasons were excluded from the analyses. No differences in socio-demographic characteristics were reported amongst those using NRT for smoking reduction, those using NRT for temporary abstinence, and those using NRT both as a mean to cut down their cigarette intake and to tide themselves over when they were unable to smoke. In contrast, this latter group had higher odds of a previous attempt to quit smoking and greater reductions in their cigarette consumption than the other two groups. Nevertheless, after the exclusion of these smokers, positive associations were still reported between the use of NRT for smoking reduction or during periods of temporary abstinence and attempts to stop smoking. Although again cross-sectional in nature, this study provides further support for the conclusion that the spontaneous use of NRT for smoking reduction or during periods of temporary abstinence may increase smokers' propensity to quit, but that quit attempts may be promoted to a larger extent amongst those using NRT for both purposes.

Study 3 (Chapter 9) was undertaken following the concern that the questions often used by surveys to assess smoking reduction and the use of NRT for such purposes, may have resulted in the recruitment of those interested in gradual cessation, since intention to quit smoking was rarely assessed. The issue being, that this may have resulted in the positive associations reported previously with attempts to quit smoking. A 'split-ballot' method was used to compare those reporting smoking reduction in response to a question asking if they were reducing their cigarette consumption, to one enquiring about whether they were doing so without an intention to quit smoking. This slight variation in question format appeared to tap into quite different populations. Those responding to the prior question were more likely to be female and of a younger age, to have a higher cigarette consumption, and to report a quit attempt in the previous year. Those using NRT for smoking reduction were also found to differ depending on whether they were asked if they were cutting down or cutting down without a motivation to quit; the prior of which were of lower social-grades, smoked more cigarettes per day, and were more likely to report a previous attempt to stop smoking. However, differences were small and likely detected due to the large sample size or confounded by the temporal nature in which the questions were presented. Moreover, regardless of the question asked, those using NRT for smoking reduction were more likely to report a previous quit attempt than those cutting down without NRT, while those attempting smoking reduction were more likely to have attempted to quit smoking in the previous year than other smokers generally. Consequently, although these findings suggests that consideration about question format may be needed in the future, it is unlikely that the previous association reported between the use of NRT for smoking reduction and attempts to quit smoking is due entirely to the recruitment of those partaking in smoking reduction with an intention to stop smoking.

Study 4 (Chapter 10) aimed to resolve the problem of determining causation in studies 1-3, by using a prospective design. The association was assessed between the use of NRT for smoking reduction and/or during periods of temporary abstinence at baseline, with attempts to quit smoking, abstinence, and cigarette consumption at follow-up. A secondary aim was to establish the stability of the use of NRT for smoking reduction and/or temporary abstinence. The use of NRT for harm reduction purposes was found to be positively associated with attempts to quit smoking and abstinence at 6 months follow-up, while change in NRT use between baseline and follow-up was associated with a significant but small reduction in cigarette intake. There was evidence of only moderate stability in NRT use over time. These findings provide further support that the use of NRT for smoking reduction and/or temporary abstinence almost certainly does not undermine cessation and may promote it, but that reductions in cigarette consumption may not occur to the extent of those found in the previous clinical trials. Failure to report reliable reductions may be at least partially dependent on the early termination of NRT use.

Study 5 (Chapter 11) aimed to determine whether the associations reported between the use of NRT for smoking reduction and/or temporary abstinence with attempts to quit smoking, may be mediated by changes in motivation to quit, alterations of one's self-efficacy to stop, and/or changes in the rewarding effects of cigarettes. Mediation analysis established that motivation to quit smoking and enjoyment of smoking were partial mediators of the association between the use of NRT for temporary abstinence and attempts to stop smoking, while only motivation mediated between the use of NRT for smoking reduction and attempts to quit. No mediating role of self-efficacy was established. This seemed to represent the fact that one's confidence in their ability to quit smoking was not associated with abstinence. Consequently, if it is the case and the use of NRT for harm reduction moves smokers towards a quit attempt, these findings suggest that it may do so by increasing their desire to quit and reducing their pleasure of smoking, but possibly does not do so by increasing their levels of self-efficacy in their own ability to stop.

Study 6 (Chapter 12) aimed to assess whether the apparent failure of smokers to compensate for the additional nicotine attained from NRT by significantly reducing their cigarette consumption, resulted in them achieving heightened nicotine levels. This was determined by assessing the association between changes in the use of NRT for harm reduction purposes and salivary cotinine concentrations. Despite little reduction in cigarette consumption, no detectable increase in nicotine intake was found. In fact, there was a trend, although not significant, towards reduced cotinine whilst using NRT. From this it was concluded that smokers may either not be using enough NRT at a population level for it to have a significant effect on cotinine levels, or may instead be compensating by adapting their smoking style, such as inhaling less smoke in or putting their cigarettes out early.

Study 7 (Chapter 13) set out to address a major concern about research to date on the use of NRT for momentary abstinence; the fact that temporary abstinence is a multi-faceted phenomenon, hasn't been treated as such, and that different forms may result in different associations with socio-demographic variables, attempts to quit smoking, and cigarette consumption. For example, temporary abstinence may occur at home, at work, in a pub or restaurant, and whilst travelling. Consequently, the present study aimed to assess the associations between the use of NRT in these various temporary abstinence situations with attempts to quit smoking and cigarette consumption. Differences amongst those using NRT in these various situations in terms of demographic characteristics, attempts to stop smoking and cigarette intake were also determined. A secondary aim was to assess how helpful smokers reported the use of NRT during these periods of momentary abstinence and whether reports differed as a function of the NRT product which was used. Interestingly, the use of NRT for temporary abstinence was found to be the most prevalent at home and whilst travelling, with those using NRT during these situations tending to be of a higher socio-economic status than those using NRT in other situations. In contrast, those using NRT in their own home or in the pub were more likely to be of lower social-grades. Just over half of smokers reported NRT was helpful during these periods. The use of NRT whilst travelling was deemed the most helpful, while the nicotine inhalator and patch received higher helpfulness ratings than the nicotine gum. Although the use of NRT in all situations requiring temporary abstinence was positively associated with previous attempts to quit smoking, those using NRT whilst in the office and at home were more likely to have attempted to stop than those using NRT whilst travelling. Quit attempts were also more prevalent amongst those using NRT in multiple situations requiring temporary abstinence, as opposed to reports of the use of NRT in only one situation. This provides further support for the assertion that the use of NRT for temporary abstinence may increase smokers’ motivation to quit, particularly among those using NRT at home and whilst at work, and to a larger extent among those using NRT in several situations.

Study 8 (Chapter 14) using an interview methodology, aimed to address two main questions which had arisen. The first being the factors which may account for the lack of reliable reductions in cigarette consumption among those using NRT for smoking reduction and/or temporary abstinence at a population level, and the second, the reasons for smokers’ preference for the nicotine patch. Twenty-one themes were identified; from which it was concluded that reductions in cigarette consumption may fail to occur as a consequence of smokers’ inability to accurately report their cigarette consumption; their varying interpretations of smoking reduction; failure to set realistic goals and to devise suitable means in which these goals may be achieved; unrealistic expectations and misperceptions about NRT; and the influence of social, emotional and environmental factors. The preference for the nicotine patch appeared to stem from its ease of use, prolonged effect, beliefs concerning its safety, past use for smoking cessation, marketing, disadvantages with other products, and smokers’ mental representation of cigarette addiction as involving depleted brain nicotine concentrations. Future surveys should aim to assess the prevalence of these factors and whether they are associated with declines in cigarette consumption and NRT preference.

Study 9 (Chapter 15) intended to take the first step in addressing the concern that healthcare professionals may not be accepting of a harm reduction approach. This was done by establishing the beliefs among frontline stop smoking practitioners and managers on the use of NRT for smoking reduction. The associations were also determined between these beliefs with clinical practice, job and personal characteristics. Around one third of managers and practitioners were found to believe that the use of NRT for smoking reduction and for long periods of time was harmful to health, while 18% believed that the use of NRT for smoking reduction may hinder cessation. The most commonly reported concerns included addiction, overdose and mouth cancer. Reports differed as a function of stop smoking managers' relationship with their commissioner, frequency of meetings with their commissioner, and feelings of involvement in the strategic planning of their service; while reports among stop smoking practitioners differed as a function of the length of time they had been working for, gender, amount of training they had received and frequency of update training. Stop smoking practitioners who believed that the use of NRT for smoking reduction may hinder cessation, were also found to be less likely to advise reduction as a treatment option. Thus it appears that those currently working in stop smoking services hold many negative opinions towards harm reduction and that this may hinder the implementation of such a strategy. Means by which to counteract these beliefs could include the improvement of communication between managers and commissioners, and increasing the training requirements of practitioners.

In conclusion, the findings from this thesis provide evidence that the spontaneous use of NRT for smoking reduction and/or temporary abstinence is unlikely to undermine smoking cessation and may actually increase the motivation of smokers to quit. In contrast, reliable reductions in cigarette consumption do not appear to occur to the extent of those found in the previous clinical trials. This militates against the possibility of an immediate reduction in harm to smokers who opt to use NRT for smoking reduction and/or during periods of temporary abstinence. A number of factors were identified which may account for this, including the possibility that smokers may instead be modifying their cigarette consumption, may not be using enough NRT, or perhaps are not setting realistic goals. Thus the use of NRT for smoking reduction and/or temporary should be considered as a suitable strategy in other countries as a means of reducing the tobacco epidemic, but smokers at the same time should be informed that the use of NRT for harm reduction purposes may have few, if any, instantaneous health benefits. However, it is clear that this is only the start of a much wider and needed research repertoire, with a number of questions remaining unanswered. These include the effectiveness of the use of NRT for smoking reduction and/or temporary abstinence among specific populations, such as those suffering from chronic mental or physical conditions; the effect of NRT use for harm reduction on relapse or maintenance of smoking abstinence; and whether significant reductions in cigarette consumption can be induced in the hope of incurring a health benefit. Of course, this list is not exhaustive.

The current findings also negate the concern that few smokers will be interested in using NRT for smoking reduction and/or temporary abstinence, with 1/6th of smokers reporting the use of NRT for harm reduction purposes. In contrast, concerns about the acceptance of a harm reduction approach among healthcare professionals may be realised, with stop smoking practitioners and stop smoking managers holding substantial negative opinions towards the use of NRT for smoking reduction. These beliefs clearly need to be addressed before English stop smoking services adopt smoking reduction as a route to quit. Future research should also focus on other factors which are pivotal in the implementation of evidence-based guidelines, i.e. resources, motivation to change and social cohesion.

Chapter 1: General Introduction

''What a weird thing smoking is and I can't stop it. I feel cosy, have a sense of well-being when I'm smoking, poisoning myself, killing myself slowly. Not so slowly maybe. I have all kinds of pains I don't want to know about and I know that's what they're from. But when I don't smoke I scarcely feel as if I'm living. I don't feel as if I'm living unless I'm killing myself'' (Hoban, 1975; pp. 32)

Development of the Smoking Epidemic

The development of the smoking epidemic in the UK is depicted in Figure 1, a four-stage model by Lopez, Collishaw and Piha (1994). Stage 1 occurred at the start of the 20th century, with male smoking increasing rapidly. During stage 2, the 1930s to 1950s, male smoking was starting to peak, while uptake and rise in smoking among women was taking hold. The peak among women occurred sometime later in the 1960s-1970s (stage 3), after which rapid declines occurred among both men and women, slowing considerably over the 1990s (stage 4). The most recent data on smoking rates in England comes from the Smoking Toolkit Study, which estimated that 23.6% of the English population were daily or non-daily smokers in July 2011 (see www.smokinginengland.info).

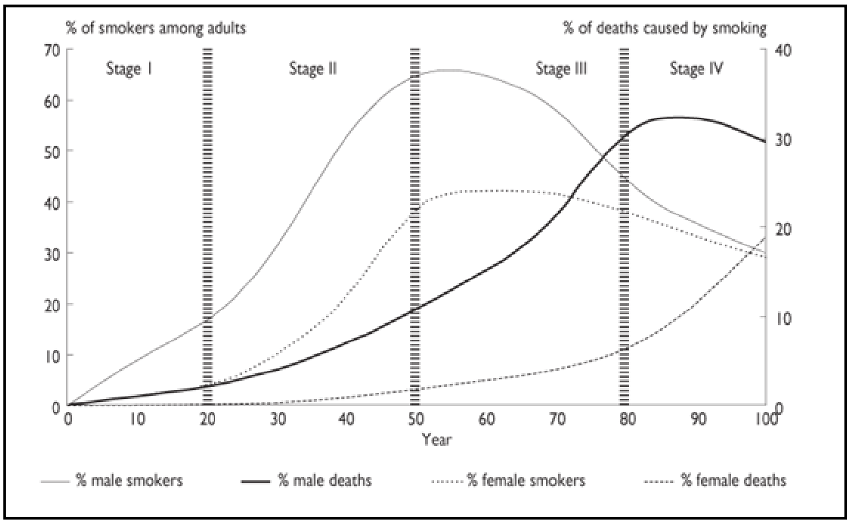


Figure 1: The Four-Stage Evolution of the Smoking Epidemic (Lopez, Collishaw & Piha, 1994)

The majority of Northern and Western European countries, North America and Australasia, also reside in stage 4, with a recent average prevalence of smoking for the 25 countries of the European Union being 32% (European Commission, 2007). In contrast, some countries in Sub-Saharan Africa are still at stage 1 of the epidemic, with low rates of cigarette smoking limited largely to men. Countries in Asia, North Africa, and Latin America, fit stage 2 of the epidemic, characterised by higher rates of male smoking, while smoking among women remains a relatively new phenomenon. Other countries in these regions are moving towards stage 3, where male smoking rates are very high but starting to fall, and female smoking rates are close to reaching their peak. For example, Asia now contains over half the world's smokers, with male smoking prevalence in excess of 50% [53% in Japan, 63% in China and 73% in Vietnam; (Edwards, 2004)].

Smoking and Health

It is estimated that cigarettes contain at least 599 chemicals, and once lit, produce a further 3000-4000 chemical compounds, many of which are carcinogenic or poisonous (United States (US) Department of Health & Human Services, 1994). These include benzene, formaldehyde, ammonia, acetone, arsenic, and hydrogen cyanide. It is therefore unsurprising that more deaths are caused each year by tobacco use than by all deaths from human immunodeficiency virus (HIV), illegal drug use, alcohol use, motor vehicle injuries, suicides, and murders combined (Centers for Disease Control & Prevention, 2008; Mokdad, Marks, Stroup & Gerberding, 2004). Estimates suggest that cigarettes cause approximately 40% of all deaths among the middle age population, and reduce a smokers' life expectancy by an average of 10 years (Doll, Peto, Boreham & Sutherland, 2004).

Smoking also contributes significantly to global morbidity (International Agency for Research on Cancer, 2004), increasing the risk of cardiovascular disease, chronic obstructive pulmonary disease and lung cancer (Cornfield et al., 2009; Yoshida & Tuder, 2006). Other less common conditions include an increased risk of bladder cancer (Brennan et al., 2000), oropharyngeal cancer (Elwoods, Pearson, Skippen & Jackson, 1984), and gastrointestinal problems (Kato, Nomura, Stemmermann & Chyou, 1992). In addition, there is a well-established link between smoking and psychological disorders (West & Jarvis, 2005; Johnson & Breslau, 2006; de Leon et al., 1995; Johnson et al., 2000; Zvolensky, 2003). In the UK around 60-80% of those with psychosis are smokers (Coulthard, Farrell, Singleton & Meltzer 2000); these individuals tend to report having started smoking at a younger age and that they smoke more heavily than those in the general population (Kumari & Postma, 2005). However, there is much debate on the direction of causation; whereas some argue that psychiatric disorders result in smoking initiation, others point towards possible influences of smoking on the pathology and development of chronic mental health problems (Boden, Fergusson & Horwood, 2010; Munafo, Hitsman, Rende, Metcalfe & Niaura, 2008).

Besides these physical and mental health impacts, the use of cigarettes also affects non-smokers who either passively inhale cigarette smoke directly or, as foeti, ingest tobacco constituents in the womb (Hill, Blakely, Kawachi & Woodward, 2007). The most recent meta-analyses have reported that non-smokers exposed to passive smoking at home have their risk of lung cancer raised by about a quarter, while heavy exposure at work doubles the risk (Taylor, Najafi & Dobson, 2007; Stayner et al., 2007). Moreover, smoking during pregnancy increases the threat of placental abruption, and has a causal link with foetal growth, which includes significant reductions in head circumference, abdominal circumference, and femur length (Salihu & Wilson, 2007). There is also limited evidence that parental smoking increases the risk of childhood leukaemia in offspring (Secretan et al., 2009).

Consequently, the health benefits of smoking cessation are self-evident. It halves the risk of contracting lung cancer and can have an immediate effect on the development of various heart diseases (Peto et al., 2000; Rich-Edwards, Manson, Hennekens & Buring, 1995). Post-operative recovery is also improved (Moller, Villebro, Pederson & Tonnesen, 2002), and mental health problems ameliorated (Mino, Shigemi, Otsu, Tsuda & Babazono, 2000). It has even been reported that life expectancy among smokers who quit at age 35 exceeds that of continuing smokers by 6-8 years (Taylor, Hasselblad, Henley, Thun & Sloan, 2002), while others have suggested that cessation by the age of 30 may eliminate the increased risk of mortality relative to non-smokers (Doll et al., 2004).

Underlying Pathology of Nicotine Dependence

Although tobacco products contain several thousand chemicals, nicotine is considered to be the principle constituent that leads to its persistent use. Others have been implicated but to a much lesser extent. For example, smokers experience a reduction of monoamine oxidase as a result of harman, norharman, anabasine and anatabine in tobacco, resulting in anti-depressant activity; thus perhaps explaining the high levels of cigarette smoking amongst those with depressive disorders (Fowler et al., 1996).

Nicotine (3-(1-methyl-2-pyrrolidinyl) pyridine) constitutes about 95% of the total alkaloid content of commercial cigarette tobacco (Gorrod & Jenner, 1975). Its main source of stimulation is one of the acetylcholine receptors, conveniently known as the nicotinic receptors, which are found in abundance in the central nervous system and at nerve-muscle junctions of skeletal muscles. Stimulation of these nicotinic receptors by nicotine releases a number of neurotransmitters including dopamine (involved in pleasure and appetite suppression), serotonin (involved in mood modulation and appetite suppression), epinephrine and nor-epinephrine (involved in arousal and appetite suppression), ACh (involved in arousal and cognitive enhancement), vasopressin (involved in memory), glutamate (involved in memory), β-endorphin (involved in mood modulation and analgesia), and δ-aminobutyric acid (involved in mood modulation and analgesia).

Dopamine is believed to be the dominant neurotransmitter in the maintenance of cigarette addiction (DiChiara, 1999), with the area of the brain thought to be responsible for the reinforcing effects of all drugs being rich in this particular compound. This brain area is known as the mesolimbic pathway, which is comprised of the ventral tegmental area, nucleus accumbens, amygdala, cingulate gyrus and frontal lobes. This assertion is supported by the finding that nicotine self-administration is diminished by either surgical or chemical ablation of dopaminergic pathways, or by the treatment with dopamine antagonists (Kameda, Dadmarz & Vogel, 2000). The release or inhibition of other neurotransmitters may also play a role in nicotine addiction, being responsible for mood modulation, the modest enhancement of performance, and the weight reducing effects of smoking (Benowitz, 1999; Chiodera et al., 1990; Chowdhury, Hosotani & Rayford. 1989; US Department of Health & Human Services, 1988). Mood modulation has been a controversial topic since individuals often report greater positive affect when smoking after a period of abstinence; thus the relief of negative affect by tobacco use may be more a function of abating withdrawal symptoms (Cinciripini, Wetter & McClure, 1997).

The physical addiction to nicotine is associated not only with nicotine's psychoactive effects, but also the development of tolerance, and the experience of withdrawal symptoms when tobacco products are no longer available (US Department of Health & Human Services, 1988). The speed of delivery of nicotine to the brain also plays a significant role (Henningfield & Keenan, 1993). Tolerance develops via neuroadaptation, which includes receptor inactivation and desensitisation, and an increase or up-regulation in receptor number (Benowitz, 1999). This usually results in the individual using more tobacco or switching to a higher nicotine containing product, which consequently leads to withdrawal symptoms when nicotine is no longer available [for example:- irritability, frustration, insomnia, decreased heart rate and increased appetite (APA, 1994)]. These symptoms peak during the first week of abstinence and return to baseline levels by four weeks (Hughes, Higgins & Hatsukami, 1990). The only exception to this pattern is weight, which may continue to increase over six months and never reduce (Filozof, Fernandez Pinilla & Fernandez-Cruz, 2004).

Theories of Dependence

Despite the clear role of nicotine and other tobacco constituents in the development of nicotine addition, this is not the whole story. Dependence progression is also influenced by genetic predisposition, the behavioural and sensory aspects of smoking, learning, our psychology, and the social environment in which we live. These concepts have been incorporated into a number of biological and psychological models of dependence; an overview of which is given below. Starting with the 'Disease Model', which recognises individual differences in the biological susceptibility to drug use, and the inherent loss of control associated with the 'dependence syndrome'; consideration will progress to those theories viewing addiction as rational choice, irrational choice, or as the product of the environment in which we live.

Dependence as Loss of Control

One of the most influential models of nicotine dependence is the Disease Model. This postulates that addicts are different from the rest of us, in that they have some abnormality which is either present in their constitution from the start, or which is triggered by drug use. This constitutional difference is seen as irreversible and the disease progressive, therefore the only sensible course of action open to an addict is to abstain. This idea classically evolved from the formulation of Alcoholics Anonymous in 1935, the ideology of which was based on the proposition that alcoholics were a specific group of people with an inherent vulnerability to alcohol, where even one drink would cause them to crave alcohol and lose control. To put it another way, alcoholism was viewed as a disease which was progressive, irreversible and incurable, but could be arrested through abstinence (Fingarette, 1989). This view was officially formulated in 1960 when Jellinek published '*The Disease Concept of Alcoholism'*, which was accepted into mainstream drug dependence treatment. Although to a much lesser extent, this concept is still acknowledged among some of those working in the area of drug control today. For example, Leshner recently put forward the argument that addictive behaviours are a form of brain disease, because all forms of drug dependence involve structural and functional changes in a common region – 'the reward' pathways (Leshner, 1997).

Evidence for a biological pre-disposition to addiction has emerged through the establishment of a relationship between personality dimensions, including those of the Tri-Dimensional Theory [for example:- novelty seeking, harm avoidance and reward dependence; (Cloninger, 1987)], and susceptibility to the continued use of drugs (Howard, Kivlahan & Walker, 1997). Impulse control problems as a personality type has also been linked to the extent of addictive substance use (Conway, Kane, Ball, Poling & Rounsaville, 2003). Twin studies provide further support, reporting a heritability of 44% for smoking initiation and 75% for nicotine dependence (Vink, Willemsen & Boomsma, 2005). Moreover, in order to elucidate the specific genetic factors, there has been an increase in interest in molecular genetic studies. These have established that a polymorphism of the dopamine D2 receptor gene, DRD2 Taq1A (Lerman et al., 1999), and a polymorphism in the serotonin transporter, 5-HTTLPR (Kremer et al., 2005), are associated with smoking behaviour. The monoamine oxidase A gene (Fowler, Logan, Wang & Volkow, 2003), and reduced-activity and inactive variants of the CYP2A6 gene (Malaiyandi et al., 2006), have also been implicated. However, meta-analyses report that these associations are only modest, with significant between study heterogeneity (Munafo & Flint, 2004). Evidence is much stronger for proximal measures of behaviour. For example, a potential association has been identified between 5-HTTLPR genotypes and attentional bias for smoking-related stimuli (Munafo, Johnstone & Mackintosh, 2005). The mechanism by which this works is an interesting question. One suggestion is that individual differences in central serotinergic neurotransmission results in altered neuromodulation of brain regions related to associative learning, whereby stimuli acquire incentive motivational value (Rogers et al., 1999).

The idea of loss of control which is fundamental to the Disease Model of addiction has since been incorporated into other theoretical frameworks. For example, feelings of loss of control have been implicated in the ‘abstinence violation effect’ (Marlatt, 1979), the process by which a single lapse back to an old pattern of behaviour leads to the full resumption of that behaviour; and in the Theory of Inhibitory Dysregulation, which claims that the central problem with addiction is the inability to control one’s pattern of use (Lubman, Yucel & Pantelis, 2004). Support for this comes from the finding that cravings are only cited in 7% of cases as a primary factor for relapse, while impulse action in 41% of cases (Miller & Gould, 1994). Impairments have also been established in the brain regions that usually allow an individual to override the impulses produced by the reward system (Lubman et al., 2004).

Among the various theories that focus on impaired control or compulsion, Self-Regulation Theory is perhaps the most highly developed (Baumeister, Heatherton & Tice, 1994). This proposes that self-regulation is governed only by a limited resource that allows people to control impulses and desires (Baumeister & Heatherton, 1996), and that this resource can be depleted or fatigued by self-regulatory demands; hence the active effort required to control behaviour in one domain, leads to a diminished capacity for self-regulation in others. This is supported by the finding that smoking cessation often leads to increased eating among individuals who normally try to regulate their diet (Spring, Wurtman, Gleason, Wurtman & Kessler, 1990). Individual differences in self-regulation also appear to exist, which may be explained by variations in brain regions (Kuhl, 2008). Self-regulation failure has been attributed to a dysfunction of the frontal lobes and the subsequent dysregulation of the different subcortical cognitive systems controlled by the prefrontal cortex (Bechara, 2005; Mishkin, 1964). For instance, deficits in frontal cortex regulation in young adolescents have been found to predict later drug consumption, especially for those in families with drug disorder histories (Dawes, Tarter & Kirisci, 1997; Aytaclar, Tarter, Kirisci & Lu, 1999).

The idea that unhealthy actions may materialise from the inability to regulate behaviour, is also born out in Control Theory (Carver & Scheier, 1982). This suggests that once a goal is set, i.e. abstinence from smoking, it serves as a reference value to which rates of behaviour change can be compared. Goal systems are assumed to be organised hierarchically from abstract, self-relevant, and highly important goals (for example:- 'I want to be a non-smoker'), to 'do' goals that are more closely related to immediate gratification (for example:- 'I want to smoke a cigarette now'). Self-regulation is the process of inhibiting a lower level goal for a higher level goal which is more self-relevant. There is evidence that smokers find this task particularly difficult, often opting for the lower level option (Sayette, 2004). In addition, smokers' goals are found to vary substantially over time (Hughes, Keeley, Fagerstrom & Callas, 2005a); with no fixed reference value self-regulation is undoubtedly going to be erratic.

Dependence as Rational Choice

The Disease Model, and the idea that addicts have no control over their behaviour, has been heavily criticised on the basis of being misleading, particularly in implying that addicts are impotent onlookers and the only way to stop them is physical restraint (Skog, 2000). One glaring contradiction in this proposition is that a person, who is believed to have lost control of his or her substance use, is expected to exercise control to abstain altogether. Secondly, Orford (2001) recently argued that there are too many similarities between drug and non-drug related addictive behaviours, such as gambling and internet addiction, for us to meaningfully conclude that there is a common underlying biological pathway central to understanding addictive behaviours. Thirdly, there are many cases where addiction appears to be occurring partially out of choice, based on the smoker weighing-up the potential costs and benefits of continued drug use (Becker & Murphy, 1988). For instance, a smoker may wish to quit and be able to do so, but sees greater benefits in continuing. This idea is known as the Rational Choice Theory of addiction. Based on economic models of behaviour, this theory states that addictive behaviours are rational to the extent that they are directed towards maximising the benefits for the individual who engages in them. 'Benefit' in this way differs from ordinary usage, being understood as achieving one's own goals in the most efficient manner possible, regardless of whether or not these goals are necessarily good for the individual.

The 'Self-Medication' hypothesis is in line with this theory (Farrell et al., 2001), which states that addicts take drugs as a means of coping with or ameliorating adverse life experiences. For example, it has been proposed that smokers may smoke in order to combat problems they have in maintaining attention. An extended version of this hypothesis involves the proposal that some drugs may actually serve a purpose in alleviating the side-effects of drugs that are used to treat psychiatric disorders. This is particularly so for smoking, in which the effect of nicotine in increasing dopamine release at certain nerve terminals has been argued to help with the side-effects of neuroleptic drugs (Poirier et al., 2002).

The Theory of Rational Choice is also compatible with the realisation that addiction is often associated with an escalation of use, proposing that the addict chooses to escalate the ‘dose’ because of a stable preference for a particular effect, and continues to engage in the activity because of choice to avoid or escape from withdrawal symptoms. This idea of habituation followed by withdrawal symptom relief is captured in the Opponent Process Theory (Solomon, 1980), which postulates that every psychological event A will be followed by its opposite psychological event B. Therefore, initial pleasant drug use leads to unpleasant withdrawal symptoms, and in order to avoid these symptoms, drug taking is maintained. There are many examples of opponent processes in the nervous system including taste, colour recognition, motor movement, touch, vision, and hearing (Solomon & Corbit, 1973).

However, a major issue with such rational choice theories is that they cannot account for the fact that many addicts choose to exercise restraint and fail. In order to rectify this, it has been proposed that perhaps addicts hold unstable preferences (Hughes et al., 2005a). In other words, preferences may change over time, particularly between when a decision is made and when it is exercised. One minute smokers may choose to try to stop using a drug, at which point their thoughts are dominated by the negative aspects of the activity, having then abstained for a while and facing the reality of loss of reward and the discomfort associated with this, they change their mind and resume their behaviour. As Skog (2000; pp. 1309) put it: *‘‘What we observe is not an inability to choose, but choices governed by strong appetites and conflicting motives.’’* This concept of ‘approach-avoidance conflict’ is indicative of many theories of motivation; the idea that something may look attractive at a distance but as one gets closer the unattractive features become more evident (West, 2006).

Dependence as Non-Rational Choice

We can also account for the finding that many addicts choose to exercise restraint and fail, if we assume a ‘choice theory’ of addiction that is ‘non-rational’. Rational decision-making theorists suggest that people make decisions based upon reasonable assessments of their self-interests (Pruitt & Carnevale, 1993), i.e. weighing up the positives and negatives of a behaviour. Critics of rational choice theory suggest that people are not merely economic beings whose behaviour can be explained by rational cost-benefit assessments and self-serving choices; rather human decisions are often determined by values, affect and habit (Zey, 1992).

Expectancy theories have taken this on board, recognising that beliefs about the consequence of an activity may contribute to behaviour. Expectancy theories state that drug use escalates into addiction not as a result of weighing-up the true costs and benefits of an activity, but because of an individual's own expectations of these. For example, smokers who hold more personal positive expectancies about quitting have been found to be more likely to report abstinence at follow-up than those possessing negative expectations (Hansen, Collins, Johnson & Graham, 1985; Rose, Chassin, Presson & Sherman, 1996). Self-efficacy expectancies appear to be particularly important, which are simply one's beliefs in their ability to perform certain behaviours (DiClemente, Prochaska & Gibertini, 1985); if a smoker wants to stop smoking but feels that they are not able to do so, it is probable they will avoid attempts at abstinence or fail even if the benefits outweigh the costs. The value assigned to expectations is also pivotal, known as 'expectancy-value' (Fishbein & Ajzen, 1975), in that smokers appear to only stop smoking if their positive expectancies hold value for them. This coincides with the finding that smokers' expectations about the health consequences of smoking cessation are only predictive of quit attempts among heavy smokers, potentially because lighter smokers do not feel that they are in bad health (Rose et al., 1996). Moreover, there is ample evidence from social psychology that hyper-responsivity occurs for more immediate expectancies, i.e. smoking will remove withdrawal symptoms, than future orientated ones, i.e. smoking may increase my risk of lung cancer (Loewenstein et al., 2003).

Hall and Fong (2007) have tried to capture this in their theory of Temporal Self-Regulation, which explains why much behaviour although appearing maladaptive to the outsider, is associated with benefits at the time to the user.

The impact of addicts belief systems on the likelihood of abstinence have also for a long time been recognised by cognition and social-cognition models, including the Protection Motivation Theory (Rogers, 1983), the Transtheoretical Model (DiClemente & Prochaska, 1982), the Protection Adoption Process Model (Weinstein & Sandman, 1992), the Theory of Planned Behaviour (Ajzen, 1991), and the Health Belief Model (Rosenstock, 1974). These propose parsimonious sets of modifiable beliefs (for example:- attitudes, perceived risk & personal control), as predictors of intentions to act. Intentions in turn are considered to determine behaviour directly, at least when formulated in accordance with TACT [Target, Action, Context & Time; (Fishbein, 1967)] or via the formation of 'implementation intentions' (Gollwitzer & Sheeran, 2006). There is evidence for the predictive utility of these models in smoking cessation (Maddux & Rogers, 1983; Norman, Conner & Russell, 1999; Kaufert, Rabkin, Syrotuik, Boyko & Shane, 1986).

Others have recognised the possibility that smokers may possess faulty decision making processes, resulting in the weighing-up of costs and benefits being far from rational (Baron, 2000). Slovic and colleagues have shown over the years how sensitive our judgements of risk are to the context in which those judgements are made and the manner in which they are elicited (for example:- Slovic, Finucane, Peters & MacGregor, 2002). Of particular relevance is that of the 'affect heuristic bias', which occurs when we judge risks using feelings rather than analytical thought as the basis for our judgements. It has been demonstrated that affect-laden imagery elicited by word associations predict adolescents' decisions to take part in health-threatening and health-enhancing behaviours, including smoking and exercise (Benthin et al., 1995).

The role of emotion in decision making is also proposed by the Cognitive Labelling Model (Schacter & Singer, 1962), which states that emotional experience results from the interaction of experienced physiological arousal and a cognitive interpretation of that arousal. This interpretation leads to a semantically based emotional label which in turn determines the emotional state which is experienced. In terms of craving, the model proposes that cues can create conditioned physiological arousal states and activate related mental processes. The potential importance of this model is that the addict's craving responses to cues could be, theoretically at least, diminished through therapeutic interventions aimed at cognitive reframing of cravings, i.e. the labels assigned.

The influence that feelings have on our beliefs and evaluations can also be extended to non-conscious mental processes. Biases can occur not just because we believe things we want to believe, but also in the very way our attention and memory operate (Ryan, 2002). An obvious case is that of attentional bias, which refers to the tendency for information processing resources to be allocated disproportionately towards certain categories of stimuli. An example of this is the 'cocktail party effect', where an individual will attend to a single person's speech against a background of competing noise, but retain the ability to switch attention to salient information in that background, including one's own name (Munafo, Mogg, Roberts, Bradley & Murphy, 2003). The idea that the use of addictive substances may be associated with processing biases towards stimuli associated with those substances, arises from the Positive Incentive Model of Addiction (Stewart, de Wit & Eikelboom, 1984), and more recently, Robinson and Berridge's (2000) Incentive Sensitisation Model. Typical methodologies to assess attentional biases include the modified Stroop Task and Attentional Probe Task. A number of studies have employed these paradigms to investigate selective processing of smoking-related cues in smokers compared to non-smokers (for example:- Johnsen, Thayer, Laberg & Asbjornsen, 1997; Mogg, Bradley, Field & Houwer, 2003;

Munafo et al., 2003), in heavy smokers compared to light smokers (for example:- Hogarth, Mogg, Bradley, Duka & Dickinson, 2003; Mogg, Field & Bradley, 2005), and in abstinent compared with non-abstinent smokers (for example:- Gross, Jarvic & Rosenblatt, 1993; Field, Mogg & Bradley, 2004). Measures of attentional bias have also been used to predict smoking cessation (Waters, Shiffman, Bradley & Mogg, 2003a), and the perceived availability of cigarettes (Wertz & Sayette, 2001). To date, these studies suggest that smokers have some attentional bias towards smoking-related stimuli and that this may be predictive of abstinence.

Finally, how one perceives themselves can no doubt be important in the maintenance of addictive behaviour. This has been recognised in an interesting and insightful theory known as the Identity Shift Theory (Kearney & O'Sullivan, 2003). This theory is used by its proponents to explain changes in a range of chronic behaviours, proposing that lasting behaviour change is only established with a corresponding change in identity (for example:- from a smoker to a non-smoker), while addiction will be maintained among those who still view themselves as an addict. The importance of identity in the development and recovery from addiction has also been recognised by other theories, including the Addicted-Self Model (Fiorentine & Hillhouse, 2000). There is evidence to suggest that the incorporation of smoking into the self-concept is predictive of intention to quit smoking (Moan & Rise, 2005; van den Putte, Yzer, Willemsen & de Bruijn, 2009; Gibbons & Eggleston, 1996), while studies examining the experience of ex-smokers point towards an identity shift, even if it is far from complete (Vangeli & West, 2011; Vangeli, Stapleton & West, 2010).

Dependence as a Learned Phenomenon

What is inherent in many of the theories discussed above, and one which is neglected by others, is the conceptualisation of addiction as a process of learning. That is, addictive behaviour is something that is learned and therefore can be unlearned. This is the central notion of ‘Learning theory’, which focuses its effort on two types of learning processes in particular: ‘operant’ and ‘classical’ conditioning. Operant conditioning is the process by which various rewards and punishments increase or decrease the likelihood of an individual repeating a particular action in the future (Skinner, 1938), while classical conditioning involves the process of an unconditioned response occurring as a result of unconditioned stimuli (Pavlov, 1927). These would claim that drug cravings arise due to the reinforcing effects of withdrawal symptom relief, and via the elicitation of cravings as a result of repeated pairing of environmental stimuli with drug effects. Such conditioned responses have been well established. For example, Ehrman, Tenes, O’Brian and McLellan (1992) looked at the effect on detoxified opioid users of receiving either an infusion of opioid delivered at a random interval or via self-injection of the same dose. When given the infusion without warning, participants experienced a greater physiological response relative to self-injection; thus simply knowing that a drug is being administered appears to have an effect on the way the person responds. More complex models have since been developed. White (1996) for example, proposes that drug-seeking behaviour involves multiple parallel learning and memory systems, and not simply just conditioning. Reinforcers are seen to work on these systems in three ways: 1) they activate the neural mechanisms involved in approach or avoidance responses; 2) they produce states that are rewarding or aversive; and 3) they alter or strengthen the representation of information stored in these systems.

The Incentive Sensitization Theory (Robsinson & Berridge, 1993), although consistent with the loss of control stipulated by the Disease Model of addiction, also recognises the importance of experience. The central thesis of the theory is that repeated exposure to addictive drugs can persistently change brain circuits that normally regulate the attribution of incentive salience to stimuli, a psychological process involved in motivated behaviour. The nature of these neuroadaptations is to render these brain circuits hypersensitive in a way that results in pathological levels of incentive salience being attributed to drug-associated cues, via a process of Pavlovian conditioning. These drug related cues then result in pathological ‘wanting’, which causes craving and thus drug-seeking behaviour. This theory stipulates that ‘wanting’ and the neural system responsible for it, is dissociated from neural systems that mediate the hedonic effects of a drug, i.e. ‘liking’. Others have also pointed towards this conception (Robsinson & Berridge, 1993), which explains why smokers do not ‘like’ smoking cigarettes but have strong cravings to smoke.

The learning process of addiction is also evident in the Craving Model proposed by Tiffany (1990), in which the initial development of addition is seen to be similar to learning other behaviours. In the beginning the behaviour, such as rolling a cigarette, is something which requires effort to perform, but over time becomes habit or automatic via the development of drug use representations in memory. At this point, controlled processes will only be engaged if an obstacle occurs, i.e. the subjective and aversive feelings of cravings, which the individual becomes compelled to overcome. Several studies have shown the activation of non-automatic processing during an urge. For example, Baxter and Hinson (2001) demonstrated in a probe reaction time paradigm, that smokers were slower to respond to trials where the automatised smoking action plans were interrupted through the elicitation of urges to smoke, compared with trials where they were not disturbed.

However, these models so far neglect the social aspect of human nature, with learning not occurring in a bubble but within the context of social interaction. Social Learning Theory was developed to capture this. Whereas strict behaviourism approaches, such as those by Pavlov (1938) and Skinner (1927), support a direct and unidirectional pathway between stimulus and response, representing human behaviour as a simple reaction to external stimuli; Social Leaning Theory asserts that human cognition acts as a mediator between stimulus and response, endorsing a reciprocal determinism in explanations of behaviour, with the environment affecting us, and us influencing our environment (Bandura, 1977; Woodward, 1982; Jones, 1989; Perry et al., 1990; Thomas, 1990; Crosbie-Brunett & Lewis, 1993). This theory has three basic tenets: that rewards or punishments influence the likelihood of behavioural repetition; that humans can learn through vicarious experience and by participating in activities; and that individuals are most likely to model the behaviour of others they identify with. This theory would propose that tobacco dependence develops via significant others 'modelling' the behaviour of smoking and providing social reinforcement for that behaviour. For example, friends expose adolescents to the immediate positive outcomes associated with having a cigarette, such as the buzz, cool image, or group membership, which can draw a young person into trying smoking (Leatherdale, Cameron, Brown, Jolin & Kroeker, 2006; Akers & Lee, 1996).

Dependence as Environmental

Those studies which view dependence as a learned behaviour recognise the importance of the environment in drug addiction, as do social cognition models, which implicate the views of others and environmental prompts (Rogers, 1983; DiClemente & Prochaska, 1982; Weinstein & Sandman, 1992; Ajzen, 1991; Risenstock, 1974). However, we cannot forget other environmental factors which may be pivotal in the maintenance and initiation of smoking. These include the acceptability of drugs in society and the legal structure in which the drug is housed. Smoking restrictions, tax increases, and the extensive stigmatisation of smoking, all appear to have driven down prevalence rates (Fichtenberg & Glantz, 2002; Kengganpanich, Termsirikulchai & Benjakul, 2009; Stuber, Galea & Link, 2009). The status of smoking as a socially unacceptable behaviour is likely to have developed via symbolic messages of moral condemnation, such as the segregation of smokers and non-smokers as a consequence of smoke-free laws (Schneider & Ingram, 1993); discrimination, which abrogate smokers' rights as ordinary citizens by placing them in a category that separates them from non-smokers, such as the refusal to hire (American Civil Liberties Union, 1998); as a consequence of fear, following the recognition of the impact of environmental smoke on health; and/or according to Attribution Theory, as a direct result of beliefs about the origin of behaviour (Weiner, 1995). This contends that where smoking is viewed as occurring within the individual's control, blame and anger will be dealt out.

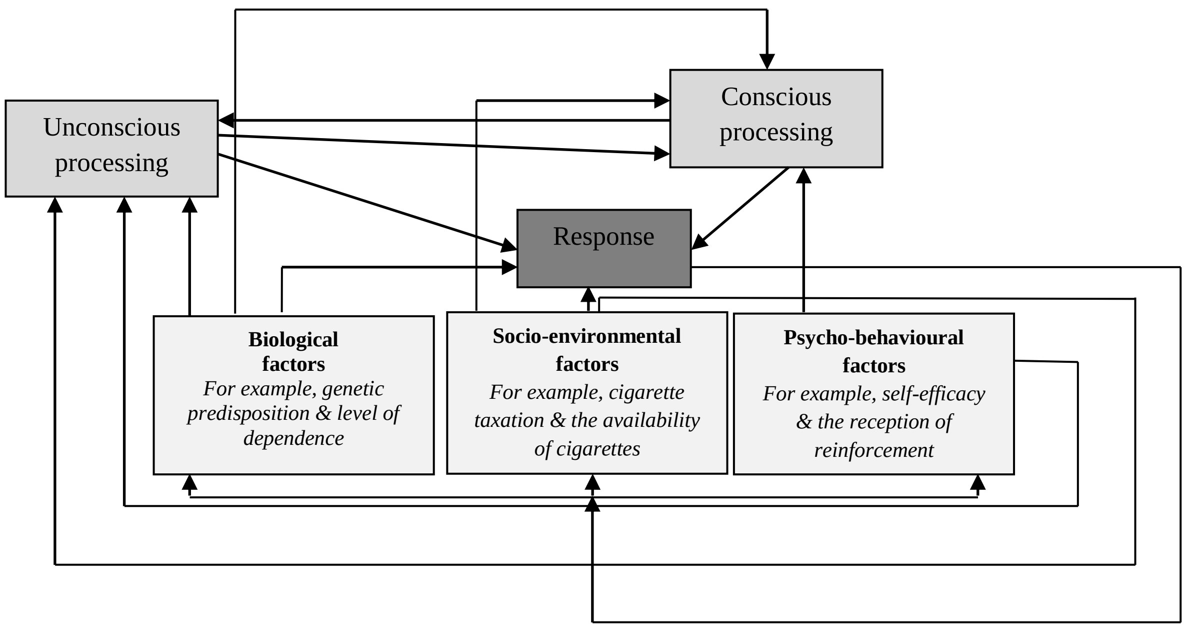


Figure 2: Model of Addictive Behaviour

A Synthetic Theory of Dependence

A potential schematic way of picturing the various factors implicated in the process of nicotine dependence is displayed in Figure 2. In this model two processing systems are central: the automatic and unconscious system, and the conscious and effortful system; both of which impact on individual responses and are influenced by biological, psycho-behavioural, and socio-environmental factors. Biological factors include the pharmacological actions of the drug, neurological differences and genetic predisposition. In contrast, psycho-behavioural factors incorporate the importance of learning, individuals' beliefs and attitudes, as well as emotions and coping styles. The third factor, socio-environmental, recognises the importance of the environment in which the addict is in, such as the impact of the regulation of cigarettes, taxation levels and availability. For example, reinforcement could affect behaviour via the formation of attentional biases in the unconscious system, thus directing smokers' attention to smoking-related stimuli. In contrast, smokers' beliefs may affect goal setting and decisions within the conscious system, either directly or indirectly via the automatic system.

A number of attempts to comprise a comprehensive theory of dependence have been made. For example, the Excessive Appetites Theory recognises that there are a range of objects and activities which humans are at risk of developing a strong attachment to, or 'appetite' for, thus finding their ability to moderate their behaviour considerably reduced (Orford, 2001). The degree of a person's 'appetite' is viewed to have multiple interacting determinants: personality, socio-economic and cultural factors, and ecological principles. A similar synthetic theory has been developed in relation to gambling addiction, which recognises the importance of ecological factors, classical and operant conditioning, habituation, and emotional and biological vulnerability [The Pathways Model of Problem & Pathological Gambling; (Blaszczynski & Nower, 2002)].

However, possibly the most complete to date is that of PRIME theory (West, 2009), which proposes a theory of motivation of addiction comprised of five levels (see Figure 3). At the lowest level are reflex responses to particular stimuli. For increased flexibility and adaptation, West proposes that a second level evolved which allowed the generation of ‘impulses’ and ‘inhibitions’; these direct or indirect an animal to act in a certain way to the presence of stimuli in the environment. The development of the mammalian cerebral cortex permitted a further, which was the capacity to form mental representations of possible future outcomes and feelings associated with these. These feelings are hypothesised to generate two forms of motives: a motive of ‘wanting’ materialising from feelings of anticipated pleasure or satisfaction, while a motive of ‘needing’ via feelings of anticipated relief. The fourth level of motivation is our capacity to form ‘beliefs’; some of which involve value judgments, i.e. notions of ‘beneficial versus harmful’, ‘pleasing versus displeasing’ etc. These can be called ‘evaluations’, and are proposed to only motivate behaviour if they generate wants or needs. Humans have also evolved the capacity to plan ahead in order to form mental representations of possible actions and to develop an intention to undertake them. These ‘plans’ are proposed to add a further level of flexibility and adaptability to our behaviour.

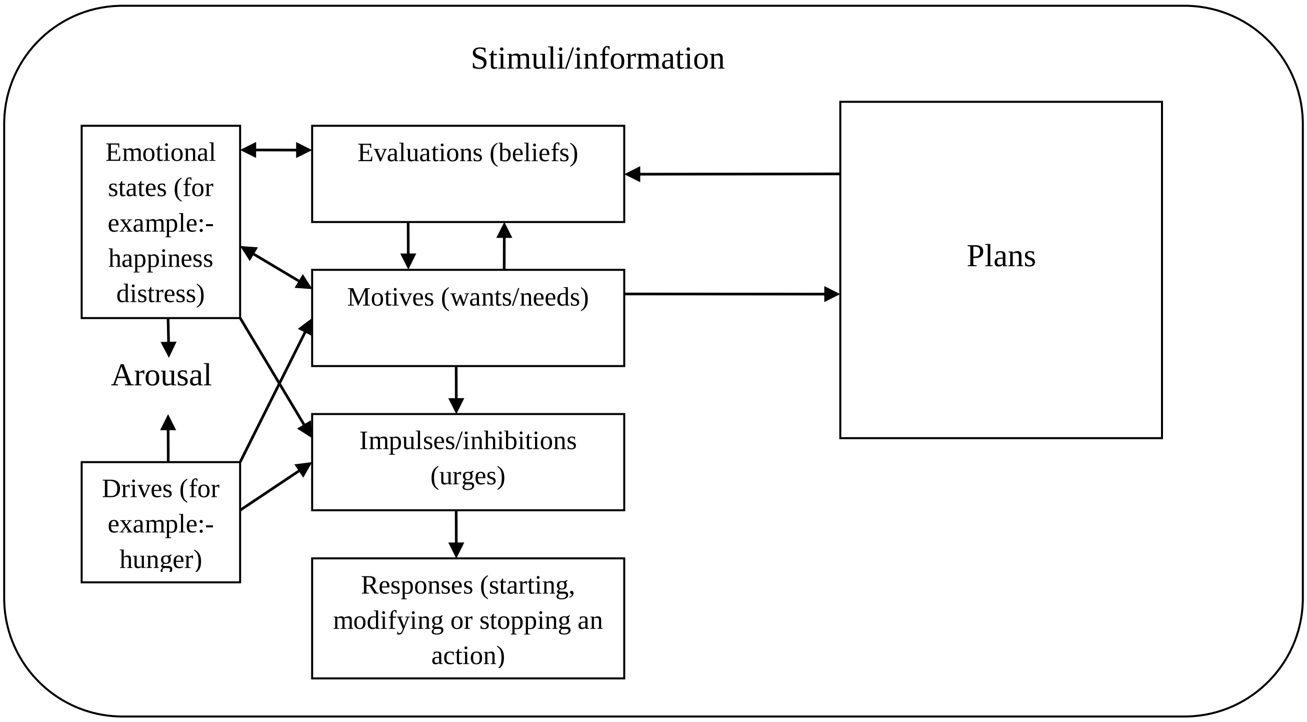


Figure 3: PRIME Theory Model of Addiction (West, 2006)

PRIME theory also has four other tenets: 1) it recognises the instability inherent in intention formation, stating that we act at any one time in pursuit of what we most want or need; 2) it acknowledges the importance of dispositions, which are viewed as changing through maturation, learning, habituation, associative learning, explicit memory, analysis and re-formulation; 3) it views the process of change as 'chaotic', involving semi-stable states with pseudo-random switching during periods of instability, and 'dialectic', involving mutually interacting elements; thus explaining why addictions manifest so differently despite often similar underlying pathologies; and 4) proposes a role for self-control and identity, the latter of which is claimed to be a very strong source of wants and needs (West, 2006).

Current Approaches to Tobacco Control

Current tobacco control strategies to reduce the burden of smoking can be systematically grouped using a definition provided by West (2006b), into those which involve influencing the behaviour of current or potential tobacco users, and those which involve limiting how far the tobacco industry can seek to influence smokers' behaviour. Although some of these approaches appear efficient, others are less effective or warrant a larger repertoire of research for further conclusions to be drawn.

Influencing the Behaviour of Current Smokers or Potential Smokers

The aim of this particular category is to reduce the number of people who use tobacco by motivating those which have started smoking to stop, and by preventing young people from starting in the first place. Historically by far the most effective of these methods is that of social coercion, and in particular, the existence of a strong taboo against women smoking. Even now most of the world's women face strong social pressures not to smoke, and smoking prevalence is much lower than in men (Mackay & Ericksen, 2006). Economic coercion through taxation also appears to be effective in decreasing cigarette consumption. Substantial scientific evidence shows that higher cigarette prices result in lower overall cigarette intake; with youth, minorities, and low-income smokers being two to three times more likely to quit or smoke less than other smokers in response to price increases (Ali & Koplan, 2010). The implementation of cleaner air laws have also shown efficacy in reducing smoking rates (Stephens, Pederson, Koval & Kim, 1997; Jha & Chaloupka, 1999). The ban in Ireland reduced smoking prevalence by two per cent within the first two years (Action on Smoking & Health (ASH), 2006), while the ban in England appears to have had a similar effect (Cancer Research UK, 2008). Other valuable strategies include the presence of campaigns delivering warnings about the health effects of smoking, and education about the effects of cigarette consumption (Bala, Strzeszynski & Cahill, 2008; Levy, Nikolayev & Mumford, 2005).

To complement these population level approaches, the National Health Service (NHS) in England provides smoking cessation services to help the most dependent smokers who wish to quit. These were established in 1999, following the publication of the Government White Paper *'Smoking Kills'* (Department of Health (DOH), 1998; West, McNeill & Raw, 2000a), and have been instrumental in reducing smoking rates (Bauld, Bell, McCullough, Richardson & Greaves, 2010). These services offer smokers either individual or group support; both of these have shown efficacy (Lancaster & Stead, 2005a; Stead & Lancaster, 2005). In recent years, studies have attempted to elucidate the evidence-based behaviour change techniques used in these behavioural interventions, and as to which of these may be associated with success rates (Michie, Churchill & West, 2011; West, Evans & Michie, 2011; West, Walia, Hyder, Shahab & Michie, 2010). However, this has been hindered somewhat by poor reporting of intervention content (West, 2006c). Nonetheless, clinical trials are available on the effectiveness of specific types of behavioural support, which may offer some indication as to the factors that are important in the services provided by stop smoking counsellors. For instance, there is evidence to suggest that Cognitive Behavioural Therapy (CBT), the formation of implementation intentions, and motivational interviewing, have the potential to reduce the prevalence of smoking (Sykes & Marks, 2001; Higgins & Conner, 2003; Colby et al., 1998). CBT enables addictive behaviours to be changed by facilitating the control of the psychological processes associated with the acquisition and maintenance of the habit, including conditioning, reinforcement, arousal, attention to cues, moods, suggestion and imagery. Common techniques include relaxation training, drug refusal, problem solving skill development, cognitive reconstructing and relapse prevention (Marks, 1993). In contrast, implementation intention formation involves the idea that goals are more likely to be realised when participants form specific plans about when, where, and how they are to be performed (Gollwitzer & Sheeran, 2006); while motivational interviewing is a technique for changing non-drug motivations in order to treat addiction (Cox & Klinger, 2004).

A more recent behavioural technique is based on 'mindfulness therapy', a method which encourages individuals to pay attention on purposes to the present moment. It is possible that this may attenuate the influence of automatic processes (Bishop et al., 2004). Rogojanski, Vettese and Antony (2011) carried out an empirical study to assess the effectiveness of a brief suppression versus mindfulness-based strategy for coping with cigarette cravings. Participants in both conditions reported significantly reduced amount of smoking and increased self-efficacy in coping with smoking urges. However, only those in the mindfulness condition demonstrated reductions in negative affect and marginal reductions in their level of nicotine dependence. There is also increasing interest in 'cue exposure therapy' (CET), where the frequent presentation of drug related cues aims to elicit cravings while drug use is prohibited, thus extinguishing urges to smoke and other responses. However, although CET reduces attentional biases towards smoking-related stimuli, it does not appear to improve clinical outcomes (Marissen et al., 2006; Conklin & Tiffany, 2002).

In addition to these behavioural interventions, Stop Smoking Services provide a plethora of medications to help smokers quit, including NRT, which has been shown to be an effective cessation aid (Silagy, Lancaster, Stead, Mant & Fowler, 2004). Bupropion, an antidepressant, has been shown to have similar efficacy to NRT, roughly doubling quit rates, but in contrast has the disadvantage of a number of unpleasant side-effects (Hughes, Stead & Lancaster, 2007; Jorenby et al., 1999). This is true also of other pharmacological therapies, including antihypertensive clonidine and varenicline, which are associated with severe drowsiness and suicidal behaviour respectively (Gourlay & Benowitz, 1995; Jorenby et al., 2006; Gonzales et al., 2006). To date, evidence for other pharmacological cessation treatments, such as selective serotonin reuptake inhibitors, anxiolytics, opioid antagonists, and nicotine vaccines, is inconclusive (Covey et al., 2000; Henningfield, Fant, Buchhalter & Stitzer, 2005; Hughes et al., 2007; King, Torello, Krishnan-Sarin & O'Malley, 2009)

However, not all tobacco control approaches aimed at reducing uptake and increasing cessation are equally successful. The use of booklets, leaflets or other self-help materials have proved ineffective (Lancester & Stead, 2005). Restricting tobacco access to minors is also rather limited, as children often obtain cigarettes from older friends or from vending machines (Fuller, 2005). Moreover, 'Quit and Win' competitions have had mixed evaluations (Cahill & Perera, 2008), with concerns about their misuse meaning that they have played a relatively small role in tobacco control strategies.

Limiting the Activities of the Tobacco Industry

The aim of this particular category is to curb the tobacco industry's efforts aimed at getting people to start smoking and not to stop. One method has been to restrict or ban promotions of tobacco products, with evidence suggesting that these, if comprehensive enough, can be effective (Jha & Chaloupka, 1999; Moodie, MacKintosh, Brown & Hastings, 2008). However, this is probably due to reduced uptake rather than increased cessation, as addicted smokers will continue regardless of the new regulations. Tobacco companies have also been increasingly trying to find ways to get around these restrictions, with many moving towards new types of promotions. For example, Marlboro has used its mailing database to promote directly with giveaways and general invitations to the Marlboro Ranch in the US (Byrnes, 2005, October 31). In the UK, tobacco companies focus on point of sale promotions and the pack itself, which fail to be covered by the '*Tobacco Advertising and Promotion Act'*, passed in 2001. This resulted in the 2011 tobacco control strategy *'Healthy Lives, Healthy People'*, pushing for the plain packaging of cigarettes and out of view sales (DOH, 2011).

Another method is to prevent miss-claiming by the tobacco industry. For most of the past 100 years cigarette manufacturers have told smokers that their products were not injurious to health (Tobacco Industry Research Committee, 1954). In January 1954, Philip Morris, R. J. Reynolds, Brown and Williamson, Lorillard, and American Tobacco, jointly placed an advertisement entitled '*A Frank Statement to Cigarette Smokers'* which appeared in 448 newspapers in 258 cities (Tobacco Industry Research Committee, 1954; Pollay, 1990). The advertisement questioned research findings implicating smoking as a cause of cancer, promised consumers that cigarettes were safe, and pledged to support impartial research to investigate allegations that smoking was harmful to health. This has clearly resulted in a public that is misinformed about the health risks of smoking (Cummings, Morley & Hyland, 2002).

A final attempt has been to try and ensure that tobacco companies do not make their cigarettes more palatable in order to increase their addictive potential. It appears that cigarettes' combination of sweet smell and other sensations associated with smoking, together with the nicotine hit, produces a lethal addictive cocktail (Palmatier et al., 2006). Past research has consistently shown that denicotinised cigarettes that include sensory and behavioural components of smoking, reduce subjective measures of tobacco craving and withdrawal, and contribute significantly to subjective reward (Butschky, Baily, Henningfield & Pickworth, 1995). Tobacco companies realised many years ago that the sensory aspects of cigarettes are extremely important for youth smokers and manipulated cigarettes accordingly (Cummings, Morley, Horan, Steger & Leavell, 2002; Carpenter, Wayne & Connolly, 2005). Similar manipulations were used to entice women after British American Tobacco reported that 'sensory pleasure', i.e. taste and enjoyment, was the major component of female preference for cigarettes (R. J. Reynolds Tobacco Co, 1986; Carpenter et al., 2005).

The Need for a New Approach: Harm Reduction

As a result of its cigarette prices and the introduction of a comprehensive tobacco advertising ban in 2002 and smoke-free legislation in 2007, as well as the other strategies mentioned above, the UK was recently ranked as having one of the strongest tobacco control policies in Europe (European Conference on Tobacco or Health, 2007). This helped the government to reach its 2008 smoking prevalence target of 21%, set out in the 1998 White Paper *'Smoking Kills'* (General Household Survey, 2008). However, there are currently 10 million people still smoking in the UK, and at the current rate of decline it is estimated that it will take over 20 years for smoking prevalence to drop by half (Royal College of Physicians, 2008). Additionally, smoking still remains the leading cause of death, disease and health inequalities, with over 30% of lower socio-economic individuals reporting some form of cigarette consumption (General Household Survey, 2008). In developing countries the situation is worse, with prevalence rising by 3.4% per year and an incidence of around 40% within Africa nations. From this it is projected that by 2030 around 70% of the estimated 10 million global deaths from tobacco will occur in developing countries, whose resources are spent battling acquired immune deficiency syndrome (AIDS) and numerous other communicable diseases (World Health Organisation, 2004; Mackay & Ericksen, 2006).

Clearly more needs to be done. Although the effectiveness of conventional policies must continue to be maximised and new policies introduced, including media campaigns which undermine the legitimacy of the tobacco industry, other more radical initiatives must be considered. A drastic proposal which has been made by many of those working in the tobacco control arena, is for us to move away from traditional prevention and cessation only strategies, towards an approach which includes tobacco harm reduction in addition to these. The idea being, that those smokers who are unable or unwilling to quit smoking could continue to use some form of tobacco but at a much lower risk to their health. Frankfurt (1971) provides a nice distinction of these two groups, with 'unwilling addicts' being those who would rather not engage in the behaviour but cannot stop, and 'willing addicts' being those who have thought about the behaviour and decided that they will continue with it.

Aims and Objectives of the Current Thesis

The overall aim of the thesis is to examine one specific type of tobacco harm reduction: the modification of cigarette use in an attempt to reduce cigarette intake with the aid of NRT. This may occur through smoking reduction, otherwise commonly known as cutting down; or via temporary abstinence, i.e. abstaining from smoking for a designated period of time.

The specific objectives of this thesis are:

1. To review the current literature on harm reduction; in particular, previous clinical trials and survey-based studies which have assessed the use of NRT for smoking reduction and/or temporary abstinence.

2. To determine the prevalence of NRT use for harm reduction purposes.
3. To determine the effectiveness of the use of NRT for smoking reduction and/or temporary abstinence at a population level, by assessing the association with:-
    a. Cigarette consumption
    b. Nicotine intake
    c. Attempts to quit smoking
    d. Smoking cessation
4. To identify those who may be the most interested in using NRT for smoking reduction and/or temporary abstinence, by assessing the association with:-
    a. Age
    b. Gender
    c. Social-grade
    d. Nicotine dependence
5. To determine smokers' beliefs, views, and understanding of the use of NRT for smoking reduction and/or temporary abstinence, and the ways in which smokers use NRT for such purposes.
6. To determine whether healthcare professionals are likely to encourage smokers to use NRT for smoking reduction and/or during periods of temporary abstinence.

Chapter 2: History of Tobacco Harm Reduction and Defining Concepts

''... 'When I use a word', Humpty Dumpty said, in a rather scornful tone, 'it means just what I choose it to mean – neither more nor less'. 'The question is', said Alice 'whether you can make words mean so many different things'...'' (Carroll, 1960; pp. 73)

Defining Harm Reduction

There is a general lack of consensus on the definition of harm reduction (Martin, Warner & Lantz, 2004; Warner & Martin, 2003; Joseph, Hennrikus, Thoele, Krueger & Hatsukami, 2004; Single, 1995; Wodak & Saunders, 1995). This is despite commentators in the 1980s, when the concept gained wide circulation, arguing that clarification of its definition, characteristics, and principles, were crucial to its successful incorporation into policy research (National Cancer Institute, 2001). Its definition is particularly contentious in regards to the debate about the necessity of a broad versus narrow approach (Ball, 2007).

In its most general 'broad' sense, harm reduction would refer to any programme, policy, or intervention, that seeks to reduce or minimise the adverse health and social consequences associated with a particular activity (Denning, Little & Glickman, 2004). This broad perspective would include virtually any policy, programme or intervention – including abstinence-oriented programmes or those preventing uptake – since at some level, the objective is to reduce the harmful consequences of the behaviour. This definition is too all encompassing, negating the point of having a specific label separate from the more traditional polices.

A narrower definition, and one that has the greatest currency, focuses on those policies, programmes and interventions that seek to reduce or minimise the adverse health and social consequences of an activity, without requiring an individual to discontinue the behaviour (Denning et al., 2004). This latter definition recognises that many individuals are unwilling or unable to abstain from particular activities at any given time, and that there is a need to provide them with options that minimise the harms caused by their continued involvement to themselves, to others, and to the community. Conceiving of harm reduction in this way means abstinence-orientated programmes and the use of criminal law to deter any drug use, would not be considered harm reduction measures. Such a definition was adopted by one of the first reports on harm reduction as applied to smoking, published by the Institute of Medicine in 2001: *''A product* [or strategy] *is harm-reducing if it lowers total tobacco-related mortality and morbidity even through use of that product* [or strategy] *may involve continued exposure to tobacco related toxicants''* (Stratton, Shetty, Wallas & Bondurant, 2001; pp. 189).

However, this definition is perhaps too constraining, in so far as a product or strategy can only be classed as an approach to harm reduction if it is shown to reduce actual harm. Not only may this take many years, but the question naturally arises as to how one would class a strategy used by smokers with the intention to reduce harm, that does not prove to do so during testing. Perhaps it is better to consider the stance of smokers and the reasons for their behaviour, and to split the classification system in the future when the 'harmfulness' of products has been realised into effective and ineffective approaches. In other words, we should currently define harm reduction as: *'the use of any product or strategy with the 'potential' to reduce harm, or where there is at least 'intention' to do so'.*

The definition used by the Institute of Medicine's report (2001) also neglects to recognise the potential implications of a harm reduction approach on non-smokers, and fails to stipulate the form in which the reductions in harm should take. More specifically, whether harm is psychological or physiological, i.e. reduced dependence and improved mental health or reduced risk of chronic morbidity and mortality. For many, physiological reductions in harm may carry greater weight, but one should still consider potential improvements in mental health; particularly as harm reduction is favoured among those suffering from psychiatric disorders (Moeller-Saxone, 2008; Melamed, Peres, Gelkopf, Noam & Bleich, 2007). Consequently, the definition which will be adopted in the current thesis is that harm reduction involves: *'any attempt to reduce the harm, psychological or physical, from smoking without complete cessation of one or more tobacco constituents. This includes an attempt to reduce harm not only to the smoker, but as a by-product, the effect of environmental smoke on those in close proximity'.* Traditionally, harm reduction approaches as applied to smoking have been grouped under the umbrella of 'tobacco harm reduction', which is the term that will be adopted throughout this thesis. However, it is important to consider the possibility that one may require greater specificity as the debate matures. One could perhaps distinguish three types of harm reduction: smoke harm reduction meaning continuing to smoke; tobacco harm reduction involving continuing to use tobacco, perhaps in a different form; and nicotine harm reduction involving continuing to use nicotine by switching from tobacco to a pure nicotine delivery system.

The Emergence of a Harm Reduction Approach in Society

Harm Reduction in the UK can be traced back to the 1920s, when the Rolleston Committee, a group of leading British physicians, concluded that in certain cases maintenance on drugs may be necessary to help drug abusers lead useful lives. Some 60 years later, the 'Merseyside Model' was developed in response to an epidemic spread of drug use, particularly heroin. This model was based on the foundation of Merseyside clinics, pharmacists, and the police force in Liverpool, working together to establish a comprehensive approach to drug use, at the centre of which were needle exchange programmes. The first international conference on the reduction of drug related harm took place in Liverpool in

1990, as a response to the interest shown in what was happening in the region. The Merseyside model has subsequently been implemented across the UK and around the world, distributing sterile injecting equipment and offering the provision of safe disposal sites (Norman, Vlahov & Moses, 1995). These have demonstrated efficacy, reducing levels of AIDS and the frequency of needle sharing (Drucker, Lurie, Wodak & Alcabes, 1998).

Harm reduction goals have now extended to include hepatitis B and C prevention, reducing overdose deaths, and improving the general health of drug users (Plant, 2004). There is plenty of evidence to demonstrate the effectiveness of these approaches in reducing a range of medical, psychological and social harms (Sheridan, 2005; Piper et al., 2007). One popular example is that of methadone maintenance. Providing a medical prescription for pharmaceutical methadone to heroin addicts has been seen in some countries as a way of solving the 'heroin problem', with potential benefits to the individual addict and to society (Bell, Hall & Byth, 1992). The UK has perhaps one of the most liberal harm reduction approaches to heroin addiction, providing regular injectable heroin to about 300 people each year (Sheldon, 2008). It is also substantially more advanced in other respects, including increasing the role of shared care arrangements for drugs users, primarily with the involvement of General Practitioners (GPs) and nurses (National Treatment Agency for Substance Misuse, 2005). In more recent years there has been an extension of the concept of harm reduction to automobile safety, teen sexual behaviour, extreme sports and alcohol (Denning et al., 2004). For the latter this has included the provision of shatter proof glasses and controlled drinking (Plant et al., 2004).

Despite the historical success of harm reduction approaches, the concept, which tends to be interchanged with others including 'risk reduction', 'harm minimisation' and 'vulnerability reduction', has generated extremes of emotion. It would appear that on the one hand, there are those who view harm reduction as a way to help drug users minimise the damage they cause to themselves and others through their continued use of drugs; while on the other hand, there are those who only believe in ‘zero-tolerance’, viewing harm reduction as an approach that encourages drug use and provides thinly-veiled support for their decriminalisation or legalisation. This ideological argument has been unproductive, and more importantly, hinders the implementation of well-intentioned and effective policies aimed at protecting people from the adverse health and social consequences associated with drug use (Ball, 2007). Partially to blame is the traditional reliance of many on the Disease Model of drug addiction, which focuses on complete abstinence, prioritising the elimination of drugs rather than preventing the adverse consequences of use (Jellinek, 1960).

The Beginnings of Tobacco Harm Reduction

The concept of harm reduction as applied to tobacco use has been with us since the introduction of the filter cigarette in the early 20th century, when various cigarette modifications were introduced to reduce concerns about the harmfulness of smoking. However, it wasn’t until the 1960s that it gained respectability, when the idea of the low tar cigarette took off with encouragement by the public health community. Three observations were persuasive: 1) a dose response between cigarettes smoked and disease outcomes was found (Doll & Hill, 1950); 2) there was a reversal of risk when smokers stopped smoking (Doll & Hill, 1950); and 3) there was a dose response between the amount of tar painted on mouse skin and the tumour response (Wynder, Graham & Croninger, 1953). It therefore seemed logical that reducing the number of harmful particles should reduce the dose and hence the disease result. What was not foreseen, was that the tobacco industry’s response would be to modify the design of the cigarette to yield lower toxin values when tested by smoke machines, according to the method of the Federal Trade Commission and International Standards Organisation, which would not apply to a smoker who often covered the vent holes and smoked each cigarette more strongly to compensate for the lower nicotine content (Kozlowski, O'Connor & Sweeney, 2001). The cigarette also became more efficient as a delivery system for nicotine though the use of ammonia technology and other additives. This first attempt to implement a harm reduction strategy therefore failed miserably.

Nevertheless, in the 1970s, leading tobacco addiction specialists began to recognise the potential of harm reduction approaches. Russell in 1974 likened the *''harsher restrictive measures''* and *'intensification'* of anti-smoking efforts to *''flogging a dead horse harder''* and stated that the *''goal of abstinence and the abolition of all smoking was unrealistic and doomed to fail''* (Russell, 1974; pp. 256-257). Tobacco harm reduction has gained even more momentum over the past decade, which is possibly due to the publication of the Institute of Medicine's report *'Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction',* commissioned by the US Food and Drug Administration in 2001. This report attempted to answer four questions on tobacco harm reduction, prior to which there was no clear synthesis of the harm reduction literature. The first three sought guidance on what happens when an individual uses a product or strategy for reducing harm: is there potential for a genuine health gain and how should this be evaluated? The fourth question addressed what happens to the population as a whole when harm reduction strategies are presented to smokers. This was an over ambitious attempt, since this question can never really be answered in advance because it will depend on many unknowns, including the regulatory framework into which the products are launched (Bates, 2001). Following this report, a conference in May 2001 was held on reducing tobacco harm, with the primary goal to identify key issues related to reducing the harms associated with tobacco use, and critical research areas that needed to be addressed (Hatsukami et al., 2002).

In the UK, there have been a number of calls for a tobacco harm reduction policy since the Institute of Medicine's report. In 2007, the Royal College of Physicians published '*Harm*

Reduction in Nicotine Addiction: Helping People who Can't Quit', which stated that: *''Harm reduction is a fundamental component of many aspects of medicine and, indeed, everyday life, yet for some reason effective harm reduction principles have not been applied to tobacco smoking''* although it is *''controversial, and challenges many current and entrenched views in medicine and public health''* it also *"has potential to save millions of lives''* and *''deserves serious consideration''* (pp. 10). Following this, in May 2008, the DOH conducted a consultation on the future of tobacco control, which included the publication of a chapter on helping people who were not able to quit and the concept of harm reduction (DOH, 2008a). Less than a year later, in January 2009, the British Medical Associations Board of Science produced a policy position entitled *'Harm Reduction a Tobacco Free Approach Supporting those Smokers Struggling to Quit'*. This argued that effective alternatives to abrupt cessation needed to be considered for certain smokers in order to allow them to obtain nicotine without being subjected to the risks of smoked tobacco.

However, it wasn't until February 2010, that a substantial shift in the policy of harm reduction occurred, with the publication of *'A Smokefree Future'*. This was the first time the UK government came out and said that it supported a harm reduction approach in their tobacco control strategy (DOH, 2010). On the same date, the Citizens Council of the National Institute for Health and Clinical Excellence published a report on its meeting to discuss smoking and harm reduction, voting overwhelmingly in favour of the position that harm reduction was a valid approach. This concept was carried forward into the tobacco control strategy, *'Healthy Lives, Healthy People'*, under the guidance of the new Conservative Government, which stated: *"We will work in collaboration with the public health community to consider what more can be done to help tobacco users who cannot quit, or who are unwilling to, to substitute alternative safer sources of nicotine . . . for tobacco. In support of this, NICE will produce public health guidance on the use of harm reduction approaches to* *smoking cessation (to be published in spring 2013)''* (DOH, 2011; pp. 36). Proposals have also been made for stop smoking services in England to extend their treatment to include certain harm reduction approaches as 'routes to quit', with a number of pilots already underway to test the feasibility of these (Croghan & Chambers, 2011).

Taxonomy of Tobacco Harm Reduction Approaches

Following the release of the Institute of Medicine's report in 2001, press coverage conveyed rather confusing messages. This included a tendency to group all the assessed approaches of harm reduction under the same umbrella, despite varying conclusions for each. This provides a cautionary note regarding the need for clear distinctions among harm reduction activities (Shiffman et al., 2002a; Bates, 2001). Although some authors have attempted to catalogue harm reduction approaches in the field of tobacco control, these have often been far from complete, with a focus mainly on a few categories (Anderson & Hughes, 2000; Stead & Lancaster, 2007; Kozlowski, 2002; Henningfield, Moolchan & Zeller 2003; Institute of Medicine, 2001; Shiffman et al., 2002a). Perhaps the most comprehensive is that by Shiffman et al. (2002a), who proposed a nomenclature and dimensional analysis of a wide range of harm reduction approaches. This was detailed and potentially very useful but does not as yet seem to have had a significant impact. Part of the reason may be that something simpler is needed, and that it did not make some important distinctions. For example, the authors failed to make a crucial distinction in the taxonomy between individual actions and government policies. A potentially useful way of classifying products and strategies that fall under the aegis of harm reduction, concerns who is to be the ultimate target. It can be users, producers of the harmful products, or other agencies such as the health service (see Figure 1).

Consideration of the issues and dimensions that will require addressing for the various tobacco harm reduction products is also necessary, in order to allow a hierarchical categorisation of harm reduction approaches during taxonomy development. This is something which will become particularly important as research increases over the coming years. Shiffman et al. (2002a) highlighted eleven such science and policy issues that require clarification for each form of harm reduction: 1) the intended effects of harm reduction (biological, behavioural or mechanical); 2) mechanisms by which the intended effects are accomplished; 3) potency, i.e. the degree of harm reduction which could be achieved; 4) toxicology; 5) complexity of toxicology; 6) toxicity; 7) population risk; 8) appeal; 9) amount of behaviour change required; 10) risk to others; and 11) the effect on dependence. For example, an approach that is highly efficacious, but is adopted by only a small number of smokers, may be classified as subordinate to one less efficacious but highly appealing, since the latter could have a greater total public health impact. Similarly, one which is somewhat safer but causes more people to adopt tobacco use, may be deemed inferior to one which is not as safe but used by fewer non-smokers.

An attempt is made below to address these eleven issues and dimensions for the various harm reduction approaches displayed in the taxonomy in Figure 1. Some are clearly easier to answer than others. For example, the intended effects, mechanism by which these occur, and the toxicology of products, are already well established. In contrast, data are lacking on potency, dependency, acceptability and population-based risks. The latter of which is hard and perhaps impossible to answer prior to the implementation of a harm reduction approach.

Producers as the Target

With producers as the target, the goal is to lead them to market less harmful products, such as smokeless tobacco, and to generate modified cigarettes which may be deemed less harmful. This is in line with previous harm reduction approaches which have involved automobile and sport safety provisions, and those which shift drug users to less toxic modes of delivery, i.e. needle exchange programmes (Denning et al., 2004).

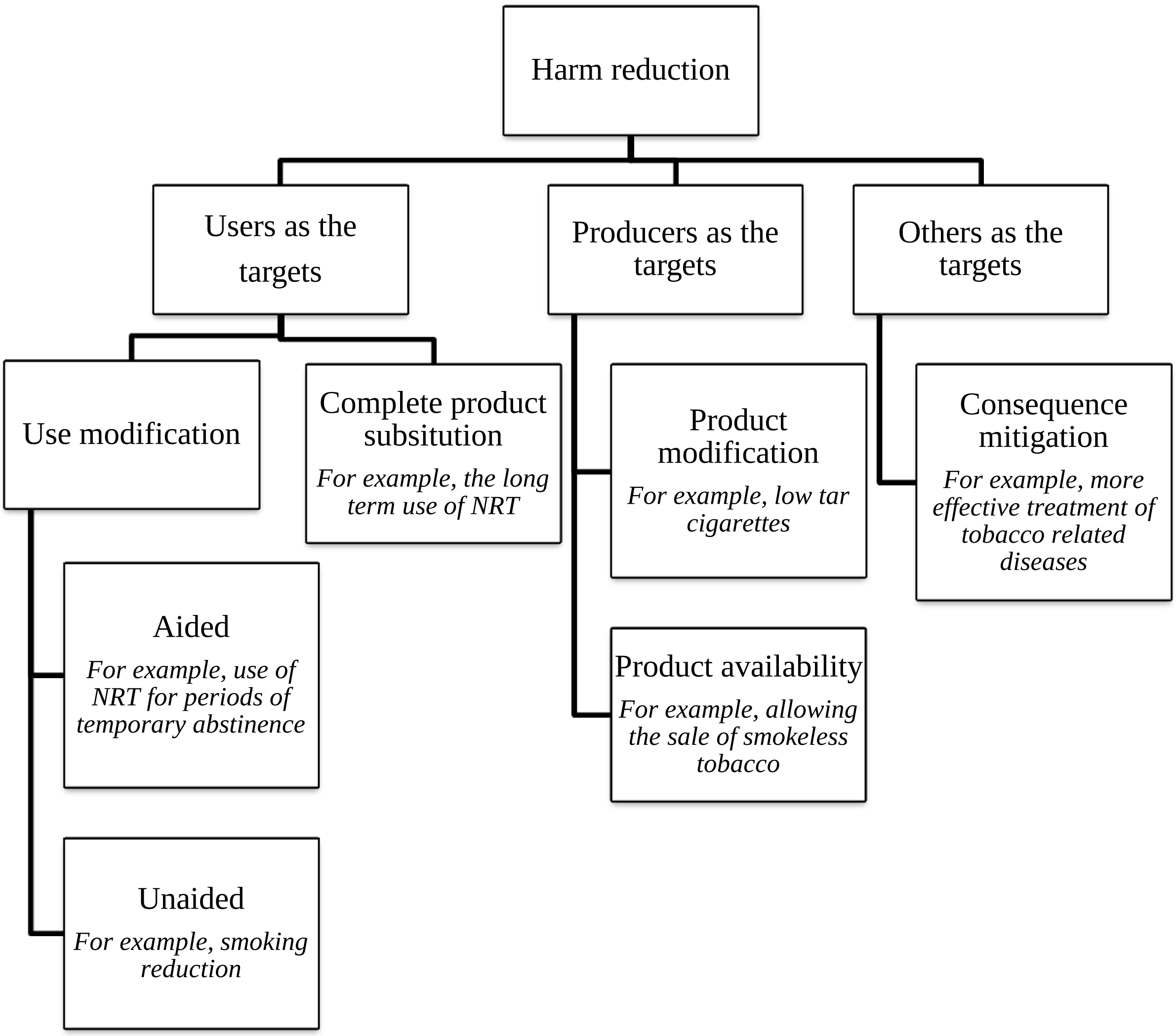


Figure 1: Taxonomy of Tobacco Harm Reduction Approaches

Product Availability: the Example of Smokeless Tobacco

Smokeless tobacco is used in many counties around the world, including those in the Middle East and on the Asian Subcontinent. However, products differ substantially. For example, the fermentation and curing process used in the production of Indian smokeless tobacco, results in the development of potential carcinogens called tobacco specific nitrosamines. Addictives are also commonly added which enhance toxicity and psychotropic effects (Choudhury, Chowdhury, Prasad & Shibahara, 2009; Gupta & Subramoney, 2006). In the West very different products are used and these fall into three categories. The first is powdered dry snuff which is made from fermented fire cured tobacco that is pulverised into powder. The second is loose leaf chewing tobacco which consists of air cured lead tobacco from Pennsylvania and Wisconsin that is shredded, coated with sweet flavouring solutions, and packaged in foil lined pouches. The third is moist snuff which consists of fire and air cured dark tobaccos that are finely ground. There is a long tradition of the use of the latter in Scandinavia, where it is known as Snus. However, moist Snus manufacturing differs substantially in Sweden to other Western countries. Traditionally, American products undergo fermentation, which imparts characteristic flavours, but results in higher concentrations of tobacco specific nitrosamines and nitrate. In Sweden moist snuff is subjected during manufacturing to heat treatments akin to pasteurisation, yielding products with very low levels of such compounds. Although similar manufacturing processes to Snus are now being used for a number of US products, including Exalt and Revel (Rodu & Godshall, 2006).

Almost half of all Swedish males use Snus rather than cigarettes, and this appears to have resulted in Sweden having the lowest standardised rate of lung cancer incidence in the world, around half that of the UK, and a much lower incidence of heart disease and oral cancers (World Health Organisation/International Agency for Research on Cancer, 2001; Schildt, Eriksson, Hardell & Magnuson, 2009; Asplund, Nasic, Janler & Stegmayr, 2003). Additionally, the mortality experience of Snus users is not significantly greater than that of non-tobacco users, and is appreciably less than that of cigarette smokers (Accortt, Waterbor, Beall & Howard, 2002). However, there is a slight increased risk of pancreatic cancer and pre-eclampsia in women relative to non-tobacco use, but the risks are still substantially lower than smoking (Boffetta, Aagnes, Weiderpass & Anderson, 2005). As such, it has been recommended that smokers of cigarettes move to using smokeless tobacco, in particular Snus like products, to reduce smoking-related morbidity and mortality.

However, more research is clearly advisable. Current findings are largely based on male participants and could have been affected by other factors in Sweden, including effective tobacco control policies. There is also a concern that Snus will function as a lead into smoking for people who would not otherwise smoke. Such ‘gateway effects’ are always contentious and hard to demonstrate, for the simple reason that we do not know what smokeless users would have done in the absence of smokeless tobacco. The data from Sweden suggests that the gateway is more likely to be an exit from smoking rather than an entrance. Among Swedish males with a primary use of Snus, no more than 20% ever start smoking, while 45% of other males become smokers (Ramstrom, 2003).

Product Modification: the Example of Modified Cigarettes

Most of the attention generated by the tobacco harm reduction debate has centred on alternative less harmful cigarettes, also known as ‘potential reduced exposure products’. Such cigarettes are given this name as it is difficult and perhaps impossible to assess their harm reduction potential in a rigorous scientific manner, short of decades of investigation (Shiffman et al., 2002a). Such modified cigarettes include 1) brands with major carcinogens removed (for example:- Advance & Omni), that claim to reduce both catechols and polyaromatic hydrocarbons (Newswire, 2001, December 11); 2) high tech pseudo cigarettes with unique means of releasing nicotine and other chemicals (for example:- Accord & Eclipse); and (3) nicotine free tobacco cigarettes [for example:- Vector and Quest; (Shiffman et al., 2002a)].

From a public health perspective, there is concern that such products bear unsubstantiated claims to reduce exposure and risk. They have entered the marketplace without governmental scrutiny and in the absence of any independent scientific evaluation of their claims. Due to compensatory smoking among smokers it is likely that they will be found to be as hazardous as ordinary cigarettes, as was the case with the downfall of the light cigarette (Shiffman et al., 2002a). The greatest danger is that these products may pose a significant threat to tobacco cessation and prevention efforts. Health concerned smokers who see the claims for novel combustible products may now think that a safer cigarette genuinely exists, making them less interested or less inclined to try to quit smoking (Parascandola, Augustson & Rose, 2009). There is also evidence that these modified products introduce new harms to the smoker, including an increased exposure to carbon monoxide and the inhalation of glass fibres (Fagerstrom, Hughes, Rasmussen & Callas, 2000; Pauly et al., 1998). It is thus necessary, before advancements in this area are made, for product analysis research outside of the tobacco industry. This is necessary, as tobacco companies are the main manufacturers of these products and so have an economic interest invested in the outcomes of studies.

Others as the Target

With others as the target, the goal is to reduce the adverse consequences of use, i.e. ‘consequence mitigation’. This may occur through the development of more effective detection and treatments of chronic obstructive pulmonary disease or lung cancer, or via chemoprevention. This is akin to developments in other areas of harm reduction including the early detection and treatment of HIV among drug users (Libman & Makadon, 2007).

Consequence Mitigation: the Example of Improving Detection of Smoking-Related Diseases

At the moment there is no national screening programme for lung cancer in the UK, however, if sensitive enough tests that are cost effective come into place in the near future, this may become a reality. At the moment three pilot tests are underway which are assessing the utility of using spiral computed tomography, fluorescence bronchoscopy, and the measurement of chemical changes in the body (Cancer Research UK, 2011). Similarly, screening programmes do not exist for oropharyngeal or mouth cancer, although there are intentions to bring in screening for chronic obstructive pulmonary disease (National Clinical Guideline Centre, 2010). Such an approach is likely to be highly successful, with the individual who is told that they have early signs of tobacco-related disease not only receiving life-saving treatment, but also perhaps being more motivated to quit or to try and reduce their cigarette intake. However, there are concerns with this approach. For one, many have argued that it may be a disincentive to cessation, in that those individuals who are told that they do not have lung cancer may adopt the view that they are at a decreased risk of mortality, and therefore, see no additional benefits in attaining abstinence. It is also unclear whether smokers would take-up the opportunity of screening, thus questioning its cost-effectiveness and potential impact (Marteau, 1993). Moreover, consideration needs to be given as to its potential side-effects, with radiation exposure being linked to cancer cell development and progression (Perquin, Baillet & Wilson, 1976); there is also always the possibility of false negatives, which may lead to an illness remaining undetected, untreated and thus progressing without medical intervention.

Consequence Mitigation: the Example of Chemoprevention

Chemoprevention involves the use of agents to prevent or minimise the occurrence of disease progression, in other words, it involves treatment with non-toxic agents to prevent cancer. Epidemiological studies and rodent based research has consistently shown that vegetables containing isothiocyanates (for example:- cruciferous vegetables such as broccoli, cauliflower, cabbage, mustard, & watercress) or myo-inositol (for example:- beans, grains &

nuts), greatly decrease the risk of lung cancer and inhibit tumour formation (World Cancer Research Fund/American Institute for Cancer Research, 1997; Hecht, 2000). However, there are limitations to the concept of chemoprevention of tobacco-related cancer. It is possible that the extensive damage from years of exposure to tobacco carcinogens may be too great for any agent to overcome. Evidence also demonstrates that tobacco exposure modifies the chemopreventive efficacy of nutrient derivatives; whereas the retinoid Isotretinoin [13-*cis*-retinoic acid (13cRA)] lowers mortality in never smokers, it increases the occurrence of cancer in current smokers (Lippman et al., 2001).

Users as the Target

With users as a target, the goal is to change their behaviour in such a way that they or others suffer less harm. This could be done through the modification of cigarette use, which includes smokers cutting down the number of cigarettes they smoke or adapting the way in which they smoke their cigarettes. These modifications could be aided or unaided. It can also be attained through complete product substitution, such as the long-term use of NRT after smoking cessation to prevent relapse. Previous harm reduction strategies which would fall into this category include controlled drinking and where a less harmful but dependence prone product was added to the mix, such as methadone (Denning et al., 2004).

Complete Product Substitution: the Example of Long-Term Nicotine Replacement Therapy

The use of nicotine for up to five years has no known harmful effects (Murray et al., 1996). In addition to the fact that the use of NRT is substantially less harmful than smoking (Benowitz, 1998), it could be argued that declines in harm to health will occur if smokers are encouraged to switch to therapeutic nicotine. However, despite the potential of this particular harm reduction strategy, few smokers appear to use NRT for extended periods (West et al., 2000b). This is potentially due to the misperception that it is the nicotine and not the other constituents of cigarettes that cause harm, the cost of purchasing NRT concurrently with cigarettes, or the unacceptability of NRT products (Siahpush, McNeill, Hammond & Fong, 2006a; Foulds et al., 1997; West et al., 2000b). Currently available medicinal nicotine products do not deliver nicotine in either the concentration or at the same speed as cigarettes, with many failing to provide necessary sensory and/or behavioural stimulation. Moreover, there is a concern among many in the tobacco control community, that allowing smokers to use NRT for extended periods of time following cessation could at some point lead back to smoking, with smokers' nicotine dependency simply being transferred to another addictive product. However, there is little evidence for this, with studies showing that the long-term use of NRT keeps even the most dependent smokers abstinent from cigarettes (Hajek et al., 1988; Shiffman, Hughes, Pillitteri & Burton, 2003a; Medioni, Berlin & Mallet, 2005; Schnoll et al., 2010); with particular efficacy among those with schizophrenia and schizoaffective disorders (Horst, Klein, Williams & Werder, 2005), and among men as opposed to women (Cepeda-Benito, Reynoso & Erath, 2004).

Use Modification: the Example of Changing Smoking Style

Many smokers adjust their smoking style, i.e. take shorter puffs, attempt not to inhale, or only smoke part of the cigarette (Okuyemi, Richter, Ahluwalia, Mosier, Nazir & Resnicow, 2002; Dolcini et al., 2003; Hughes, Gust & Pechacek, 1987; Pomerleau, Pomerleau, Majchrezak, Kloska & Malakuti, 1990; Johnson, Kalaw, Lovato, Baillie & Chambers, 2004). 'Half-butting' or 'bumming a puff from a friend' appear to be particularly common among youth smokers, with Johnson et al. (2004; pp. 1285) reporting the following quote from a seventeen year old male: *''You just kinda resist the craving, just spread it out over the day,* *and try not to really think about it too much. Sometimes, I'd take like a couple of drags of a cigarette and put it out and then later take a couple of drags . . . and y'know, make that cigarette kind of last.''* Smokers often report that they believe that these modifications make smoking a risk-free behaviour, however, the implicit understanding is that these approaches are ineffective, and that even those reporting that they do not inhale take at least some tobacco toxicants into their lungs. Nonetheless, risk of mortality and morbidity does appear to be reduced compared to smokers who do not apply such modifications when they smoke their cigarettes. For example, Prescott, Scharling, Oster and Schnohr (2002) reported that smokers who did not inhale tobacco smoke had a risk of myocardial infarction intermediary between never smokers and 'inhalers', while Dolcini et al. (2003) that 36% of their adolescent sample who inhaled more smoke into the mouth or back of the throat had lower carbon monoxide levels than those who inhaled into their lungs. However, in the long-term this is unlikely to be a successful harm reducing technique, with compensatory smoking being triggered when nicotine levels fall below their 'normal rate'. Pomerleau et al. (1990) have noted that maintenance in reductions of puff frequency occur in less than ten per cent of smokers, while Law, Morris, Watt and Wald (1997) found that long-term adaptations to inhalation rates were only prevalent amongst the lightest of smokers. Moreover, research on the effectiveness of modifications to smoking style is limited by smokers ability to accurately report their behaviour; whereas smokers can report whether they inhale or not, they do not seem to be able to estimate the depth of their inhalations, which is perhaps the pivotal factor in determining whether there is a decreased health risk from such attempts (Herling & Kozlowski, 1988).

Chapter 3: A Potential Approach to Harm Reduction: Smoking Reduction and Temporary Abstinence

In recent years there has been increasing interest in one type of harm reduction: the modification of cigarette use in an attempt to reduce cigarette intake. This may occur through smoking reduction, otherwise commonly known as cutting down, i.e. reducing the number of cigarettes smoked per day; or via temporary abstinence, i.e. abstaining from smoking for a designated period of time (for example:- when at work, in the home, in pubs & restaurants). There are a number of questions which naturally arise in relation to this: 1) What is the current prevalence of attempts at smoking reduction and/or temporary abstinence? 2) Who is likely to partake in these behaviours? 3) Do they result in reductions in cigarette consumption? 4) If so, are these reductions maintained? 5) Do reductions in disease risk occur? 6) Do these behaviours undermine or promote smoking cessation? 7) What is the effect on continuing smokers and non-smokers of promoting smoking reduction and temporary abstinence?

Estimates of Prevalence

Bans on smoking in indoor public areas are now commonplace across the globe (ASH Scotland, 2009; Ministry of Health, 2006; New York State Department of Health, 2006; Office of Tobacco Control, 2005; Hyland et al., 2009; Lund, Lund, Rise, Aaro & Hetland, 2005; DOH, 2008b). Smokers also appear to be adopting smoke-free homes in the hope of reducing the health consequences of smoking on those around them (Borland et al., 2006; Gilpin, White, Farkas & Pierce, 1999). Consequently, it may be assumed that the majority of smokers must have to temporarily abstain at some point. Recent data from the UK suggests that only two per cent of smokers now smoke at work and while in pubs or bars, and that less than 60% smoke in their own home (Lee, Glantz & Millett, 2011). However, this does not mean that the 40-98% of 'other' smokers are temporarily abstaining, instead perhaps adopting the ritual of smoking outside (Borland, Chapman, Owen & Hill, 1990).

More direct evidence is available regarding smoking reduction, with an estimated 20-60% of US smokers reporting decreased cigarette consumption at any one time, while almost 20-30% report having moved to non-daily smoking (Bjornson, Nides, Hughes & Lindgren, 1999; Hughes, Cummings & Hyland, 1999; Farkas, 1999; Gilpin & Pierce, 2002; Gilpin & Pierce, 2002; Hassmiller, Warner, Mendez, Levy & Romano, 2003; Falba, Jofre-Bonet, Busch, Duchovny & Sindelar, 2004; Husten, McCarty, Giovino, Chrismon & Zhu, 1998; Office of Applied Studies, 2003). Such variance in prevalence may be due to differences in the samples recruited, the point in time when data were collected, differences in the methodologies used to assess smoking reduction, and study design. For example, Hughes et al. (1999) determined rates of reduction among smokers following the failure of a smoking cessation intervention. It is possible that such smokers who fail to quit smoking may be more motivated to reduce their cigarette intake than those in the general population. These previous studies also neglected to assess whether reductions were (a) the ultimate goal or (b) in preparation for quitting. The latter of which may be a more prevalent behaviour, and thus denotes the possibility that reductions for purely harm reduction purposes were not assessed (Shiffman et al., 2007a).

One study based on a UK sample of smokers rectified this latter issue, by asking smokers if they had attempted to cut down and whether their attempt was a prelude to smoking cessation (West, McEwen, Bolling & Owen, 2001a). The authors reported that 33% of the 1,012 smokers surveyed had attempted to cut down without an intention to quit smoking. However, reports of smoking reduction were retrospective, inducing a further problem of recall bias. Studies of special populations, such as prisoners and pregnant women, have also directly assessed attempts to cut down, reporting a higher prevalence than in the general population (Durrah & Rosenberg, 2004; Floyd, Rimer, Giovino, Mullen & Sullivan, 1993; Hickner, Westenberg & Dittenbir, 1984). Moreover, there are many continuing smokers who report an interest in smoking reduction. Breitling, Rothenbacher, Stegmaier, Raum and Brenner (2009) analysed data from a population-based survey in Germany of older adults aged 50-74. They reported that only 11% of smokers were content with their smoking behaviour, 30% wanted to reduce their smoking levels, and 59% wanted to quit smoking entirely. Around 75% of smokers in inpatient psychiatric settings also report a desire for smoking reduction (Moeller-Saxone, 2008; Melamed et al., 2007). Qualitative data supports these conclusions (Richter, McCool, Okuyemi, Mayo & Ahluwalia, 2002).

Associated Characteristics

It is important to determine which socio-demographic and smoking characteristics are associated with attempts at smoking reduction and temporary abstinence, in order to distinguish those smokers who may be the most receptive of a harm reduction programme. The preference being, that this will be the 10-15% of smokers who would continue to use some form of tobacco even in the existence of the most effective tobacco control programmes (Stratton et al., 2001). Such information is also desirable methodologically speaking, when deciding whether smokers are reducing with or without an intention to quit smoking. If smokers are reducing as a step towards cessation, one would expect to see those who reduce their smoking to have similar characteristics to those who quit. On the other hand, if they are reducing as an alternative to cessation, one would expect to see reducers differ from quitters. Harm reduction has also been hypothesised as a central strategy for those of lower socio-economic status, as a means of reducing the social inequalities in smoking cessation (Siahpush, McNeill, Borland & Fong, 2006b); and for those suffering from chronic mental and psychological disorders, who are less likely to attempt to stop smoking (Kumari & Postma, 2005). Consequently, it is of further interest to determine whether it is these individuals most interested in attempting smoking reduction and abstaining during periods of temporary abstinence.

To date, studies suggest variation amongst reducers relative to other smokers and those attempting to quit. Hughes et al. (1999) reported that compared to quitters, reducers were more likely to be female, non-white and better educated. In contrast, Farkas (1999) reported that reducers were more likely to be heavier smokers of Hispanic or Afro-Caribbean origin; gender, age and education were not significant predictors. On the other hand, Gilpin and Pierce (2002) reported that women smoked fewer cigarettes per day, as did younger minority groups and those who were better educated. Moreover, compared to those who quit smoking and the general population, smokers who become non-daily smokers tend to be married, have higher educational attainments, and better psychosocial conditions (Lindstrom & Isacsson, 2002a; Lindstrom & Isacsson, 2002b). Other studies have noted that smoking reduction is more common among highly dependent smokers who suffer from chronic disorders, who have higher body mass indexes, lower levels of perceived stress, have been smoking for longer periods of time, smoke other types of tobacco besides cigarettes, and who use illicit drugs (Berg et al., 2010a; Okuyemi et al., 2002; Godtfredsen, Holst, Prescott, Vestbo & Osler 2002a; Godtfredsen, Osler, Vestbo, Anderson & Prescott, 2003; Godtfredsen, Prescott, Osler & Vestbo, 2001; McDermott et al., 2008; Cnattinguis & Thorslund, 1990; Falba et al., 2004; Severson, Andrews, Lichtenstein, Wall & Zoref, 1995).

Taken together these findings point towards a higher prevalence of smoking reduction among women of an older age, those of higher socio-economic status, and those who are more nicotine dependent. This may be as hypothesised, as smokers with a greater reliance on cigarettes find it harder to quit (Hyland et al., 2006; Zhou et al., 2009; Hymowitz et al., 1997; Jaen et al., 1993; Der & Graham., 1999; Dale et al., 2001); perhaps resulting in more of them trying to cut down instead. Women also tend to hold greater concerns about their own health and well-being, leading them to set goals in order to achieve reductions in cigarette consumption (Allgower, Wardle & Steptoe, 2001). The finding that those cutting down have better educational attainments is perhaps counterintuitive, as lower socio-economic smokers are less likely to achieve abstinence and would as such be expected to opt for harm reduction strategies (Hyland et al., 2004; Hymowitz et al., 1997; Kotz & West, 2009; Jaen et al., 1993; Der & Graham, 1999). Thus it appears that smoking reduction is not, at least based on the data presented here, a means by which to lessen the social inequalities in health. One mechanism by which lower socio-economic status may reduce intention to change behaviour across the board is via their greater dependence on cigarettes (Siahpush et al., 2006b).

Of importance, is that those reporting reductions in their cigarette intake appear to differ to those attempting to quit, suggesting dissimilar motivational underpinnings for these two behaviours. Consequently, smoking reduction may be targeting a new set of smokers who have become discontent and uninterested in traditional treatments. However, thus far, data are mixed regarding whether or not those suffering from chronic mental and physical conditions are more likely to opt to reduce their cigarette consumption. Future research should aim to determine the interest among these smokers, due to the possibility that they may benefit the most from a harm reduction approach (Kumari & Postma, 2005). Moreover, a major issue with the current studies is their failure to stipulate whether reductions were the result of periods of temporary abstinence, attempts to cut down or gradual cessation. Thus future research should also aim to determine the demographic characteristics of those attempting smoking reduction and temporary abstinence specifically with harm reduction in mind.

Extent of Reductions in Cigarette Consumption

One common argument is that smokers cannot reduce their smoking significantly. This belief is based on the observation that when smokers who are trying to stop consume a few cigarettes per day, most go back to smoking the same number of cigarettes as prior to their quit attempt (Hill, Weiss, Walkers & Jolley, 1988; Hughes et al., 1992). Clinicians and others fail to realise that this observation is based on a selected subset of smokers who were so dependent that they failed despite treatment, and who were usually told that reduced smoking is not possible. There is empirical evidence that smokers can indeed initiate reductions. For example, the Lung Health Study reported that among the 60% of smokers who had reduced their smoking, 39% had reduced their intake by more than half (Bjornson et al., 1999). In the US Community Intervention Trial for Smoking Cessation (COMMIT), seventeen per cent of smokers decreased their smoking by 5-24%, fifteen per cent by 25-49% and eight per cent by 50-99% (Hughes et al., 1999). More recently, Mooney, Johnson, Breslau, Bierut and Hatsukami (2011) noted that 44% of their sample of 6,955 smokers decreased their cigarette consumption by an average of 54%, and experienced a concurrent reduction in nicotine dependence. Other studies have also noted smokers' capability to reduce cigarette consumption, and that the presence of smoke-free workplaces and living in smoke-free homes is associated with a reduction in intake over time (Godtfredsen et al., 2002a; Meyer, Hapke, Rumpf, Schumann & John, 2003; Falba et al., 2004; Farkas, 1999; Gilpin & Pierce, 2002; Farrelly, Evans & Sfekas, 1999; Gilpin et al., 1999).

Although these data as a whole suggest that significant reductions in the number of cigarettes smoked per day can be attained, they failed to report whether reductions were the result of cutting down, gradual cessation, or due to temporary abstinence. The only study to rule out temporary abstinence as a reason for reductions in cigarette intake, noted declines in consumption of only one to two cigarettes per day over a one year period (West et al., 2001a);

however, it is unclear whether these reductions occurred with or without an intention to quit smoking. The finding of only a small decrease in cigarette intake in this case may well be due to conceptual problems, including a reliance on retrospective self-report and that smokers may have been assessed in a ‘maintenance phase’ of reduction. A better test would be to measure any change in cigarette consumption among those starting or stopping to cut down during the course of the study. Moreover, it is perhaps easier to foresee reductions among those attempting to cut down, with such individuals possibly being more motivated as a result of concerns about the effect of smoking on their health. In contrast, those who temporarily abstain may do so in the majority of cases as a result of forced smoking restrictions. Smokers who opt for temporary abstinence may also have a tendency to smoke more heavily prior to and following the smoke-free period, and even when this is not the case, abstinence may not be frequent enough or last for a significant period of time for reductions to be induced (Borland et al., 1990; Chapman, Haddad & Sindhusake, 1997).

Maintenance of Reductions in Cigarette Consumption

The COMMIT trial, a multi-centre public health intervention that focussed on cessation and did not promote reduction in itself, reported that 40% of smokers managed to reduced and maintain their reductions for three years (Farkas, 1999). Moderate stability has also been reported in the California Tobacco Survey, a non-intervention study. Hughes et al. (1999) noted that 21% of smokers reduced their consumption and maintained this reduction until four years follow-up. This 21% was composed of eleven per cent who reduced and maintained a reduction of 5-24%, seven per cent who maintained a reduction of 25-49% and three per cent who maintained a reduction of over 50%. However, several public health efforts to reduce smoking were ongoing at the time, which may have impacted on the maintenance of reductions reported. Studies among smokers trying to stop smoking have also found that many who relapse often return to a lower level of smoking and maintain some amount of reduced smoking for up to 40 months post-cessation (Hughes, Lindgren, Connett & Nides, 2004a; Hughes, Hymowitz, Ockene, Simon & Vogt, 1981; Norregaard, Tonnesen, Simonsen, Peterson & Sawe, 1992).

However, an issue with these studies is that NRT was also provided, which in addition to the cessation intervention, may have enabled smokers to cope better with their reductions in cigarette intake. Therefore, although it appears that smokers are able to maintain reductions in their cigarette consumption, for firmer conclusions to be drawn, population-based studies in the absence of any smoking cessation intervention, either behavioural and/or pharmacological, are required. It is also necessary in the future to determine whether reductions are purely as a result of attempts at harm reduction or are a prelude to smoking cessation. Data are also lacking on whether declines in cigarette intake as a result of smoking restrictions are well maintained, with indirect evidence suggesting that smokers are inept at sustaining decreases in consumption following smoking bans (Owen & Borland, 1997).

Reductions in Disease risk

Since the risks of smoking are dose-related (National Cancer Institute, 2001; Doll & Peto, 1978), a health benefit may be expected to be incurred following smoking reduction. However, this assumption is problematic for a number of reasons. The first is that the dose-response function for risk from smoking is based on between-subject differences at one point in time. Whether this same dose-response relationship applies to within-subject changes has not been adequately tested in prospective trials, with meta-analyses reporting evidence of a non-linear relationship between dose and health outcomes (Law & Hackshaw, 1997). The second issue is whether smokers will maintain any reductions for their lifetime. Currently there is no long-term data verifying this. Thirdly, even if reductions occur, it is quite probable that compensatory smoking will result. According to the 'nicotine regulation hypothesis', smokers work to maintain a steady level of nicotine exposure (McMorrow & Fox, 1983), and as a consequence, any reduction in parameters which determine the level of nicotine exposure (for example:- a reduction in cigarette consumption), will lead to compensatory increases in the remaining parameters (for example:- increased toxin intake from each cigarette). Finally, it is possible that reducers will already have accumulated harmful substances in their bodies from their previous more intensive smoking habit, precluding a reversed dose-response regarding mortality and morbidity.

Nonetheless, evidence regarding cardiovascular risk factors points towards a potential benefit. Eliasson, Hjalmarson, Kruse, Landefelt and Westin (2001) reported that those smokers who achieved successful reduction experienced a concurrent reduction in fibrinogen, haemoglobin, haematocrit, red blood cell count, white blood cell count, and an increase in the High Density Lipoprotein/Low Density Lipoprotein ratio (HDL/LDL), between baseline and nine weeks follow-up. Although a similar conclusion was drawn by Hatsukami et al. (2005), a study by Stein and colleagues (2002) failed to report any difference among reducers and non-reducers in homocysteine, an independent risk factor for atherosclerosis. Evidence also suggests only a small decrease in the risk of a heart attack following smoking reduction (Godtfredsen et al., 2003), although the presence of smoking restrictions has been associated with fewer hospital admissions for myocardial infarction (Sargent, Shepard & Glantz, 2004). There is also evidence of better clinical outcomes following intermittent claudication among those reporting declines in their cigarette intake (Hughson, Mann, Tibbs, Woods & Walton, 1978).

Data on respiratory conditions is more extensive. For example, The Lung Health Study reported that the main factors associated with reduction of age related declines in pulmonary function and of respiratory symptoms, were sustained smoking abstinence, and to a lesser extent, intermittent abstinence (Gross, 1994; Kanner, Connett, Williams & Buist, 1999). Improved lung function was also reported in a study by Simmons et al. (2005), and has been demonstrated among smokers on a methadone maintenance programme who managed to achieve reductions in cigarette intake (Stein, Weinstock, Lerman & Anderson, 2005). Moreover, Godtfredsen et al. (2002b) reported that reductions in hospitalisation for chronic obstructive pulmonary disease occurred among those reducing their consumption by 50% or more, while Hecht et al. (2004) noted decreases in two lung cancer carcinogens NNAL (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol), a metabolite of the tobacco specific lung carcinogen NNK (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone), and its O-glucuronide, NNAL-Gluc. In contrast, Burchfiel et al. (1995) failed to report any difference in FEV (Forced Expiratory Volume) rate among a prospective cohort study of more than 4,000 middle aged and elderly men who did and did not reduce their consumption. This may have been due to the failure to assess duration and amount smoked at baseline, and thus concurrently failing to adjust for these in the analysis. Interestingly, there is also evidence for the recovery of the immune system. Pulera et al. (1997) reported increased antibodies against benzo(a)pyrene diolepoxide-DNA adducts, which are indicators of DNA damage, among those cutting down.

However, whether smoking reduction actually results in a decrease in lung cancer risk is rather contentious; whereas some studies have reported reductions in risk among those moving from heavy to light smoking (Benhamou, Benhamou, Auguier & Flamant, 1989; Godtfredsen, Prescott & Osler 2005), Lubin et al. (1984) failed to report a reduction in risk following the analysis of data from a large case control study. Evidence is also less then consistent regarding whether decreases in cigarette intake reduce complications following surgery (Bluman, Mosca, Newman & Simon, 1998; Moller, Villebro, Pederson & Tonnesen, 2002). Moreover, whereas as a 50% reduction in cigarette consumption in one study appeared to reduce the Relative Risk of mortality (Lubin et al., 1984), a large Norwegian study reported on evidence to suggest that even reductions in the magnitude of 50% do not reduce the risk of premature death (Tverdal & Bjartveit, 2006). Finally, giving birth to a higher birth weight baby appears to be associated with a reduction in smoking among pregnant women (Li, Windsor, Perkins, Goldenberg & Lowe, 1993).

Although the findings from these studies suggest some benefits may be attained from smoking reduction, clearly more extensive data are necessary. The studies to date are few and far between, based on small samples of reducers, and methodological differences make it hard to draw firm conclusions. For example, the definition of smoking reduction was not always the same, nor was the duration of reduction always defined. Moreover, whereas some studies included very heavy smokers, others used light to moderate smokers. The current focus on biomarkers is also precarious as we do not know if they accurately predict disease onset, and even if they do, it is currently unclear as to the extent of reduction in a given biomarker that is needed to produce a reduction in subsequent disease risk. It is also likely that smokers who were seeking assistance in these previous studies were informed that smoking reduction was impossible and that cessation was the only option. Thus studies on smoking reduction some decades ago may not reflect the same smokers and health effects today.

Association With Attempts to Quit Smoking

Undermining Smoking Cessation

In recent years researchers have become concerned that encouraging smoking reduction and temporary abstinence among smokers could undermine attempts at smoking cessation (Stratton et al., 2001). This comes from a long standing debate within the harm reduction literature, with many arguing that belted drivers may feel too secure, drive even faster, and so kill more pedestrians; while methadone and free needle-exchange programmes might induce more people to take-up risky behaviours and/or maintain drug use among addicts (Hirschhorn, 2002). A common argument is that attempting to cut down cigarette consumption could give smokers an easy way out and a false sense of dealing with their habit, and thereby decrease their motivation to quit. In other words, smokers may become content with their smoking, believing rightly or wrongly, that they have reduced some of the harm to their health (Institute of Medicine, 2001). In accordance with this, smokers have been reported to be overly confident that reductions in cigarette intake will incur a health benefit (Gilpin & Pierce, 2002), while one's perceived susceptibility in the chance of getting a disease appears to be predictive of intention to change behaviour (Rosenstock, 1974). A concern is that smokers rate their own susceptibility to health risks as being comparably lower than their peers prior to any attempt at smoking reduction (van der Pligt, 1994; Reppucci, Revenson, Aber & Reppicci, 1991; Ayanian & Clearly, 1999). If declines in the number of cigarettes smoked per day heighten this 'unrealistic optimism', there is no doubt that smokers' motivation to quit may be undermined (Weinstein, 1982).

Another argument is that smokers may be unable to cope with withdrawal symptoms and cravings during smoking reduction or momentary abstinence, causing them to rationalise that complete cessation will be too difficult a task (Niaura, Shadel, Britt & Abrams, 2002). Many of the signs and symptoms of withdrawal from nicotine that occur following abstinence are likely to be present in those attempting to cut down or to abstain from smoking for short periods of time, including dysphoric or depressed mood, irritability, frustration, anger, anxiety, difficulty concentrating and restlessness (West, Ussher, Evans & Rashid, 2006). If these withdrawal symptoms become too unbearable, reductions in motivation to quit may prevail. However, evidence suggests that those cutting down adapt quite well to lower nicotine intake, at least when a structured approach to smoking reduction is used (Cinciripini et al., 1995).

Moreover, it may be hypothesised that as one reduces their consumption to lower levels, each cigarette will become more rewarding, with those following periods of momentary abstinence being assigned as more enjoyable. Such increased 'liking' of cigarettes could come from two sources: 1) the removal of withdrawal symptoms and/or 2) the perceptual and sensory properties associated with cigarette use. Because enjoyment of smoking is one of the most commonly reported motives for continuing smoking (McEwen, West & McRobbie, 2008; Fidler & West, 2009; West et al., 2001a), it could be hypothesised that increasing the pleasure of smoking will reduce smokers' motivation to quit. To date, the only study to actively assess this hypothesis, noted that those reducing their consumption without pharmacological help actually had lower levels of enjoyment of smoking compared to other smokers generally, although differences were minimal (Etter, Laszlo & Perneger, 2004).

Another argument is that smoking reduction could lead to an increase in smokers' responsiveness to external cues in the environment. This may occur as a by-product of the 'rebound effect', a phenomenon where surges in the frequency of thoughts about an activity occur directly as a result of an attempt to suppress them (Wegner, Schneider, Carter & White, 1987). These thoughts consequently result in heightened attentional bias towards smoking-related stimuli (Wenzlaff & Wegner, 2000). This increased attentional bias may also lead to other psychological processes, including conditioned withdrawal or conditioned compensatory responses (Niaura et al., 1988), which may undermine cessation attempts. Extent of attentional bias has been found to predict drug cravings and success with smoking cessation (Field, Munafo & Franken, 2009; Waters et al., 2003b). Moreover, there is evidence that lighter smokers have a greater tendency than heavier smokers to respond to external cues (Herman, 1974).

Researchers have also recently theorised that self-regulation is governed only by a limited resource that allows people to control impulses and desires (Baumesiter & Heatherton, 1996), and that self-regulatory resources can be depleted or fatigued by self-regulatory demands; hence, the active effort required to control behaviour in one domain, leads to a diminished capacity for self-regulation in others. In other words, smokers who are attempting to exert control over smoking reduction may not have the resources available to quit smoking, because cognitive energy has been depleted. Evidence for this model comes from the finding that smoking cessation leads to increased eating particularly among individuals who normally try to regulate their diet (Spring et al., 1990).

Finally, according to the Restraint Model used by dietary researchers, a reliance on cognitive control over eating can result in the adoption of a 'what the hell' attitude when these cognitive processes are disrupted, leaving dieters vulnerable to uncontrolled eating (Polivy & Herman, 1985). Applying this to smoking reduction, it may be hypothesised that conscious attempts to control smoking – as opposed to normal physiological control – if disrupted, could result in disinhibition of behaviour. As a consequence, this could increase cigarette consumption and hence make smoking cessation more difficult. This is in accordance with the abstinence violation effect, which states that violation of strict smoking 'rules' leads to the temporary abandonment of attempts to restrain consumption (Marlatt & Gordon, 1985). During smoking reduction this may occur if smokers have a cigarette during a time in which abstinence was planned, with violation causing a 'what the hell' attitude and 'binge' smoking.

Promoting Smoking Cessation

Although all these arguments seem feasible, others have made the converse case that reduced smoking may actually promote smoking cessation. One proposal being, that reducing cigarette consumption could teach individuals that they can manage without tobacco for several hours, thereby increasing their levels of self-efficacy in their ability to quit; a factor incorporated into many social cognition models, including the Health Action Process Approach (Schwarzer, 2008), and which has been implicated in the process of smoking cessation (Gwaltney, Metrik, Kahler & Shiffman, 2009). Self-efficacy may also be increased because reduction allows smokers to practice coping strategies that can be used to deal with smoking urges when they quit, and has been shown to reduce negative affect, which thus makes these coping behaviours more effective (Cinciripini et al., 1995; Cinciripini et al., 1997). Moreover, reduction can be thought of as a step towards cessation, with confidence increasing linearly following the completion of some aspect of a task (Bandura, 1977). There is evidence to support the view of an increase in smokers' confidence to quit during attempts at smoking reduction (O'Connor & Langlois, 1998).

Smoking reduction may also promote cessation in those who have consistently failed with abrupt cessation, and who have adopted the attitude that they do not want to quit smoking, by allowing them to test something which is not associated with previous failure. Through repeated success with smoking reduction, smokers' motivation to quit will gradually increase until they eventually get to the point where they become curious and interested in seeing whether giving up completely would be possible. There is evidence of increased motivation to stop smoking among those cutting down (Pisinger, Vestbo, Borch-Johnsen & Jorgensen, 2005), and that it is one of the strongest predictors of smoking abstinence (West et al., 2001a; Hagimoto, Nakamura, Morita, Masui & Oshima, 2009; Fidler & West, 2011).

It has also been argued that smoking reduction could increase the propensity of smokers to quit through reducing nicotine intake, thereby decreasing nicotine dependency. Although compensatory smoking often occurs during attempts to cut down, this is generally far from complete, with smokers over time decreasing their 'normal' levels of nicotine

(Sutton, Russel, Iyer, Feyerabend & Salooyee, 1982). The theory behind this is that smokers who are less dependent are more likely to attempt to quit and have less trouble or difficulties stopping when they do (Killen, Fortmann, Telch & Newman, 1988). Previous randomised controlled trials and population-based studies have reported a reduction in nicotine dependence among those attempting smoking reduction (Etter et al., 2002; Joseph et al., 2008; Mooney et al., 2011). However, these data were confounded by the use of the Fagerstrom Test for Nicotine Dependence (Fagerstorm & Schnieder, 1989), a central measure of which is cigarette intake, thus lower scores may simply reflect reductions in the amount smoked.

Finally, it has been argued that conditioning principles are important in the promotion of attempts to quit smoking, and that attempts at harm reduction may impact on these in several ways (Pavlov, 1927; Skinner, 1938). One claim of classical conditioning theories is that decreasing the frequency of a behaviour results in a decrease in its association with environmental cues, thus weakening the urge to partake in the behaviour when the cues are present. For smoking reduction this is likely to transpire since the occurrence of pairing smoking with smoking stimuli is reduced, while the smoker who is temporarily abstaining experiences smoking stimuli in the abstinence of cigarette consumption. Another important principle is that of ‘shaping’, a form of operant conditioning, whereby making successive approximations of the target behaviour results in the target behaviour being achieved. This may occur during smoking reduction, with each cigarette that is eliminated acting as a reward to the smoker, thus moving them towards the target of complete abstinence.

Evidence to Date

The majority of population-based studies at least appear to discredit the first school of thought, i.e. that smoking reduction (whether as a result of smoking restrictions or an attempt to cut down), does not decrease the propensity of smokers to quit. For example, Hill and colleagues reported that smokers who had cut down to 1-9 cigarettes per day at the end of a smoking cessation treatment, were no less likely to go on to quit smoking compared to those who smoked at their normal rate at the end of treatment (Hill et al., 1988). Likewise, Hughes et al. (1999) reported that subjects with a greater amount of reduction between baseline and year two did not have a smaller incidence of reporting at least one quit attempt in the last year, or of stopping smoking between years two and four. Similarly, Meyer et al. (2003) in their German sample of smokers noted that the probability of a quit attempt was equal among those who had reduced their smoking, those smokers who had not attempted to reduce their cigarette intake, and those who had attempted to quit.

Other studies point towards the possibility that if significant reductions occur above a threshold that this may actually increase smokers' motivation to stop altogether. For example, Farkas (1999) reported that moderate and heavy smokers who reduced their consumption but remained in these groups, were no more likely to have attempted to quit smoking than other smokers; however, those who became light smokers as a result of smoking reduction, were more likely to report a quit attempt. Hughes et al. (2004a), Hyland et al. (2005) and Falba et al. (2004) have also reported that large or moderate reductions prospectively predicted an increased likelihood of cessation at follow-up. Moreover, those who reduced by large amounts and then quit smoking were less likely to relapse than those who did not reduce prior to quitting; thus negating the argument that smoking reduction may increase the risk of relapse (Falba et al., 2004).

Further supportive evidence for a beneficial effect of smoking reduction on attempts at cessation, comes from the finding that non-daily smokers are more likely than daily smokers to report plans to quit smoking and confidence in their ability to stay off cigarettes (Gilpin & Pierce, 2002; Hennrikus, Jeffrey & Lando, 1996; Lindstrom & Isacsson, 2002a; Lindstrom &

Isacsson, 2000b); while simply formulating a plan to reduce cigarette intake has been shown to be associated with abstinence (Dijkstra & DeVries, 2000). In addition, smoking restrictions in the workplace and at home are associated with quitting activity (Farelly et al., 1999; Farkas, Gilpin, Distefan & Pierce, 1999; Gilpin et al., 1999). Farkas et al. (1999) reported that those who lived or worked under complete smoking bans were more likely to have quit smoking in the preceding year and less likely to have relapsed. However, this relationship could be for a number of reasons: it may be that smoking restrictions induced temporary abstinence which consequently increased smokers' motivation to quit, or that the imposition of restrictions and quit attempts both stemmed from a general tendency of smokers to try and mitigate the harmful effects of smoking. Moreover, usually when smoking restrictions are put into place advice on smoking cessation is concurrently provided, which may act as a potent motivator.

Another major issue with studies to date is that quit attempts were generally not biologically verified. This will always be difficult because most quit attempts do not last more than 48 hours (Hughes et al., 1992). Moreover, although biochemical validation of cessation is feasible, several lines of evidence suggest that in minimal contact population-based studies this is not always necessary (Velicer, Prochaska, Rossi & Snow, 1992; Lichtenstein & Glasgow, 1992). Studies to date have also tended to compare self-selected groups of reducers and non-reducers, with the possibility being that those who choose to reduce might be a priori more motivated to stop smoking. On the other hand, if they are more dependent, this may minimise any causal effect of reduction. Finally, there is the issue as to whether reductions were a prelude to quitting or the end goal, a factor which could clearly impact on cessation rates. The only study to separate these, reported that whereas attempts to cut down as a means to stop smoking were associated with future quit attempts, reducing for its own sake was not (West et al., 2001a).

Effect on Continuing Smokers and Non-Smokers

Even if it is the case that smoking reduction is associated with improved clinical outcomes and increases the propensity of smokers to quit, the promotion of reduction could still have unintended consequences in populations other than smokers not trying to stop. For example, it could undermine resolve among those about to quit or send a message that small amounts of smoking are safe. Obviously, this is hard to determine. The one small trial in which reduction was offered as an alternative goal to cessation reported similar rates of attempts to quit smoking among those who switched to reduction and those who stuck with the cessation programme (Glasgow, Morray & Lichtenstein, 1989). Moreover, there is evidence to suggest that offering smokers the option to cut down doubles the number of smokers willing to participate in smoking control efforts (Glasgow et al., 2006). However, larger and more rigorous studies are needed before definitive conclusions can be reached about population level harms. Hypotheses can nonetheless be made using the risk/use equilibrium developed by Kozlowski and colleagues in 2001. This states that when risks from a product are relatively small, the level of increased use needed to maintain public health equilibrium becomes very high. For example, even if smoking reduction only decreases risk by 10%, those partaking in smoking reduction would have to increase 1.2 times for the public health problems to be equal. In other words, if 1000 people smoked normally, an additional 1200 would need to reduce their cigarette consumption. However, even if it is the case and promoting smoking reduction or temporary abstinence leads to greater total public health harm, avoiding or objecting to the fair presentation of information on effective harm reduction products to smokers could represent a violation of human rights, if it prevents them from making informed choices to reduce health risks (Kozlowski, 2002). Thus questions about population level risks need to be considered in conjunction with the rights of smokers to be informed about the effectiveness of harm reduction approaches.

Chapter 4: Improving Smokers' Success of Attempts at Smoking Reduction and Temporary Abstinence: The Utility of Behavioural Support and Nicotine Replacement Therapy

Smokers may find it difficult to cut down or to temporarily abstain as a consequence of increased urges to smoke and withdrawal symptoms. In recognition of this, researchers and policy makers have assessed the utility of aiding smoking reduction and temporary abstinence with behavioural support and medicinal nicotine. Each of these will be considered in turn below.

Behavioural Interventions

There is evidence to support the effectiveness of behavioural interventions for smoking reduction. In the 1980s, Glasgow and colleagues reported on two studies in which behavioural coping strategies were used as a controlled smoking intervention, producing modest long-term reductions in cigarette consumption of 24% and 14% (Glasgow, Klesges & Vasey, 1983a; Glasgow, Klesges, Klesges, Vasey & Gunnarson, 1985). Some ten years earlier, Shapiro et al. (1971) reported at the end of an eight-week reduction programme, declines in cigarette intake of around 75% in the experimental group, while reductions of just two per cent in the control group. In recent years, research has grown on the utility of behavioural support for smoking reduction among smokers with a desire to quit (Tappin et al., 2005; Fiore et al., 1990; Foxx & Axelroth, 1983; Cinciripini et al., 1995; Law & Tang, 1995), however, few studies have assessed its efficacy among smokers reducing for harm reduction purposes.

This was recently rectified by Riggs et al. (2001), who performed a cross-over trial with twenty smokers not interested in quitting within the next two months. They compared selective elimination (the removal of cigarettes rated as easiest to give up), with a method involving successively increasing the inter-cigarette interval (the time between each cigarette). Although both treatments decreased self-reported cigarettes per day by around 40%, increasing the inter-cigarette interval was rated as easier to implement, liked by more smokers, and resulted in higher rates of reductions of 50% or more in cigarette consumption. Motivation to quit was also concurrently augmented. However, participants also received nicotine gum *ad libitum* during the course of the study, making the source of the reduction less clear.

Riley et al. (2002) a year later assessed the feasibility of two self-help behavioural interventions to reduce and maintain reductions in cigarette consumption. They randomly assigned participants to one of two behavioural interventions: manual based selective elimination reduction (SER) or computerised scheduled reduction (CSR), which involved smokers using a device that told them when to smoke. These produced reductions in cigarette consumption of 37% and 20% respectively, with 30% and 16% reducing their cigarette consumption by 50% or more. These reductions were well maintained over the first 12 months. Fourteen per cent of the CSR and 9% of the SER participants reported a quit attempt during the 7 weeks of the study. At post treatment 6.8% of the CSR, but none of the SER participants, met seven-day point prevalence criteria for abstinence which was carbon monoxide verified. At 12 months follow-up, 11.4% of the CSR group versus 6.1% of the SER group were abstinent, which are quit rates comparable to those from self-help smoking cessation interventions (Lancaster & Stead, 2005b). An issue with this study is that smokers also received information on harm reduction, self-management strategies, adherence advice (for example:- only carrying those cigarettes needed for the day & avoiding smoking triggers), and relapse prevention, which may have had a potent impact. Moreover, without a control group it is difficult to determine whether the mere participation in the programme, rather than the behavioural support provided, resulted in the declines in cigarette intake that were established. Glasgow et al. (2009) recently rectified this issue by comparing a smoking reduction intervention that combined telephone counselling and tailored newsletters to an enhanced usual-care group. They failed to report any difference at 12 months between groups, with consistent effects across education, ethnicity, health literacy and dependence. The failure to report a difference among groups may have been due to the health education mailings received by the usual-care group in addition to biological assessments.

There is also evidence that behavioural interventions may mitigate the tendency of smokers to compensate for the reduction in nicotine intake from cigarettes by increasing puff frequency, with reports of decreased carbon monoxide and cotinine (Glasgow et al., 1985; Glasgow et al., 1983a; Glasgow, Klesges, Godding & Gelgelman, 1983b). One surprising finding in the 1983b study, was that reductions in carbon monoxide were greater than reductions in the number of cigarettes smoked, resulting in 0% compensation. This may be because the study also taught smokers to smoke less intensely and to change to lower carbon monoxide yield cigarettes, or the small sample size (*n*=9). One exception to this was the study by Riggs et al. (2001), which although reporting reductions in carbon monoxide, failed to establish declines in either cotinine or thiocyanate. This may be due to the long half-lives of these latter two measures (7-14 days), with the short period of the study being insufficient to detect changes (Benowitz, 1983).

Thus we can conclude from these studies that behavioural interventions do not at least have a detrimental effect on smokers' attempts to cut down, and that they may, in certain circumstances, induce reductions in cigarette consumption and increase smokers' motivation to quit. However, further research is undoubtedly required to draw firmer conclusions. A study assessing the impact of healthcare professionals' advice to smokers to reduce their cigarette consumption would be of interest, particularly in allowing one to determine whether these findings are applicable to those not participating in clinical trials. Future studies should also pay more attention to behaviour change theories, since interventions which are theoretically grounded are generally more effective than interventions that lack a theoretical basis (Baranowski, Anderson & Carmack, 1998). To date, although studies have used a number of techniques from theoretical models, none of the interventions were explicitly based on or had extensive theoretical underpinnings. One exception to this rule exists: the development of a smoking reduction intervention utilising Social Cognitive and Self-Efficacy Theories, the Transtheoretical Model and Social-Ecological Theory (Bandura, 1997; Glasgow et al., 2000; Prochaska, Diclemente & Norcross, 1992; Spence & Lee, 2003; Sorensen, Barbeau, Hunt & Emmons, 2004). Current feasibility and pilot data from this appears promising (Levinson et al., 2008; Gaglio et al., 2010).

Use of Nicotine Replacement Therapy

Despite the utility of behavioural support, more emphasise has been placed in recent years on the possibility of using NRT to aid those who are attempting to cut down or to temporarily abstain. Evidence suggests that the use of medicinal nicotine products in these ways is appealing to smokers (Shiffman, Gitchell, Rohay, Hellebusch & Kemper, 2007b), which according to Hall (2005) is critical to their public health utility.

History of Nicotine Replacement Therapy

Considerable evidence now supports the view that cigarette smoking is primarily maintained by an addiction to nicotine (Benowitz, 2008). Nicotine creates dependence by activating the mesolimbic dopaminergic system, and physiological withdrawal symptoms occur when nicotine is no longer administered (Malin et al., 1992). This concept has been capitalised on by the development of cessation treatments that emphasise nicotine replacement. The first NRT product was introduced in 1984 in the form of nicotine gum to assist smoking cessation. This became the dominant product until the introduction of the nicotine patch in the early 1990s. In the UK there are currently seven different forms of medicinal nicotine delivery: gum (2mg & 4mg), patch (5mg, 7mg, 10mg, 14mg, 15mg, 21mg, 25mg), nasal spray (10mg), inhalator (10mg), sublingual tablet [microtab; (2mg)], lozenges (1mg, 1.5mg, 2mg & 4mg), and quickmist (1mg). Monopolised by four main brands (NiQuitin, Nicotinell, Nicorette & NicAssit); nicotine gum, mictrotabs, and nicotine lozenges, come in a variety of flavours (for example:- fresh fruit, mint, liquorice, cherry & lemon). The nicotine dose and speed of delivery vary between the products. The nasal spray has one of the fastest speeds of delivery, with nicotine peaking at 10 minutes after a dose of spray, and the patch the slowest, with nicotine peaking after 4-9 hours of putting the patch on. All the products are available in the UK from pharmacists, on NHS prescription, and recently on general sale.

These have proved efficacy, with a two fold increase in the odds of abstinence among those using medicinal nicotine (Silagy et al., 2004). Although there have been some concerns over its safety, abuse, and dependence potential, a large body of evidence suggests that nicotine is not a significant risk factor for cardiovascular disease, does not cause cancer, and does not cause respiratory diseases such as emphysema (Benowitz, 1998; Smith, Livingston & Doolittle, 1997). It is also almost impossible that toxication or overdose on nicotine will occur, because smokers have a strong tendency to titrate their nicotine levels to reach their own ‘comfort zone’. That said, there are concerns about nicotine’s safety during pregnancy (Slotkin, 1998), and its effect on inflammation and the immune response (Sopori et al., 1998). The abuse potential of NRT products, defined as the ability to facilitate use in non-users, has also been shown to be very low, with novices generally perceiving nicotine as moderately unpleasant (Foulds et al., 1997). In terms of its dependence potential, only three per cent of smokers use NRT after three months and these tend to be heavier smokers (West et al., 2000b).

Licensing of Nicotine Replacement Therapy for Harm Reduction Purposes

In 2005, a number of changes were made to reduce the quantity of cautions and contra-indications for NRT. This was in recognition of the much greater risks associated with continued smoking. NRT was permitted to be used by smokers with heart disease, adolescent and pregnant smokers, and a few products (i.e. Nicorette gum & the Nicorette inhalator), were licensed for cutting down smoking as a stepping stone to stopping completely (Medicines & Healthcare products Regulatory Agency (MHRA), 2005). A year later, Nicorette lozenges were permitted for ‘cut down to quit’, and Nicorette lozenges and gum for ‘temporary abstinence’ (MHRA, 2006).

Following advice from the Commission on Human Medicines (CHM) in 2009, the MHRA also permitted other companies to manufacture these products for gradual cessation and temporary abstinence. At the same time the MHRA approved an extension to the indication of the nicotine inhalator to include a ‘harm reduction’ element, meaning that it could be used by smokers who wished to reduce their cigarette intake without a specific intention to quit completely and without a limit to the duration of use (MHRA, 2010). The CHM also agreed the principle for many other currently licensed forms of NRT. These included the Nicorette invisi patch, NiQuitin patch, Nicotinell patch, NiQuitin gum, NiQuitin lozenges, Nicorette lozenges, Nicorette inhalator, NicAssist inhalator, and Nicorette quickmist.

This new indication is now evident on product packaging, with the statement: *"This product relieves and/or prevents craving and nicotine withdrawal symptoms associated with tobacco dependence. It is indicated to aid smokers wishing to quit or reduce prior to quitting, to assist smokers who are unwilling or unable to smoke, and as a safer alternative to smoking for smokers and those around them''*. Nonetheless, smokers are still advised to reduce as much as possible, quit if they feel they are able to do so, and to seek advice after 6 months of use. Numerous countries worldwide have also now extended their licensing of NRT to include an indication for temporary abstinence and in some cases smoking reduction. These include Australia, Austria, Brazil, Canada, Denmark, Norway, France, New Zealand, Columbia, Portugal and Venezuela (Shiffman, Fant, Buchalter, Gitchell & Henningfield, 2005). However, there are many others who still hold great opposition towards such an approach. For example, the US Food and Drug Administration is largely resistant regarding the use of NRT for non-cessation purposes, despite the Institute of Medicine's report concluding almost a decade ago that: *''The FDA* [Food & Drug Administration] *should therefore be prepared to consider the chronic administration of nicotine products as a reasonable exposure reduction strategy''* (Stratton et al., 2001; pp. 227).

Reductions in Cigarette Intake and the Association With Smoking Cessation

The change of licensing of NRT to include an indication for harm reduction was primarily on the basis that there does not appear to be any situation in which it is safer to smoke than use NRT. Adverse events from concurrent NRT and cigarette use were also deemed to be minimal. This was a conclusion drawn by the MHRA in 2006, which stated that the use of NRT for harm reduction: *‘‘. . . has been authorised in ten other European countries, the first in 1997, and that post-marketing surveillance did not indicate a different profile of adverse events that could be related to the smoking reduction indication’’* (MHRA, 2006; pp. 13)

A third reason was the belief that the use of NRT for these purposes may result in even greater reductions in cigarette consumption and further increase the propensity of smokers to quit. A number of mechanisms have been proposed by which this may occur. The first is that the use of NRT for harm reduction purposes may reduce the rewarding effects of cigarettes, making them less pleasurable. Obtaining nicotine from a source other than cigarettes means that smokers are already partly satiated with nicotine, thus the relief of withdrawal symptoms will be less pronounced (Fagerstrom & Hughes, 2002). This is firmly based on the foundations of operant conditioning, which state that behaviour is increased if it is followed by positive reinforcement and will decrease if it is followed by punishment or where extinction occurs, i.e. where there is a lack of consequence following behaviour (Skinner, 1953). The use of medicinal products during attempts at smoking reduction is likely to consequence in extinction, with cigarettes no long having a positive effect since the smoker is already partially saturated with nicotine from NRT; if nicotine overdose occurs, negative reinforcement may also come into play (Mensch & Holden, 1979). Transdermal nicotine products do appear to produce a dose-related reduction in the subjective rewarding qualities of smoking (Rose, Behm & Westman, 2001).

If it is the case that smoking reduction results in extinction it may be argued that this could have a secondary effect on smokers’ attentional bias towards smoking-related cues. According to Robinson and Berridge’s (2001) Incentive Sensitization Theory, drug-related cues are able to produce a conditioned dopamine response. This occurs as a result of classical conditioning, whereby a neutral stimuli (for example:- having a drink) repeatedly occurring at the same time as unconditioned stimuli (for example:- having a cigarette), is eventually able to elicit a conditional response (i.e. having a drink stimulates the urge to smoke). This newly conditioned stimulus thus acquires an ‘incentive salience which means that it ‘grabs’ attention, becomes attractive and ‘wanted’, and guides behaviour to the incentive (Robinson & Berridge, 1993)]. If nicotine levels are maintained by NRT during smoking reduction, drug-related cues may become unpaired with the effects of abused drugs in the brain, resulting in the loss of their ‘incentive salience’ and so they no longer capture the smokers’ attention.

Secondly, it has been argued that the use of NRT during an attempt to cut down may increase motivation to quit by reducing withdrawal symptoms and cravings, thus encouraging smokers to believe that stopping smoking need not be uncomfortable. Evidence has pointed towards an association between the ability to cope with smoking urges and smoking abstinence (Niaura et al., 2002). Thirdly, the use of NRT for smoking reduction and during periods of temporary abstinence may increase smokers’ self-efficacy to stop, by helping them to learn that they can cope without cigarettes for several hours without undue discomfort and that NRT can act as an acceptable substitute. Physiological cravings for nicotine have been demonstrated to effect smokers’ reports of confidence in their ability to quit smoking (McIntyre, Mermelstein & Lichtenstein, 1980). Finally, NRT may abate the compensatory smoking which generally occurs when smokers reduce their cigarette consumption, because the nicotine in NRT allows nicotine levels to be titrated to their pre-reduction state. This may aid a reduction in cigarette consumption, with lighter smokers finding it easier to quit smoking (Killen et al., 1988).

In contrast, an opposing school of thought has argued that the use of NRT during smoking reduction and/or temporary abstinence may undermine motivation to quit. One claim is that it may do so by increasing smokers’ relative comfort. In other words, if smokers do not experience the negative withdrawal symptoms, and perhaps stigma of having to smoke outside, they will not be motivated to make a quit attempt. There is evidence that repeated temporary withdrawal is a significant motivator for smoking cessation (Hatsukami, Hughes, Pickens & Svikis, 1984). Moreover, if smokers do not use enough NRT, and withdrawal symptoms fail to be abated as a consequence, smokers may come to the conclusion that attempting to quit smoking would be too difficult a task with the currently available aids. There is evidence that smokers outside of clinical trials underuse NRT, incorrectly use NRT, or terminate its use after a relatively short period of time (Shiffman et al., 2003a; Shiffman, Hughes, Di Marino & Sweeney, 2003b).

Finally, others have argued that smoking reduction with NRT could undermine cessation as it maintains nicotine dependency, whereas those who are encouraged to cut down or temporarily abstain without pharmacological help will gradually adjust to lower and lower nicotine levels until their dependency is diminished. Frequencies of urges to smoke have been shown to decrease during smoking reduction (Cinciripini et al., 1995). A more extreme version of this argument is that total nicotine exposure could actually increase, since smokers cutting down with pharmacological help would be obtaining nicotine from two sources. However, current evidence suggests that nicotine intake (as measured by saliva cotinine) and dependence remain broadly stable when smokers use NRT concurrently with cigarettes, with smokers having a natural tendency to titrate their nicotine levels to their pre-NRT state (Fagerstrom & Hughes, 2002).

Chapter 5: Efficacy of Using Nicotine Replacement Therapy for Smoking Reduction and During Periods of Temporary Abstinence: A Meta-Analysis

Introduction

To help resolve the long standing debate as to whether the use of NRT for harm reduction purposes undermines or promotes cessation, and to determine its effect on cigarette consumption, a number of clinical trials have been conducted. Over the years, researchers have collated data from these randomised controlled trials, reporting that the use of NRT as part of a smoking reduction intervention is effective at helping smokers to reduce their cigarette consumption, and leads more of them to go on to stop smoking than usual-care, no-treatment and placebo NRT control groups (Hughes & Carpenter, 2006; Hughes, 2000; Fagerstrom, 2005; Tonnesen, 2002; Zellweger et al., 2001; Moore et al., 2009; Wang et al., 2008; Stead & Lancaster, 2007; Asfar, Ebbert, Klesges & Relyea, 2011).

However, a number of methodological issues with these reviews are evident. Many failed to focus exclusively on studies assessing NRT pharmacology and those recruiting smokers who were unwilling or unable to quit smoking, while others excluded randomised controlled trials based on clinical samples; the exact population who appear to be the most interested in a harm reduction approach (Lemmonds, Mooney, Reich & Hatsukami, 2004; Moeller-Saxone, 2008). There also appeared to be a general bias towards point-prevalence cessation or sustained abstinence measures, and physiological as opposed to psychological outcomes, such as motivation to quit, self-efficacy and quality of life. Assessment of both attempts to quit smoking and cessation is necessary in order to determine whether the use of NRT for harm reduction increases the likelihood of an attempt to quit, the success of a quit attempt when one is made, or both of these. Moreover, understanding potential psychological implications is a prerequisite to assessing the full health benefits of a harm reduction approach. Since the publication of these reviews the research literature has also become sufficiently more mature. It therefore seems an appropriate time to take stock of the evidence that has accumulated to date in order to inform future policy decisions. Accordingly, the current chapter is based on a meta-analysis of previous randomised controlled trials that offered smokers who were unwilling or unable to quit smoking the use of NRT as part of a smoking reduction programme.

Table 1: Articles Found and Selected for Inclusion in the Systematic Review

Database search	**Articles identified**
EMBASE	548
MEDLINE	633
Web of Science	613
PsycINFO	223
Total from databases without duplicates	1210
Other sources	
Found from reference lists	4
Independent journal searches	3
Total from all sources	1217
Initial selection	639
Preliminary selection	15
Final selection	13

Methods

Search Strategies

The electronic databases, EMBASE, MEDLINE, Web of Science and PsycINFO, were searched up to February 2011. The search combined four parameters, one relating to smoking (smok*, cigarette, tobacco), one relating to NRT (nicotine, NRT), one to smoking reduction and temporary abstinence (smoking reduction, cut down, cutting down, reduce, schedule, gradual, controlled smoking, temporary abstinence, smoke-free, smoking restriction, harm reduction, risk reduction), and one to smoking cessation (quit, cessation, intention, motivation, cease, desire, stop). Selected studies references were then screened and independent journal searchers conducted. The title and abstract of studies thus found were assessed for inclusion and exclusion criteria.

Selection

Initial selection was undertaken on the basis of abstracts for studies published in English, and whose focus was on a target population of smokers and not health professionals or policy makers. After this initial selection, the full texts of studies were retrieved. Studies that were included in the final selection had 1) to involve smokers who were unable or unwilling to quit smoking and who were instructed to use NRT for smoking reduction and/or during periods of temporary abstinence; 2) to assess the association with cigarette consumption and/or with quitting behaviour; 3) not duplicate data from other included studies; 4) include at least two treatment groups with randomisation of participants to these; and 5) involve a period of less than 5 years between baseline and follow-up to allow a realistic prospect of detecting meaningful associations. Fifteen studies were identified, two of which were combined because they comprised of data from the same sample of smokers (Etter et al., 2002 & Etter et al., 2004). This resulted in a final selection of thirteen studies (see Table 1).

Data Abstraction and Outcomes

Data were abstracted by two researchers using a structured data abstraction form. Disagreements were listed and resolved. All of the studies focussed on the use of NRT for smoking reduction, while none has considered the use for periods of temporary abstinence. All thirteen of the randomised controlled trials had assessed the association between the use of NRT for smoking reduction and cigarette consumption. The primary outcomes for the review were percentage reduction in cigarette consumption from baseline or the number of those attaining a 50% reduction or more. Eight randomised controlled trials involved measures of toxin exposure. All thirteen assessed quitting activity. The primary outcomes for the review were quit attempts, seven-day point prevalence cessation and sustained abstinence.

Quality Assessment

Assessment of the included randomised controlled trials quality was undertaken using guidelines proposed in the NHS CRD Report No. 4 (NHS Centre for Reviews & Dissemination, 2001). Table 2 summarises the results. According to these criteria most of the studies were of moderate to high quality; blinding participants and investigators and reliably randomising smokers to intervention arms. For many of the studies quality criteria were hard to assess, pointing to the need in future for more complete reporting of intervention design. Moreover, although blinding occurred in a number of cases, the effectiveness of this blinding was not tested. It is possible that those in the placebo arms may have surmised they were not in the NRT arms due to the withdrawal symptoms experienced (Etter et al., 2004).

Statistical Analysis

A meta-analysis using the DerSimonian-Laird random effects model was carried out in STATA (version 12), with measures at the longest point of follow-up extracted and used in the analysis. For smoking outcomes we summarised data with Relative Risks (*RR*), which is the preferred statistic of the Cochrane Tobacco Addiction Review Group. Sensitivity analyses were conducted by comparing overall pooled statistics with and without the inclusion of potential outliers. The findings were corroborated using the Mantel-Haenszel fixed effects model. Meta-analyses were not conducted where outcome variables were assessed by less than two studies, where heterogeneity was detected, or where data could not be accurately pooled due to the diversity of the methods used. In such cases a narrative description of the findings is given instead. PRISMA guidelines were followed throughout (Moher, Liberati, Tetzlaff & Altman, 2009).

Table 2: Summary of the Quality Assessment of Included Studies

Study	Was assignment of treatment really random and randomisation method described?	Was allocation concealed and concealment method described?	Were groups similar at baseline?	Were eligibility criteria specified?	Who was blinded to treatment allocation?	Were ITT analyses used and were drop outs accounted for?
Batra (2005)	Yes, computer generated list	Yes, sealed envelope	Yes[b]	Yes	P&I	Yes Yes
Bolliger (2000)	Yes, computer generated list	Yes, sealed envelope	Yes[b]	Yes	P&I	Yes Yes
Etter (2004)	Yes, computer generated list	Likely, method not described	Yes	Yes	P	Yes Yes
Haustein (2003)	Yes, computer generated list	Yes, sealed envelope	Yes	Yes	P&I	Yes Yes
Rennard (2006)	Likely, method not described	Likely, method not described	Yes	Yes	P&I	Yes Yes
Wennike (2003)	Yes, computer generated list	Yes, sealed envelope	Yes[b]	Yes	P&I	Yes Yes
Wood-Baker (2001)	Yes, computer generated list	Yes, sealed envelope	Yes	Yes	P&I	Yes Yes
Tonnensen (2005)	Likely, method not described	Likely, method not described	Yes[b]	Yes	Unclear	Yes Yes
Carpenter (2004)	Likely, method not described	Likely, method not described	Yes	Yes	Unclear	Yes Yes
Joseph (2008)	Yes, computer generated list	Yes, sealed envelope	Yes	Yes	P	Unclear Unclear
Kralikova (2002)	Likely, method not described	Likely, method not described	Unclear[c]	Unclear	Unclear	Unclear Unclear
Chan (2011)	Yes, computer generated list	Yes, sealed envelope	Yes[b]	Yes	P	Yes Yes
Carpenter (2003)	Likely, method not described	Likely, method not described	Yes[b]	Yes	Unclear	Yes Yes

Note: ITT=intention to treat; P=participants; I=investigators
[b] Small imbalance in gender
[c] Data only available on the entire sample

Results

Recruitment and Methodology

The randomised controlled trials recruited smokers who were unable or unwilling to quit smoking, but were prepared to cut down their cigarette consumption. Advertisements in newspapers and on the radio were generally used, or participants were invited to take part via their clinician. One study pro-actively recruited participants by telephoning households and identifying people who smoked using a marketing firm (Carpenter, Hughes, Solomon & Callas 2004). Trials in general recruited around 350 to 600 participants. There were five exceptions: 900 smokers recruited in one study (Etter et al., 2004) and 50-200 smokers in four other studies (Haustein et al., 2003; Joseph et al., 2008; Tonnesen et al., 2005; Carpenter et al., 2003). Treatment periods varied from less than 2 months (Chan et al., 2011; Carpenter et al., 2004), 3-6 months (Carpenter et al., 2003; Etter et al., 2004; Tonnesen et al., 2005; Kralikova et al., 2002), 7-12 months (Wennike et al., 2003; Batra et al., 2005; Haustein et al., 2003; Wood-Baker, 2001; Rennard et al., 2006), and to over 18 months (Bolliger et al., 2000; Joseph et al., 2008). In all trials expect those by Etter et al. (2004), Kralikova et al. (2002), and Carpenter et al. (2004), smoking status was validated by carbon monoxide analysis. Demographic and smoking characteristics of recruited smokers at baseline varied among the studies, with an average age of 34-58, cigarette consumption per day of 18-30, carbon monoxide levels of 16-30ppm and FTND [Fagerstrom Test for Nicotine Dependence; (Fagerstrom & Schneider, 1989] of 5.0-6.6. The biggest differences occurred in gender, with the proportion of male participants ranging from 26-88%. This seems to represent a population of smokers which are similar in characteristics to typical heavy smokers.

The studies randomised interested smokers to active NRT and either placebo NRT (Batra et al., 2005; Haustein, Batra & Landfeldt, 2003; Wennike, Danielsson, Landfeldt, Westin & Tonnesen, 2003; Bolliger et al., 2000; Rennard et al., 2002; Kralikova, Kozak, Rasmussen & Cort, 2002; Wood-Baker, 2001) or usual-care/no-treatment control groups (Carpenter, Hughes & Keely, 2003; Joseph et al., 2008). Four studies had multiple arms: NRT, placebo NRT or no-treatment (Etter, Laszlo & Perneger, 2004); NRT, no-treatment or an abrupt smoking cessation intervention (Tonnesen et al., 2005); NRT, no-treatment or motivational advice (Carpenter et al., 2004); NRT with adherence and reduction counselling, NRT with reduction counselling only or usual-care (Chan et al., 2011). Chan et al., combined the first two groups for many of the analyses. The study by Haustein and colleagues (2003) also compared long-term and short-term reduction. These results are not reported here, since data were not available for the comparison of active and placebo groups for these conditions.

The active NRT groups were provided with a specific NRT product, which usually varied in strength depending on the smokers level of nicotine dependency (gum, inhaler, patch), or were given the choice between nicotine gum, the inhaler or patches of varying doses. Where NRT was compared with placebo NRT, participants received a product similar in design and content to the equivalent NRT product with nicotine removed. Smokers were also provided with extensive behavioural support, with only one exception (Etter et al., 2004). This included additional clinic visits, information booklets, instructions on the different types of NRT, information on the beneficial effects of smoking reduction, and details of the different methods that could be used to achieve smoking reduction, i.e. hierarchical and delay strategies. In contrast, usual-care groups were given advice to quit and provided with NRT if a quit date was set, while no-treatment controls received assessment calls and information booklets only (Etter et al., 2004; Carpenter et al., 2004). Motivational advice provided in one study (Carpenter et al., 2004), involved the five R’s of quitting smoking outlined by the US Public Health Service national guidelines (Fiore, Bailey & Cohen, 2000). Because the failure to mention cessation is unethical, all groups were advised to quit smoking and in the majority of cases provided with NRT if they opted to do so (see Table 3).

Table 3: Characteristics of the Selected Studies for Inclusion in the Systematic Review

Reference	Participant and smoking characteristics			Aims	NRT group instructions	Control group instructions	Additional aspects	Outcomes
	NRT	Control	Second control					
Batra 2005 Sweden	184 participants, mean age 42.4 (*SD* 9.9), 54.1% male. Average cigarettes per day 27.9 (*SD* 9.2), FTND of 5.7 (*SD* 1.8) & CO 29.1 (*SD* 10.8) ppm.	180 participants, mean age 43.5 (*SD* 10.3), 35.2% male. Average cigarettes per day 29.6 (*SD* 9.5), FTND of 5.9 (*SD* 1.9) & CO 28.2 (*SD* 10.2) ppm.		Efficacy of nicotine gum compared to placebo gum for smoking reduction.	Instructed to use 4mg gum for 12 months whenever they had an urge to smoke (around 6-24 pieces per day). Told to reduce as much as possible	Instructed to use placebo gum for 12 months whenever they had an urge to smoke (around 6-24 pieces a day). Told to reduce as much as possible	Telephone support and additional clinic visits as necessary, where counselling on reduction was provided.	Point prevalence reduction of >50% Sustained Reduction of >50% Reduction in biomarkers Seven-day point prevalence cessation Motivation to quit Adverse events
Bolliger 2000 Switzerland	200 participants, mean age of 46.4 (*SD* 10.5), 43.0% male. Average cigarettes per day 28.2 (*SD* 11.4), FTND of 5.5 (*SD* 2.1) & CO 27.1 (*SD* 11.5) ppm.	200 participants, mean age of 45.8 (*SD* 20.5), 52.0% male. Average cigarettes per day 30.3 (*SD* 12.1), FTND of 5.6 (*SD* 2.0) & CO 25.1 (*SD* 11.1) ppm.		Efficacy of the nicotine inhaler compared to placebo inhaler for smoking reduction.	Instructed to use 10mg inhaler for 18 months as needed (around 6-12 cartridges per day). An initial goal of a 50% reduction was given.	Instructed to use placebo inhaler for 18 months as needed (around 6-12 cartridges per day). An initial goal of a 50% reduction was given.	Additional clinic visits where counselling on smoking reduction was provided. Smokers were also given information on the best ways to reduce their cigarette consumption. Smoking cessation was recommended as ultimate goal.	Reduction in cigarette consumption Point prevalence reduction of >50% Sustained reduction of >50% Seven-day point prevalence cessation Sustained abstinence Motivation to quit Adverse events Quality of life
Haustein 2003 Germany	97 participants mean age of 42, 50% male. Average cigarettes per day 24, FTND of 5 & CO of 28ppm.	96 participants mean age of 42, 50% men. Average cigarettes per day 24, FTND of 6 & CO of 28ppm.		Efficacy of nicotine gum compared to placebo gum for smoking reduction.	Instructed to use 4mg gum for 9 months and to reduce as much as possible.	Instructed to use placebo gum for 9 months and to reduce as much as possible.	Information not available	Point prevalence reduction >50% Sustained reduction of >50% Seven-day point prevalence cessation Sustained abstinence Adverse events Quality of life

Table 3: Characteristics of the Selected Studies for Inclusion in the Systematic Review (Continued)

Reference	Participant and smoking characteristics			Aims	NRT group instructions	Control group instructions	Additional aspects	Outcomes
	NRT	Control	Second control					
Carpenter 2003 US	32 participants, mean age of 44 (*SD* 9), 37% male. Average cigarettes per day 23 (*SD* 10), & FTND of 6 (*SD* 2).	35 participants, mean age of 43 (*SD* 12), 26% male. Average cigarettes per day 24 (*SD* 10), & FTND of 6 (*SD* 2).		Efficacy of nicotine patch/gum/ inhaler for smoking reduction compared to usual-care.	Instructed to use NRT for 6 months (4mg gum, 7, 14 or 21mg patch or 10mg inhaler) with a goal of 50% reduction in cigarette consumption by the end of week 4.	The usual-care group was given brief advice to quit at the initial visit and NRT was provided if a quit date was set.	Both groups received clinic visits where the personal relevance of smoking and rewards of quitting were discussed. They were also given a stop smoking booklet. For the NRT group, counsellors also discussed problems, reviewed progress and set goals. Participants were told about reduction methods (hierarchical versus scheduled reduction) and given brief advice to quit.	Reduction in cigarette consumption Reduction in biomarkers Quit attempts Seven-day point prevalence cessation Motivation to quit
Kralikova 2002 Czech Republic	Information only available on the entire sample: 314 participants, mean age of 46, 42% male. Average cigarettes per day 25.			Efficacy of the nicotine gum/inhaler compared to placebo gum/inhaler for smoking reduction.	Instructed to use NRT for 6 months (4mg gum or 10mg inhaler) (6-12 inhaler cartridges per day and 24 pieces of gum per day)	Instructed to use placebo gum or placebo inhaler for 6 months.	All smokers were provided with additional clinic visits, brief behavioural reduction advice and were recommended to quit smoking.	Sustained reduction of >50% Reductions in biomarkers Sustained abstinence Nicotine withdrawal/urges to smoke
Wood-Baker 2001 Australia	218 participants, mean age of 42.9, 46% male. Average cigarettes per day 29.0, FTND of 6.6 & CO of 25.8.	218 participants, mean age of 45.3, 45% male. Average cigarettes per day 27.4, FTND of 6.4 & CO of 25.9.		Efficacy of nicotine gum compared to placebo gum for smoking reduction.	Instructed to use nicotine gum (2mg or 4 mg) for 12 months.	Instructed to use placebo gum for 12 months.	Both received additional clinic visits and literature on ways to achieve smoking reduction.	Point prevalence reduction >50% Sustained reduction >50% Seven-day point prevalence cessation Sustained abstinence Quality of life

Table 3: Characteristics of the Selected Studies for Inclusion in the Systematic Review (Continued)

Reference	**Participant and smoking characteristics** NRT	Control	Second control	**Aims**	**NRT group instructions**	**Control group instructions**	**Additional aspects**	**Outcomes**
Carpenter 2004 US	212 participants, mean age 38 (*SD* 12), 68% male. Average cigarettes per day 23 (*SD* 10) & FTND of 5.6 (*SD* 2.4).	*Motivation interviewing* 197 participants, mean age 39 (*SD* 13), 74% male. Average cigarettes per day 21 (*SD* 8) & FTND of 5.5 (*SD* 2.1).	*No-treatment* 207 participants, mean age 41(*SD* 14), 68% male. Average cigarettes per day 22 (*SD* 9) & FTND of 5.4 (*SD* 2.1).	Efficacy of nicotine gum/ patch/ inhaler for smoking reduction compared to motivational advice and no-treatment controls.	Instructed to use NRT (4mg gum or 7, 14, or 21mg patch). Told to reduce smoking as much as possible for 6 weeks. After this time NRT only offered when a quit date was set.	Motivational interviewing group were provided with motivational advice based on the 5 R's of quitting and offered NRT if a quit date was set. No-treatment controls received assessment calls only.	Both the motivation advice and reduction group received counselling and brief advice to quit. The reduction group also received advice to reduce by either scheduled or hierarchical reduction and were provided with information on NRT. A reduction goal was also formed and advantages and the disadvantages of using NRT to reduce cigarette consumption were discussed.	Reduction in cigarette consumption Sustained reduction >50% Quit attempts Seven-day point prevalence cessation Motivation to quit Rate of reduction and cessation
Etter 2004, Sweden	265 participants, mean age 43.2, 54% male. Average of cigarettes per day 29.8 (*SD* 10.3) & FTND score 6.0.	*Placebo* 269 participants, mean age 41.7 years, 49% men. Average of cigarettes per day 29.4 (*SD* 9.4) & FTND score 5.9.	*No-treatment* 389 participants, mean age 42.9 years, 44% men. Average cigarettes per day 30.2 (*SD* 10.4) & FTND score 6.2.	Efficacy of nicotine patch/ gum/ inhaler / combined NRT for smoking reduction compared to placebo NRT for smoking reduction and no-treatment controls.	Instructed to use NRT (25mg patch, 4mg gum, 10mg inhaler or a combination of NRT products). Initially NRT was provided for 5 days but more could be ordered for up to 6 months of treatment.	Instructed to use placebo NRT. Initially NRT was provided for 5 days but more could be ordered for up to 6 months of treatment. No-treatment controls did not receive any form of intervention.	All three groups received an information booklet after enrolment and at 3 months. This covered the reasons for reducing smoking and addressed smoking cessation clinics. Placebo and NRT groups also received information leaflets on the various NRT products.	Reduction in cigarette consumption Point prevalence reduction >50% Quit attempts Seven-day point prevalence cessation Motivation to quit Rate of reduction and cessation Nicotine withdrawal/urges to smoke Adverse events

Table 3: Characteristics of the Selected Studies for Inclusion in the Systematic Review (Continued)

Reference	**Participant and smoking characteristics** NRT	Control	Second control	**Aims**	**NRT group instructions**	**Control group instructions**	**Additional aspects**	**Outcomes**
Rennard 2006 US	215 participants, mean age 45.9 (*SD* 8.6), 26% male. Average cigarettes per day 29.3 (*SD* 10.1), FTND of 6.5 (*SD* 2.0) & CO 29.7 (*SD* 10.7) ppm.	214 participants, mean age 45.9 (*SD* 12.3), 49% male. Average cigarettes per day 30.4 (*SD* 9.9), FTND of 6.6 (*SD* 1.9) & CO 29.5 (*SD* 9.0) ppm.		Efficacy of the nicotine inhaler compared to placebo inhaler for smoking reduction.	Instructed to use 10mg inhaler for 12 months (6-12 cartridges per day), and encouraged to reduce smoking as much as possible.	Instructed to use placebo inhaler for 12 months (6-12 cartridges per day), and encouraged to reduce smoking as much as possible.	Nine clinic visits where both placebo and NRT conditions received information on possible ways to reduce smoking. Cessation was also recommended at 6 months.	Reduction in cigarette consumption Point prevalence reduction >50% Sustained reduction >50% Reduction in biomarkers Seven-day point prevalence cessation Motivation to quit Adverse events Quality of life
Wennike 2003 Denmark	205 participants, average age 45 (*SD* 10), 35% male. Average cigarettes per day 24 (*SD* 7) & CO 29 (*SD* 9) ppm.	206 participants, average age 44 (*SD* 10), 31% male. Average cigarettes per day 24 (*SD* 7). & CO 27 (*SD* 9) ppm.		Efficacy of nicotine gum compared to placebo gum for smoking reduction	Instructed to use nicotine gum (2mg or 4mg) for 12 months and to reduce cigarette consumption as much as possible.	Instructed to use placebo gum for 12 months and to reduce cigarette consumption as much as possible.	Both groups received brief information on smoking reduction, its effect on health, and suggestions on ways to reduce intake, i.e. longer time to first cigarette and removal of habitual cigarettes. Smoking cessation was recommended as the ultimate goal.	Reduction in cigarette consumption Point prevalence reduction >50% Sustained reduction >50% Reduction in biomarkers Seven-day point prevalence cessation Motivation to quit Quality of life Rate of reduction and cessation
Joseph 2008 US	78 participants, average age 57 (*SD* 9), 70% male. Average cigarettes per day 28 (*SD* 13) & FTND 6 (*SD* 2).	74 participants, average age 58 (*SD* 10), 65% male. Average cigarettes per day 27(*SD* 11) & FTND 6 (*SD* 2).		Efficacy of nicotine gum for smoking reduction compared to usual-care.	Instructed to use nicotine 4mg gum for 18 months (6-8 pieces per day). Patches were offered if they could not reduce their consumption with nicotine gum by 50%.	Provided with usual-care	Smoking reduction group received information on reduction methods (for example:- not smoking at work), about the relationship between smoking and health, and were encouraged to quit smoking. The usual-care group received an initial visit where the importance of cessation was reiterated and they were encouraged to seek help to stop smoking.	Reduction in cigarette consumption Reduction in biomarkers Sustained abstinence Nicotine withdrawal/urges to smoke Adverse events Quality of life Views about smoking reduction

Table 3: Characteristics of the Selected Studies for Inclusion in the Systematic Review (Continued)

Reference	**Participant and smoking characteristics** NRT	Control	Second control	**Aims**	**NRT group instructions**	**Control group instructions**	**Additional aspects**	**Outcomes**
Tonnesen 2005 Sweden	33 participants, average age 34 (*SD* 9), 36% male. Average cigarettes smoked per day 18 (*SD* 5) & FTND of 4.8.	*Cessation group* 27 participants, average age 37 (*SD* 9), 37% male. Average cigarettes smoked per day 20 (*SD* 6) & FTND of 5.4.	*No-treatment* 50 participants, average age 35 (*SD* 8), 46% male. Average cigarettes per day 20 (*SD* 4) & FTND 5.5.	Efficacy of nicotine gum/inhaler for smoking reduction compared to no-treatment controls and a smoking cessation intervention with NRT.	Instructed to use NRT (2 or 4mg gum or 10mg inhaler) for 4 months as needed (up to 25 pieces per day of the gum and 12 inhaler cartridges per day). Told to reduce as much as possible.	The cessation group were instructed to stop smoking and were given 2 or 4mg gum or 10mg inhaler. No-treatment controls were instructed to continue smoking as normal.	Both the reduction and cessation groups received information on NRT products and written information regarding the general conduct of the study and the proper use of the study medication.	Reduction in cigarette consumption Seven-day point prevalence cessation Adverse events Views about smoking reduction
Chan 2011 Hong Kong	479 participants, average age 41.5 years (*SD* 10.3), 78% male. Average cigarettes per day 19.8 (*SD* 9.4), FTND of 5.3 (*SD* 2.4) & CO 16.4 (*SD* 8.5)	*Reduction counselling* 449 participants, average age 42.4 years (*SD* 10.3), Average cigarettes per day 20.1 (*SD* 10.1), FTND of 5.2 (*SD* 2.3) & CO 18.2 (*SD* 9.7)	*Usual-care* 226 participants, average age 42.5 years (*SD* 11.2), 88% male. Average cigarettes per day 19.2 (*SD* 8.9), FTND of 4.8 (*SD* 2.3) & CO 16.7 (*SD* 8.9)	Efficacy of reduction and adherence counselling with nicotine gum/patches, compared to reduction counselling with gum/patches and usual-care.	Instructed to use nicotine patches or gum (4 or 2mg) for eight weeks and were told to reduce as much as possible.	The reduction counselling group were told to reduce as much as possible and were given the option between the patch or gum for 8 weeks. The usual-care group were advised on the hazards of smoking and importance of cessation.	At baseline participants received a self-help quitting pamphlet. Reduction counselling involved information on the best methods of smoking reduction and motivation bolstering. Adherence counselling involved identifying issues with non-adherence and instructions to use NRT as recommend. The usual-care group were also provided with advice on the health hazards of smoking and importance of smoking cessation.	Reduction in cigarette consumption Point prevalence reduction >50% Reduction in biomarkers Seven-day point prevalence cessation

Note: NRT=Nicotine Replacement Therapy; *SD*=Standard Deviation; FTND=Fagerstrom Test for Nicotine Dependence; CO=carbon monoxide

Participant Selection Criteria

There did not appear to be an operational definition among studies of what constituted a smoker who was unwilling or unable to quit smoking, with the time-frame for intention to quit varying from not ready to quit in the next month, to not ready to quit in the next 6 months. Those under the age of 18 or over 60 years of age were often excluded, as were those with chronic psychological or physical disorders. There were three exceptions: Tonnesen et al. (2005) recruited smokers with chronic asthma, Kralikova et al. (2002) smokers with respiratory disease and Joseph et al. (2008) smokers with heart disease.

Choice of Nicotine Replacement Therapy and Adherence

A high level of compliance to the NRT regimen was evident (Batra et al., 2005; Rennard et al., 2006; Wennike et al., 2003; Chan et al., 2011; Tonnesen et al., 2005). Similar levels of compliance in active and control conditions were found. Of those which gave participants a choice between different NRT products, a preference for the nicotine patch was established (Carpenter et al., 2003; Carpenter et al., 2004; Etter et al., 2002; Chan et al., 2011).

Table 4: Change in Cigarette Consumption Between Baseline and Follow-up as a Function of Treatment Group

Study	Length of follow-up	Treatment group (Percentage change in cigarette consumption)			
		Active NRT %(*n*)	Placebo NRT %(*n*)	Usual-care/ no- treatment %(*n*)	Motivational advice %(*n*)
Joseph et al. (2008)	72 weeks	35 (-9.7)	-	32 (-8.6)	-
Etter et al. (2004)	104 weeks	33 (-9.8)	25 (-7.7)*	25 (-7.7)**	-
Carpenter et al. (2003)	24 weeks	44 (-11)	-	12 (-3)***	-
Carpenter et al. (2004)	6 weeks	30 (-7)	-	15 (-3)***	28 (-6)
Bolliger et al. (2000)	96 weeks	74 (-22)	27 (-8)***	-	-
Rennard et al. (2006)	60 weeks	53 (-14.6)	40 (-12.2)*	-	-
Wennike et al. (2003)	96 weeks	46 (-11)	39 (-9.4)	-	-
Chan et al. (2011)	24 weeks	52 (-10)	-	32 (-6)***	--

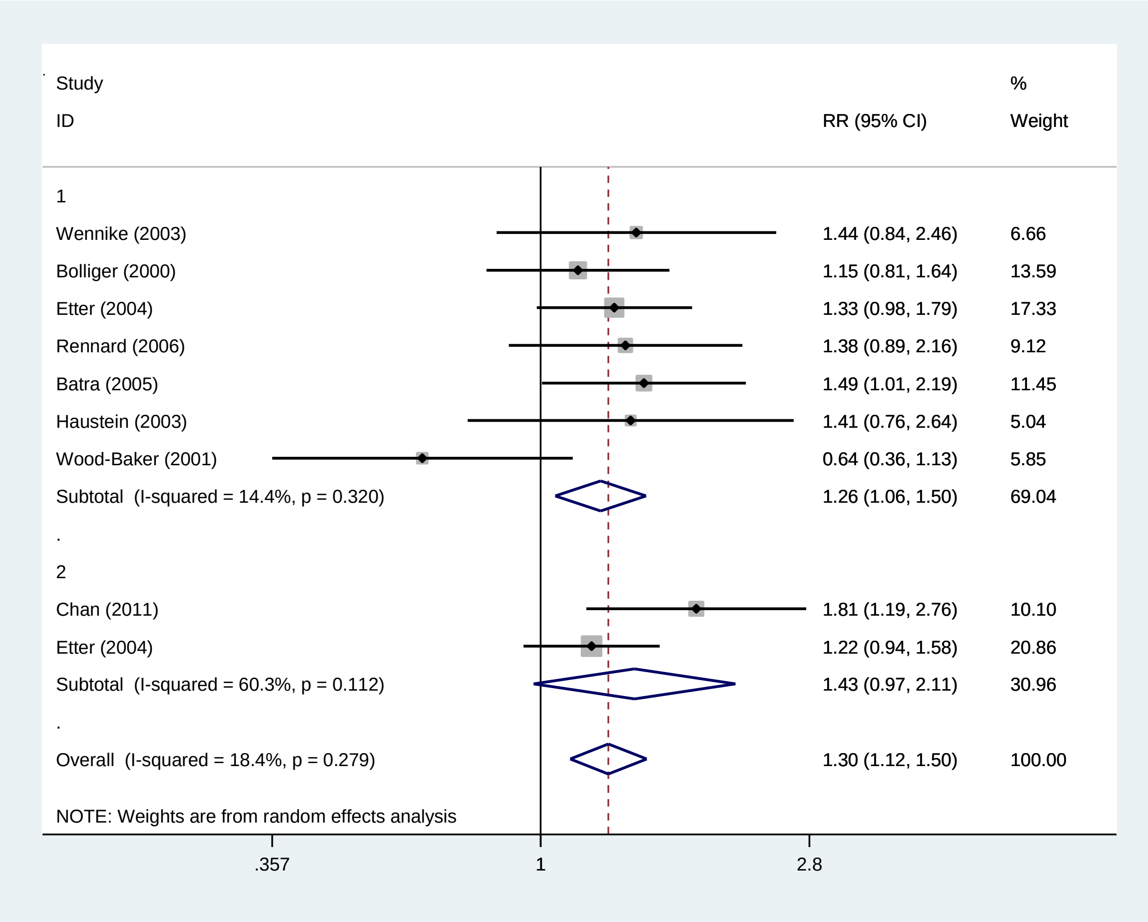
Note: *n*=number; NRT=Nicotine Replacement Therapy; - =Not applicable
Significant difference between active NRT and control groups (*$p<0.05$, ** $p<0.01$, ***$p<0.001$)

Percentage Reduction in Cigarette Consumption from Baseline

Nine studies assessed and reported on the average percentage reduction in cigarette consumption between baseline and follow-up. Most showed a superiority of active NRT relative to placebo NRT and usual-care/no-treatment controls. An average reduction [Standard Deviation (*SD*)] of 45.9% (14.24) was reported in the active NRT groups, 32.8% (*SD* 7.85) in the placebo groups and 23.2% (*SD* 9.36) in the usual-care/no-treatment groups. No superiority relative to motivational advice was established (see Table 4). Even where differences were not significant, those using NRT experienced large reductions in their consumption, which appeared to be well maintained. One further study did not assess percentage reduction in cigarette intake from baseline, but the number of smokers that were smoking fewer than seven cigarettes per day at follow-up. This study noted a superiority of NRT relative to no-treatment controls, but not relative to a smoking cessation intervention (Tonnesen et al., 2005).

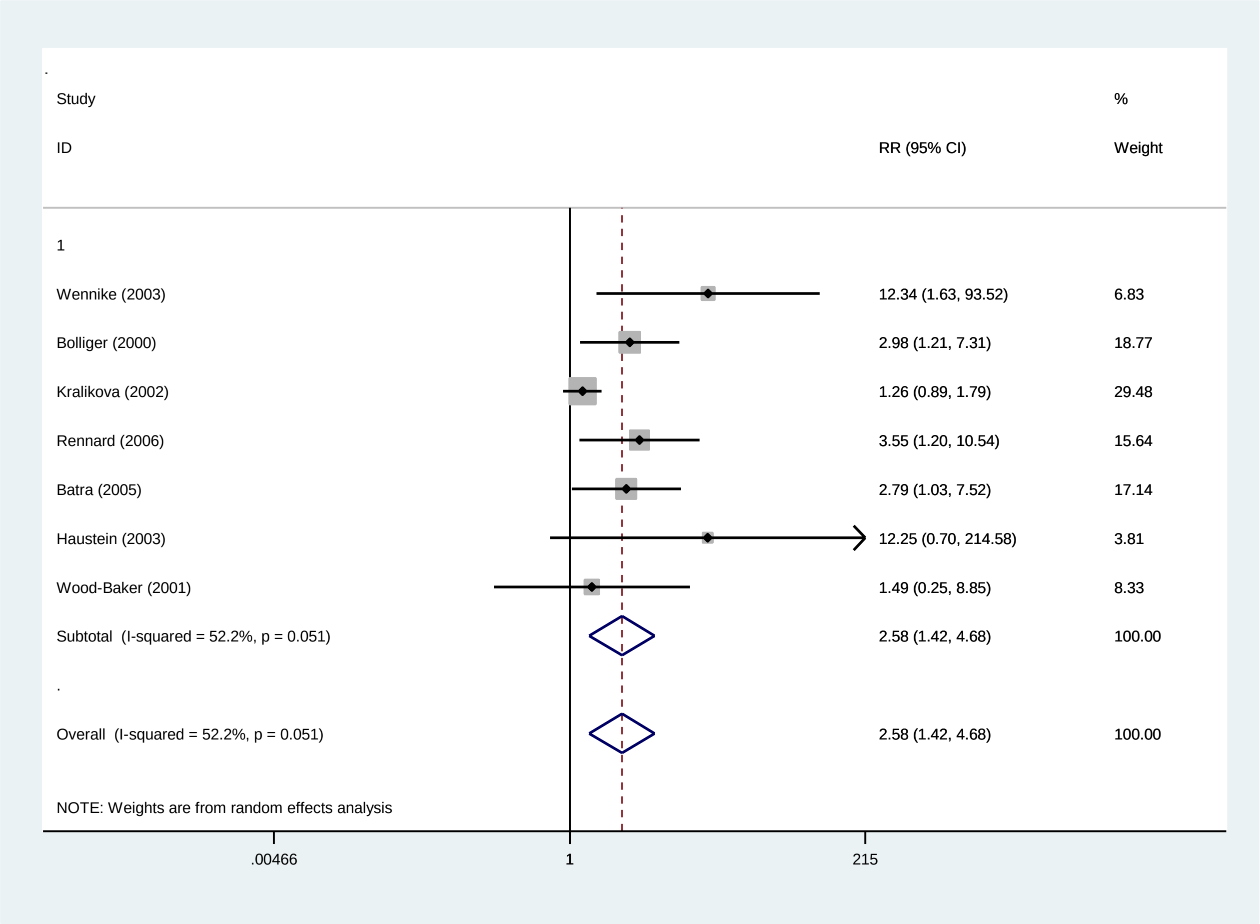
Point-Prevalence Reduction of 50% in Cigarette Consumption

Eight studies assessed the number of smokers attaining a point prevalence reduction in cigarette consumption of 50% or more. A meta-analysis was conducted on those studies comparing the use of NRT for smoking reduction to usual-care/no-treatment and placebo NRT groups. Follow-up ranged from 6 months (Chan et al., 2011), to 12-15 months (Haustein et al., 2003; Batra et al., 2005; Rennard et al., 2005; Wood-Baker, 2001), to over 18 months (Bolliger et al., 2000; Wennike et al., 2003; Etter et al., 2004). The overall active NRT effect was statistically significant [Relative Risk (*RR*) 1.30; Confidence Interval (CI) 1.12-1.50; (see Figure 1)]; with the proportion of smokers achieving reductions of 50% or more with NRT being 1.4 times that of usual-care/no-treatment controls (*RR* 1.43; CI 0.97-2.11), and 1.3 times that of placebo controls (*RR* 1.26; CI 1.06-1.50). A fixed effects model corroborated these findings (Overall *RR* 1.30; CI 1.15-1.48; I-squared=18.5, *p*=0.278). Because the study given the largest amount of weight used self-reported smoking status, which may have biased the findings, in that a substantial number of the control groups reported declines in cigarette consumption (Etter et al., 2004); a meta-analysis was conducted excluding this study. This appeared to have little impact on the overall effect size of active NRT compared to placebo NRT (*RR* 1.23; CI 0.99-1.55; I-squared=36.9, *p*=0.147).



Note: 1=active NRT versus placebo controls; 2=active NRT versus usual-care/no-treatment controls
Pooled estimates are DerSimonian Relative Risks (Random Effects)

Figure 1: Meta-Analysis of Point Prevalence Reduction of 50% or More in Cigarette Consumption



Note: 1=active NRT versus placebo controls
Pooled estimates are DerSimonian Relative Risks (Random Effects)

Figure 2: Meta-Analysis of Sustained Reduction of 50% or More in Cigarette Consumption

Sustained Reduction of 50% in Cigarette Consumption

Eight studies assessed the number of smokers sustaining a reduction of 50% or more in cigarette consumption. A meta-analysis was conducted on those studies comparing the use of NRT for smoking reduction to placebo NRT groups. Follow-up ranged from 6 months (Carpenter et al., 2004) to 12-15 months (Haustein et al., 2003; Batra et al., 2005; Rennard et al., 2005; Wood-Baker, 2001; Kralikova et al., 2002), to over 18 months (Bolliger et al., 2000; Wennike et al., 2003). The overall active NRT effect was statistically significant [Relative Risk (*RR*) 2.58; Confidence Interval (CI) 1.42-4.68; (see Figure 2)]. A fixed effects model corroborated these findings (Overall *RR* 1.99; CI 1.50-2.64), with moderate heterogeneity (I-squared=56.0, p=0.034). Because the study given the largest amount of weight used self-reported smoking status, which may have biased the findings, in that a substantial number of the control groups reported declines in cigarette consumption (Kralikova et al., 2002); a meta-analysis was conducted excluding this study. This appeared to increase the overall effect size of active NRT compared to placebo NRT (*RR* 3.30; CI 1.97-5.51; I-squared=0.0, p=0.642). A superiority of active NRT relative to usual-care but not motivational advice was established in another study (Carpenter et al., 2004).

Reductions in Biomarkers

Seven studies assessed reductions in biomarkers from baseline to follow-up which ranged from 6 months (Carpenter et al., 2003; Chan et al., 2011), 12-15 months (Kralikova et al., 2002; Batra et al., 2005; Rennard et al., 2006), to over 18 months (Joseph et al., 2008; Wennike et al., 2003). In six of the studies greater reductions in cotinine, carbon monoxide, and thiocyanate were reported amongst active NRT groups relative to placebo NRT and usual-care groups. The one exception being the study by Joseph et al. (2008), which failed to establish between-group differences or reductions over time in nicotine intake. Compensatory smoking was evident in a number of the studies, with declines in cigarette consumption being substantially greater than the reductions in biomarkers. This was despite those in the active NRT conditions reporting declines in the intensity of their smoking and the total quantity of smoke inhaled (Etter et al., 2004). The randomised controlled trials also failed to report a significant difference between active and control groups in the prevalence or frequency of angina, white blood cell count, HDL/LDL, fibrinogen, C-reactive protein, F_2-isoprostane, total NNAL or 1-hydroxypyrene, at any time point (Joseph et al., 2008; Rennard et al., 2006; Batra et al., 2005). However, changes were established in respiratory status, intensity of coughs, shortness of breath, blood pressure, pulse rate, phlegm, white blood cell count, HDL/LDL and C-reactive protein, among those reducing their consumption by 50% or more, irreverent of group assignment (Rennard et al., 2006; Kralikova et al., 2002).

Quit Attempts

Three studies assessed the number of smokers which had attempted to quit smoking between baseline and 6 months follow-up (Carpenter et al., 2003; Carpenter et al., 2004; Etter et al., 2004). Due to significant heterogeneity, which was not resolved with the exclusion of any study (I-squared=77.3, p=0.012), the results could not be pooled in a meta-analysis. Although a superiority of active NRT relative to no-treatment controls was established (Etter et al., 2004; Carpenter et al., 2004), no superiority relative to placebo NRT (Etter et al., 2004), motivational advice (Carpenter et al., 2004), or usual-care groups (Carpenter et al., 2003), was found. In fact, the latter study reported that 34% of the usual-care group, but just 25% of those cutting down with active NRT, had made at least one quit attempt.

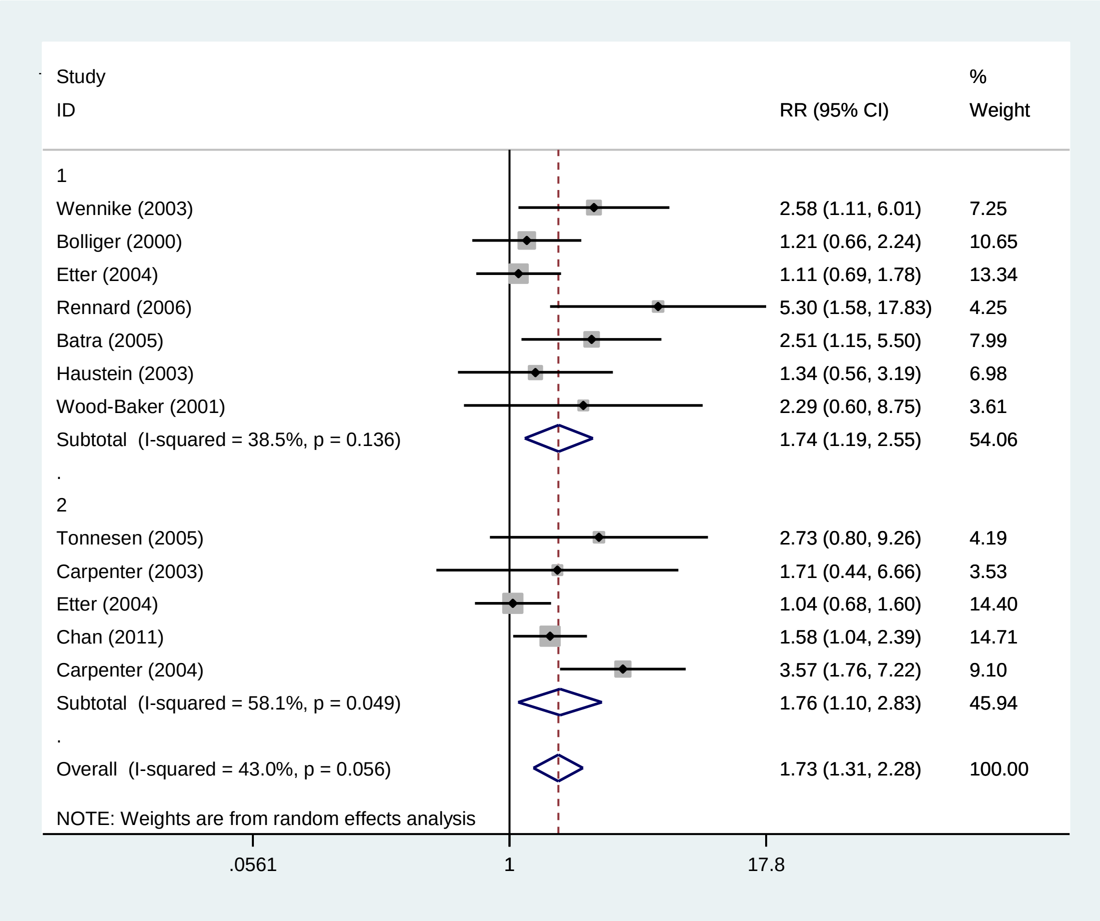
Seven-day Point Prevalence Cessation

Eleven studies assessed the number of smokers attaining seven-day point prevalence cessation. Follow-up ranged from less than 6 months (Tonnesen et al., 2005; Carpenter et al., 2003; Carpenter 2004; Chan et al., 2011), 12-18 months (Batra et al., 2005; Wood-Baker, 2001; Rennard et al., 2006; Haustein et al., 2003) and to over 24 months (Bolliger et al., 2000; Wennike et al., 2003; Etter et al., 2004). A meta-analysis was conducted on those studies comparing the use of NRT to usual-care/no-treatment and placebo NRT groups. The overall active NRT effect was statistically significant [Relative Risk (*RR*) 1.73, Confidence Interval (CI) 1.31-2.28; (see Figure 3)]; with the proportion of smokers achieving seven-day point prevalence cessation with NRT being 1.8 times that of usual-care/no-treatment controls (*RR*

1.76; CI 1.10-2.83), and 1.7 times that of placebo NRT groups (*RR* 1.74; CI 1.19-2.55). A fixed effects model corroborated these findings (Overall *RR* 1.64; CI 1.36-1.98; I-squared=43.8, *p*=0.052). Because the study given the largest amount of weight used self-reported smoking status, which may have biased the findings, in that a substantial number of the control groups reported seven-day point prevalence cessation (Etter et al., 2004); a meta-analysis was conducted excluding this study. This appeared to have little impact on the overall effect size of active NRT compared to placebo NRT (RR 1.98; CI 1.32-2.98; I-squared=23.1, p=0.260), or compared to usual-care/no-treatment controls (RR 2.13; CI 1.35-3.36; I-squared=27.7, p=0.246); with an overall significant effect (RR 2.01; CI 1.52-2.65; I-squared=15.7, p=0.299). No superiority relative to those receiving an abrupt smoking cessation intervention (Tonnesen et al., 2005), or motivational advice (Carpenter et al., 2004), was established.

Sustained Abstinence

Eight studies assessed the number of smokers attaining sustained abstinence. Follow-up ranged from 12-18 months (Batra et al., 2005; Wood-Baker, 2001; Rennard et al., 2006; Haustein et al., 2003; Joseph et al., 2008; Kralikova et al., 2002), to over 24 months (Bolliger et al., 2000; Wennike et al., 2003). A meta-analysis was conducted on those studies comparing the use of NRT to placebo NRT groups. The overall active NRT effect was statistically significant [Relative Risk (*RR*) 2.26, Confidence Interval (CI) 1.33-3.85; (see Figure 4)]. A fixed effects model corroborated these findings (Overall *RR* 2.50; CI 1.49-4.21; I-squared=0.0, *p*=0.787). Because the study given the largest amount of weight used self-reported smoking status, which may have biased the findings, in that a substantial number of the control groups reported sustained abstinence (Kralikova et al., 2002); a meta-analysis was conducted excluding this study. This appeared to have a significant impact on the overall effect size of active NRT compared to placebo NRT (*RR* 4.11; CI 1.33-12.67; I-squared=0.0, *p*=0.897). No superiority of NRT relative to usual-care was established (Joseph et al., 2008).



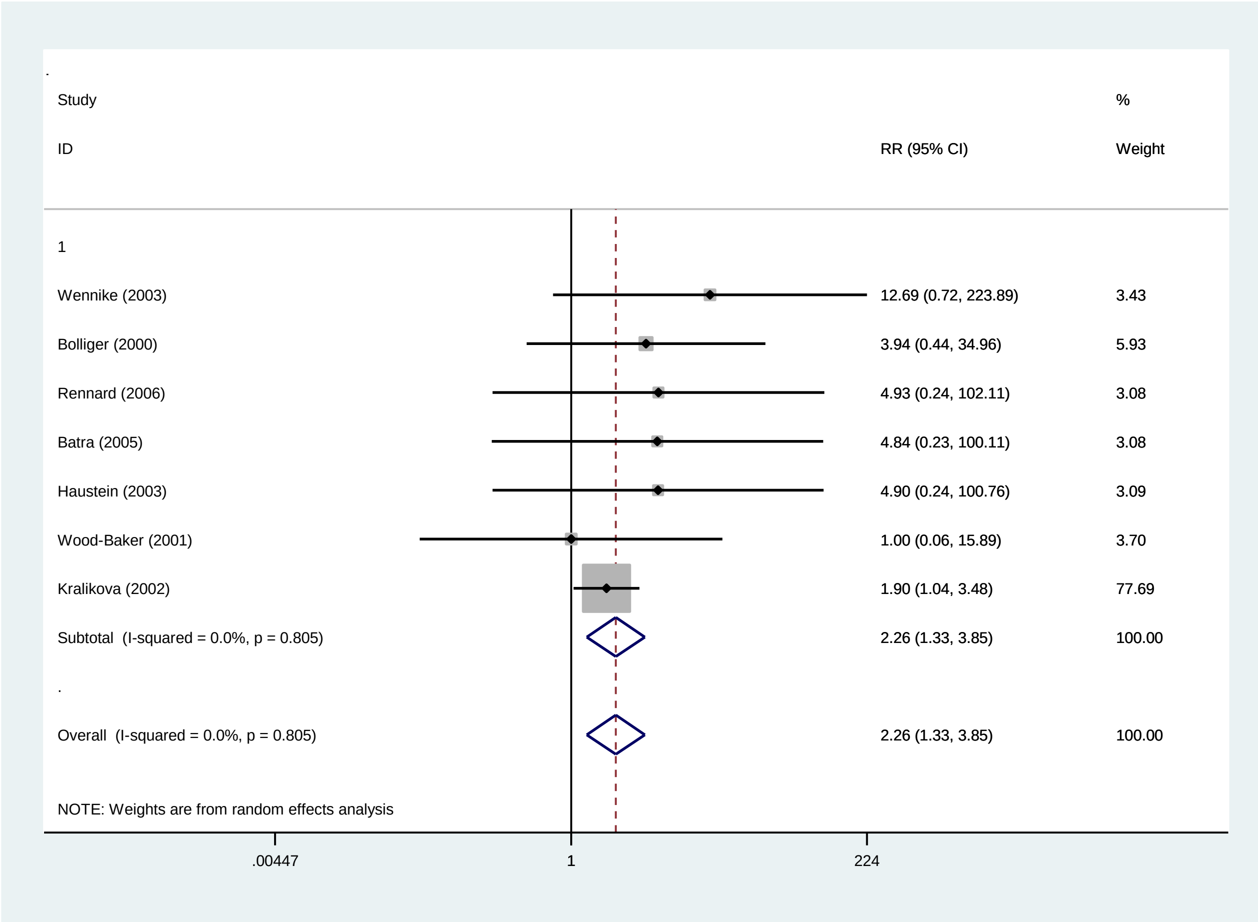
Note: 1=active NRT versus placebo controls; 2=active NRT versus usual-care/no-treatment controls
Pooled estimates are DerSimonian Relative Risks (Random Effects)

Figure 3: Meta-Analysis of Seven-day Point Prevalence Cessation

Motivation to Quit

In the randomised controlled trials greater increases in motivation to quit and self-efficacy for smoking cessation were found in the active NRT groups relative to usual-care and motivational advice (Carpenter et al., 2003; Carpenter et al., 2004). No superiority was reported relative to placebo NRT (Batra et al., 2005; Bolliger et al., 2000; Etter et al., 2004;

Rennard et al., 2006; Wennike et al., 2003), while results were mixed relative to no-treatment controls (Carpenter et al., 2004; Etter et al., 2004).



Note: 1=active NRT versus placebo controls
Pooled estimates are DerSimonian Relative Risks (Random Effects)

Figure 4: Meta-Analysis of Sustained Abstinence

Rate of Reduction and Smoking Cessation

Two studies assessed the relationship between the extent of reductions in cigarette consumption and the odds of smoking cessation (Etter et al., 2004 & Carpenter et al., 2004). Both reported a positive relationship, with larger reductions in cigarette intake associated with a higher probability of reporting abstinence. For example, Etter et al. (2004) found 11.4% of those who reduced their cigarette consumption by at least 50% had attained seven-day point prevalence cessation at 6 months follow-up, compared to 1.6% of those who did not reduce by half. Wennike et al. (2003) also noted that motivation to quit increased to a larger extent among 'successful reducers'.

Nicotine Withdrawal/Urges to smoke

Etter et al. (2004) reported that the 'pleasure of smoking', the 'psychoactive benefits of smoking', positive responses to 'I love the taste of cigarettes' and self-perceived dependence on cigarettes, were lower in the NRT group relative to control groups. In contrast, reports of the ease of reducing cigarette consumption were higher among those using active NRT to cut down. Joseph et al. (2008) and Kralikova et al. (2002) also reported lower nicotine dependence among those using NRT for smoking reduction.

Quality of Life

Six trials reported on changes in health related quality of life (Wennike et al., 2003; Wood-Baker, 2001; Rennard et al., 2006; Bolliger et al., 2000; Haustein et al., 2003; Joseph et al., 2008). Small improvements across several quality of life domains (for example:- physical functioning & emotional well-being), were established, with greater reductions among those reducing by larger amounts. There was no difference among active and control conditions.

Adverse Events

Treatment adverse events were mostly mild (Haustein et al., 2003; Rennard et al., 2006; Tonnesen et al., 2005; Batra et al., 2005; Bolliger et al., 2000; Etter et al., 2004; Joseph et al., 2008). A number of serious adverse events did occur: depression (Tonnesen et al., 2005); throat irritation and coughing (Rennard et al., 2006; Batra et al., 2005; Bolliger et al., 2000); constipation (Tonnesen et al., 2005); abdominal bleeding (Tonnesen et al., 2005); abdominal pain (Tonnesen et al., 2005); leg or arm pain (Tonnesen et al., 2005); and death (Etter et al., 2004). Studies generally failed to report higher rates of serious events among the active treatment groups, although non-serious events were slightly more common.

Views About Smoking Reduction and Nicotine Replacement Therapy

Tonnesen et al. (2005) reported that 54% of participants agreed 'very much' or 'extremely' that they would be able to reduce their consumption even more; 61% reported that they were motivated to maintain a reduction; 64% that NRT was a good aid to smoking reduction; 45% that they would miss NRT; 58% that they thought NRT helped them cut down; and 39% that NRT relieved cravings to smoke. Forty-one per cent also agreed that NRT induced smoking satisfaction similar to that from a cigarette. Moreover, smokers were found to be interested in smoking reduction due to the belief that it would improve their health, despite smokers reporting the concern that it was not safe to smoke and use NRT at the same time (Joseph et al., 2007).

Excluded Studies

Four excluded studies which were not included due to the abstinence of a control group corroborate these findings. Hurt et al. (2000) reported that those who significantly reduced their cigarette consumption with NRT had concurrent reductions in thiocyanate, and cotinine levels from baseline, but not expired carbon monoxide levels, NNAL or 4-aminobiphenyl-hemoglobin. A slight reduction in withdrawal symptoms was also noted.

Fagerstrom, Tejding, Westin and Lunell (1997) also reported significant reductions in cigarette consumption, carbon monoxide and measures of nicotine withdrawal, but not cotinine, among those using NRT for smoking reduction. At the end of the intervention 93% of participants reported that they were more motivated to give up as a consequence of the study, with seven subjects quitting during the intervention. Hecht et al. (2004) reported reductions in cigarette consumption and NNAL among those instructed to reduce their cigarette consumption with the aid of nicotine gum, or the nicotine patch if they were unable to attain reductions of at least 50%. However, decreases were modest and less than the reductions in the number of cigarettes smoked. For example, among those reducing their cigarette consumption by over 70%, reductions in NNAL of only 30% prevailed. Finally, Jimenez-Ruiz et al. (2002) reported that 29% of smokers with chronic obstructive pulmonary disease who were instructed to reduce their cigarette intake with the aid of NRT, experienced reductions in cigarette consumption and improved respiratory symptoms.

A study by Hanson, Zylla, Allen, Li and Hatsukami (2008) was also excluded because they failed to report on the statistical analysis between active and placebo NRT groups, both of which were encouraged to reduce their cigarette consumption. Overall, 50% of smokers had reduced their intake by half over the course of the study and seven per cent had quit smoking at 6 months follow-up. A study by Etter et al. (2007), which was a continuation of their 2002 and 2004 studies, was also excluded as follow-up extended over 5 years. They reported that the initial effects of active NRT treatment on smoking reduction had dissipated. However, significantly reducing cigarette consumption, regardless of initial group assignment, was associated with a higher chance of subsequently quitting smoking. Finally, two further studies were excluded because they involved cross-over designs, rather than the randomisation of participants to a specific group. The first examined the effects of an intervention involving contingent momentary reinforcement with active NRT, compared to one involving contingent momentary reinforcement with placebo NRT, and a third arm involving non-contingent momentary reinforcement. Smokers who were recruited had been diagnosed with schizophrenia and were followed-up for 5 days in each treatment. Contingent momentary reinforcement was found to decrease cigarette consumption, but the nicotine patch did not enhance this effect (Tidey, O'Neill & Higgins, 2002). Moreover, cotinine levels were found to be higher when smokers were using NRT. In contrast, Fagerstrom and colleagues (Fagerstrom, Hughes, Rasmussen & Callas, 2000; Fagerstrom, Hughes & Callas, 2002) compared the efficacy of the nicotine inhaler to modified cigarettes for smoking reduction, with smokers using each product for two weeks. Cigarette consumption, carbon monoxide levels, and cotinine concentrations, were found to decrease when the inhaler was used, but only cigarette consumption when modified cigarettes were used. In contrast, motivation to quit remained stable for both conditions.

Discussion

In line with the findings from the previous reviews (Hughes & Carpenter, 2006; Hughes, 2000; Fagerstrom, 2005; Tonnesen, 2002; Zellweger et al., 2001; Moore et al., 2009; Wang et al., 2008; Stead & Lancaster, 2007), the current meta-analysis found that use of NRT as part of a smoking reduction programme increases the chances of smokers attaining a 50% reduction or more in cigarette consumption, sustained abstinence, and point prevalence cessation, relative to placebo NRT, usual-care and no-treatment controls. In contrast, attempts to quit smoking and motivation to quit were only increased relative to the latter group. There was also some evidence that smoking reduction with the aid of NRT reduced urges to smoke, resulted in declines in toxin intake, and improved measures of health related quality of life; but that improvements in biomarkers and health related outcomes were restricted to those reducing their cigarette consumption by 50% or more, irrelevant of group assignment. No evidence was found of serious adverse events.

Interestingly, rates of cessation among those using NRT for smoking reduction were similar to those found for tailored cessation interventions (Prochaska, Velicer, Fava, Rossi & Tosh, 2001; Lancaster, Silagy, Silagy & Ketteridge, 1996), suggesting that this approach is as cost effective as traditional tobacco control policies (West et al., 2000a). Sustained abstinence may have even been higher had it not been the case for the inappropriate criteria in many studies, that quit attempts had to occur in the first 6 weeks of treatment. This means that only ‘early quitters’ could be classified as sustained abstainers, and that unfortunately, any participants who became abstinent at a later date and managed to sustain their abstinence were not taken into account. Previous reviews had attempted to rectify this issue by formulating their own criteria. For example, Moore and colleagues (2009) categorised smokers as long-term abstainers if they had quit smoking and remained smoke-free for 6 months. However, these were potentially biased reports, with extrapolation required for a number of smokers in instances where follow-up ceased before this time. Moreover, some of the additional studies included in the current review failed to report on the necessary data at all follow-up points for this to be calculated. Consequently, future studies should perhaps take a more relaxed attitude, and use measures of sustained abstinence which allow for relapse early on and delays in attempts to quit. It is of further interest that although quit attempts were more prevalent, and motivation to quit greater, among those using NRT compared to no-treatment controls, little difference was established relative to those reducing with placebo NRT; hence pointing towards the possibility that smoking reduction *per se* may increase smokers’ motivation to quit and the likelihood of a quit attempt, while the use of NRT may be pivotal in whether or not these attempts to quit translate into sustained abstinence. In other words, NRT for smoking reduction may not promote quit attempts, but the success of those quit attempts when they are made. The failure to also establish a difference relative to usual-care controls may reflect study design, with the usual-care group being provided with brief advice to quit and free NRT (Carpenter et al., 2003).

It is unsurprising that those using NRT for smoking reduction in the clinical trials were able to attain significantly greater reductions in their cigarette consumption than control groups, since the objective of NRT is to abate withdrawal symptoms and urges to smoke; thus making momentary abstinence more bearable and allowing smokers to eliminate certain cigarettes. Coinciding with this are the reports of declines in urges to smoke and withdrawal symptoms among those receiving active NRT (Etter et al., 2004; Joseph et al., 2008; Kralikova et al., 2002). On the other hand, the concurrent reduction in nicotine dependence and total nicotine intake is rather surprising. There is substantial evidence that smokers have a strong tendency to titrate their nicotine levels to a ‘set point’; hence it would be assumed that smokers reducing their consumption with NRT would compensate for the reduction in nicotine from cigarettes by using adequate amounts of medicinal nicotine, thus allowing the maintenance of their pre-reduction nicotine state (Fagerstrom & Hughes, 2002). One possible explanation for this is that NRT products provide nicotine in much lower concentrations than the traditional cigarette (Russell, Feyeraband & Cole, 1976; Lawson et al., 1998), making it difficult for smokers to compensate for the nicotine lost from their large reductions in cigarette consumption. For example, the average amount of gum chewed by smokers produce plasma nicotine concentrations about 1/3rd to 2/3^{rds} of that obtained from smoking (Fagerstrom, 1988). The patch is likely to be worse, failing to respond in accordance with urges to smoke (Fagerstrom & Hughes, 2002). However, even if this were the case, one may expect smokers to compensate by smoking each remaining cigarette harder. This was also disputed, with those using NRT for smoking reduction reporting a lower puff frequency, while reductions in carbon monoxide of around 50-70% of that in cigarette consumption.

The question which naturally arises is how smokers were able to reduce their nicotine intake. Conceivably, it is likely that the behavioural support provided in many of the interventions was pivotal; however, it could also be that those smokers who significantly reduced their consumption are better at dealing with urges to smoke, perhaps as a result of their strong desire to mitigate the harmful effects of smoking (Joseph et al., 2008). Many of the trials also took place over extended periods of time, thus allowing gradual reductions in nicotine dependence to occur which could be suitably managed. Population-based studies of those reducing their consumption have reported declines in nicotine dependence over many months (Mooney et al., 2011).

The findings here also negate any concern about the possible side-effects of using NRT for smoking reduction, with few adverse events reported. Previous studies have similarly concluded the safety of the concurrent use of NRT and cigarettes (Fagerstrom & Hughes, 2002). However, whether improvements to smokers' physical condition occur as a result of using NRT for smoking reduction is another question. From the findings reported here, use of NRT for smoking reduction does not appear to incur a health benefit over smoking reduction without active NRT. However, reducing consumption by over 50%, irrelevant of group assignment, was associated with reductions in disease biomarkers, respiratory symptoms and blood pressure (Rennard et al., 2006; Kralikova et al., 2002). Since such reductions are more common among those using active NRT, smokers should be advised that significant improvements to health may only be attained if large reductions in the number of cigarettes they smoke per day are induced, and that NRT may help them to reach that goal. However, caution should be taken when drawing strong conclusions from these clinical trials. Although there is evidence for an association between biomarkers and disease result, there is no knowing how much of a change in a given biomarker may be required, and for how long, for a reduction in disease risk to occur (Vasan, 2006). A longitudinal randomised controlled trial is necessary to assess the association between the use of NRT for smoking reduction and chronic illness; however, this is likely to be complicated by the time-lapse of disease progression, making any such study highly labour intensive and cost-ineffective.

Unlike the previous reviews, the current meta-analysis benefits from the inclusion of studies on those who may be the most interested in a harm reduction approach, i.e. smokers suffering from respiratory conditions and heart disease (Tonnesen et al., 2005; Kralikova et al., 2002; Joseph et al., 2008). It is of interest that findings were similar to randomised controlled trials excluding these populations, with even larger reductions in cigarette consumption occurring in some of the studies. Previous smoking cessation studies have also demonstrated greater efficacy of smoking interventions in patients with chronic conditions compared with the general population (Thomson & Rigotti, 2003; Crouse & Hagaman, 1991; Frid et al., 1991). If it is the case that smoking reduction with NRT is particularly successful among those suffering from chronic disorders, this is of grave importance, with such individuals tending to smoke more heavily and finding abrupt cessation a rather difficult task (Kumari & Postma, 2005; Borrelli, Bock, King, Pinto & Marcus, 1996). The finding of improved quality of life also points towards the possibility that smoking reduction may have a secondary effect of improving mental health functioning. However, the literature on this topic to date is rather mixed; whereas some studies point towards an improvement in depressive symptoms following reductions in cigarette consumption, specifically when cessation is attained, others do not (Prochaska et al., 2007; Glassman, Covey, Stetner & Rivelli, 2001; Tsoh et al., 2000).

It may therefore be concluded that smoking reduction with the aid of NRT should perhaps be added to clinicians' current armamentarium for smokers who have tried to quit smoking and failed many times, and for those who, for other reasons, are not motivated to give up. However, prior to this research is required in to how best to implement such an approach alongside traditional tobacco control strategies, since healthcare professionals often fail to adequately put into practice evidence-based guidelines (Cranney, Warren, Barton, Gardner & Walley, 2001). It will also need to be ensured that this approach is seen as separate to methods of 'gradual cessation', because if this language is used, it may deter smokers who would benefit from such an approach (Fagerstrom, 1999). Additionally, there is a potential caveat to the above findings which needs to be addressed, especially if we intend to extrapolate these findings to smokers at a population level who are spontaneously using NRT for smoking reduction. The caveat being, that the randomised controlled trials on top of instructing smokers to reduce, also provided participants with extensive behavioural support, including additional clinic visits, advice on the best methods of smoking reduction and continuous feedback. Over the past three decades a number of trials have proved the efficacy of behavioural interventions for smoking reduction (Glasgow et al., 1983a; Glasgow et al., 1985; Shapiro et al., 1971; Riggs et al., 2001; Riley et al., 2002; Glasgow et al., 2009). Moreover, in many of the clinical trials participants were instructed to stop smoking, which may have had a potent impact. Although the importance of these instructions in smoking reduction studies is unknown, there is evidence to suggest that recommendations to quit by healthcare professionals are effective interventions for smoking cessation (Stead, Bergson & Lancaster, 2008).

The free provision of NRT may also have been a compelling motivator (Hughes, Wadland, Fenwick, Lewis & Bickel, 1991). Indeed, the one trial which was analogous to the use of NRT purchased from retail outlets, showed lower efficacy than the other studies (Etter et al., 2004). However, the finding that higher odds of an attempt to quit smoking occurred among more 'successful' reducers, regardless of whether NRT was used, suggests that any impact of the receipt of NRT on the propensity of smokers to quit is likely to be minimal (Hughes et al., 1999). To rectify this issue a study is required to assess reduction alone, versus

NRT alone, and reduction plus NRT. If this were to prove the efficacy of providing NRT free of charge, consideration would need to be given as to whether smokers who are interested in reducing their smoking are provided with such services. A major barrier of implementing this in practice is cost, in that many of the studies provided NRT and behavioural support for long periods of time (for example:- Bolliger et al., 2000). Future studies should therefore also determine whether recommended treatment lengths are sufficient to produce a substantial effect on cigarette consumption and attempts to quit smoking (West et al., 2000a).

There are also a number of methodological issues with the studies that need to be considered. The first is that all of the randomised controlled trials focussed exclusively on the use of NRT for smoking reduction, failing to consider the use for periods of temporary abstinence. We are currently unaware as to whether instructing smokers to temporarily abstain with the aid of NRT induces reductions in cigarette consumption and promotes smoking abstinence. Secondly, a significant minority of the studies relied heavily on self-report and failed to validate smoking status. However, in some cases this may be advantageous, because taking continuous biological measurements could act as an intervention in itself or result in decreased participation (Etter & Perneger, 1998). Drop-out rates were also high, more so in placebo groups (for example:- Wennike et al., 2003), which was not always taken into account in the analyses. It is likely that that those who dropped out failed to reduce, and therefore, any intention to treat analysis would elevate the differences between placebo and NRT, and superiority of active treatment. Thirdly, providing smokers with active NRT versus placebo NRT may not be an accurate comparison of smoking reduction with and without pharmacological help, if as evidence suggests, placebo effects occur (Etter & Laszlo, 2007). Two factors may contribute to this: 1) the characteristics of the placebo product, including its taste, gestures associated with it use and so forth, and 2) the intervention itself, such as providing placebo packages. It would be of interest to compare those reducing their smoking with NRT to those instructed to simply reduce their cigarette consumption.

A fourth issue is that most of the clinical trials only assessed seven-day point prevalence cessation. Future studies should follow the published recommendations for measuring abstinence. An appropriate report would consist of prolonged abstinence as a primary outcome, in addition to point prevalence and quit attempts as secondary outcomes, since delayed effects of reduction on quitting behaviour may be expected (Hughes et al., 2003). Fifthly, it is quite plausible that despite attempts to advertise solely for those unwilling or unable to quit smoking, that studies also recruited those with an interest in quitting, since many mentioned to participants that cessation was one of the treatment goals. In studies where this was not the case, active treatment groups still showed greater superiority for smoking cessation (for example:- Carpenter et al., 2004). Extensive evidence has also demonstrated the volatile nature of intentions to quit (Hughes et al., 2005a), making it quite plausible that they changed from the initial eligibility assessment to the trials commencement; thus it is perhaps wrong to assume that smokers who are unable or unwilling to quit smoking represent a stable detectable subpopulation who can be recruited for treatment. There also appears to be very few smokers with an end goal of reduction, with most, when probed further, reporting interest in reduction as a means to quit (Shiffman et al., 2007a). Moreover, the behavioural support and free NRT provided to control groups may have diluted the effect of NRT for smoking reduction on the propensity of smokers to stop smoking. The efficacy of brief advice has been demonstrated previously (Stead et al., 2008). Finally, caution should be taken when generalising these findings about recalcitrant smokers to countries in which they did not occur. For example, as the UK has a relatively liberal regulatory framework for NRT compared to America, it is possible that American smokers may hold more negative beliefs about the use of NRT for harm reduction purposes; this could affect the extent to which smokers comply with intervention instructions, with a correlation between positive beliefs about NRT and usage rates (Etter & Perneger, 2001).

Conclusion

Clinical trials demonstrate that the use of NRT as part of a smoking reduction programme has the propensity to move smokers towards a quit attempt and can induce sizable reductions in cigarette consumption. Declines in toxin intake also occur but to a much lesser extent. However, it is unclear whether these findings are applicable outside of this highly controlled setting, where little behavioural support is provided and NRT is not usually free of charge.

Chapter 6: Effectiveness of Using Nicotine Replacement Therapy for Smoking Reduction and During Periods of Temporary Abstinence: A Systematic Review

Introduction

Clinical trials have demonstrated the efficacy of using NRT as part of a smoking reduction programme (see Chapter 5). It is important to consider whether similar findings emerge outside of these carefully controlled trials, i.e. the effectiveness of NRT amongst those spontaneously reducing their cigarette consumption. Although previous reviews have attempted to overview survey-based studies assessing unprompted attempts to cut down without pharmacological help, they have largely neglected research assessing the use of NRT for harm reduction purposes (Hughes & Carpenter, 2006; Hughes, 2000; Tonnesen, 2002; Zellweger, 2001). The current chapter aimed to rectify this, by collating data from studies on smokers using NRT during attempts to cut down and/or during periods of temporary abstinence, who were not doing so as part of a tobacco control programme. A secondary aim was to determine the current prevalence of NRT use for these purposes. This is important from a policy perspective, providing an indication as to the interest smokers may have in population-based reduction programmes, including the implementation of smoking reduction as a route to quit in stop smoking services (Croghan & Chambers, 2011).

There are a number of reasons why one may hypothesise that the findings reported in the previous clinical trials will not generalise beyond their highly structured setting. First, at a population level NRT is not usually given for free and little behavioural support is provided; both of which are associated with improved clinical outcomes (Glasgow et al., 1983a; Glasgow et al., 1985; Shapiro et al., 1971; Riggs et al., 2001; Riley et al., 2002; Glasgow et al., 2009; Hughes et al., 1991). NRT may also be less effective than in clinical trials due to the absence of professional advice, the inclusion of less-motivated smokers, or poor compliance (Shiffman et al., 2003a; Shiffman et al., 2003b; Leischow, Ranger-Moore, Muramoto & Matthews, 2004; Hughes, Peters & Naud, 2011). Studies in humans have observed that the greater the use of NRT the lower the cigarette consumption or nicotine intake from cigarettes (Hatsukami, Mooney, Murphy, LeSage, Babb & Hecht, 2007; Benowitz, Zevin & Jacob, 1998). For example, Benowitz et al. (1998) reported that in a group of smokers not interested in quitting and housed in an inpatient setting, increased doses of transdermal nicotine (i.e. 21mg, 44mg & 63mg), led to orderly decreases in nicotine intake from cigarettes (i.e. 3%, 10% & 40% respectively). Additionally, study samples could be more likely to reflect those who are interested in using NRT for smoking reduction and/or during periods of temporary abstinence in the population, which includes smokers with psychiatric disorders (Lemmonds et al., 2004; Moeller-Saxone, 2008).

In terms of prevalence, it is probable that few smokers will be found to be reducing their cigarette consumption or temporarily abstaining with the aid of NRT, if we base our hypothesis on smoking cessation; previous studies have reported that only around $1/5^{th}$ of smokers use NRT when they attempt to quit (Zhu, Melcer, Sun, Rosbrook & Pierce, 2000). Moreover, NRT has historically been emphasised as a cessation only medication, which may have led to concerns among smokers about using NRT concurrently with cigarettes (Joseph et al., 2008). Previous studies have also shown that a large majority of smokers incorrectly believe that it is the nicotine and not the other constituents of cigarettes which cause them harm (Etter & Perneger, 2001; Bansal, Cummings, Hyland & Giovino, 2004; Cummings, Hyland, Giovino, Hastrup & Bauer, 2004; Johnson, Stevens, Hollis & Woodson, 1992; Hajek et al., 1999; Siahpush et al., 2006a), and that they may underestimate the necessity of medical intervention (Horne, 2003). Escalating costs of nicotine medication is also likely to result in under-utilisation (Curry, Grothaus, McAfee & Pabiniak, 1998), because most smokers who are ‘harm reducing’ purchase their NRT over-the-counter (Hammond et al., 2008), and must fund medicinal nicotine on top of their continued purchase of cigarettes. Smokers may also be deterred from using NRT by healthcare professionals, who often hold varying and contradictory views on harm reduction approaches (Martin et al., 2004; Warner & Martin, 2003).

Table 1: Articles Found and Selected for Inclusion in the Meta-analysis

Database search	**Articles identified**
EMBASE	548
MEDLINE	633
Web of Science	613
PsycINFO	223
Total from databases without duplicates	1210
Other sources	
Found from reference lists	4
Independent journal searches	3
Total from all sources	1217
Initial selection	639
Final selection	13

Methods

Search Strategies

The electronic databases, EMBASE, MEDLINE, Web of Science and PsycINFO, were searched up to February 2011. The search combined four parameters, one relating to smoking (smok*, cigarette, tobacco), one relating to NRT (nicotine, NRT), one to smoking reduction and/or temporary abstinence (smoking reduction, cut down, cutting down, reduce, schedule, gradual, controlled smoking, temporary abstinence, smoke-free, smoking restriction, harm reduction, risk reduction), and one to smoking cessation (quit, cessation, intention, motivation, cease, desire, stop). Selected studies references were then screened and independent journal searches conducted. The title and abstract of studies thus found were then assessed for inclusion and exclusion criteria.

Selection

Initial selection was undertaken on the basis of abstracts for studies published in English, and whose focus was on a target population of smokers and not health professionals or policy makers. After this initial section, the full texts of studies were retrieved. Studies that were included in the final selection had 1) to involve the assessment of smokers who were interested in using, had used, or were currently using NRT for smoking reduction and/or during periods of temporary abstinence; 2) to involve smokers who had not taken part in a harm reduction programme; and 3) to assess the issue of prevalence and/or association with cigarette consumption and/or association with quitting behaviour. Thirteen studies were selected (see Table 1).

Data Abstraction and Outcomes

Data were abstracted by two researchers using a structured data abstraction form. Disagreements were listed and resolved. Eleven of the studies assessed prevalence of NRT use for smoking reduction and/or temporary abstinence, while five studies assessed cigarette consumption or/and quitting activity. These studies were grouped according to study design: cross-sectional (Hammond et al., 2008; Etter & le Houezec & Landfeldt, 2003; Hughes, Pillitteri, Callas, Callahan & Kenny, 2004b[b]), prospective (Hughes et al., 2004a) or mixed design (Levy, Thorndike, Biener & Rigotti, 2007). For those measuring cessation, the primary outcomes for the review were quit attempts and smoking status. For studies measuring

[a]Denotes study 1 of the published paper by Hughes, Lindgren, Connett and Nides (2004b)
[b]Denotes study 2 of the published paper by Hughes, Lindgren, Connett and Nides (2004b)

consumption, the primary outcomes were differences in cigarette consumption, average percentage reduction from baseline, or the number of those attaining a reduction in cigarette consumption of 50% or more.

Quality Assessment

Assessment of the included studies quality was undertaken using criteria adapted from the Newcastle-Ottawa scale (www.ohri.ca/programs/clinical_epidemiology/nosgen.pdf), recommended by Cochrane reviewers (Higgins & Green, 2008). Table 2 summarises the results. In general most of the studies were viewed as poor to moderate quality, either failing to recruit a representative sample of an adequate size or failing to assess the current use of NRT for harm reduction, focussing instead on the past use or interest in using NRT for such purposes.

Table 2: Summary of the Quality Assessment of Included Studies

Study	Representative sample	Adequate sampled size recruited	Assessment of current NRT use	Prospective follow-up/Cross-sectional/Retrospective (if applicable)
Hammond (2008)	Yes	Yes	No	Cross-sectional/Retrospective
Levy (2007)	Yes	Yes	No	Cross-sectional/Retrospective/Prospective
Bansal (2004)	Yes	Yes	No	-
Hughes (2004a)	No	Yes	Yes	Prospective
Etter (2003)	No	Yes	No	Cross-sectional
Al-Delaimy (2005)	Yes	Yes	No	-
Thorndike (2002)	Yes	Yes	No	-
Shiffman (2007a)	Yes	Yes	No	-
Cunningham (2008)	Yes	Yes	No	-
Hughes (2004b[a])	No	No	Yes	Retrospective
Hughes (2004b[b])	No	No	No	-
Hughes (2005b)	No	No	No	-
Shiffman (2003b)	No	Yes	Yes	-

NRT=Nicotine Replacement Therapy; - =Not applicable

Statistical Analysis

Due to the extensive diversity of methods used across the studies, a meta-analysis could not be conducted, thus a narrative description of the findings is given instead. Data were collated where possible for estimates of prevalence, with 95% confidence intervals reported unless otherwise stated. PRISMA guidelines were followed throughout (Moher et al., 2009).

Results

Study Characteristics

Recruitment generally involved telephone surveys using random digit dialling with a panel of respondents. Three studies used advertisements in pharmacies or via newspapers (Hughes et al., 2004b[ab]; Hughes, Adams, Franzon, Maguire & Guary, 2005b). Hughes et al. (2005b) also recruited smokers who had phoned a help line for the inhalator or who had recently collected a prescription for the product. A further three studies recruitment participants who had taken part in a smoking cessation programme and had failed to quit smoking (Etter et al., 2003; Shiffman et al., 2003b; Hughes et al., 2004a). Of the five studies assessing cigarette consumption and/or attempts to stop smoking, one compared smokers who were using NRT for smoking reduction prospectively to those who were cutting down without NRT (Hughes et al., 2004a); one cross-sectional survey and one mixed design survey compared smokers who had used NRT for smoking reduction and/or temporary abstinence to those who had not done so (Levy et al., 2007; Etter et al., 2003); and one cross-sectional survey compared those who had used NRT for smoking reduction and/or temporary abstinence to those who had used NRT for smoking cessation purposes [(Hammond et al., 2008); see Table 3]. A further study compared smokers' current cigarette consumption to their retrospectively reported cigarette intake prior to NRT use (Hughes et al., 2004b[a]).

The use of NRT for smoking reduction was either assessed by asking participants a) if they had ever used NRT to reduce the amount they smoked or b) if they were interested in using NRT for smoking reduction. In contrast, the use of NRT for temporary abstinence was either defined in terms of having ever used NRT to tide oneself over and examples given, for example on planes, in restaurants and on trains (Levy et al., 2007; Etter et al., 2003), or by asking participants if they had ever or were interested in using NRT during periods of time when they were unable to smoke/where smoking was not permitted (Hammond et al., 2008; Thorndike, Biener & Rigotti, 2002; Cunningham & Selby, 2008; Hughes et al., 2005b; Hughes et al., 2004b[a]; Hughes et al., 2004[b]). One study used open-ended questions to assess the reasons for NRT use, with responses coded into four pre-determined categorises: *''to try to quit; to tide one over in situations where I cannot smoke; to replace some cigarettes so I smoke less; and just curious''* (Al-Delaimy, Gilpin & Pierce, 2005). Only five studies checked that smokers were reducing without an aim to quit smoking (Levy et al., 2007; Shiffman et al., 2007a; Shiffman et al., 2003b; Hughes et al., 2005b; Bansal et al., 2004), while many did not allow smokers to report using NRT both during attempts at smoking reduction and during periods of temporary abstinence. Levy et al. (2007) restricted their analysis to the nicotine patch and gum, Hughes et al. (2005b) the inhalator, while Hughes et al. (2004b[ab]), Shiffman et al. (2003b) and Hughes et al. (2004a) to the nicotine gum.

Prevalence of Nicotine Replacement Therapy use

Five studies assessed the past ever use of NRT for harm reduction purposes (Levy et al., 2007; Etter et al., 2003; Thorndike et al., 2002; Al-Delaimy et al., 2005; Bansal et al., 2004); of these, four considered the use of NRT separately for smoking reduction and three for periods of temporary abstinence. These studies respectively provided data on 10,609 and 11,655 smokers. Nine per cent (Confidence Interval (CI) 8.3-9.3) of smokers were found to have ever used NRT to reduce their cigarette consumption and 4.8% (CI 4.4-5.2) for periods of time when they were unable to smoke. Three further studies assessed the percentage of smokers initially choosing NRT for smoking reduction and/or temporary abstinence (Hughes et al., 2005b; Hughes et al., 2004b[a]; Hughes et al., 2004b[b]). In total data were collated on 1,011 smokers; of which, 3.4% (CI 2.42-4.66) reported that they had initially purchased NRT to tide them over during periods of temporary abstinence, while 11.0% (CI 9.20-13.06) for smoking reduction. Two further studies assessed smokers' interest in using NRT for harm reduction; however, data could not be combined due to differences in the methodologies used (see Table 4). Interestingly, the patch was by far the most commonly used form of NRT, with a number of smokers combining its use with the nicotine gum (Hammond et al., 2008; Shiffman et al., 2007a; Bansal et al., 2004). Moreover, it appeared that a minority of smokers had used NRT both during attempts to cut down and during periods of temporary abstinence (Levy et al., 2007; Hughes et al., 2004b[a]), and that interest in using NRT for such purposes may be increased by informing smokers that NRT can be used concurrently whilst smoking (Etter et al., 2003).

Prevalence did not differ between countries or as a function of the extent to which smoking restrictions were imposed (Hammond et al., 2008), but did vary as a function of smokers' characteristics. The use of NRT for harm reduction was more common among males who were married and with a higher nicotine dependency (Levy et al., 2007; Etter et al., 2003; Al-Delaimy et al., 2004). The use of NRT for smoking reduction was also associated with older age, while the use of NRT for temporary abstinence with white ethnicity (Levy et al., 2007). Those using NRT for these purposes also tended to have higher educational attainments and were more reliant on cigarettes than those using NRT for smoking cessation (Hammond et al., 2008; Hughes et al., 2004a[a]). The use of NRT for harm reduction purposes was not linked to smokers' income (Hammond et al., 2008; Levy et al., 2007).

Table 3: Characteristics of the Selected Studies for Inclusion in the Meta-analysis

Study	Aims	Recruitment	Participants	Outcomes
Hammond (2008) US, UK, Canada and Australia	Compared those who had used NRT for smoking reduction, temporary abstinence and for abrupt cessation purposes in the past year	Probability sample with random digit dialling.	**Canada** 1,660 participants, 57.2% male, 67.1% aged 40+. 30.4% of high income and 15.2% with higher education. Smoked an average 17.1 (*SD* 9.4) cigarettes per day. **UK** 1,617 participants, 56.5% male, 69.6% aged 40+. 27.1% of high income and 13.6% with higher education. Smoked an average 17.2 (*SD* 9.2) cigarettes per day. **US** 1,644 participants, 59.0% male, 71.1% aged 40+. 22.6% of high income and 18% with higher education. Smoked an average 18.7 (*SD* 11.5) cigarettes per day. **Australia** 1,591 participants, 55.3% male, 59.7% aged 40+. 31.9% of high income and 14.5% with higher education. Smoked an average 18 (*SD* 10.1) cigarettes per day.	Prevalence of NRT use for harm reduction Intention to quit Quit attempt in the past 12 months
Levy (2007) US	Compared those who had ever used NRT to cut down, to delay their smoking or to delay and cut down, with those who had not used NRT for such purposes	Probability sample with random digit dialling.	3,084 participants, 41% over the age of 40. 48.1% male. 24.1% with BA/BSc or higher and 24.2% with an income of $75,000+. Average cigarettes per day 31.15. 62.0% reported smoking within 30 minutes of wakening.	Prevalence of NRT use for harm reduction Cigarette consumption Quit attempt in the past year Motivation to quit 50% reduction from baseline to follow-up Quit attempt between baseline and follow-up Smoking status at follow-up
Bansal (2004) US	Prevalence of NRT use for harm reduction	Probability sample with random digit dialling.	1,046 participants. Mean age of 41 years and 45.4% male. 20% non-white, 50% reported more than 12 years in formal education, 25% smoked more than 25 cigarettes per day.	Prevalence of NRT use for harm reduction
Hughes (2004a) US	Whether those who failed to quit following a cessation programme managed to reduce their intake with and without the use of NRT	Smokers were recruited from cardiology clinics.	1,722 participants. Mean age 58 (*SD* 7) and 55% male. 54% had more than a high school education. Average cigarettes per day 32 (*SD* 13).	50% reduction in cigarette consumption between baseline and follow-up

Table 3: Characteristics of the Selected Studies for Inclusion in the Meta-analysis (Continued)

Study	Aims	Recruitment	Participants	Outcomes
Etter (2003) Sweden	Assessed the impact of messages that NRT could be used for harm reduction purposes on smokers' motivation to quit	Smokers who had participated in Stop-tabac.ch were sent emails asking if they would like to participate.	2,027 participants in total (299 control, 281 received a temporary abstinence message and 230 received a reduction message). Mean age of 37 and 41% male. Average cigarettes per day 20.	Prevalence of NRT use for harm reduction Motivation to quit in response to messages that NRT could be used for harm reduction Impact of messages on motivation to use NRT Perceived risk of NRT use
Al-Delaimy (2005) US	Prevalence of NRT use for harm reduction	Probability sample with random digit dialling	5,498 smokers	Prevalence of NRT use for harm reduction
Thorndike (2002) US	Prevalence of NRT use for harm reduction	Probability sample with random digit dialling	3,024 smokers. 48.5% male, with a 45% between the age of 31 and 45. 58% had an income above $30,000	Prevalence of NRT use for harm reduction
Shiffman (2007a) US	Interest in using NRT for smoking reduction	Probability sample with random digit dialling	1,000 participants, 52.5% male with 34.1% over the age of 45. 29.9% smoked more than 26 cigarettes per day.	Interest in using NRT for smoking reduction
Cunningham (2008) Canada	Interest in using NRT for smoking reduction	Probability sample with random digit dialling	825 smokers. Mean age 43.8 (*SD* 14.35), 48.1 male with 70.8 household income >$30,000. Average cigarette consumption of 17.85 (*SD* 8.8). 27.6% smoked within 5 minutes of wakening.	Interest in using NRT for smoking reduction
Hughes (2005b) US	Reasons for using the nicotine inhalator	Advertisements, pharmacy attained prescription records and those calling a helpline about the inhalator.	535 smokers. Mean age 44 and 37% male. 68% had a college education or more. Average cigarette consumption of 25 and FTND of 5.3.	Prevalence of NRT use for harm reduction Stability of NRT use
Hughes (2004b[a]) US	Reasons for initially using the nicotine gum and currently using the gum.	Advertisements in newspapers and pharmacy.	266 smokers. Mean age of 46 (*SD* 13) and 38% male. Average cigarette consumption per day of 21 (*SD* 14) and mean FTND of 5 (*SD* 2).	Prevalence of NRT use for harm reduction Retrospective change in cigarette consumption
Hughes (2004b[b]) US	Reasons for initially using the nicotine gum	Advertisements placed in newspapers.	100 smokers. Mean age 50 years (*SD* 10) and 41% male. Average cigarette consumption of 30 (*SD* 15) and FTND of 6.7 (*SD* 1.8).	Prevalence of NRT use for harm reduction
Shiffman (2003b) US	Reasons for using NRT concurrently with cigarettes following the failure of a smoking cessation intervention	Those enrolled in a smoking cessation intervention and who had not quit smoking and continued to use NRT.	2,655 smokers. Mean age 42.2 (*SD* 12.8) and 55.8% male. Average cigarette consumption 26.6 (11.9). Average of 13.6 (*SD* 2.1) years in education.	Prevalence of NRT use for harm reduction Extent of NRT use whilst concurrently smoking.

Note: NRT=Nicotine Replacement Therapy; *SD*=Standard Deviation; FTND=Fagerstrom Test for Nicotine Dependence; CO=carbon monoxide

Table 4: Prevalence of the use of Nicotine Replacement Therapy for Smoking Reduction and/or Temporary Abstinence

Study and population	**Participants**	**Measure**	**Use of NRT for TA %(*n*)**	**Use of NRT for SR %(*n*)**	**Use of NRT for TA and SR %(*n*)**
Hammond et al. (2008) NRT users	6,532 smokers from the UK, Canada, US and Australia.	Use of NRT in the past year	Overall 1.5 (101) Canada 1.6 (26) US 1.8 (30) UK 1.5 (26) Australia 1.4 (22)	Overall 1.4 (90) Canada 1.6 (27) US 1.0 (17) UK 1.5 (24) Australia 1.4 (19)	-
Levy (2007) NRT & non-NRT users	3,084 smokers from the US	Past ever use of NRT	2.4 (77)	11.3 (349)	4.4 (137)
Etter (2003) NRT & non-NRT users	2,027 smokers from Sweden	Past ever use of NRT	14.0 (284)	23.0 (466)	-
Thorndike (2002) NRT & non-NRT users	3,024 smokers from the US	Past ever use of NRT	-	-	13.7 (414)[a]
Al-Delaimy (2005) NRT & non-NRT users	5,498 smokers from the US	Past ever use of NRT	3.6 (145)	1.3 (75)	-
Shiffman (2007a) NRT & non-NRT users	1,000 smokers from the US	Interest in using NRT	-	5.5 (55)	-
Cunningham (2008) NRT & non-NRT users	825 smokers from Canada	Interest in using NRT	-	-	4.0 (33)[a]
Hughes (2005b) NRT users	535 smokers from the US	Initial reasons for using NRT	1.6	8.4	-
Hughes (2004b[a]) NRT users	266 smokers from the US	Initial reasons for using the NRT and current reasons for using NRT	1[b]	6[b]	8[c]
Hughes (2004b[b]) NRT users	100 smokers from the US	Initial reasons for using NRT	4	2	-
Shiffman (2003b) NRT & non-NRT users	2,655 smokers from the US	Current use of NRT	1	3.5	-
Bansal (2004) NRT & non-NRT users	1,046 smokers from the US	Past ever use of NRT	-	13.1 (137)	-

Note: NRT=Nicotine Replacement Therapy, TA=temporary abstinence, SR=smoking reduction - =Not applicable

[a] Prevalence of NRT use for smoking reduction and/or temporary abstinence

[b] Initial reasons for using NRT

[c] Current reasons for using NRT

Extent and Stability of Nicotine Replacement Therapy use

Shiffman et al. (2003b) reported that those concurrently using NRT and cigarettes – of which 40% were doing so for harm reduction purposes – used nicotine gum on average [Standard Deviation (*SD*)] 4.4 (2.1) times per week and chewed 2.6 (*SD* 3.5) pieces per day. Hughes et al. (2005b) assessed the stability of the use of NRT over a 6 month period, with an estimated 8% of smokers using NRT for harm reduction at baseline and 7% at follow-up. However, it is unclear whether those using NRT at both time points were the same smokers.

Views About Smoking Reduction and Nicotine Replacement Therapy

Etter and colleagues (2003) assessed smokers perceived risk of using medicinal nicotine, reporting that 77% of their sample thought the concomitant use of NRT and cigarettes was 'somewhat' or 'much' more dangerous than smoking alone. Of interest, is that prevalence declined when smokers were informed about the safety of using NRT concurrently while smoking. Around 1/3rd of participants also believed that NRT could increase dependence on cigarettes, cause cancer and/or myocardial infarction. Such beliefs were not associated with intention to use NRT for smoking reduction and/or temporary abstinence in the future.

Cigarette Consumption

Both of the cross-sectional studies and the one mixed design survey reported that the use of NRT for smoking reduction and/or temporary abstinence was associated with a higher cigarette consumption – of around one to two cigarettes per day – relative to those not using NRT for such purposes (Levy et al., 2007; Etter et al., 2003), or those using NRT for smoking cessation (Hammond et al., 2008). Only one of the studies adjusted for socio-demographic variables and nicotine dependence (Hammond et al., 2008). The prospective analysis by Levy et al. (2007) also failed to establish any association at two years follow-up between the past use of NRT for harm reduction purposes and a reduction of 50% or more in cigarette consumption. In contrast, Hughes et al. (2004a) found greater reductions among reducers who had used NRT at any time point over the previous year. Smokers who had used NRT at years two, three, four and five, also had more reduction in those years than non-NRT users at the same points in time. Finally, Hughes et al. (2004b[a]) reported that smokers average cigarette consumption [Standard Deviation (*SD*)] prior to the use of NRT for smoking reduction was 28 (*SD* 23), while their current average cigarette intake was 11 (*SD* 11) cigarettes per day.

Attempts to Quit Smoking and Smoking Cessation

In cross-sectional analyses a positive association was reported between the use of NRT for smoking reduction and past attempts to quit smoking, while no association was established between attempts to quit smoking and the use of NRT for temporary abstinence (Levy et al., 2007). In contrast, both those using NRT for smoking reduction and those using NRT for periods of temporary abstinence were less likely to report a quit attempt than those using NRT for abrupt cessation purposes (Hammond et al., 2008). Intention to quit also did not vary among those using NRT for either smoking reduction and/or temporary abstinence relative to other smokers generally (Levy et al., 2007), or those using NRT during an attempt to quit smoking (Hammond et al., 2008). Moreover, in the only prospective analysis the past use of NRT for smoking reduction and/or temporary abstinence was not found to be associated with attempts to quit smoking or smoking status at two years follow-up (Levy et al., 2007). Interestingly, messages informing smokers that NRT could be used to manage smoke-free situations appeared to have no detectable impact on motivation to quit, while a message that it could be used for smoking reduction increased motivation to stop smoking

(Etter et al., 2002). Only one of these studies adjusted for confounding variables (Hammond et al., 2008).

Discussion

In the current systematic review we found that less than nine per cent of smokers had ever used NRT for smoking reduction and that less than five per cent had ever used NRT during periods of temporary abstinence. There was no consistent evidence that the use of NRT in these ways resulted in reductions in cigarette consumption or increased the propensity of smokers to quit; however, there was also no evidence that the use of NRT for smoking reduction and/or during periods of temporary abstinence undermined attempts at cessation.

This is the first review to collate data on the prevalence of NRT use for smoking reduction and/or temporary abstinence. The finding that few smokers have ever used NRT for such purposes is unsurprising, with studies suggesting that less than 1/5th of smokers who are attempting to quit smoking utilise medicinal nicotine (Zhu et al., 2000). The cost of concurrently purchasing NRT and cigarettes is likely to partially account for the low prevalence of use. Several studies have shown that the provision of free NRT can increase uptake (Bauer, Carlin-Menter, Celestino, Hyland & Cummings, 2006; Miller et al., 2005), while it has been suggested that providing NRT in smaller boxes may go some way in driving down cost, and allow smokers to experiment with NRT products in order to find the one most suited to their needs (McClure & Swan, 2006). Smokers also hold many negative opinions towards NRT (Bansal et al., 2004; Cummings et al., 2004; Johnson et al., 1992; Hajek et al., 1999; Siahpush et al., 2006). However, previous attempts to increase the use of NRT by targeting smokers' perceptions have proved largely ineffective (Willemsen, Wiebing, van Ernst & Zeeman, 2006; Mooney, Babb, Jensen & Hatusukami, 2005). Moreover, Etter and colleagues (2003) failed to establish an association between intentions to use NRT for harm reduction purposes and beliefs about the harmful effects of using NRT whilst smoking; although, this may have been due to the intention-behaviour-gap, with greater positive attitudes towards NRT having been associated with its greater use (Etter & Perneger, 2001).

Another explanation could be that pharmaceutical industries have historically directed their heavily invested consumer advertising of NRT towards those smokers who are already primed to stop smoking or to reduce on their own (Cummings & Hyland, 2005). Moreover, product labelling has been rather cautious and out-dated. Although this has now largely been rectified in the UK, in other countries including the US, NRT product labels imply to consumers that the medication is only for cessation purposes and dangerous if taken for prolonged periods of time (Shiffman, Ferguson, Rohay & Gitchell, 2008). However, despite these differences in NRT regulatory frameworks, there does not appear to be any evidence for between country instability in NRT use (Hammond et al., 2008). In contrast, variation does exist between studies and as a function of socio-demographic and smoking characteristics. The former of which may be due in part to differences in the methods of recruitment and/or whether studies ensured that smokers were using NRT for smoking reduction without an intention to quit smoking. It is possible that where intention to quit was not assessed that many smokers interpreted the question along the lines of gradual cessation, which is a more prevalent behaviour (Shiffman et al., 2007a). Similarly, differences may exist depending on whether enforced temporary abstinence (for example:- at work), or both enforced and voluntary abstinence (for example:- at home & at work), are measured. This certainly needs to be addressed to allow accurate comparisons.

The latter finding, that the use of NRT for smoking reduction and during periods of temporary abstinence was more common among males of an older age and higher nicotine dependency, gives some indication as to those who may be the most receptive of a harm reduction approach. This largely coincides with studies on the characteristics of those using

NRT for smoking cessation, with NRT use being more prevalent among female smokers of an older age and higher nicotine dependency (Kotz, Fidler & West, 2009; Shiffman, Brockwell, Pillitteri & Gitchell, 2008; Botello-Harbaum, Schroeder, Collins & Moolchan, 2010; Emmons et al., 2000). Slight differences in gender may reflect varying underlying motivations of the two behaviours or confounding effects of study design. Since smokers with a greater reliance on cigarettes are likely to find it harder to cope with momentary abstinence, it is perhaps of little surprise that they were more likely to opt to use NRT. There is also evidence that those of an older age hold greater positive beliefs about medication generally (Horne & Weinman, 1999); while a higher prevalence of NRT use may have been assumed among women, since they tend to have a better awareness of generic medication (Yelkur & Capella, 1995), and higher rates of help seeking behaviours (Bertakis, Azari, Helms, Callahan & Robbins, 2005). It is perhaps of further interest that the use of NRT for smoking reduction and/or temporary abstinence was not associated with socio-economic status when compared to other smokers generally. This suggests one means by which the social inequalities in achievements of smoking cessation may be reduced (Kotz & West, 2009). Such inequalities may reflect higher dependency among those of lower social-grades on the one hand (Siahpush et al., 2006b) or social disadvantage with financial and psychological stress on the other (Marsh & McKay, 1994; Cohen & Williamson, 1988). Smokers of lower incomes also tend to attribute their smoking to its alleged anxiolytic properties (Parrott, 1999). In order to draw firmer conclusions, future studies should aim to assess differences among those ‘harm reducing’ with and without NRT, rather than the reliance on comparisons between those using NRT for smoking reduction and/or temporary abstinence and other smokers generally.

Future studies assessing the prevalence of NRT use for harm reduction also need to consider a number of methodological issues. First there has been a predominance of studies focussing on the past use of NRT and interest in using NRT; measures which are highly confounded by smokers' ability to accurately remember situations in which they used NRT for harm reduction purposes, and by the fact that intentions are a rather unstable psychological phenomenon (Hughes et al., 2005a). Secondly, studies to date are comprised solely of Westernised samples; it is possible that findings may differ to other countries outside of the Western World without extensive smoking restrictions or perhaps where smoking is more socially acceptable. Thirdly, many of the studies which used self-selection through advertisement are likely to be largely unrepresentative of 'spontaneous' NRT users. More weight should therefore be given to studies using sampling methods such as random digit dialling, whose aim is to attain a population-based cohort.

In contrast to the previous clinical trials, the use of NRT for smoking reduction at a population level does not appear to be associated with decreased cigarette consumption. Although no randomised controlled trials has considered the use of NRT for temporary abstinence, the lack of reductions in cigarette intake is also rather surprising; one would assume that NRT would mitigate a tendency to compensate prior to and following smoking restrictions, with a reduction in cigarette consumption consequently occurring. It is possible that these conflicting findings are due to the lack of behavioural support and free-provision of NRT outside of clinical trials. Since behavioural methods of smoking reduction are endorsed among smokers (Riggs et al., 2001), research is required to assess whether providing behavioural support to those who are spontaneously using NRT for smoking reduction can induce reliable reductions in cigarette intake. However, the failure to report lower cigarette consumption among those using NRT could also be due to more heavily dependent smokers opting in the first place for medicinal nicotine products. If this were the case, we may not expect to find a difference in cigarette consumption in cross-sectional analyses comparing those using NRT for smoking reduction and/or during periods of temporary abstinence and other smokers generally; unless reductions were substantial and below that of smokers not using NRT for harm reduction purposes. Prospective studies can partially resolve this issue, with Hughes et al. (2004a) reporting a reduction in cigarette consumption over time. The failure of the prospective study by Levy et al. (2004) to report a decline may have been due to the assessment of past ever use rather than current use of NRT. The pre-cessation intervention smokers received in the first part of the study by Hughes and colleagues (2004a) could also have had a potent effect, while those who cut down following the enrolment on a cessation programme are likely to be a priori more motivated to change their behaviour.

It is also possible that rather than reducing cigarette consumption, smokers may instead be modifying their smoking behaviour, i.e. reducing their toxin intake by taking less frequent puffs or putting their cigarettes out early (Fagerstrom & Hughes, 2002). The extent and length of NRT use are also important factors to be considered, with poor compliance often occurring outside of clinical trials (Shiffman et al., 2002b; Shiffman et al., 2003a; Shiffman et al., 2003b; Leischow et al., 2004). The only study in the present review to assess this, noted the sporadic nature of concurrent cigarette and NRT use (Shiffman et al., 2003b). Thus it is possible that reliable reductions in toxin intake and cigarette consumption may be incurred if smokers are encouraged to use high doses of NRT for prolonged periods of time (Hatsukami et al., 2007).

The findings regarding the association with smoking cessation are also far from consistent. In the cross-sectional analyses the use of NRT for smoking reduction was associated with increased odds of a previous attempt to quit smoking relative to other smokers generally (Levy et al., 2007). However, this could be for many reasons: it may be that the use of NRT for smoking reduction increases smokers' motivation to quit; it may be that the use of NRT and attempts at cessation are both manifestations of a general tendency to try and mitigate the harmful effects of smoking; it could also be that the use of NRT for reduction is an after effect of a failed quit attempt. Moreover, because those using NRT for smoking reduction were not compared to those doing so without pharmacological help, the possibility arises that the act of smoking reduction increased the likelihood of a quit attempt rather than the use of NRT. In contrast, no association was reported cross-sectionally between quit attempts and the use of NRT during periods of temporary abstinence. This is unsurprising, if we assume that smokers are using NRT for such purposes simply as a means to tide themselves over, and not, as some may do so during reduction, as a method of reducing the health consequences of smoking. However, there does appear to be a substantial number of smokers who may be using NRT during periods of temporary abstinence as a method of reduction, for such individuals a positive relationship with attempts to quit smoking could be envisaged (Levy et al., 2007; Hughes et al., 2004b[a]).

Prospective analyses partially resolve the issue of causality inherent in the cross-sectional studies, with the only prospective study to date failing to find a beneficial effect of the use of NRT for harm reduction purposes on attempts to stop smoking (Levy et al., 2007). However, this study was plagued by methodological issues: 1) a follow-up of two years and no intermediate assessments; 2) the measurement of past ever NRT use as opposed to current use; and 3) a failure to adjust for confounding variables. Nonetheless, we can conclude from the limited number of studies to date, that there is no evidence that the use of NRT for smoking reduction or during periods of temporary abstinence undermines smoking cessation. However, more rigorously conducted research will be needed before we can draw conclusions about whether it promotes attempts to quit smoking. Such research should aim to select representative samples who have not participated in health behaviour change interventions in recent months; should adequately control for nicotine dependency and any other potential confounding variables; and where possible, should measure current NRT use, the extent of NRT use, length of use, and verify smoking status. Further studies ought to also ensure that smokers are reducing as a goal in itself, which will safeguard against the recruitment of those reducing as a means to quit; thus preventing spurious associations. Moreover, due to the substantial overlap in the use of NRT for periods of temporary abstinence and smoking reduction (Levy et al., 2007; Hughes et al., 2004b[a]), methodologies should be used that allow smokers to opt for both of these options. Future studies should also aim to ascertain whether differences in efficacy exist among the various NRT products which are used. Although smokers appear to hold a preference for the nicotine patch, it is unclear whether this is more effective than non-transdermal products, which are better able to abate momentary urges to smoke (Fagerstorm & Hughes, 2002). Finally, these findings only provide evidence relative to other smokers generally or those using NRT for smoking cessation. It is currently unclear as to the effectiveness of NRT for harm reduction purposes relative to those reducing their cigarette consumption or temporarily abstaining without pharmacological help.

Conclusion

A significant minority of smokers have used NRT during attempts at smoking reduction and/or during periods of momentary abstinence. Only a few survey-based studies have attempted to assess whether the use of NRT in these ways is associated with cigarette consumption and/or attempts to quit smoking. These suggest that the use of NRT for harm reduction purposes does not undermine smoking cessation, and that with more rigorously conducted research, may be found to promote attempts to quit. In contrast, there is little evidence for sizeable reductions in cigarette consumption.

Chapter 7: The use of Nicotine Replacement for Smoking Reduction and During Periods of Temporary Abstinence: A National Survey of English Smokers

Introduction

The current chapter is concerned with whether the spontaneous use of NRT during attempts at smoking reduction and to ease discomfort during enforced temporary abstinence, has the potential value of reducing smoke intake and increasing the propensity of smokers to stop smoking. This study eliminates some of the issues with the previous survey-based studies (see Chapter 5): assessing the current use of NRT for smoking reduction and/or temporary abstinence; controlling for potential confounding variables; ensuring the recruitment of a representative sample; and assessing whether cigarette consumption and attempts to quit smoking vary as a function of the NRT product which is used. A secondary aim was to provide details of the prevalence of the use of NRT for these purposes, associated socio-demographic characteristics, and the extent to which it is the same smokers who are using NRT for smoking reduction and during periods of momentary abstinence.

Current studies suggest that around nine per cent of smokers have ever used NRT for smoking reduction and five per cent for periods of time when they were unable to smoke (see Chapter 6). Only one previous study has considered the use of NRT for harm reduction purposes in a UK population-based sample, reporting a prevalence of three per cent in 2005 (Hammond et al., 2008). Although this demonstrates that a large minority of NRT use is now not associated with an attempt at cessation, it does mean that a substantial amount of smokers are perhaps reducing their cigarette consumption or temporarily abstaining without pharmacological help. This assumption is on the basis that extensive smoking restrictions are now in place in the UK, meaning that most smokers must abstain at some point, while previous studies have reported that around 50% of smokers are attempting to reduce their cigarette consumption at any one time (West et al., 2001a).

What may account for this? The low prevalence of use may be due to the escalating cost of nicotine medications, with those using NRT for harm reduction purposes generally purchasing NRT over-the-counter (Hammond et al., 2008). Evidence has shown that when cost barriers are reduced, utilisation of NRT increases (Curry et al., 1998). However, cost is probably not the only explanation for the underuse of nicotine medication by smokers. The medicalisation of NRT and the ingrained advice over many years that NRT is solely for abrupt cessation purposes may also be held to account. The Necessity-Concerns Framework also provides some direction. This suggests that when faced with a decision regarding taking treatment, patients weigh-up their perceived personal need for the treatment against their concerns about potential adverse effects (Horne, 2003). It is now well established that many smokers hold the belief that it is the nicotine and not the smoke that does harm (Cummings et al., 2004; Siahpush et al., 2006a), and that they underestimate the efficacy and need for medicinal nicotine (Bansal et al., 2004; Etter & Perneger, 2001).

Of course, current estimates of prevalence may also be confounded by the methodologies adopted by survey-based studies, including reports based on preceding use, only allowing smokers to report the use of NRT either for periods of temporary abstinence or for smoking reduction, and a reliance on random digit dialling during recruitment (Link, Battaglia, Frankel, Osborn & Mokdad, 2006). Moreover, since the publication of these data the UK has seen a number of regulatory changes to the licensing of NRT and adaptations to tobacco control policy (MHRA, 2010), which may have contributed to an increase in the number of smokers opting to use medicinal nicotine products (Szatkowski, Coleman, McNeill & Lewis, 2011). Although available evidence does not suggest large changes a few years following the liberalisation of licensing of NRT for gradual cessation (Shahab et al., 2009), assessing whether changes have occurred following the licensing of NRT for harm reduction purposes is of importance, and of particular interest to countries who may be considering whether or not to relax their NRT regulatory framework (MHRA, 2010).

In relation to this, it is of interest to determine the extent to which it is the same smokers who are using NRT. One might imagine there would be some overlap because of a generally more favourable attitude towards NRT; it might also be the case that the two behaviours share a common underlying motivation – the desire to minimise the amount smoked. Thus smokers who use NRT for temporary abstinence may do so in part because they believe that it offers an opportunity to cut down. At present there is only limited data available on this, with two studies estimating that around four to eight per cent of smokers have ever used NRT as a means to reduce their cigarette consumption and in order to abstain during periods of time when they were unable to smoke (Levy et al., 2007; Hughes et al., 2004b[a]).

It is of further interest to assess how far the use of NRT for smoking reduction and/or during periods of temporary abstinence is associated with socio-demographic variables and nicotine dependence. Previous studies have reported that women of a younger age, higher socio-economic status, and who are heavier smokers, are more likely to report reductions in their cigarette consumption (Hughes et al., 1999; Gilpin et al., 2002; Farkas et al., 1999; Berg et al., 2010a; Godtfredsen et al., 2001; McDermott et al., 2008); although men generally experience larger reductions in daily cigarette intake relative to women (Joseph et al., 2005; Hughes et al., 1999). Whether this applies to those who report reductions as a consequence specifically of attempts to cut down or periods of temporary abstinence is unclear, with many reductions perhaps being the result of gradual cessation attempts. It may be hypothesised that because smokers of higher nicotine dependency (Hyland et al., 2006; Zhou et al., 2009;

Hymowitz et al., 1997; Jaen et al., 1993; Der & Graham, 1999; Dale et al., 2001), and lower socio-economic status (Hyland et al., 2004; Hymowitz et al., 1997; Kotz & West, 2009; Jaen et al., 1993; Der & Graham, 1999), find it harder to quit, that this may lead more of them to try and cut down instead. Women and those of an older age also tend to be more conscious about their well-being, resulting in a greater number of such smokers perhaps attempting to reduce their cigarette consumption and setting goals to achieve abstinence (Allgower et al., 2001; Nurmi, 1992). However, findings from previous studies assessing the association between age, gender, and attempts to quit, are less than consistent. Whereas some report a superiority of women and those of an older age (Hagimoto et al., 2010; Rose, Chassin, Presson & Sherman, 1996; Whitson, Heflin & Burchett, 2006), others have reported that men and younger smokers are more likely to attempt to stop smoking (Hyland et al., 2004; Hymowitz et al., 1997; Dale et al., 2001; Hyland et al., 2006); while auxiliary studies have failed to establish a relationship between age and/or gender and an endeavour for abstinence (West et al., 2001a; Hagimoto et al., 2010; Rose et al., 1996; Zhu, Sun, Billings, Choi & Malarcher, 1999; Abdullah, Lam, Chan & Hedley, 2006).

Regarding the use of NRT, it may be hypothesised that smokers with a greater nicotine dependency will be more likely to opt to use medicinal nicotine during attempts to cut down and periods of momentary abstinence, with such individuals reporting greater efficacy of medicinal nicotine; possibly because urges to smoke and withdrawal symptoms are likely to be abated to a larger extent (Silagy et al., 1994). This may apply in particular to those of a lower social-grade who tend to be more dependent on cigarettes (Siahpush et al., 2006b). The use of NRT may also be higher among smokers of an older age who often hold greater positive beliefs about medication (Horne & Weinman, 1999), although younger females have a greater awareness of generic medicines (Yelkur & Capella, 1995), and higher rates of help seeking behaviours (Bertakis et al., 2005). In line with this, the use of NRT for smoking cessation has been found to be more common among female smokers of an older age and higher nicotine dependency; however, use also appears to be more prevalent among those of a higher socio-economic status (Kotz et al., 2009; Shiffman et al., 2008; Botello-Harbaum et al., 2010; Emmons et al., 2000). This latter finding may reflect issues with the concurrent cost of purchasing NRT and cigarettes; with the costs incurred being too great for prolonged use among lower socio-economic status individuals. Of course it is possible that a different demographic opt to use NRT for traditional smoking cessation purposes to those doing so during attempts at harm reduction. Current limited data on this latter group suggests this may be the case, with those using NRT for smoking reduction and/or during periods of temporary abstinence being more likely to be male, of an older age, and higher nicotine dependency than other smokers generally, while there has been a general failure to report any association with socio-economic status (Levy et al., 2007; Etter et al., 2003). Moreover, there is data to suggest that those using NRT in an attempt to quit smoking abruptly have lower educational attainments and dependency on cigarettes than those using NRT for harm reduction purposes (Hammond et al., 2008).

Determining which socio-demographic factors are associated currently with attempts at smoking reduction and the use of NRT for harm reduction purposes in England is important, not only in allowing the development of a better understanding of the causes of effects of these behaviours but also in the shaping of future policy. For instance, if smokers of lower social-grades are more likely to use NRT for smoking reduction and/or during periods of temporary abstinence, this may be one means by which to minimise the social inequalities in smoking abstinence, where the more deprived socio-economic groups are less likely to become ex-smokers following attempts at abrupt cessation (Kotz & West, 2009). Identifying prevalence as a function of gender, age and dependence, will also provide some indication as to those who may be most receptive of a harm reduction approach and as to whether these individuals differ to those opting to quit smoking abruptly. Failure to find a difference would suggest similar motivational underpinnings for attempts at abstinence and harm reduction, the implication being, that harm reduction approaches may not be targeting a sub-set of smokers they are aimed at, i.e. those who have become discontented with traditional treatment options. Public health improvements may as such not be realised.

There is also only limited data available on how far smokers who report currently using NRT for smoking reduction and/or temporarily abstinence smoke fewer cigarettes than those who are doing so without pharmacological help (see Chapter 6). NRT had been found to aid smoking reduction in clinical trials (see Chapter 5), but this may not necessarily generalise to the ‘real world’, where NRT is not usually given free of charge and little behavioural support is provided. Previous survey-based studies point towards the possibility that significant reductions in cigarette consumption may be confined to the randomised controlled trials (see Chapter 6). However, this may be due to the reliance on cross-sectional data. If it is the case that smokers who have a disposition towards greater nicotine dependency are more likely to use NRT, one might not see evidence that smokers using NRT for harm reduction purposes smoke fewer cigarettes than other smokers, since if they had not used NRT, their cigarette consumption might have been higher.

It is of further interest to assess whether the use of NRT for smoking reduction and/or temporary abstinence detracts from or promotes smoking cessation. Clinical trials suggest strongly that using NRT for smoking reduction can increase the rate at which smokers stop smoking (see Chapter 5). However, there is no data regarding the use of NRT for periods of temporary abstinence, and it is possible that the findings from the clinical trials would not generalise beyond the highly structured setting in which clear instructions are given and there is regular follow-up. This issue is of considerable importance, for if it were the case that the use of NRT for smoking reduction and temporary abstinence undermined cessation it would almost certainly have a negative public health impact. This might happen if smokers are falsely reassured that they are reducing their harm from smoking and are therefore less motivated to try to stop. At a population level data on this issue is rather mixed. Although positive associations between attempts to quit smoking and the use of NRT for harm reduction purposes have been reported retrospectively, they have not been reported prospectively (Levy et al., 2007).

A final issue concerns whether cigarette intake and attempts to quit smoking vary as a direct result of the NRT product which is used. Although all forms of NRT are efficacious at relieving urges to smoke, evidence points towards a slight superiority of the nicotine patch (Silagy et al., 2004). This is possibly because it provides a prolonged and maintained nicotine infusion, and eliminates compliance problems evident with the other medical nicotine products (West et al., 2000b; Moolchan et al., 2005). However, the nicotine patch is poor at allowing smokers to titrate their nicotine levels and fails to provide behavioural relief, which are potentially important factors for achieving reductions in cigarette consumption (Fagerstrom & Hughes, 2002). This is partially resolved by the nicotine inhalator which requires user interaction, mimicking cigarette manipulation and puffing behaviours. Another hypothesis may assume a superiority of the gum and nasal spray, which provide sensory stimulation, and so have a bigger impact on initial cravings (Rose & Levin, 1991). The nasal spray also provides quick withdrawal symptom relief, with absorption of nicotine through the nasal route resulting in kinetic profiles similar to that of tobacco smoke (Hurt et al., 1998). However, concerns about the ineffectiveness of the gum and nasal spray without concomitant counselling have been raised (Foulds et al., 1992). The fact that smokers appear to hold a preference for the nicotine patch makes such an assessment of particular importance (see Chapter 6), especially as the MHRA out of a concern over its efficacy delayed its indication for harm reduction purposes for more than half a decade (MHRA, 2010).

Methods

Study Design and Sampling

Data for this study were obtained between February 2007 and March 2011 from the Smoking Toolkit Study. This study consists of monthly cross-sectional household computer-assisted interviews of adults aged 16+ in England, carried out by the British Market Research Bureau. The baseline survey uses a form of random location sampling, with respondents drawn from 165,665 aggregated output areas, each containing 300 households. These output areas are stratified by ACORN characteristics (see http://www.caci.co.uk/acorn/acornmap.asp) and region, and are then selected to be included in the various interviewers' lists. ACORN (acronym for A Classification Of Residential Neighbourhoods) is a geo-demographic information system categorising all UK postcodes into various types based upon census data and other information such as lifestyle surveys. The population is divided into five categories from 'wealthy achievers' (25.1%) to 'hard pressed' (22.4%). They are also broken down into 17 categories from 'wealthy executives' (8.6%) to 'inner city adversity' (2.1%), and into 57 categories from 'wealthy mature professionals', 'large houses' (1.7%) to 'multi-ethnic, crowded flats' (1.1%). This approach to profiling ensures an appropriate mix of areas by socio-economic group. Interviewers visit their selected areas and interview one participant per household over the age of 16, until quotas based upon the 2001 census (i.e. working status, age & gender) are fulfilled. Interviewers have the choice of which houses are likely to fulfill their quotas, rather than being sent to specific households in advance. Consequently, response rates are not appropriate, unlike random probability sampling, where interviewers have no choice as to the properties sampled.

Smokers and recent ex-smokers are asked at baseline whether they would be willing to be re-contacted. Those which agree are mailed a short follow-up three months later, followed by a second at 6 months if they respond to the first. Half of all the respondents are also randomly selected, after stratification by age and social-grade, to provide a saliva sample using a swab posted with the follow-up questionnaires. The saliva is assayed for cotinine, the primary metabolite of nicotine, enabling biochemical assessment of smoking during the preceding few days (SRNT Subcommittee on Biochemical Verification, 2002). One reminder letter is sent to participants to complete the follow-up and those that respond are given £5 remuneration. Due to funding constraints the three month postal questionnaire was discontinued in February 2010.

Ethical Approval

Ethical approval was granted by the University College London Research Ethics Committee.

Measures

Smoking status was assessed by asking: ‘Which of the following best applies to you? – (I smoke cigarettes (including hand-rolled) every day; I smoke cigarettes (including hand-rolled), but not every day; I do not smoke cigarettes at all, but I do smoke tobacco of some kind (for example:- pipe or cigar); I have stopped smoking completely in the last year; I stopped smoking completely more than a year ago; I have never been a smoker (i.e. smoked for a year or more); don’t know). Those who responded that they smoked cigarettes every day, or that they smoked but not every day, were coded as current cigarette smokers. Current smokers were asked questions about socio-demographic characteristics (i.e. gender, age & social-grade), cigarette consumption, and time to first cigarette of the day as a measure of nicotine dependence (Fagerstrom, 2003). Social-grade was classified as follows: AB=higher and intermediate professional/managerial; C1=supervisory, clerical, junior managerial/administrative/professional; C2=skilled manual workers; D=semiskilled and unskilled manual workers; E=on state benefit, unemployed, lowest grade workers.

Participants were asked: ‘Are you currently trying to cut down on how much you smoke’ – (yes; no; don’t know). In July 2009 this was changed to: ‘Are you currently trying to cut down on how much you smoke but not currently trying to stop?’ – (yes; no; don’t know). If they answered ‘yes’ they were asked: ‘Which, if any, of the following are you currently using to help you cut down the amount you smoke? – (nicotine patch; nicotine gum; nicotine lozenges/tablets; nicotine inhaler; nicotine nasal spray; I don’t know; none of these; other). All smokers were asked: ‘Do you regularly use any of the following in situations when you are not allowed to smoke? – (nicotine patch; nicotine gum; nicotine lozenges/tablets; nicotine inhaler; nicotine nasal spray; I don’t know; none of these; other). Finally, they were asked: ‘How many serious attempts to stop smoking have you made in the last 12 months?’ Those reporting one or more quit attempts were classified as having made a quit attempt in the past year. For further information on the measures used in the Smoking Toolkit Study see www.smokinginengland.info.

Analysis

Parametric Assumptions

For regression analyses the assumption of ‘non-multicollinearity’ was assessed by calculating Tolerance Values and Variance Inflation Factors (Menard, 1995; Myers, 1990). A further four assumptions were assessed for least-squares regression: ‘independent errors’ using the Durbin-Watson test (Durbin & Watson, 1951); ‘normality’ using histograms and normal probability plots; and ‘homoscedasticity’ and ‘linearity’, using plots of the standardised residuals against predicted values (Levene, 1960). There was no evidence that these assumptions were violated. The assumption of 'linearity' for logistic regression analysis was assessed by calculating the interaction term between the predictor and its log transformation (Hosmer & Lemeshow, 1989). A non-linear relationship was established between age and attempts at smoking reduction (β=-0.001; Wald χ^2 (*df* 1)=35.117, *p*<0.001), and between age and the use of NRT for smoking reduction (β=0.001; Wald χ^2 (*df* 1)=12.576, *p*<0.001). Although there was a linear relationship between age and the use of NRT for temporary abstinence (β=0.000; Wald χ^2 (*df* 1)=0.152, *p*>0.05), for consistency age was categorised for further analyses.

Finally, the assumption of 'normality' required for ANOVA analysis was assessed using the Kolmogorov-Smirnov (K-S) statistic, while 'homogeneity of variance' using Levene's statistic (Levene, 1960). Cigarette consumption was statistically non-normal among those using the nicotine gum, lozenges, the inhalator, patch, and a combination of NRT products, during attempts at smoking reduction and during periods of temporary abstinence. Although cigarette consumption among those using the nicotine nasal for temporary abstinence was also statistically non-normal, cigarette consumption was normally distributed among those using the nicotine nasal spray for smoking reduction (D(22)=0.176, *p*>0.05). Because the large sample size means that the K-S test may be significant even when the distribution only differs slightly from normal, histograms and P-P plots were also calculated. These confirmed the non-normality present in the data. Although variances in cigarette consumption were found to be equal among those using NRT for smoking reduction (*F*(5, 2892)=1.550, *p*>0.05), they were not among those using NRT for temporary abstinence (*F*(6, 2732)=3.912, *p*<0.001). Square root transformations amended this heterogeneity (*F*(6, 2732)=1.567), *p*>0.05). Despite this, transformations were unsuccessful at resolving issues with non-normality, thus non-parametric tests were sought (see Appendix A).

Statistical Analysis

STROBE guidelines for the reporting of epidemiological studies were followed throughout (von Elm et al., 2007), with missing data dealt with prior to analysis using the listwise deletion procedure. For the reporting of prevalence data, an iterative marginal weighting technique was used in order to maximise the reliability of the sample data and minimise any statistical bias. This was achieved by performing the least amount of weighting required to correct for sample disproportionalities that may have distorted estimates. The process works by setting separate nationally representative target profiles for gender, working status, prevalence of children in the household, age, social-grade and region, and the process repeated until all variables match the specified targets.

To assess whether changes had occurred in prevalence of smoking reduction and the use of NRT for smoking reduction and/or temporary abstinence over the course of the study, the Curve Estimation Procedure in SPSS version 18.0 was adopted. This produced curve estimation regression statistics and related plots for 11 different regression models (i.e. Linear, Logarithmic, Inverse, Quadratic, Cubic, Compound, Power, S-curve, Growth, Exponential & Logistic). Those models explaining the largest amount of variance are reported. The association between smoking reduction and the use of NRT for smoking reduction and temporary abstinence with gender, age, nicotine dependence and social-grade, was assessed by logistic regression analyses, controlling for potential confounding variables as appropriate (i.e. age, gender, social-grade & time to first cigarette of the day). Associations between harm reduction behaviours were also assessed with logistic regression analyses. Least-squares and logistic regression analyses were adopted to determine the associations between smoking reduction, and use of NRT for smoking reduction and/or temporary abstinence, with cigarette consumption and attempts to quit smoking; and to assess the extent to which these associations, if they existed, varied as a function of the NRT products which were used. These were undertaken with and without adjustment for socio-demographic variables and time to first cigarette of the day as a measure of dependence (Fagerstrom, 2003); 95% confidence intervals were used unless otherwise stated.

Kruskal-Wallis tests were adopted to assess whether differences in cigarette consumption existed amongst those using the various NRT products for smoking reduction and/or during periods of temporary abstinence. Post-hoc analysis was carried out using multiple Mann-Whitney tests with the Bonferroni correction applied (effects are reported at a 0.003 level of significance). Corresponding effect sizes were also calculated (r=Z score/ $\sqrt{\text{total}}$ sample size). Finally, Chi-squared analysis was used to assess whether difference in the percentage of quit attempts existed amongst those using the various NRT products. To assess significance, standardised residuals were compared to the critical values that correspond to an alpha of 0.05 (+/-1.96), an alpha of 0.01 (+/-2.58) or an alpha of 0.001 (+/-3.10). Odds Ratios were then calculated where significance was evident.

Power

Post-hoc power analysis using G*Power 3 (Erdfelder, Faul & Buchner, 1996), revealed that for the assessment of the association between smoking reduction and the use of NRT for temporary abstinence with attempts to quit smoking, an Odds Ratio of 1.1 could be detected with 99% power using an alpha of 0.001, 100% power using an alpha of 0.01, while 100% power using an alpha of 0.05. For the assessment of the association between the use of NRT for smoking reduction and attempts to quit smoking, an Odds Ratio of 1.1 could be detected with 81% power using an alpha of 0.001, 95% power using an alpha of 0.01, while 99% power using an alpha of 0.05.

Results

Between February 2007 and March 2011, 91,514 adults were surveyed; of whom, 20,188 reported that they were current smokers. Fifty-two per cent of the smokers were male (*n*=10,453) and 48.2% (*n*=9,735) female, with a mean age [Standard Deviation (*SD*)] of 40.5 (16.12) years. The percentages of participants residing in each social-grade were as follows: AB (15.5%; *n*=3,137), C1 (23.3%; *n*=5,101), C2 (24.6%; *n*=4,966), D (21.5%; *n*=4,334) and E (13.1%; *n*=2,649). The mean (*SD*) daily cigarette consumption was 13.1(8.47), with 32.6% (*n*=6,591) reporting smoking after 61 minutes of wakening, 13.8% (*n*=2,779) between 31 and 60 minutes after wakening, 33.4% (*n*=6,750) within 6-30 minutes of wakening, and 19.8% (*n*=3,997) less than 5 minutes after wakening. Thirty-five per cent (*n*=7,144) of smokers reported a quit attempt in the previous 12 months. Table 1 shows the socio-demographic and smoking characteristics of respondents when split into the cohorts of interest. A total of 54.7% (*n*=11,039) of the participants reported that they were attempting to cut down; with 13.5% (*n*=2,733) using NRT for smoking reduction. Thirteen per cent (*n*=2,547) of the sample also reported using NRT for temporary abstinence. There was a substantial overlap in these behaviours: 9.0% (*n*=1,810) of smokers reported that they were reducing their intake and using NRT during periods of temporary abstinence, while 7.4% (*n*=1,487) of smokers reported that they were using NRT both as a means to cut down their cigarette consumption and during periods of time when they were unable to smoke. The most commonly used forms of NRT were the nicotine patch and nicotine gum (see Table 2).

Table 1: Socio-Demographic Characteristics and Nicotine Dependency of Respondents as a Function of Smoking Reduction and the use of Nicotine Replacement Therapy for Smoking Reduction and/or Temporary Abstinence

	SR vs no SR (*n*=11,039 vs *n*=9,149)		SR with NRT vs SR without NRT (*n*=2,733 vs *n*=8,306)		TA with NRT vs other smokers (*n*=2,547 vs *n*=17,641)	
	SR	No SR	SR with NRT	SR without NRT	TA with NRT	TA without NRT
Age %(*n*)						
16-24	20.5 (2,261)	20.3 (1,853)	17.5 (478)	21.5 (1,783)	18.8 (480)	20.6 (3,636)
25-34	21.1 (2,326)	19.4 (1,778)	19.1 (523)	21.7 (1,803)	18.7 (477)	20.6 (3,627)
35-44	21.3 (2,353)	21.3 (1,950)	22.9 (627)	20.8 (1,726)	23.0 (585)	21.1 (3,720)
45-54	16.7 (1,848)	17.4 (1,588)	18.8 (514)	16.1 (1,334)	18.9 (481)	16.8 (2,957)
55-64	12.4 (1,373)	11.7 (1,072)	13.9 (379)	12.0 (995)	13.5 (343)	11.9 (2,103)
65+	7.9 (877)	9.9 (901)	7.8 (219)	8.0 (665)	7.1 (181)	9.1 (1,598)
Gender %(*n*)						
Male	50.4 (5,567)	53.4 (4,886)	49.2 (1,345)	50.8 (4,222)	49.0 (1,247)	52.2 (9,206)
Female	49.6 (5,472)	46.6 (4,262)	50.8 (1,388)	49.2 (4,085)	51.0 (1,300)	47.8 (8,435)
Social-grade %(*n*)						
AB	15.7 (1,730)	15.4 (1,407)	16.5 (451)	15.4 (1,279)	16.1 (409)	15.5 (2,728)
C1	25.3 (2,794)	25.2 (2,306)	26.0 (711)	25.1 (2,083)	25.7 (655)	25.2 (4,446)
C2	24.7 (2,725)	24.5 (2,241)	24.3 (664)	24.8 (2,061)	23.0 (587)	24.8 (4,379)
D	21.2 (2,340)	21.8 (1,994)	19.6 (536)	21.7 (1,805)	21.4 (545)	21.5 (3,790)
E	13.1 (1,149)	13.1 (1,200)	13.6 (371)	13.0 (1,078)	13.8 (352)	13.0 (2,297)
Time to first cigarette %(*n*)						
>61 minutes	35.3 (3,887)	29.6 (2,704)	29.5 (804)	37.2 (3,083)	25.0 (637)	33.9 (954)
31-60 minutes	14.9 (1,646)	12.4 (1,133)	15.2 (416)	14.9 (1,230)	14.5 (369)	13.7 (2,410)
6-30 minutes	32.7 (3,604)	34.4 (3,146)	35.7 (974)	31.8 (2,630)	36.7 (933)	33.1 (5,818)
<5 minutes	17.0 (1,875)	23.2 (2,123)	19.6 (536)	16.2 (1,339)	23.8 (606)	19.3 (3,392)

Note: *n*=number; NRT=Nicotine Replacement Therapy; SR=smoking reduction; TA=temporary abstinence
Data were weighted to match the 2001 census

Table 2: Prevalence of the Various Forms of Nicotine Replacement Therapy Among Respondents as a Function of Their use for Smoking Reduction and/or Temporary Abstinence

Product used for smoking reduction	*n* (%)	CI (95%)
Single NRT use	83.7 (2,288)	82.6-84.9
Patch	44.8 (1,025)	42.-8-46.8
Gum	28.7 (657)	26.9-30.6
Inhalator	13.8 (316)	10.5-13.2
Lozenges	11.8 (271)	12.4-15.2
Nasal Spray	0.8 (19)	0.46-1.2
Combined NRT use	16.3 (445)	14.9-17.7
Patch & gum	36.0 (160)	31.5-40.4
Patch & inhalator	18.7 (83)	15.0-22.3
Gum & Lozenges	8.3 (37)	5.8-10.9
Gum & inhalator	7.2 (32)	4.8-9.6
Patch & lozenges	5.6 (25)	3.5-7.8
Patch, inhalator & gum	4.5 (20)	2.6-6.4
All five products	4.3 (19)	2.4-6.2
Patch, inhalator, gum & lozenges	3.6 (16)	1.9-5.3
Patch, lozenges & gum	3.4 (15)	1.7-5.1
Other combination	8.5 (38)	5.9-11.1
Product used for temporary abstinence	*n* (%)	CI (95%)
Single NRT use	88.2 (2,246)	87.1-89.2
Patch	39.3 (882)	37.6-41.0
Gum	31.2 (702)	29.7-32.9
Lozenges	7.7 (172)	6.7-8.6
Inhalator	17.1 (384)	15.8-18.4
Nasal Spray	4.7 (106)	4.0-5.5
Combined NRT use	11.8 (301)	10.8-12.9
Patch & gum	35.6 (108)	30.5-41.3
Patch & inhalator	19.6 (59)	15.1-24.1
Gum & inhalator	10.3 (31)	6.9-13.7
Gum & lozenges	6.0 (18)	3.3-8.7
Patch, lozenges & gum	4.7 (14)	2.3-7.0
All five products	4.3 (13)	2.0-6.6
Patch, inhalator & gum	4.0 (12)	1.8-6.2
Patch & lozenges	3.7 (11)	1.5-5.8
Patch, inhalator, gum & lozenges	3.7 (11)	1.5-5.8
Other combination	6.0 (24)	4.9-11.0

Note: CI=confidence interval; *n*=number; NRT=Nicotine Replacement Therapy
Data were weighted to match the 2001 census

All curve estimations were a significant fit for the assessment of changes in the prevalence of smoking reduction over the course of the study. The linear model explained the largest amount of variance [R^2=0.238; F(df 1,48)=14.989, p=0.001; (see Figure 1)]. It was established that there had been a significant decline in the number of smokers reporting that they were reducing their cigarette consumption over time (β=-5.351E-8; *t*=-3.869, *p*=0.001). The linear model also explained the largest amount of variance in the prevalence of NRT use for smoking reduction (R^2=0.011; *F(df* 1,48)=0.527, *p*=0.471; see Figure 2), and for temporary abstinence over the course of the study [(R^2=0.044; *F*(*df* 1,48)=2.220, *p*=0.143; (see Figure 3)]. However, there was no evidence of a significant change since 2007 in the use of NRT for either smoking reduction (β=-6.545E-9; *t*=-0.726, *p*=0.471), or during periods of temporary abstinence (β=-1.766E-8; *t*=-1.490, *p*=0.143).

After controlling for socio-demographic characteristics (i.e. age, gender & social-grade) and time to first cigarette of the day, a strong positive association was found between the use of NRT for temporary abstinence and the use of NRT for smoking reduction (Odds Ratio (*OR*) 27.94; Confidence Interval (CI) 24.56-31.77; *p*=0.001). The odds of reporting an attempt to cut down were also higher amongst those using NRT during momentary abstinence than other smokers generally (*OR* 2.36; CI 2.16-2.58; *p*=0.001).

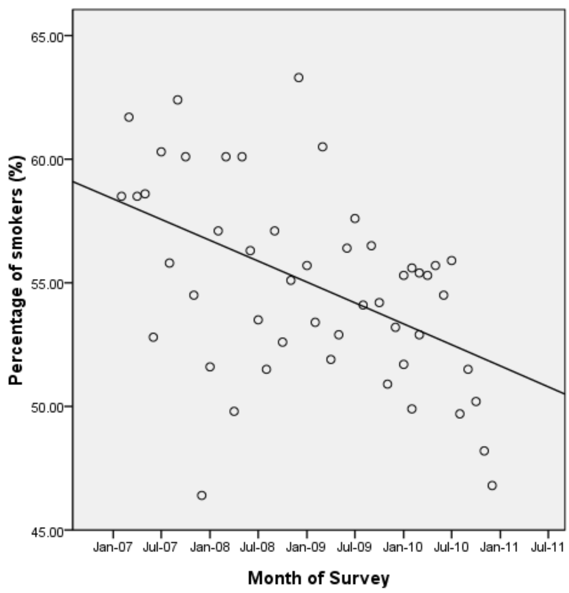


Figure 1: Percentage of Smokers Reporting That They Were Reducing Their Cigarette Consumption Across the Waves of the Study

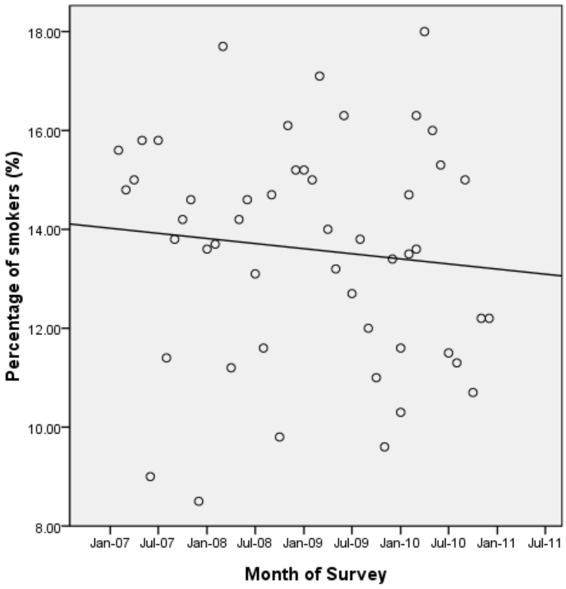


Figure 2: Percentage of Smokers Reporting That They Were Using Nicotine Replacement Therapy for Smoking Reduction Across the Waves of the Study

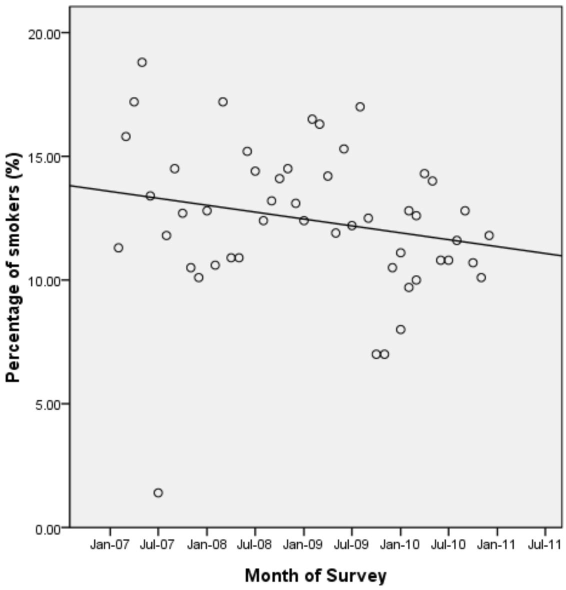


Figure 3: Percentage of Smokers Reporting That They Were Using Nicotine Replacement Therapy for Temporary Abstinence Across the Waves of the Study

Table 3 shows the associations between smoking reduction and the use of NRT for smoking reduction and/or during periods of temporary abstinence with socio-demographic variables and nicotine dependence. Women and younger respondents were more likely to report that they were reducing their cigarette consumption and using NRT for temporary abstinence. Middle-aged smokers were also more likely to report the use of NRT for smoking reduction compared to those over 65 years of age. Social-grade was not associated with the use of NRT for smoking reduction and/or temporary abstinence. In contrast, those in social-grade C1 were less likely to report smoking reduction than those in social-grade E. Those with a lower nicotine dependency were also more likely to report attempting smoking reduction, while those smoking after 61 minutes of wakening were less likely to report the use of NRT for smoking reduction and/or temporary abstinence relative to those smoking within five minutes of wakening.

Table 3: Association Between Smoking Reduction and the use of Nicotine Replacement Therapy for Smoking reduction and/or Temporary abstinence With Socio-Demographic Characteristics and Nicotine Dependence

	SR vs no SR (*n*=11,039 vs *n*=9,149)		SR with NRT vs SR without NRT (*n*=2,733 vs *n*=8,306)		TA with NRT vs other smokers (*n*=2,547 vs *n*=17,641)	
	OR	CI (95%)	*OR*	CI (95%)	*OR*	CI (95%)
Age (Reference category=65+)						
16-24	1.39***	1.25-1.54	0.87	0.73-1.04	1.20*	1.01-1.43
25-34	1.47***	1.33-1.63	0.96	0.82-1.14	1.28**	1.09-1.51
35-44	1.39***	1.25-1.53	1.19*	1.01-1.40	1.50***	1.28-1.77
45-54	1.37***	1.24-1.52	1.20*	1.02-1.43	1.49***	1.26-1.76
55-64	1.44***	1.29-1.61	1.20*	1.00-1.43	1.48***	1.24-1.77
Gender (Female=1)	1.16***	1.10-1.22	1.07	0.97-1.82	1.18***	1.08-1.28
Social-grade (Reference category=E)						
AB	0.93	0.84-1.03	1.11	0.95-1.29	1.09	0.94-1.26
C1	0.92*	0.85-0.99	1.09	0.96-1.23	1.05	0.93-1.18
C2	0.95	0.88-1.03	0.98	0.87-1.11	0.95	0.85-1.07
D	0.94	0.86-1.02	0.92	0.80-1.04	0.96	0.85-1.09
Time to first cigarette (reference <5 minutes)						
>61 minutes	1.70***	1.57-1.84	0.67***	0.59-0.76	0.63***	0.56-0.71
31-60 minutes	1.71***	1.55-1.88	0.88	0.76-1.02	0.88	0.77-1.01
6-30 minutes	1.33***	1.24-1.44	0.93	0.83-1.05	0.94	0.85-1.05

Note: *OR*=Odds Ratio; CI=confidence interval; SR=smoking reduction; TA=temporary abstinence; NRT=Nicotine Replacement Therapy
Significant difference between groups (*** p<0.001, ** p<0.01, *p<0.05)
Adjusted for age, gender, social-grade and time to first cigarette of the day

Table 4: Reports of Average Cigarette Consumption and Percentage of Previous Attempts to Quit Smoking Among Respondents as a Function of Smoking Reduction and the use of Nicotine Replacement Therapy for Smoking Reduction and/or Temporary Abstinence

	SR vs no SR (*n*=11,039 vs *n*=9,149)		SR with NRT vs SR without NRT (*n*=2,733 vs *n*=8,306)		TA with NRT vs other smokers (*n*=2,547 vs *n*=17,641)	
	SR	No SR	SR with NRT	SR without NRT	TA with NRT	TA without NRT
Quit attempt in the previous 12 months %(*n*)	48.4 (5,333)	19.8 (1,809)	71.9 (1,300)	43.8 (4,033)	64.0 (1,626)	31.3 (5,517)
Cigarette consumption per day M(*SD*)	12.0 (7.57)	14.4 (9.30)	12.8 (7.85)	11.8 (7.46)	13.9 (8.39)	13.0 (8.48)

Note: *n*=number; SR=smoking reduction; TA=temporary abstinence; NRT=Nicotine Replacement Therapy
Data were weighted to match the 2001 census

Table 4 shows the average cigarette consumption per day and percentage of smokers reporting a quit attempt in the previous 12 months, as a function of attempts to cut down and the use of NRT for smoking reduction and/or temporary abstinence. Table 5 shows the results of the regression analyses on this data. Smokers reporting trying to reduce their cigarette consumption smoked on average 2.54 cigarettes fewer per day than those not reducing their cigarette intake. After adjustment for socio-demographic variables and time to first cigarette, this was 1.67 cigarettes per day fewer. People who used NRT to reduce their cigarette consumption smoked 0.98 cigarettes per day more than reducers not using NRT, but this difference declined to 0.39 per day after adjustment. In contrast, although smokers using NRT for temporary abstinence smoked 0.86 cigarettes more per day prior to adjustment, after adjustment no significant difference was established relative to other smokers generally. Smokers reporting attempts to reduce their cigarette consumption were also much more likely to report having tried to quit smoking in the past year than those who were not currently trying to cut down. Moreover, those using NRT for smoking reduction were substantially more likely to report a quit attempt than those reducing without NRT. These associations did not change greatly by adjustment. Smokers using NRT for temporary abstinence were also much more likely to report trying to quit smoking compared to other smokers generally.

Table 5: Association Between Smoking Reduction and the use of Nicotine Replacement Therapy for Smoking Reduction and/or Temporary Abstinence With Cigarette Consumption and Previous Attempts to Quit smoking

	Unadjusted			Adjusted[a]		
	SR vs no SR (*n*=11,039 vs *n*=9,149)	SR with NRT vs SR without NRT (*n*=2,733 vs *n*=8,306)	TA with NRT vs other smokers (*n*=2,547 vs *n*=1,7641)	SR vs no SR (*n*=11,039 vs *n*=9,149)	SR with NRT vs SR without NRT (*n*=2,733 vs *n*=8,306)	TA with NRT vs other smokers (*n*=2,547 vs *n*=17,641)
	OR CI (95%)	*OR* CI (95%)	*OR* CI (95%)	*OR* CI (95%)	*OR* CI (95%)	*OR* CI (95%)
Quit attempt in the previous 12 months	3.86*** 3.63-4.11	3.38*** 3.09-3.70	4.01*** 3.69-4.36	3.91*** 3.67-4.16	3.52*** 3.21-3.86	4.12*** 3.78-4.87
	β CI (95%)	β CI (95%)	β CI (95%)	β CI (95%)	β CI (95%)	β CI (95%)
Cigarette consumption per day	-2.54*** -2.78-(-)2.31	0.98*** 0.66-1.31	0.86*** 0.50-1.21	-1.67*** -1.87-1.47	0.39** 0.10-0.68	0.19 -0.11-0.50

Note: *n*=number; *OR*=Odds Ratio; CI=confidence interval; β=beta coefficient; SR=smoking reduction; NRT=Nicotine Replacement Therapy; TA=temporary abstinence
Significant difference between groups (*** $p<0.001$, ** $p<0.01$, * $p<0.05$)
[a]Adjusted for age, gender, social-grade and time to first cigarette of the day

Table 6 shows the average cigarette consumption per day and percentage of attempts to quit smoking in the previous 12 months amongst those using the assortment of NRT products for temporary abstinence and/or smoking reduction. Cigarette consumption was found to vary as a function of the NRT product used during attempts to cut down (χ^2=43.12 (*df* 5), *p*=0.001). The use of the nicotine gum was associated with lower cigarette consumption compared to use of nicotine lozenges (*U*=71700.0; *r*=-0.10), the nicotine inhalator (*U*=802778.5; *r*=-0.14), nicotine patch (*U*=265536.5; *r*=-0.14), and combined NRT (*U*=111541.0; *r*=-0.16). A significant difference was also found in relation to the various NRT products used for temporary abstinence (χ^2=45.80 (*df* 5), *p*=0.001). The use of nicotine gum was associated with lower cigarette consumption compared to the inhalator (*U*=111663.5; *r*=-0.12), patch (*U*=249083.5; *r*=-0.15), and the use of a combination of NRT products (*U*=82578.0; *r*=-0.15).

Table 6: Reports of Average Cigarette Consumption and Percentage of Previous Attempts to Quit Smoking Among Respondents as a Function of the Nicotine Replacement Therapy Product Used for Smoking Reduction and/or Temporary Abstinence

	Quit attempt in the previous 12 months %(*n*)	Cigarette consumption per day M(*SD*)
Smoking reduction without NRT (*n*=8,306)	41.1 (340)	11.8 (7.46)
Smoking reduction with NRT (n=2,733)		
Patch (*n*=1025)	73.5 (753)	13.3 (8.09)
Gum (*n*=657)	63.8 (418)	11.2 (7.44)
Lozenges (*n*=271)	67.7 (182)	12.7 (7.54)
Inhalator (*n*=316)	69.6 (220)	13.1 (7.59)
Nasal spray (*n*=19)	89.5 (17)	11.3 (8.17)
Combined use (*n*=445)	75.7 (226)	13.7 (7.96)
Temporary abstinence without NRT (*n*=17,641)	31.3 (5,517)	13.0 (8.48)
Temporary abstinence with NRT (n=2,547)		
Patch (*n*=882)	65.5 (576)	14.6 (8.31)
Gum (*n*=702)	60.4 (422)	12.4 (7.81)
Lozenges (*n*=172)	67.3 (115)	12.7 (7.62)
Inhalator (*n*=384)	66.7 (256)	14.6 (8.74)
Nasal spray (*n*=106)	44.2 (46)	14.1 (8.62)
Combined use (*n*=301)	70.1 (2,11)	15.4 (9.11)

Note: M=mean; *SD*=Standard Deviation; *n*=number; NRT=Nicotine Replacement Therapy
Data were weighted to match the 2001 census

Attempts to quit smoking also differed among those using NRT for smoking reduction (χ^2=28.61 (*df* 5), *p*=0.001). This seemed to represent the fact that based on the Odds Ratios [*OR*; Confidence Interval (CI)], those using the nicotine gum were 79% (*OR* 0.21; CI 0.05-0.91) less likely to report a quit attempt than those using the nicotine nasal spray, 36% (*OR* 0.64; CI 0.52-0.77) less likely than those using the nicotine patch, and 43% (*OR* 0.57; CI 0.43-0.74) less likely that those using a combination of NRT products. In contrast, those using a combination of NRT products were 49% more likely to report that they had attempted to quit smoking in the previous 12 months than those using nicotine lozenges (*OR* 1.49; CI 1.06-2.08). Quit attempts also varied as a function of the product used for temporary abstinence (χ^2=29.30 (*df* 5), *p*=0.001). Based on the Odds Ratios, those using the nicotine nasal spray were 48% less likely to report a quit attempt than those using nicotine gum (*OR* 0.52; CI 0.34-0.79), 61% less likely than those using nicotine lozenges (*OR* 0.59; CI 0.23-0.64), 60% less likely than those using the nicotine inhalator (*OR* 0.40; CI 0.26-0.62), 58% less likely than those using the nicotine patch (*OR* 0.42; CI 0.28-0.63), and 66% less likely that those using a combination of NRT products (*OR* 0.34; CI 0.21-0.54).

Table 7: Association Between the use of Nicotine Replacement Therapy for Smoking Reduction and/or Temporary Abstinence With Cigarette Consumption as a Function of the Nicotine Replacement Therapy Product Used

	β(CI 95%)
NRT use for SR vs SR without NRT (*n*=2,733 vs *n*=8,306)	
Patch (*n*=1,025)	0.93 (0.51-1.35)***
Gum (*n*=657)	-0.68 (-1.20-(-)0.15)**
Lozenges (*n*=271)	0.03 (-0.83-0.77)
Inhalator (*n*=316)	0.23 (-0.48-0.94)
Nasal spray (*n*=19)	-0.65 (-3.43-2.13)
Combined use (*n*=445)	1.01 (0.43-1.66)***
NRT use for TA vs TA without NRT (*n*=2,547 vs *n*=17,640)	
Patch (*n*=882)	0.72 (0.23-1.21)**
Gum (*n*=702)	-0.95 (-1.50-(-)0.39)***
Lozenges (*n*=172)	-1.03 (-2.12-0.06)
Inhalator (*n*=384)	0.61 (-0.12-1.33)
Nasal spray (*n*=106)	0.46 (-0.92-1.84)
Combined use (*n*=301)	1.19 (0.37-2.02)**

Note: *n*=number; β=beta coefficient; CI=confidence interval; NRT=Nicotine Replacement Therapy; SR=smoking reduction; TA=temporary abstinence
Significant difference between groups (*** p<0.001, ** p<0.01, *p<0.05)
Adjusted for age, gender, social-grade and time to first cigarette of the day

Tables 7 and 8 show the results of the regression analyses for the association between the use of NRT for smoking reduction and/or temporary abstinence with cigarette consumption and previous attempts to quit smoking, as a function of the NRT product which was used. Compared to those not using NRT for harm reduction purposes, those using the nicotine gum reported lower cigarette consumption, while those using the nicotine patch or a combination of NRT products reported higher cigarette consumption. No association was reported between the use of nicotine lozenges, the inhalator or nasal spray and cigarette consumption. In contrast, those who were reducing their cigarette consumption or temporarily abstaining with NRT, regardless of the NRT product which they used, were more likely to report a quit attempt than those doing each of these behaviours without pharmacological help.

Table 8: Association Between the use of Nicotine Replacement Therapy for Smoking Reduction and/or Temporary Abstinence With Previous Attempts to Quit Smoking as a Function of the Nicotine Replacement Therapy Product Used

	OR(CI 95%)
NRT use for SR vs SR without NRT (*n*=2,733 vs *n*=8,306)	
Patch (*n*=1,025)	4.04 (3-51-4.65)***
Gum (*n*=657)	2.49 (2.12-2.93)***
Lozenges (*n*=271)	3.18 (2.46-4.12)***
Inhalator (*n*=316)	3.59 (2.84-4.55)***
Nasal spray (*n*=19)	9.50 (2.78-32.46)***
Combined use (*n*=445)	4.57 (3.69-5.67)***
NRT use for TA vs TA without NRT (*n*=2,547 vs *n*=17,641)	
Patch (*n*=882)	4.58 (3.98-5.26)***
Gum (*n*=702)	3.26 (2.80-3.80)***
Lozenges (*n*=172)	5.12 (3.73-6.99)***
Inhalator (*n*=384)	4.46 (3.63-5.48)***
Nasal spray (*n*=1,06)	1.95 (1.34-2.85)***
Combined use (*n*=301)	5.37 (4.17-6.91)***

Note: *n*=number; *OR*=Odds Ratio; CI=confidence interval; NRT=Nicotine Replacement Therapy; SR=smoking reduction; TA=temporary abstinence
Significant difference between groups (*** p<0.001, ** p<0.01, *p<0.05)
Adjusted for age, gender, social-grade and time to first cigarette of the day

Discussion

Just over 50% of smokers reported that they were reducing their cigarette consumption, 14% that they were using NRT for smoking reduction, and 13 per cent that they were using NRT during periods of temporary abstinence. There appeared to be a substantial overlap in these behaviours, with those using NRT during an attempt to cut down being more likely to also be using NRT during periods of time when they were unable to smoke. Although prevalence of smoking reduction declined over time since 2007, there was no evidence of any change in NRT use over the course of the study. The most commonly used product appeared to be the nicotine patch followed by the nicotine gum. The use of NRT for smoking reduction and/or temporary abstinence was associated with a number of demographic variables. Those attempting to reduce their cigarette consumption with the aid of NRT were more nicotine dependent and more likely to report being middle-aged, while those using NRT for temporary abstinence were more likely to be female, of a younger age, and of a higher nicotine dependency than other smokers generally. Those using NRT for smoking reduction smoked on average half a cigarette more per day than other smokers, while no difference in cigarette consumption was found among those using NRT for temporary abstinence and those temporarily abstaining without pharmacological help. Higher odds of a previous attempt to quit smoking were also established among those using NRT for smoking reduction and/or temporary abstinence compared to smokers not using NRT for such purposes. Such relationships appeared to be dependent on the NRT product which was used, with cigarette consumption being lowest among those using the nicotine gum, while attempts to quit were more prevalent among those using the nicotine patch and a combination of NRT products.

The high prevalence of reported attempts at smoking reduction is consistent with evidence that most UK smokers would like to stop and are concerned about the health consequences of smoking (Office for National Statistics, 2007). Previous studies from the UK, Germany, and US, have also established that almost 50% of smokers are reducing their smoke intake spontaneously at any one time (West et al., 2001a; Hughes et al., 1999; Farkas, 1999). It is of interest that there has been a slight decline in the prevalence of smoking reduction since 2007. This may be partially due to the concurrent decline in smoking prevalence during this period (see www.smokinginengland.info), resulting in a sub-set of smokers who are less motivated to change their smoking behaviour. It may also be the case than smokers are instead attempting to quit abruptly, possibly enticed by the smoking ban (Hackshaw, McEwen, West & Bauld, 2010). In contrast, there was no evidence of a decline or increase in the use of NRT for smoking reduction or during attempts to temporarily abstain. This would coincide with previous data which failed to report any change in NRT use pre- and post- the licensing of NRT for gradual cessation (Shahab et al., 1999).

A possible reason for why the prevalence of NRT use for harm reduction purposes was higher than that reported previously in the UK (i.e. Hammond et al., 2008), is likely to revolve around differences in the methods of sampling and assessment of smoking reduction and/or temporary abstinence. The study by Hammond et al. (2008) involved telephone surveys using random digit dialling with a panel of respondents, whereas the current study used household surveys using random location sampling. The Smoking Toolkit Study appears to yield demographic and smoking data very similar to other large national surveys, so there are grounds for believing that the sample is representative (Fidler et al., 2011). With regards to questioning, Hammond et al. (2008) measured the use of NRT over the past year, as opposed to the current use, and did not allow smokers to report using NRT both during attempts to cut down and during periods of temporary abstinence. Nevertheless, only 1/7th of smokers appear to be using NRT, which means that a substantial amount are attempting to reduce or temporarily abstain without pharmacological help. This possibly results from the escalating cost of nicotine medications (Hammond et al., 2008); the medicalisation of NRT and the ingrained advice over many years that NRT is solely for abrupt cessation purposes; and the underestimation of the personal need for NRT and concerns about potential adverse effects (Cummings et al., 2004; Siahpush et al., 2006a; Bansal et al., 2004; Etter & Perneger, 2001). Clearly there is a need for public campaigns to address this, if it is the case that smoking reductions and momentary abstinence are more successful with pharmacological help.

The strong association noted between the use of NRT for smoking reduction and temporary abstinence could be due to smokers using periods of temporary abstinence as a means of reducing their cigarette consumption. There is evidence that the implementation of public smoking bans induces a decline in cigarette intake among smokers (Fichtenberg & Glantz, 2002). The use for both purposes could also reflect a general positive attitude towards

NRT, which would coincide with the finding of an association between the past use of NRT for smoking reduction and the use of NRT during attempts at smoking cessation (Levy et al., 2007). If this is the case, it would be of interest to assess cigarette consumption and attempts to stop smoking among those using NRT only for smoking reduction, only for periods of time when they are unable to smoke, and those using NRT for both purposes. If the latter results in greater NRT use, or is associated with a stronger motivation for behaviour change, it may be hypothesised that increased odds of an attempt to quit smoking could prevail.

The finding that older male smokers were less likely to be attempting smoking reduction may reflect the fact that those more motivated to reduce their harm from smoking have achieved cessation at a younger age, while women tend to be more conscious about their well-being and health (Allgower et al., 2001). This is in line with previous studies reporting that older men are less likely to attain reductions in their cigarette consumption (Hughes et al., 1999; Gilpin et al., 2002; Farkas et al., 1999; Berg et al., 2010a; Godtfredsen et al., 2001; McDermott et al., 2008). However, in contrast to these previous studies, those of social-grade C1 were less likely to report attempting smoking reduction than those in social-grade E. Prior reports that those experiencing reductions are better educated and have higher incomes may be due to the failure to assess the reasons for reduction, i.e. they may have been the consequence of harm reduction or gradual cessation attempts. This finding is of particular importance for those involved in policy decisions regarding harm reduction, in that it points towards the possibility that smoking reduction may be a means in which to reduce the social inequalities in health; with those of higher social-grades consistently being more likely to report attempts to stop smoking (Kotz & West, 2009; Hyland et al., 2004; Hymowitz et al., 1997; Kotz & West, 2007; Jaen et al., 1993; Der & Graham, 1999). The lower dependency among those reporting attempts to cut down could simply reflect reductions in cravings for cigarettes that have occurred as a consequence of decreased cigarette consumption, with such individuals perhaps being a priori more reliant on cigarettes. In contrast, if it is the case and those of lower dependency are more likely to attempt smoking reduction, this would suggest that the behaviour of reduced cigarette consumption may have similar motivational underpinnings as attempts to attain smoking abstinence (Hyland et al., 2006; Zhou et al., 2009; Hymowitz et al., 1997; Jaen et al., 1993; Der & Graham, 1999; Dale et al., 2001); thus harm reduction strategies may not be targeting a separate set of smokers who have become discontent with traditional treatments.

Although other studies have also reported that highly dependent smokers are more likely to have used NRT for harm reduction purposes in the past, and have failed to establish an association with socio-economic status; to the contrary, greater usage of NRT for smoking reduction and/or temporary abstinence was noted among males of an older age (Levy et al., 2007; Etter et al., 2003). Although these discrepancies may reflect differences in the choice of comparison group, i.e. other smokers generally versus those cutting down or abstaining without pharmacological help, the current findings are somewhat in line with what may be hypothesised. For example, females and those of a younger age appear to have a greater awareness of generic medication (Yelkur & Capella, 1995), and higher rates of help seeking behaviours (Bertakis et al., 2005), and so may be expected to be more likely opt to use NRT during attempts to cut down. Of interest, is that those using NRT for harm reduction in the current study appear to differ somewhat to those reporting the use of NRT as a means to stop smoking (Kotz et al., 2009; Shiffman et al., 2008; Botello-Harbaum et al., 2010; Emmons et al., 2000); militating against the view of similar motivational underpinnings for these two behaviours. Future studies should aim to gain a better understanding of other socio-demographic factors which may be associated with the use of NRT for harm reduction purposes, in order to understand the demographic of those who may be most interested in such an approach. This information may be utilised by campaigns aimed at increasing the uptake of NRT, allowing them to direct interventions at those most opposed of a harm reduction approach: presently this appears to be males of an older age, and who although being less nicotine dependent, may nonetheless report difficulty with abstinence.

The finding that smoking reduction was associated with smoking only a few cigarettes less than other smokers is not surprising. Any reduction in cigarette consumption is likely to result in a concurrent decrease in nicotine intake, thus trigging compensatory smoking, i.e. smoking more cigarettes prior to or following the period of reduction. This is in line with previous surveys which have reported, at least among a minority of smokers, only moderate to small reductions in cigarette consumption (Godtfredsen et al., 2002a; Pisinger et al., 2005; Meyer et al., 2003; West et al., 2001a; Falba et al., 2004; Hughes et al., 1999; Gilpin & Pierce, 2002). West and colleagues (2001a) for example, noted reductions of only one to two cigarettes per day, while a prospective study in the US of older smokers found reductions of just 5% (Falba et al., 2004).

It may have been hypothesised that the use of NRT would help to mitigate the tendency of smokers to compensate for the drop in nicotine, resulting in greater reductions in cigarette consumption, perhaps to a level of those reported in the previous clinical trials. It is therefore interesting that its use relative to smoking reduction without NRT was not associated with lower cigarette intake. This may be partially due to the cross-sectional nature of the study, with smokers who were more nicotine dependent having a greater odds of NRT use. Nicotine dependency was controlled for in the analysis using time to first cigarette of the day, which is a reliable and valid measure (Haddock, Lando, Klesges, Talcott & Renaud, 1999; Heatherton, Kozlowski, Frecker, Rickert & Robinson, 1989), and argued to be the best single indicator of nicotine dependence (Fagerstrom, 2003); however, because nicotine dependence is multi-faceted with different aspects being tapped into by different instruments (Hughes et al., 2004c), the choice of a single measure may not have been adequate. Thus it would be of use to assess the association between the use of NRT for harm reduction purposes and other measures of nicotine dependence in the future. It may also be the case that NRT was having an effect not cigarette consumption, but on the amount of smoke ingested per cigarette, with smokers decreasing puff frequency or putting their cigarettes out early (Okuyemi et al., 2002). A measure of actual toxin intake is required to determine whether this is the case.

The current findings also point towards the possibility that some NRT products may be more effective than others, with the use of the nicotine gum being associated with lower reports of average cigarette consumption, while the nicotine patch with higher cigarette consumption. The use of a combination of NRT products was also associated with greater cigarette intake. The superiority of the nicotine gum may be expected because it provides behavioural substitution and an instant hit of nicotine, making it suitable for those who have to abstain for a relatively short period of time. In contrast, it is rather counterintuitive that combined NRT was associated with higher cigarette consumption, since it has been consistently shown to be more effective than monotherapy (Fagerstrom, Schneider & Lunell, 1993; Silagy et al., 2004). This may simply be due to the cross-sectional nature of the study, with more highly dependent smokers opting to use multiple NRT products in order to maintain nicotine levels to their pre-reduction state. Perhaps, as already mentioned, our measure of nicotine dependence was not reliable enough to counteract the confounding effects of this in the current study. Smokers also appeared to be combining NRT products in multiple ways, some of which may be advantageous while others less so. This is clearly an interesting area for future research.

If it is the case that nicotine patches are the least effective of all the NRT products, this is of concern, in light of the fact that it is the most commonly used product for smoking reduction and/or temporary abstinence. Previous clinical trials and survey-based studies have also reported a preference for the nicotine patch among smokers (Carpenter et al., 2003; Carpenter et al., 2004; Etter et al., 2002; Hammond et al., 2008; Shiffman et al., 2007a; Bansal et al., 2004). It may be that smokers find the patch easier to use and more familiar, in that the patch is one of the most popular products used to support smoking cessation (West et al., 2001b); along with smokers disregard for product information, in that the patch until recently was not licensed for such purposes. This clearly needs to be assessed further and smokers adequately informed about the effectiveness of the various NRT products.

Finally, the finding that those who were using NRT for smoking reduction and/or during periods of temporary abstinence were more likely to report having made a quit attempt in the past 12 months than those not using NRT for such reasons; suggests that the use of NRT for harm reduction purposes probably does not inhibit smokers from attempting to stop, and may encourage them to quit smoking. Intuitively, it may have been predicted that NRT use for temporary abstinence would not promote attempts to quit smoking, if we assume that it occurs simply because of smoke-free laws. The positive association may be because temporary abstinence acts as a sort of quit attempt, and through this, smokers learn that they can cope without cigarettes for several hours, or smokers may have been using NRT for temporary abstinence as a method of reduction. Only a few studies have assessed the association between NRT use for smoking reduction and/or temporary abstinence with attempts to quit smoking outside of clinical trials, either reporting no association or a positive association (Levy et al., 2007; Hammond et al., 2008). Those reducing their smoking with or without pharmacological help were also more likely to report an attempt to quit smoking than other smokers generally. This is in line with previous studies on spontaneous smoking reduction (Falba et al., 2004; Farkas, 1999; Hyland et al., 2005), indicating a potential benefit, although to a lesser extent, of simply reducing one’s cigarette consumption without the presence of medicinal nicotine.

Of interest, is that unlike cigarette consumption, all NRT products were positively associated with previous attempts to quit smoking. However, odds were lowest among users of the nicotine nasal spray for temporary abstinence and users of the gum for smoking reduction. This may be partially due to the underuse of these products as a direct result of their initial side-effects and embarrassment of nasal administration. It is perhaps surprising that although the gum resulted in the greatest reductions in cigarette consumption it did not promote cessation to the largest degree, since previous clinical trials have reported a positive association between the extent of reductions in cigarette intake and the odds of smoking cessation (Etter et al., 2002; Carpenter et al., 2004). Perhaps this only holds among those significantly cutting down their cigarette consumption, i.e. by 50% or more. Alternatively, it may be that gum users are a priori less nicotine dependent on cigarettes which materialises in a lower cigarette consumption than other smokers in cross-sectional analyses; although evidence appears to oppose this assumption (Hajek et al., 1988). Nevertheless, what can be taken from this is that the use of the nicotine patch, the preferred product for harm reduction, does not appear to have a detrimental effect on the likelihood of smokers attempting to quit.

As with all survey-based studies, there are certain limitations that apply to the Smoking Toolkit Study. First, the data presented are all estimates of smoking prevalence in the population. Although the Smoking Toolkit Study provides fairly similar estimates to other population-based surveys [For example:- the Health Survey for England and the General Lifestyle Survey (Fidler et al., 2011)], they may not fully reflect true smoking prevalence. This could be due to inaccuracies in the responses of participants (West, Zatonski, Prezewozniak & Jarvis, 2007), or perhaps a tendency for smokers to be less likely to agree to participate in such surveys in the first place. Secondly, response rates for the baseline surveys cannot be given due to the use of random location sampling – a structured form of conventional quota sampling – which unlike random probability sampling, gives interviewers the choice as to the properties sampled. Other limitations include the lack of data on ethnicity at baseline or follow-up and that the Smoking Toolkit Study is restricted to data from England, so cannot document the whole of the UK. The findings regarding NRT use specifically may also not be applicable to other countries with less liberal regulatory frameworks.

There are also a number of limitations that need to be considered in relation to the data used in the current chapter. In particular, the majority of the data were cross-sectional in nature, which limits the conclusions that can be drawn in relation to the association between NRT use for harm reduction purposes and attempts to quit smoking. Nonetheless, the finding in previous clinical trials that use of NRT for harm reduction purposes at baseline predicted quit attempts at follow-up, provides greater support for the conclusion that NRT use for harm reduction purposes increases smokers' propensity to quit (Moore et al., 2009), rather than NRT use being an after-effect of a failed quit attempt (Yong, Borland, Hyland & Siahpush, 2008). There is also evidence that quitting history is predictive of future quitting success, with previous quit attempts being associated with long-term abstinence from cigarettes, while the duration of the longest previous quit attempt appears to be positively related to the duration of the new one (Garvey, Bliss, Hitchcock, Heinold & Rosner, 1992; Hymowitz, Sexton, Ockene & Grandits, 1991; Borland, Owen, Hill & Schofield, 1991). Other limitations include the fact that smoking status was not objectively verified, although undesirable this does not appear to pose a major bias. The prevailing view is that the problem of misreporting is not sufficiently large to warrant routine biochemical verification in population surveys (Rebagliato, 2002). For example, reviews of studies have found that only a small percentage of self-declared non-smokers have elevated cotinine levels in population-based studies (Patrick et al., 1994). Biases may nonetheless prevail in self-reported cigarette consumption, on the basis of evidence that when respondents are asked how many cigarettes they smoke each day, there is a tendency to round the figure down to the nearest multiple of 10 (Kozlowski, 1986). Moreover, cigarette consumption is not a very good measure of actual toxin intake because smokers differ in how they smoke their cigarettes, i.e. their puff frequency (Griffiths, Henningfield & Bigelow, 1982). There was also a reliance on self-report to assess quitting behaviour retrospectively, which may have resulted in some recall bias or misreporting. There is evidence to suggest that large proportions of unsuccessful quit attempts fail to be reported, particularly if they only last a short time or occurred long ago (Berg et al., 2010b). Therefore, estimates of quit attempts may be considerably underestimated and estimates of the success of quit attempts may be overestimated. However, it is difficult to envisage that these biases would have led to the specific patterns of findings observed. The current measure of NRT use for temporary abstinence was also based only on those situations which were enforced, i.e. smoking was not allowed. Differing findings may occur in situations of what one may call voluntary temporary abstinence, i.e. the use of NRT for at home, where there may be more motivation for behaviour change.

The current results may also be confounded by a number of other variables not controlled for, including the amount of NRT used and the length of time smokers had been reducing their cigarette consumption or temporarily abstaining for. There is evidence that compliance to the NRT regimen is poor at a population level (Shiffman et al., 2002b; Shiffman et al., 2003a; Shiffman et al., 2003b), and this may be a factor in the failure to report lower consumption relative to those not using NRT. Moreover, although the measure of social-grade is a well-established approach to measuring socio-economic status, previous studies have noted variations in health outcomes when using other measures such as educational level and income (Braveman et al., 2005). Consequently, socio-economic differences could well be found among those using NRT for harm reduction if one of these alternatives is adopted. There is some evidence for this, with Hammond et al. (2008) only reporting variations in socio-economic status among those using NRT for harm reduction and those using NRT for smoking cessation when educational level but not income was assessed. However, some of these alternative measures tend to be highly biased. In terms of income, those with serious health problems often receive financial assistance, meaning that reverse causation problems are compounded (Disney, Grundy & Johnson, 1997). It is also a rather difficult measure, especially for older individuals whose income may come from a variety of sources. Lower response rates also occur for this indicator of socio-economic status (Department of Social Security, 1998). In contrast, measures of education are problematic in that most of today's older population left school at the minimum age with few academic qualifications. This means that the extent of differentiation possible is limited and education variables may only allow the most advantaged to be distinguished from the rest of the population.

Conclusion

The use of NRT for smoking reduction and/or during periods of temporary abstinence is quite common in England, with prevalence having remained relatively stable since 2007. It appears that the use of NRT for smoking reduction is more common among smokers who report a greater reliance on their cigarettes, while the use of NRT for temporary abstinence appears to be more common among younger female smokers and those with higher nicotine dependency. Although NRT use during attempts to cut down and momentary abstinence was not associated with reduced cigarette consumption relative to those not using NRT for such purposes, it was associated with higher odds of reporting a previous attempt to quit smoking. Of interest, is that the strength of these relationships varied as a function of the NRT product which was used, with the nicotine gum associated with the lowest cigarette consumption but also one of the lowest odds of an attempt to stop smoking. The findings lend support to the conclusion that the use of NRT by continuing smokers may not reduce harm from smoking but probably does not detract from attempting to stop and may promote it.

Chapter 8: The Combined use of Nicotine Replacement Therapy for Smoking Reduction and During Periods of Temporary Abstinence: A Re-Analysis of a National Survey of English Smokers

Introduction

There are a significant minority of smokers who report that they are attempting to reduce their cigarette consumption with NRT and at the same time also report that they are using NRT when they are unable to smoke (Levy et al., 2007; Hughes et al., 2005b[a]; see Chapter 7). This finding not only points towards the popularity of harm reduction approaches among a sub-set of smokers, but throws into light the possibility that the inclusion of this group in previous analyses may have masked the true independent effects of the use of NRT for smoking reduction and during periods of temporary abstinence. The failure to eliminate those using NRT for harm reduction purposes in the comparison groups may also have been a major confound, veiling any associations. Consequently, the present chapter aimed to ascertain whether similar findings emerge to those reported in Chapter 7, when those using NRT both as a means to reduce their cigarette consumption and during periods of temporary abstinence are excluded from the analysis, and where comparison groups consist of those not using NRT for any type of harm reduction. A secondary aim was to determine whether those using NRT for multiple purposes differ to those using NRT only to cut down or only when they are unable to smoke.

Both UK and American based studies have reported a prevalence of four to eight per cent for the concurrent use of NRT for smoking reduction and temporary abstinence (Levy et al., 2007; Hughes et al., 2002b; see Chapter 7). Because the US presently does not license NRT for harm reduction purposes, while the UK has a relatively liberal regulatory framework, it may be concluded that the combined use of NRT for harm reduction purposes is not dependent on the way in which medicinal nicotine products are governed (MHRA, 2010). The use of several harm reduction strategies has been noted previously by Okuyemi and colleagues in 2002. They found that a considerable number of smokers modified their smoking behaviour using at least two or three methods: intentionally limiting cigarettes; smoking less than half a cigarette; setting a daily limit; changing cigarette brand; reducing the number of cigarettes smoked; smoking only on some days; switching to lighter tar cigarettes; and not inhaling deeply. There is also evidence pointing towards the pervasiveness of multiple approaches among those striving to quit smoking (Prochaska & DiClemente, 1983; Baer, Foreyt & Wright, 1977). Baer and colleagues (1977) reported that among fifty-nine smokers, nineteen recalled using two techniques in a previous quit attempt, nine three techniques, and eleven more than four techniques. These included delaying smoking, externally imposing restrictions, environmental stimulus control, challenges from others, reinforcement, religious conversion and cost-benefit analysis. Moreover, concurrent strategies as a means to reduce harm have been demonstrated for other health behaviours including dietary restraint, self-harm, diabetes self-care and sexual health (Klesges, Elliott & Robinson, 1997; Jones, Purcell, Singh & Finer, 2005; Madge et al., 2008; Jones et al., 2003).

This overlap in tobacco harm reduction activities could be for a number of reasons: it may that those using NRT for smoking reduction and during periods of temporary abstinence are purely doing so as a means to use up excess NRT left over from a previous unsuccessful quit attempt; it may also reflect a generally favourable attitude towards NRT; or the result of smokers using periods of temporary abstinence as a means to reduce their cigarette consumption. There is evidence that many smokers hold a positive stance towards medicinal nicotine, with those using NRT for harm reduction purposes being more likely to use it as an aid during future attempts to quit smoking (Levy et al., 2007). Conversely, it is possible that some smokers who opt to use NRT for periods of time when they were unable to smoke may experience decreases in cigarette consumption as a by-product, leading them to report smoking reduction despite this not being a prior intention. Moreover, success in changing one or more lifestyle behaviours has been shown to increase self-efficacy to improve others (Prochaska, Spring & Nigg, 2008). Consequently, it may be the case that temporarily abstaining with NRT increases smokers' confidence and motivation to reduce their cigarette consumption, or vice versa.

It is of interest to determine whether the inclusion of those using NRT for both smoking reduction and temporary abstinence in previous studies, and the failure to control for the use of NRT for harm reduction in the comparison groups, may have impacted on the associations reported between attempts at harm reduction and socio-demographic and smoking characteristics. For example, in Chapter 7 it was reported that those attempting to cut down and those using NRT for temporary abstinence were more likely to be female. As a consequence, the substantial number of smokers who were reducing their smoking with NRT and using NRT for temporary abstinence may have precluded a difference in gender among those cutting down with and without pharmacological help. Such an analysis will allow firmer conclusions to be drawn regarding those smokers who may be the most receptive of the various harm reduction approaches. Moreover, if it is found that those using multiple forms of harm reduction differ to those using only one technique, this will have ramifications for future research, including the need to evaluate harm reduction practices besides those of interest. To date, only one previous study has assessed this, reporting differences in age, marital status, and ethnicity, amongst those using NRT to tide themselves over, those using NRT to reduce their consumption, and those using NRT for both of these purposes (Levy et al., 2007);

however, this study relied on the measurement of past ever use of NRT for harm reduction which may have resulted in spurious associations.

Nevertheless, there are numerous hypothesises as to why differences may occur. Based on the assumption that higher nicotine dependent smokers experience more withdrawal symptoms and cravings, heavier smokers may be more likely to use NRT both during attempts at smoking reduction and periods of temporary abstinence, relative to lighter smokers who can cope without pharmacological help (Killen et al., 1988). Use of NRT for temporary abstinence and smoking reduction may also be more prevalent amongst those of higher social-grades, who experience more frequent periods of momentary abstinence, are less inept at covering the costs of concurrent NRT and cigarette use, and hold greater concerns about their own health (Marmot, Ryff, Bumpass, Shipley &, Marks, 1997). Likewise, women and those of an older age tend to be more conscious about their well-being, which may lead them to experiment with multiple ways to reduce harm (Allgower et al., 2001; Nurmi, 1992).

It is of further interest to determine whether the inclusion of those using NRT for multiple purposes may have impacted on the associations reported previously between harm reduction approaches, attempts to quit smoking, and cigarette consumption. One may assume for instance that temporary abstinence in the majority of cases will be enforced, with smokers simply using medicinal nicotine as means to keep withdrawal symptoms at bay. Thus we would not predict NRT use for this purpose to be associated with attempts to quit smoking. The association reported previously between the use of NRT for temporary abstinence and quit attempts may be due to the inclusion of a group of smokers who are also concurrently using NRT as means to cut down, which is a behaviour more obviously associated with motivation to quit.

There is evidence that the adoption of multiple techniques in order to change behaviour is more efficacious than single approaches (Schwartz, 1992), while social cognition models recognise the diversity of behaviour, implicating various factors in the process of change (Rogers, 1983; DiClemente & Prochaska, 1982; Weinstein & Sandman, 1992; Ajzen, 1991; Risenstock, 1974). Moreover, the use of multiple harm reduction approaches appears to be associated with smoking fewer cigarettes per day and increased odds of reporting a previous attempt to quit smoking (Okuyemi et al., 2002; Levy et al., 2007). For example, Levy et al. (2007) established that those who had used NRT as a means to cut down and during periods of time when they were unable to smoke, were more likely to have made a quit attempt in the past year than those who had used NRT only to tide themselves over, but not relative to those who has used NRT as a means to reduce their cigarette consumption. However, they failed to report any differences among these three groups in smoking status or the likelihood of a reduction in cigarette consumption by 50% or more at two years follow-up.

If it is the case that the combined use of NRT is more efficacious at a population level, this may occur for a number of reasons. First it may be theorised that an increased quantity of NRT will be used amongst this group of smokers, ensuring that nicotine is topped up to a level closer to that of the smokers' pre-reduction state. This could result in greater suppression of urges to smoke and withdrawal symptoms, increasing smokers' self-efficacy in their ability to quit. It may also concurrently decrease the enjoyment of smoking via a dampening of the extent to which cigarettes cause relief. The amount of NRT used has been found to predict reductions in the number of cigarettes smoked per day (Hatsukami et al., 2007). Secondly, such smokers may simply be a priori more motivated to change their smoking behaviour compared to those using NRT only during attempts at smoking reduction or during periods of temporary abstinence; although they may also conversely have higher nicotine dependency, which could make reductions in cigarette consumption and quit attempts more difficult. Thirdly, we may assume that such smokers will be abstinent during the day for a longer period of time, giving more of an opportunity for a reduction in consumption to occur.

Methods

Study Design and Sampling

Data for this study were obtained between February 2007 and March 2011 from the Smoking Toolkit Study. See methods section in Chapter 7 for more details.

Ethical Approval

Ethical approval was granted by the University College London Research Ethics Committee.

Measures

Smoking status was assessed by asking: 'Which of the following best applies to you? – (I smoke cigarettes (including hand-rolled) every day; I smoke cigarettes (including hand-rolled), but not every day; I do not smoke cigarettes at all, but I do smoke tobacco of some kind (for example:- pipe or cigar); I have stopped smoking completely in the last year; I stopped smoking completely more than a year ago; I have never been a smoker (i.e. smoked for a year or more); don't know). Those who responded that they smoke cigarettes every day, or that they smoked but not every day, were coded as current cigarette smokers. Current smokers were asked questions about socio-demographic characteristics (i.e. gender, age & social-grade), cigarette consumption, and time to first cigarette of the day as a measure of nicotine dependence (Fagerstrom, 2003). Social-grade was classified as follows: AB=higher and intermediate professional/managerial; C1=supervisory, clerical, junior managerial/administrative/professional; C2=skilled manual workers; D=semiskilled and unskilled manual workers; E=on state benefit, unemployed, lowest grade workers.

Participants were also asked: 'Are you currently trying to cut down on how much you smoke' – (yes; no; don't know). In July 2009 this was changed to: 'Are you currently trying to cut down on how much you smoke but not currently trying to stop?' – (yes; no; don't know). If they answered 'yes' they were asked: 'Which, if any, of the following are you currently using to help you cut down the amount you smoke? – (nicotine patch; nicotine gum; nicotine lozenges/tablets; nicotine inhaler; nicotine nasal spray; I don't know; none of these; other). All smokers were asked: 'Do you regularly use any of the following in situations when you are not allowed to smoke? – (nicotine patch; nicotine gum; nicotine lozenges/tablets; nicotine inhaler; nicotine nasal spray; I don't know; none of these; other). Finally, they were asked: 'How many serious attempts to stop smoking have you made in the last 12 months?' Those reporting one or more quit attempts were classified as having made a quit attempt in the past year. For further information on the measures used in the Smoking Toolkit Study see www.smokinginengland.info.

Analysis

Parametric Assumptions

For regression analyses the assumption of 'non-multicollinearity' was assessed by calculating Tolerance Values and Variance Inflation Factors (Menard, 1995; Myers, 1990). A further four assumptions were assessed for least-squares regression: 'independent errors' using the Durbin-Watson test (Durbin & Watson, 1951); 'normality' using histograms and normal probability plots; and 'homoscedasticity' and 'linearity', using plots of the standardised residuals against predicted values (Levene, 1960). There was no evidence that these assumptions were violated. The assumption of 'linearity' for logistic regression analysis was assessed by calculating the interaction term between the predictor and its log transformation (Hosmer & Lemeshow, 1989). A non-linear relationship was established between age and NRT use for smoking reduction (β=0.001; Wald χ^2 (*df* 1)=12.069, $p<0.001$). Although there was a linear relationship between age and NRT use for temporary abstinence (β=0.000; Wald χ^2 (*df* 1)=0.048, $p>0.05$), and age and NRT use for both smoking reduction and temporary abstinence (β=0.000; Wald χ^2 (*df* 1)=0.459, $p>0.05$), age was categorised for all further analyses for consistency.

Finally, the assumption of 'normality' required for ANOVA analysis was assessed using the Kolmogorov-Smirnov (K-S) statistic, while 'homogeneity of variance' using Levene's statistic (Levene, 1960). Cigarette consumption was statistically non-normal among those using NRT for smoking reduction (D(1305)=0.162, $p<0.001$), those using NRT for temporary abstinence (D(1145)=0.187, $p<0.001$), and those using NRT for both purposes (D(1586)=0.174, $p<0.001$). Log and square root transformations were unsuccessful in correcting the non-normality that was present. Variances in cigarette consumption were found to be unequal among those using NRT for smoking reduction or temporary abstinence, and those using NRT for both of these purposes ($F(2, 4033)=4.283$, $p<0.01$). Square root transformations ($F(2, 4044)=0.624$, $p>0.05$) and log transformations ($F(2, 403)=2.455$, $p>0.05$) amended this heterogeneity. Because the large sample size means that the K-S test may be significant even when the distribution only differs slightly from normal, histograms and P-P plots were also calculated. These confirmed the non-normality present in the data for cigarette intake. Consequently, non-parametric tests were sought (see Appendix B).

Statistical Analysis

STROBE guidelines for the reporting of epidemiological studies were followed throughout (von Elm et al., 2007), with missing data dealt with prior to analysis using the listwise deletion procedure. For the reporting of prevalence data, an iterative marginal weighting technique was used in order to maximise the reliability of the sample data and minimise any statistical bias. This was achieved by performing the least amount of weighting required to correct for sample disproportionalities that may have distorted estimates. The process works by setting separate nationally representative target profiles for gender, working status, prevalence of children in the household, age, social-grade and region, and the process repeated until all variables match the specified targets.

Associations between the use of NRT for smoking reduction, the use of NRT for temporary abstinence, and the use of NRT for both of these purposes, with socio-demographic characteristics and nicotine dependency, were assessed by logistic regression analyses, using SPSS version 18.0. Logistic regression was also used to determine the association between attempts to quit smoking and NRT use for smoking reduction, NRT use for temporary abstinence and NRT use for both of these purposes; while least-squares regression was used to assess the association between cigarette consumption and the use of NRT amongst these three groups. This was undertaken with and without adjustment for socio-demographic variables and time to first cigarette of the day as a measure of dependence (Fagerstrom, 2003); 95% confidence intervals were used unless otherwise stated. To determine whether between-group differences in cigarette consumption, socio-demographic variables (i.e. age & social-grade) and nicotine dependency, existed among those using NRT for smoking reduction, those using NRT for temporary abstinence, and those using NRT for both purposes, Kruskal-Wallis tests were adopted. Post-hoc was conducted using multiple Mann-Whitney tests with the Bonferroni correction applied (effects are reported at 0.01 level of significance). Corresponding effect sizes were also calculated ($r = Z\ score/\sqrt{\text{total sample size}}$). Chi-squared analyses were used to assess differences among these three groups in reports of previous attempts to quit smoking and gender. To assess significance, standardised residuals were compared to the critical values that correspond to an alpha of 0.05 (+/-1.96), an alpha of 0.01

(+/-2.58) or an alpha of 0.001 (+/-3.10). Odds Ratios were then calculated where significance was evident.

Power

Post-hoc power analysis using G*Power 3 (Erdfelder, Faul & Buchner, 1996), revealed that for the assessment of the association between NRT use for smoking reduction with attempts to quit smoking, an Odds Ratio of 1.1 could be detected with 72% power using alpha 0.001, 91% power using an alpha of 0.01, while 98% power using an alpha of 0.05. For the assessment of the association between the use of NRT for temporary abstinence and attempts to quit smoking, an Odds Ratio of 1.1 could be detected with 97% power using alpha 0.001, 100% power using an alpha of 0.01, while 100% power using an alpha of 0.05.

Results

Between February 2007 and March 2011, 91,514 adults were surveyed; of whom, 20,188 reported that they were current smokers. Fifty-two per cent of the smokers were male (*n*=10,453) and 48.2% (*n*=9,735) female, with a mean age [Standard Deviation (*SD*)] of 40.5 (16.12) years. The percentages of participants residing in each social-grade were as follows: AB (15.5%; *n*=3,137), C1 (23.3%; *n*=5,101), C2 (24.6%; *n*=4,966), D (21.5%; *n*=4,334) and E (13.1%; *n*=2,649). The mean (*SD*) daily cigarette consumption was 13.1(8.47), with 32.6% (*n*=6,591) reporting smoking after 61 minutes of wakening, 13.8% (*n*=2,779) between 31 and 60 minutes after wakening, 33.4% (*n*=6,750) within 6-30 minutes of wakening and 19.8% (*n*=3,997) within 5 minutes of wakening. Thirty-five per cent (*n*=7,144) of smokers reported having made a quit attempt in the previous 12 months. Six per cent (*n*=1,246) of smokers reported that they were reducing their cigarette consumption with NRT but were not using NRT during periods of temporary abstinence, while 5.3% (*n*=1,060) reported that they were using NRT for temporary abstinence but were not using NRT for smoking reduction; seven per cent (*n*=1,487) were using NRT for both purposes.

Table 1 shows the characteristics of respondents when split into cohorts of interest. Table 2 shows the results of the regression analyses on this data. Women were more likely to report the use of NRT for smoking reduction, the use of NRT for temporary abstinence, and the use of NRT both during attempts to cut down and when they were unable to smoke. Those smokers of higher nicotine dependency were also more likely to report the use of NRT for smoking reduction or during periods of temporary abstinence, while those of a younger age were more likely to report the use of NRT for temporary abstinence, and were more likely to report the use of NRT for smoking reduction and temporary abstinence. In contrast, those aged 16-24 were less likely to report the use of NRT for smoking reduction relative to those aged 65+. No associations with social-grade were established.

Gender (χ^2=3.01 (*df* 2), *p*=0.222), age (χ^2=2.70 (*df* 2), *p*=0.259) and social-grade (χ^2=1.55 (*df* 2), *p*=0.460), did not vary amongst those using NRT for smoking reduction, those using NRT for temporary abstinence, or those using NRT for both purposes. In contrast, nicotine dependency did vary amongst these three groups (χ^2=66.27 (*df* 2), *p*=0.001). Those using NRT for temporary abstinence reported being more nicotine dependent than those using NRT for smoking reduction (*U*=627279.00; *r*=-0.15), and those using NRT both as a means to tide themselves over and to reduce cigarette consumption (*U*=778239.00; *r*=-0.13).

Table 3 shows the average cigarette consumption per day and percentage of smokers reporting a quit attempt in the previous 12 months as a function of NRT use for smoking reduction, use of NRT for temporary abstinence, and the use of NRT for both purposes. Table 4 shows the results of the regression analyses on this data. After adjusting for socio-demographic variables and time to first cigarette of the day, those using NRT for smoking reduction reported smoking on average 0.81 cigarettes more per day than those reducing their consumption without pharmacological help. Those using NRT for temporary abstinence also smoked on average 1.54 cigarettes more per day than those not using NRT for such purposes. In contrast, those using NRT during attempts to cut down and during periods of temporary abstinence smoked on average 0.82 cigarettes less per day than other smokers generally.

Table 1: Socio-Demographic Characteristics and Nicotine Dependency of Respondents as a Function of the use of Nicotine Replacement Therapy for Smoking Reduction, for Temporary Abstinence and for Both Purposes

	SR with NRT[a] vs SR without NRT[b] (*n*=1,246 vs *n*=7,983)		TA with NRT[c] vs TA without NRT[b] (*n*=1,060 vs *n*=16,395)		SR & TA with NRT[d] vs other smokers[b] (*n*=1,487 vs *n*=16,395)	
	SR with NRT	SR without NRT	TA with NRT	TA without NRT	SR & TA with NRT	SR & TA without NRT
Age %(*n*)						
16-24	15.4 (192)	21.6 (1,725)	18.2 (193)	21.0 (3,445)	19.3 (287)	21.0 (3,445)
25-34	19.0 (237)	21.8 (1,741)	18.1 (192)	20.7 (3,389)	19.2 (286)	20.7 (3,389)
35-44	25.1 (312)	20.6 (1,644)	25.5 (270)	20.8 (3,408)	21.2 (315)	20.8 (3,408)
45-54	18.4 (229)	15.9 (1,267)	18.5 (196)	16.6 (3,727)	19.1 (315)	16.6 (2,727)
55-64	13.5 (168)	12.0 (956)	12.5 (133)	11.8 (1,935)	14.2 (211)	11.8 (1,935)
65+	8.6 (107)	8.2 (651)	7.2 (76)	9.1 (1,491)	7.1 (105)	9.1 (1,491)
Gender %(*n*)						
Male	48.2 (600)	51.0 (4,071)	47.4 (502)	52.5 (8,606)	50.1 (746)	52.5 (8,606)
Female	51.8 (646)	49.0 (3,911)	52.6 (558)	47.5 (7,789)	49.9 (742)	47.5 (7,789)
Social-grade %(*n*)						
AB	15.7 (196)	15.5 (1,235)	14.5 (154)	15.4 (2,532)	17.1 (255)	15.4 (2,532)
C1	26.7 (332)	24.9 (1,986)	26.0 (275)	25.1 (4,114)	25.5 (380)	25.1 (4,114)
C2	25.9 (323)	25.0 (1,997)	23.2 (246)	24.7 (4,056)	22.9 (341)	24.7 (4,056)
D	18.2 (227)	21.8 (1,738)	22.3 (236)	21.7 (3,563)	20.7 (308)	21.7 (3,563)
E	13.4 (167)	12.9 (1,027)	14.0 (148)	13.0 (2,130)	13.7 (207)	13.0 (2,130)
Time to first cigarette %(*n*)						
>61 minutes	30.4 (378)	37.9 (3,013)	19.9 (211)	34.1 (4,476)	28.7 (437)	34.1 (4,476)
31-60 minutes	15.5 (193)	14.8 (1,179)	13.9 (147)	13.6 (2,216)	15.0 (223)	13.6 (2,216)
6-30 minutes	34.8 (433)	31.5 (2,507)	37.1 (392)	33.0 (5,384)	36.4 (541)	33.0 (5,384)
<5 minutes	19.2 (239)	15.8 (1,261)	29.1 (308)	19.3 (3,153)	20.0 (297)	19.3 (3,153)

Note: *n*=number; NRT=Nicotine Replacement Therapy; SR=smoking reduction; TA=temporary abstinence
Data weighted to match the 2001 census
[a] Excluding those using NRT for temporary abstinence
[b] Excluding those using NRT for smoking reduction and/or temporary abstinence
[c] Excluding those using NRT for smoking reduction
[d] Excluding those using NRT only for smoking reduction or only for temporary abstinence

Table 2: Association Between the use of Nicotine Replacement Therapy for Smoking Reduction, for Temporary Abstinence and for Both Purposes, With Socio-Demographic Characteristics and Nicotine Dependence

	SR with NRT[a] vs SR without NRT[b] (*n*=1,246 vs *n*=7,983)		TA with NRT[c] vs TA without NRT[b] (*n*=1,060 vs *n*=16,395)		SR & TA with NRT[d] vs other smokers[b] (*n*=1,487 vs *n*=16,395)	
	OR	(CI 95%)	*OR*	(CI 95%)	*OR*	(CI 95%)
Age (Reference category=65+)						
16-24	0.74*	0.58-0.95	1.14	0.88-1.48	1.24	0.99-1.54
25-34	0.88	0.70-1.10	1.23	0.96-1.58	1.34**	1.08-1.65
35-44	1.19	0.95-1.48	1.64***	1.29-2.09	1.47***	1.19-1.81
45-54	1.10	0.88-1.39	1.44**	1.12-1.84	1.58***	1.27-1.95
55-64	1.08	0.84-1.38	1.37*	1.05-1.78	1.61***	1.29-2.01
Gender (Female=1)	1.14*	1.01-1.28	1.23***	1.15-1.47	1.12*	1.01-1.24
Social-grade (Reference category=E)						
AB	1.06	0.85-1.31	1.07	0.85-1.34	1.07	0.88-1.29
C1	1.13	0.96-1.34	1.12	0.94-1.34	0.99	0.85-1.15
C2	1.04	0.88-1.23	1.01	0.85-1.20	0.88	0.76-1.03
D	0.89	0.74-1.07	1.02	0.85-1.22	0.90	0.76-1.05
Time to first cigarette (reference <5 minutes)						
>61 minutes	0.66***	0.56-0.78	0.40***	0.33-0.48	0.88	0.76-1.02
31-60 minutes	0.91	0.75-1.11	0.68***	0.56-0.83	1.02	0.94-1.34
6-30 minutes	0.89	0.75-1.04	0.78***	0.68-0.91	1.12	0.97-1.29

Note: *n*=number; *OR*=Odds Ratio; CI=confidence interval; NRT=Nicotine Replacement Therapy; SR=smoking reduction; TA=temporary abstinence

[a] Excluding those using NRT for temporary abstinence

[b] Excluding those using NRT for smoking reduction and/or temporary abstinence

[c] Excluding those using NRT for smoking reduction

[d] Excluding those using NRT only for smoking reduction or only for temporary abstinence

Significant difference between groups (*** $p<0.001$, ** $p<0.01$, *$p<0.05$)

Adjusted for age, gender, social-grade and time to first cigarette of the day

The use of NRT for smoking reduction and/or temporary abstinence was also associated with higher odds of reporting an attempt to quit smoking in the previous 12 months, with and without adjustment for potential confounding variables. Those using NRT for smoking reduction were three times more likely to report a quit attempt than those reducing their smoking without NRT. Those using NRT for temporary abstinence were also almost three times as likely to report a past quit attempt compared to other smokers generally, while those using NRT both during attempts at smoking reduction and during periods of temporary abstinence were seven times as likely to report a quit attempt in the previous 12 months.

Table 3: Reports of Average Cigarette Consumption and Previous Attempts to Quit Smoking Among Respondents as a Function of the use of NRT for Smoking Reduction, for Temporary Abstinence and for Both Purposes

	SR with NRT[a] vs SR without NRT[b] (*n*=1,246 vs *n*=7,983)		TA with NRT[c] vs TA without NRT[b] (*n*=1,060 vs *n*=16,395)		SR & TA with NRT[d] vs other smokers[b] (*n*=1,487 vs *n*=16,395)	
	SR with NRT	SR without NRT	TA with NRT	TA without NRT	SR & TA with NRT	SR & TA without NRT
Cigarette consumption per day M(*SD*)	13.1 (7.82)	11.7 (7.41)	16.0 (8.65)	13.0 (8.53)	12.5 (7.87)	13.0 (8.53)
Quit attempt in the previous 12 months %(*n*)	67.0 (833)	40.2 (3,200)	50.5 (534)	28.6 (4,684)	73.7 (1,093)	28.6 (4,684)

Note: *n*=number; NRT=Nicotine Replacement Therapy; SR=smoking reduction; TA=temporary abstinence; *SD*=Standard Deviation; M=mean
Data weighted to match the 2001 census
[a] Excluding those using NRT for temporary abstinence
[b] Excluding those using NRT for smoking reduction and/or temporary abstinence
[c] Excluding those using NRT for smoking reduction
[d] Excluding those using NRT only for smoking reduction or only for temporary abstinence

Cigarette consumption was found to vary as function of whether NRT was used for smoking reduction, for temporary abstinence or for both purposes (χ^2=140.92 (*df* 2), *p*=0.001). The use of NRT for smoking reduction (*U*=595344.50; *r*=-0.18), and the use for both smoking reduction and temporary abstinence (*U*=684317; *r*=-0.22), was associated with lower cigarette consumption than the use of NRT solely as a means to tide one over. The use of NRT for both purposes was also associated with lower consumption than the use of NRT for smoking reduction (*U*=985528.50; *r*=-0.05). Reports of an attempt to quit smoking were also found to differ among these three groups (χ^2=155.83 (*df* 2), *p*=0.001). This seems to represent the fact that based on the Odds Ratios [*OR*; Confidence Interval (CI)], that those using NRT for smoking reduction were 84% (*OR* 1.84; CI 1.57-2.17) more likely to report a quit attempt than those using NRT for temporary abstinence, while those using NRT for both purposes were 48% (*OR* 1.48; CI 1.26-1.74) more likely to report a quit attempt than those using NRT for smoking reduction.

Table 4: Association Between the use of Nicotine Replacement Therapy for Smoking Reduction, for Temporary Abstinence and for Both Purposes, With Cigarette Consumption and Previous Attempts to Quit Smoking

	Unadjusted			Adjusted[e]		
	SR with NRT[a] vs SR without NRT[b] (*n*=1,246 vs *n*=7,983)	TA with NRT[c] vs TA without NRT[b] (*n*=1,060 vs *n*=16,395)	SR & TA with NRT[d] vs other smokers[b] (*n*=1,487 vs *n*=16,395)	SR with NRT[a] vs SR without NRT[b] (*n*=1,246 vs *n*=7,983)	TA with NRT[c] vs TA without NRT[b] (*n*=1,060 vs *n*=16,395)	SR & TA with NRT[d] vs other smokers[b] (*n*=1,487 vs *n*=16,395)
	OR CI (95%)	*OR* CI (95%)	*OR* CI (95%)	*OR* CI (95%)	*OR* CI (95%)	*OR* CI (95%)
Quit attempt in the previous 12 months	2.84*** 2.51-3.20	2.62*** 2.34-2.96	7.18*** 6.34-8.07	3.01*** 2.67-3.40	2.67*** 2.38-3.05	7.34*** 6.69-8.48
	β CI (95%)	β CI (95%)	β CI (95%)	β CI (95%)	β CI (95%)	β CI (95%)
Cigarette consumption per day	1.39*** 0.95-1.84	2.78*** 2.27-3.33	-0.58* -1.21-(-)0.43	0.81*** 0.42-1.20	1.54*** 1.09-2.00	-0.82*** -1.27 (-) -0.43

Note: *n*=number; *OR*=Odds Ratio; β=beta coefficient; CI=confidence interval; NRT=Nicotine Replacement Therapy; SR=smoking reduction; TA=temporary abstinence

[a] Excluding those using NRT for temporary abstinence

[b] Excluding those using NRT for smoking reduction and/or temporary abstinence

[c] Excluding those using NRT for smoking reduction

[d] Excluding those using NRT only for smoking reduction or only for temporary abstinence

Significant difference between groups (*** *p*<0.001, ** *p*<0.01, **p*<0.05)

Discussion

Six per cent of smokers reported that they were reducing their cigarette consumption with the aid of NRT, five per cent that they were using NRT for periods of temporary abstinence, and seven per cent that they were using NRT for both of these purposes. Women and those of higher nicotine dependency appeared to be more likely to report the use of NRT for smoking reduction or temporary abstinence, relative to those doing each of these without pharmacological help. It also appeared that whereas those using NRT for temporary abstinence were less likely to be of an older age, that those using NRT for smoking reduction were less likely to report being of a very young age relative to those cutting down without pharmacological help. The use of NRT for both smoking reduction and temporary abstinence was also more common among women and those of a younger age. Although no between-group differences in socio-demographic characteristics were reported, those using NRT for temporary abstinence appeared to have a higher nicotine dependency than those using NRT for smoking reduction and those using NRT for multiple harm reduction purposes. Whereas the use of NRT for smoking reduction or temporary abstinence was associated with higher cigarette consumption than those cutting down or temporarily abstaining without NRT, those using NRT for both purposes smoked on average one cigarette less per day than other smokers. All three behaviours were positively associated with attempts to quit smoking. Between-group differences in cigarette consumption and quit attempts were established, with those using NRT for multiple harm reduction purposes smoking fewer cigarettes per day and being more likely to report a quit attempt in the previous year. Those using NRT for smoking reduction also smoked less and reported a previous quit attempt more often than those using NRT during periods of temporary abstinence.

Even after controlling for the combined use of NRT for harm reduction purposes, and any use in the comparison groups, those with a higher nicotine dependency were more likely to report the use of NRT for periods of temporary abstinence or for smoking reduction. This is in line with previous studies reporting that NRT use is more prevalent amongst those who smoke within 30 minutes of wakening (Heatherton et al., 1989; Cummings, Hyland, Ockene, Hymowitz & Manley, 1997; Levy et al., 2007). This has substantial implications for the interpretation of findings from preceding survey-based studies. Since it appears that those who are less reliant on cigarettes have greater success at smoking cessation (Pinto, Abrams, Monti & Jacobus, 1987; Hill et al., 1994), the failure to control for nicotine dependency may well have led to the underestimation of the propensity of NRT for harm reduction purposes to increase smokers' motivation to quit. The finding that women and those of a younger age were more likely to report the use of NRT for temporary abstinence is also in line with the findings from Chapter 7; however, an association also prevailed between the use of NRT for smoking reduction and gender, and a weaker association was found between NRT use for smoking reduction and age. This suggests that the inclusion of those using NRT for multiple purposes may have masked the true associations present between demographic characteristics and attempts at harm reduction.

These findings are consistent with those by Levy et al. (2007), who also controlled for the combined use of NRT. Consequently, future studies assessing socio-demographic correlates of NRT use for smoking reduction should adequately control for NRT use for periods of temporary abstinence and vice versa. Moreover, because age and gender are significant predictors of attempts to quit smoking, there is a need to ensure that these are adequately controlled for in future analyses; failure to do so could confound any relationship reported between the use of NRT for harm reduction and abstinence (Hymowitz et al., 1997). Another repercussion of these findings is that those who use NRT for smoking cessation and harm reduction purposes appear to be very similar (Zhu et al., 2000; Kotz et al., 2009). Thus harm reduction strategies may not be capturing the attention of a chronic set of smokers who it is aimed at, i.e. those who are unwilling or unable to quit smoking. Any harm reduction policy or intervention needs to take this into account, and focus attention on encouraging those least receptive of such an approach.

Interestingly, there did not appear to be any significant difference among those using NRT for smoking reduction, those using NRT for temporary abstinence, and those using NRT for both these purposes, in terms of socio-demographic characteristics. These findings are generally in line with those reported previously. Levy et al. (2007) found no difference in gender or social-grade, but that those who had used NRT for smoking reduction were older than those who had used NRT to tide themselves over or for both purposes. This latter finding may have been due to the measurement of past versus current use of NRT for harm reduction; the use of continuous versus dichotomous or ordinal variables (MacCallum, Zhang, Preacher & Rucker, 2002); the sample selected; the decision to choose a control group of smokers not attempting any form of harm reduction; and the questions used to assess the use of NRT for smoking reduction and/or periods of temporary abstinence. For example, Levy et al. (2007) evaluated the use of NRT for temporary abstinence by asking smokers if they had ever used NRT when they were not trying to quit but had to delay smoking for some reason, in contrast to asking smokers in the current study whether they used NRT when they were unable to smoke; the latter of which focuses more so on enforced periods of abstinence. However, differences in nicotine dependency were noted, with those using NRT during periods of time when they were unable to smoke being more reliant on cigarettes than those using NRT for multiple harm reduction purposes. This is opposite to the hypothesis that heavier smokers would be more likely to use NRT both as means to cut down and during momentary abstinence, under the assumption that they experience more withdrawal symptoms and cravings than lighter smokers (Killen et al., 1988). Of course, due to the cross sectional nature of this study, it is possible that this reflects a reduction in dependency amongst those using NRT for both purposes, and that they were a priori more dependent on cigarettes. It is perhaps less surprising that those using NRT for temporary abstinence were more dependent than those using NRT for smoking reduction, since it may be assumed that smokers highly reliant on cigarettes would require pharmacological aid when they were unable to smoke, with lighter smokers being able to abstain relatively comfortably for short periods of time.

Interestingly, after controlling for the combined use of NRT during attempts at smoking reduction and during periods of temporary abstinence, cigarette consumption was significantly higher among those using NRT for smoking reduction or temporary abstinence relative to those not using NRT for such purposes. The combined use of NRT in contrast was associated with lower cigarette consumption relative to other smokers generally. This certainly points towards the possibility that the use of NRT for smoking reduction or temporary abstinence at a population level does not decrease cigarette consumption, and that smokers should perhaps be encouraged to use NRT for multiple harm reduction purposes. Of course, it does appear that those who use NRT for harm reduction may be a priori more dependent on cigarettes; thus even if the use of NRT resulted in decreased consumption over time, we may not see evidence of this in cross-sectional data if it remains higher than that of other smokers. Cigarette consumption is also not that strongly correlated with actually toxin intake (Perez-Stable, Benowitz & Marin, 1995). Consequently, it cannot be ruled out that those using NRT for harm reduction purposes may instead modify how they smoke their cigarettes.

In the between-group analysis, those using NRT for smoking reduction and temporary abstinence were also found to smoke fewer cigarettes than those using NRT for only one of these purposes. This finding is consistent with previous data (Okuyemi et al., 2002), and may reflect either that those using NRT for several reasons experience a reduction in consumption over time as a result of higher levels of NRT use (Hatsukami et al., 1997); that such smokers are a priori more motivated to change their smoking behaviour; or that those using NRT for multiple purposes are abstinent more often, allowing them to learn that they can manage without cigarettes for extended periods of time. Prospective data are required to disentangle these possible hypotheses. Future research should also assess whether the combined use of other harm reduction approaches is advantageous. There is some evidence that the use of oral tobacco and varenicline is effective during attempts to cut down (Ebbert, Croghan, North & Schroeder, 2010).

It is of further interest that those using NRT for harm reduction were still more likely to report a quit attempt following the exclusion of those using NRT for both smoking reduction and temporary abstinence. Nevertheless, the odds were decreased. Moreover, those using NRT for both purposes were seven times as likely to report a quit attempt than other smokers generally, and significantly more likely to have quit smoking in the past year than those using NRT only during attempts to cut down or for periods of temporary abstinence. Levy et al. (2007) reported similar findings. Although further prospective research is necessary, these findings point towards the possibility that the use of NRT for smoking reduction or temporary abstinence may increase the propensity of smokers to quit, and that the combined use of NRT for both purposes may augment these odds further.

As with the previous cross-sectional study, the current study suffers from a number of limitations. Self-report of quit attempts and smoking status may be inaccurate due to recall bias and social desirability. However, it is unclear how these may have resulted in the current pattern of findings. The determination of cause and effect is also difficult in cross-sectional data such as these. For example, the association between the use of NRT for smoking reduction and quit attempts could be due to NRT increasing motivation to quit; that both manifest from a general tendency to try and mitigate the harmful effects of smoking; or that those who make a quit attempt and relapse are more likely to opt to use NRT as a means to cut down their cigarette consumption. The survey was also designed to assess a wide range of tobacco-related issues, not NRT use for harm reduction specifically, resulting in questions that were limited in scope. For example, it is unclear whether smokers interpreted the question used to assess smoking reduction as intended, i.e. cutting down as a goal in itself as opposed to gradual cessation. It may also be that smokers had initially brought NRT to aid an attempt to stop smoking, but since they had not quit at the time of the baseline survey, reported instead that they were attempting to cut down. It has been suggested previously that some of the commonly reported demographic disparities in health-related indices may in fact be attributable to differences in perceptions of the meanings of survey questions (Andersen, Mullner & Cornelius, 1987; Angel & Thoits, 1987). Thus research is required to determine how smokers interpret questions on harm reduction to ensure the reliability of the current results. Finally, although the survey is representative of English smokers, findings may not generalise to countries with less liberal regulatory NRT frameworks.

Conclusion

It appears that around six per cent of smokers are using NRT for smoking reduction, five per cent are using NRT for temporary abstinence, and seven per cent are using NRT for both of these purposes. These three groups did not differ in terms of socio-demographic characteristics; however, those using NRT during momentary abstinence did appear to have a higher nicotine dependency. Although the use of NRT for smoking reduction or temporary abstinence was not associated with lower cigarette consumption, the use of NRT for both of these purposes was. Moreover, although all three behaviours were positively related with attempts at cessation, the use of NRT for smoking reduction and temporary abstinence was associated with the highest odds a quit attempt in the previous year. Thus it appears that failing to control for those using NRT for multiple harm reduction purposes may have a significant effect on reported associations with cigarette intake and attempts to stop smoking.

Chapter 9: A 'Split-ballot' Approach to Assess the Influence of Question Wording on Reports of Attempts at Smoking Reduction: A National Survey of English Smokers

''A question's form amplifies and diminishes tendencies people have to agree or disagree, to speak openly or save face, and to feel threatened or comfortable. Question asking is a skill, and changes in word choice, suggested responses, presumptions, and form affect answers people provide . . . . . Question wording puts words in answerers' mouths'' (Kellermann, 2007; pp. 1)

Introduction

Contradictory findings among previous population-based surveys assessing the use of NRT for smoking reduction and/or temporary abstinence (see Chapter 6) do not appear to be dependent on country of origin, despite differing regulatory frameworks (Hammond et al., 2007; Shahab et al., 2009). Although partially explained by recruitment and study design variations, another pivotal factor may well be differences in the questions used to assess whether smokers were using NRT for harm reduction purposes. The current chapter aimed to take a first step in ascertaining whether this could be the case, by using a split-ballot approach, whereby smokers were either asked if they were reducing their cigarette consumption or if they were cutting down without an intention to quit smoking. Differences in the prevalence of the use of NRT for smoking reduction, socio-demographic characteristics, cigarette consumption, and previous attempts to quit smoking, were determined among these two groups.

It has long been established that the format of questions influences the replies given, since the numerous question-wording experiments in the 1940s and 1950s. This includes the context of the question, range of alternative answers presented, and deviations from wording (Cantril, 1944; Payne, 1951). Moreover, it is of little doubt that individual belief systems, prior experience, emotional state and current circumstance, influence judgements which are made (Plous, 1993). A now classic example comes from an experiment conducted by Loftus and Palmer (1974) on the reliability of eyewitness testimony. Following the viewing of a video car crash, participants who were asked *''How fast were the cars going when they smashed into each other?''*, were consistently found to reported a higher estimate of speed than when smashed was replaced by collided, bumped, hit or contacted.

The importance of question formatting has subsequently been recognised within social and health research. For example, Fowler in a pivotal book *'Improving Survey Questions: Design and Evaluation'*, noted that one of the challenges to good question development is: *''Ensuring that all respondents have a shared common understanding of the meaning of the question. Specifically, all respondents should have the same understanding of the key terms of the question, and their understanding of those terms should be the same as that intended by the person writing the question''* (Fowler, 1995; pp. 9). According to leading experts, this may be a particular problem when assessing smoking prevalence, beliefs about cigarette consumption, and smoking-related health indices (Hannestad, Rortveit, Daltveit & Hunskaar, 2003; West & Schneider, 1987; Ross & Perez, 1998; Blaxter, 1987), with a handful of studies demonstrating the confounding effects of question design (Brener, Grunbaum, Kann, McManus & Ross, 2004; Mullen, Carbonari, Tabak & Glenday, 1991; Suessbrick, Schober & Conrad, 2001). For example, individuals have been shown to interpret smoking cigarettes as anything from (a) taking even a single puff to (b) cigarettes they have finished, and from (c) cigarettes they have borrowed to (d) only those they have bought; with 10% of answers changing from yes to no, or no to yes, when smokers are given a standard definition of what counts as smoking a cigarette (Suessbrick, Schober & Conrad, 2001). Moreover, slight changes to questions, questionnaire type, and whether smokers are given multiple response or dichotomous response categories, appears to influence the number reporting various smoking-related behaviours (Brener et al., 2004; Mullen et al., 1991). Applying this to surveys on harm reduction, it is quite plausible that previous variations among studies are at least partially attributable to variations in measurement and question format.

Although there is evidence that smokers can reduce their cigarette consumption spontaneously (Bjorson et al., 1999; Hughes et al., 1999; Farkas, 1999; Godtfredsen et al., 2002; Meyer et al., 2003; Falba et al., 2004; Mooney et al., 2011), and that this may increase their propensity to quit smoking (Hill et al., 1988; Hughes et al., 1999; Meyer et al., 2003; Farkas et al., 1999; Hyland et al., 2005; Hughes et al., 2004a; Falba et al., 2004), substantial inter-study variation exists. For example, Bjornson et al. (1999) reported that a large majority of smokers in their sample reduced their cigarette consumption by 50% or more, while West et al. (2001) reported reductions in the range of only one to two cigarettes per day. These discrepancies may be for a number of reasons: the use of cross-sectional versus prospective data; length of follow-up; the extent of control over confounding variables; and the choice of comparison groups. Alternatively, differences in measurements may be held to account, specifically the failure to stipulate the reasons for reductions in cigarette consumption. It appears that smokers are more interested in reducing their smoking with an end goal of cessation, rather than as a means of continuing smoking at a reduced level (Shiffman et al., 2007a; Hughes, Callas & Peters, 2007; Orleans, Rimer, Chistinzio, Keintz & Fleisher, 1991); thus those studies failing to stipulate that smoking reduction should not involve any quitting intention, may well have resulted in the recruitment of those reducing with an aim to quit, rather than those reducing for harm reduction purposes. Moreover, because survey questions on harm reduction often occur in cloud of those on smoking abstinence, smokers could have a strong tendency to view smoking reduction as synonymous with cessation. This may occur especially where a question is ill defined, with smokers perhaps assuming it is related in some way with attempts to quit smoking, particularly as there has been historical bombardment of cessation only approaches in society. Previous research has noted that we respond to questions using the context in which they are presented (Plous, 1993). The classic example is that of the 'halo effect' demonstrated in an experiment in the 1920s, in which army supervisors evaluated their officers' intelligence using contextual features including their physique and general character (Thorndike, 1920).

If it is the case that studies assessing harm reduction activities are recruiting smokers with an intention to quit, this could be a major confound. Not only are those with a goal to quit smoking gradually more motivated to stop smoking than those simply attempting to cut down (Peters, Hughes, Callas & Solomon, 2007), but meta-analyses have consistently reported that gradual reduction as a route to abstinence is nearly as efficacious as abrupt cessation (Law & Tang, 1995; Lindson, Aveyard & Hughes, 2010). Moreover, previous survey-based studies which separated those cutting down to quit and those cutting down for harm reduction purposes, only established an increase in the propensity to quit smoking among the former group (West et al., 2001a). On the other hand, there is evidence that unplanned quit attempts, as would most likely be the case among those cutting down without a specific intention to quit smoking, demonstrate more success than planned ones (Ferguson, Shiffman, Gitchell, Sembower & West, 2009; Larabie, 2005; West & Sohal, 2006). The idea behind this is that smokers are inconsistent planners, with those acting at the point in time when they want to quit smoking being more likely to do so (West et al., 2009). In other words, planning ahead is counterproductive.

Such a failure may also account for the variation among studies interested in the use of NRT as an aid to smoking reduction. Amongst those foundering to determine whether smoking reduction was a goal in itself or as a route to smoking cessation, some reported a superiority of NRT for cutting down in relation to both attempts to quit smoking and reductions in cigarette consumption, while others that consumption was higher than those not using NRT for such purposes (Etter et al., 2002; Hughes et al., 2004a; Hughes et al., 2004b[a]). In contrast, the only study to assess the use of NRT for smoking reduction without an intention to quit smoking, reported higher consumption among those using NRT to cut down and no association with a 50% reduction or more in cigarette intake (Levy et al., 2007). Those using NRT for smoking reduction were nonetheless more likely to have made a previous quit attempt but were no more likely to be abstinent at follow-up. Moreover, there is substantial variation in the reported prevalence of NRT use for harm reduction purposes (see Chapter 6), which may also be attributable to question formatting disparities.

If it is the case that previous studies have recruited those who are reducing with a goal of cessation, this could be of concern to policy makers; many of which have already used the positive association noted between attempts at smoking reduction and smoking cessation to inform health policy about the potential importance of implementing a harm reduction approach (MHRA, 2010). However, this would only occur if it is shown that those reducing without an intention to quit smoking are less likely to be abstinent than the general population, or where those using NRT for smoking reduction without an intention to stop smoking have a lower propensity to quit than those reducing without NRT. Although, methodologically speaking, even a slight difference in the odds of abstinence would point towards the need for caution in future surveys.

One method of assessing whether differences in question format may account for the previous discrepancies in research on tobacco harm reduction, is with the 'split-ballot' or 'split-half' technique. This involves alternative forms of a question being administered to comparable samples of respondents, with the main analysis being the comparison of the marginal distributions of answers to the different question forms (Cantril, 1944; Payne, 1951). According to Petersen (2002; pp. 151): *"No other instrument can reliably demonstrate the diverse effects of questionnaire monotony, the cognitive processes involved in grasping and* *interpreting question wording, fluctuating attention levels, heuristic processing of information, suggestive signals imparted by scale categorises, or implicit threats that are subjectively perceived by respondents''*. This method was most popular during the 1940s, having gained new prominence in recent years in both policy and health research (Kalton, Collins & Brook, 1978; Godenhjelm, Honkanen & Ahvonen, 2005; Herek, Capitanio & Widaman, 2003; Schuman & Kalton, 1985; Schuman & Presser, 1981).

A useful analysis would therefore be to compare smokers responding to a question asking if they are reducing their cigarette consumption, to those who report smoking reduction in response to a question stipulating that reductions must occur without an intention to quit smoking. If those responding to the former are not found to differ to those responding to the latter, we may conclude that smokers are interpreting the questions in the same way, and potentially as intended for harm reduction purposes, i.e. reduction as a means in itself. Consequently, any prior inter-study variation may be due more so to other factors, such as study design and recruitment. In contrast, if respondents are found to differ, it may be concluded that previous variations in the associations between smoking reduction and the use of NRT for smoking reduction with clinical outcomes, are in part due to the methodologies used to assess smoking reduction; with the recruitment of those perhaps with and without a prior motivation to quit smoking, versus those who are unwilling or unable to do so. If this is the case, it would be of further interest to assess whether those reporting smoking reduction in response to these differing questions both demonstrate superiority in the propensity to quit smoking relative to other smokers generally, and those who report using NRT for harm reduction relative to those cutting down without pharmacological help. There is evidence that differences exist among those using NRT for harm reduction purposes and those doing so as a means to cut down prior to smoking cessation; with the prior being more nicotine dependent, less ethnically diverse and less likely to smoke low tar cigarettes (Shiffman et al., 2007a). On the basis of this, it appears possible to distinguish these two groups.

Methods

Study Design and Sampling

Data for this study were obtained between November 2006 and March 2011 from the Smoking Toolkit Study. See methods section in Chapter 7 for more details.

Ethical Approval

Ethical approval was granted by the University College London Research Ethics Committee.

Measures

Smoking status was assessed by asking: ‘Which of the following best applies to you? – (I smoke cigarettes (including hand-rolled) every day; I smoke cigarettes (including hand-rolled), but not every day; I do not smoke cigarettes at all, but I do smoke tobacco of some kind (for example:- pipe or cigar); I have stopped smoking completely in the last year; I stopped smoking completely more than a year ago; I have never been a smoker (i.e. smoked for a year or more); don’t know). Those who responded that they smoke cigarettes every day, or that they smoked but not every day, were coded as current cigarette smokers. Current smokers were asked questions about socio-demographic characteristics (i.e. gender, age & social-grade), cigarette consumption per day, and time to first cigarette of the day as a measure of nicotine dependence (Fagerstrom, 2003). Social-grade was classified as follows:

AB=higher and intermediate professional/managerial; C1=supervisory, clerical, junior managerial/administrative/professional; C2=skilled manual workers; D=semiskilled and unskilled manual workers; E=on state benefit, unemployed, lowest grade workers.

Between November 2006 and June 2009 participants were asked: ‘Are you currently trying to cut down on how much you smoke?’ – (yes; no; don’t know), while between July 2009 and March 2011 participants were asked: ‘Are you currently trying to cut down on how much you smoke but not currently trying to stop?’ – (yes; no; don’t know). Those responding during the prior waves were categorised as Group1 and the latter as Group2, with smokers reporting attempts at smoking reduction referred to as SR1 and SR2 respectively. SR1 and SR2 were additionally asked: ‘Which, if any, of the following are you currently using to help you cut down the amount you smoke? – (nicotine patch; nicotine gum; nicotine lozenges/tablets; nicotine inhaler; nicotine nasal spray; I don’t know; none of these; other). Those reporting the use of NRT for smoking reduction in Group1 are defined as NRTSR1 and those in Group2 as NRTSR2. Finally, all participants were asked: ‘How many serious attempts to stop smoking have you made in the last 12 months?’ Those reporting one or more quit attempts were classified as having made a quit attempt in the past year. For further information on the measures used in the Smoking Toolkit Study see www.smokinginengland.info.

Analysis

Parametric Assumptions

For regression analyses the assumption of ‘non-multicollinearity’ was assessed by calculating Tolerance Values and Variance Inflation Factors (Menard, 1995; Myers, 1990). A further four assumptions were assessed for least-squares regression: ‘independent errors’ using the Durbin-Watson test (Durbin & Watson, 1951); 'normality' using histograms and normal probability plots; and 'homoscedasticity' and 'linearity', using plots of the standardised residuals against predicted values (Levene, 1960). There was no evidence that these assumptions were violated. The assumption of 'linearity' for logistic regression analysis was assessed by calculating the interaction term between the predictor and its log transformation (Hosmer & Lemeshow, 1989). A non-linear relationship was established between age and smoking reduction among those in Group1 (β=-0.001; Wald χ^2 (*df* 1)=32.478, $p<0.001$), and Group2 (β=-0.001; Wald χ^2 (*df* 1)=8.452, $p<0.01$). The association between age and NRT use for smoking reduction among those in Group1 (β=0.001; Wald χ^2 (*df* 1)=10.814, $p<0.001$) was also non-linear. Although there was a linear relationship between age and NRT use for smoking reduction among those in Group2 (β=0.001; Wald χ^2 (*df* 1)=2.955, $p>0.05$), for clarity age was categorised for all further analyses.

Finally, the assumption of 'normality' required for *t*-test analysis was assessed using the Kolmogorov-Smirnov (K-S) statistic, while 'homogeneity of variance' using Levene's statistic (Levene, 1960). Cigarette consumption and age were non-normal among those in Group1 (D(13211)=0.063, $p<0.001$ versus D(13211)=0.144, $p<0.001$) and Group2 (D(9282)=0.075, $p<0.001$ versus D(9282)=0.145, $p<0.001$). Cigarette consumption was also non-normal among SR1 (D(7474)=0.167, $p<0.001$) and SR2 (D(4878)=0.166, $p<0.001$); and among SRNRT1 (D(1859)=0.167, $p<0.001$), and SRNRT2 (D(1204)=0.172, $p<0.001$). Variances in cigarette consumption were unequal among SRNRT1 and SRNRT2 (F=4.742, $p<0.05$). Heterogeneity was also evident among those in Group1 and Group2 in terms of age (F=5.996, $p<0.01$). Heterogeneity was resolved for the unequal variances in cigarette consumption among SRNRT1 and SRNRT2 using square root (F=0.812, $p>0.05$) and log transformations (F=0.001, $p>0.05$). Since the large sample size means that the K-S test may be significant even when the distribution only differs slightly from normal, histograms and P-

P plots were also calculated. These confirmed the non-normality present in the data for cigarette consumption. Since square root and log transformations were unsuccessful, non-parametric tests were sought (see Appendix C).

Statistical Analysis

STROBE guidelines for the reporting of epidemiological studies were followed throughout (von Elm et al., 2007), with missing data dealt with prior to analysis using the listwise deletion procedure. For the reporting of prevalence data, an iterative marginal weighting technique was used in order to maximise the reliability of the sample data and minimise any statistical bias. This was achieved by performing the least amount of weighting required to correct for sample disproportionalities that may have distorted estimates. The process works by setting separate nationally representative target profiles for gender, working status, prevalence of children in the household, age, social-grade and region, and the process repeated until all variables match the specified targets

Differences among those in Group1 and Group2 in terms socio-demographic characteristics, nicotine dependence, cigarette consumption, and previous attempts to quit smoking, were assessed using Mann-Whitney and Chi-squared tests. Mann-Whitney and Chi-squared analyses were also used to determine differences amongst those classified as SR1 and SR2, and those classified as SRNRT1 and SRNRT2, in terms of socio-demographic characteristics, nicotine dependence, cigarette intake, and previous attempts to stop smoking. For Mann-Whitney tests corresponding effect sizes were also calculated (r=Z score/$\sqrt{\text{total}}$ sample size). To assess significance of the Chi-squared tests, standardised residuals were compared to the critical values that correspond to an alpha of 0.05 (+/-1.96), an alpha of 0.01 (+/-2.58) or an alpha of 0.001 (+/-3.10). Odds Ratios were then calculated where significance was evident. Associations between smoking reduction, and the use of NRT for smoking reduction, with past quit attempts, cigarette consumption and socio-demographics and smoking characteristics, were determined by logistic regression analyses and least-squares regression analyses. This was undertaken separately for those in Group1 and those in Group2, with adjustments for socio-demographic variables and time to first cigarette of the day as a measure of dependence (Fagerstrom, 2003); 95% confidence intervals were used unless otherwise stated. SPSS version 18.0 was adopted for all analyses.

Power

Post-hoc power analysis using G*Power 3 (Erdfelder, Faul & Buchner, 1996), revealed that for the assessment of differences in cigarette consumption among those classified as SR1 and SR2, an effect size of 0.1 could be detected with 99% power using alpha 0.001, 100% power using an alpha of 0.01, while 100% power using an alpha of 0.05. For the assessment of differences in cigarette consumption among those classified as SRNRT1 and SRNRT2, an effect size of 0.1 could be detected with 32% power using alpha 0.001, 62% power using an alpha of 0.01, while 84% power using an alpha of 0.05.

Results

Between November 2006 and June 2009, 55,144 adults were surveyed, while 41,597 were surveyed between July 2009 and March 2011; of which 12,735 (Group1) and 8,774 (Group2) respectively were current smokers. Characteristics of these two samples are given in Table 1. Group1 were 6% more likely to be female (χ^2=15.248 (*df* 1), *p*=0.001; Odds Ratio (*OR*) 1.06; Confidence Interval (CI) 1.01-1.12), 27% more likely to have made a quit attempt (χ^2=73.441 (*df* 1), *p*=0.001; *OR* 1.27; CI 1.20-1.34), were more likely to report being of a higher social-grade (*U*=60340000.00, *p*=0.001; *r*=-0.03), to smoke more cigarettes per day

(U=59760000.00, p=0.001; r=-0.03), and to have lower nicotine dependency (U=59480000.00, p=0.001; r=-0.03), than those in Group2. No difference in age was established (U=61570000.00; p=0.206).

Table 1: Socio-Demographic Characteristics and Nicotine Dependency of Respondents in Group1 and Group2

	Group1[a] (*n*=12,735)	Group2[b] (*n*=8,774)
Age M(*SD*)	40.2 (16.12)	40.7 (16.10)
Cigarette consumption per day M(*SD*)***	13.3 (8.43)	12.8 (8.51)
Gender %(*n*)***		
Male	51.2 (6,522)	52.7 (4,620)
Female	48.8 (6,213)	47.3 (4,154)
Social-Grade %(*n*)***		
AB	15.2 (1,937)	16.0 (1,408)
C1	24.7 (3,151)	25.7 (2,259)
C2	24.8 (3,164)	24.6 (2,158)
D	22.7 (2,887)	20.0 (1,754)
E	12.5 (1,597)	13.6 (1,195)
Time to first cigarette of the day %(*n*)***		
>60 minutes	37.5 (4,766)	28.1 (2,454)
31-60 minutes	8.9 (1,132)	18.9 (1,647)
5-30 minutes	33.8 (4,289)	33.2 (2,900)
<5 minutes	19.8 (2,520)	19.8 (1,730)
Quit attempt in the previous 12 months M(*SD*)	38.1 (4,844)	32.6 (2,859)

Note: *n*=number; M=mean; *SD*=Standard Deviation; *n*=number
Data were weighted to match the 2001 census
Significant difference between groups (***p<0.001, **p<0.01, *p<0.05)
[a] Group1: Participants recruited between November 2006 and June 2009
[b] Group2: Participants recruited between July 2009 and March 2011

Fifty-seven per cent (n=7,195) of smokers in Group1 reported that they were reducing their cigarette consumption in response to the question 'Are you currently trying to cut down on how much you smoke?' (SR1). In contrast, 52.8% (n=4,630) of smokers in Group2 reported that they were reducing their cigarette consumption in response to the question 'Are you currently trying to cut down on how much you smoke but not currently trying to stop?' (SR2). Of these, 24.6% (n=1,769; SRNRT1) and 24.5% (n=1,136; SRNRT2) respectively, were using NRT to aid their attempts at smoking reduction. Table 2 shows the socio-demographic and smoking characteristics of these factions. Table 3 shows the results of the regression analyses on this data. Both Group1 and Group2 who reported that they were reducing their cigarette consumption were more likely to be female, aged 55-64, of a lower nicotine dependency and of social-grade C1 and C2 than other smokers. In contrast, Group1 and Group2 who reported using NRT for smoking reduction appeared to be more nicotine dependent than those reducing without pharmacological help. Those using NRT in Group1 were also more likely to report being over the age of 65 than to report being 16-24, and to report being of social-grade AB than E. In contrast, those using NRT in Group2 were more likely to report being 25-54 than over 65 years of age.

Assessment of the differences among SR1 and SR1, showed that SR1 tended to be of lower social-grade (U=17850000.00, p=0.02, r=-0.03), were less nicotine dependent (U=17470000.00, p=0.001; r=-0.04), and more likely to be female (χ^2=6.271 (*df* 1), p=0.012). No difference in age was found (U=18080000.00; p=0.077). In contrast, there was no evidence of a difference in gender (χ^2=0.376 (*df* 1), p=0.540), age (U=1120350; p=0.775) or nicotine dependence (U=1087497.00; p=0.115) among SRNRT1 and SRNRT2. However, those categorised as SRNRT1 tended to report being of lower social-grade (U=1072097.50, p=0.019; r=-0.04).

Table 4 shows the percentage of quit attempts and average cigarette consumption among those cutting down and using NRT for smoking reduction. Table 5 shows the results of the regression analyses on this data. Those in Group1 and Group2 who were reducing their smoking were four times more likely to report a quit attempt and smoked a few cigarettes less than other smokers. Both those in Group1 and Group2 who were using NRT for smoking reduction were also more likely to report an attempt to quit smoking than those cutting down without NRT. However, whereas SRNRT1 smoked 0.33 cigarettes more per day, there was no difference in consumption among those in Group2 who were and were not using NRT.

Table 2: Socio-Demographic Characteristics and Nicotine Dependency of Respondents as a Function of Smoking Reduction and the use of Nicotine Replacement Therapy for Smoking Reduction

	SR vs no SR (Group1[a]) (n=7,195 vs n=5,540)		SR vs no SR (Group2[b]) (n=4,630 vs n=4,144)		SR with NRT vs SR without NRT (Group1[a]) (n=1,769 vs n=5,426)		SR with NRT vs SR without NRT (Group2[b]) (n=1,136 vs n=3,494)	
	SR (SR1)	No SR	SR (SR2)	No SR	SR with NRT (SRNRT1)	SR without NRT	SR with NRT (SRNRT2)	SR without NRT
Age %(n)								
16-24	21.2 (1,526)	20.7 (1,147)	20.1 (931)	19.6 (814)	17.6 (312)	22.4 (1,214)	17.6 (200)	20.9 (731)
25-34	21.3 (1,531)	19.1 (1,057)	20.7 (960)	19.8 (821)	20.3 (360)	21.6 (1,171)	18.1 (206)	21.6 (754)
35-44	21.5 (1,546)	21.6 (1,194)	20.7 (959)	21.3 (884)	22.1 (392)	21.3 (1,154)	23.2 (263)	19.9 (696)
45-54	16.6 (1,193)	16.6 (921)	16.9 (782)	17.9 (741)	19.0 (336)	15.8 (857)	18.9 (214)	16.3 (568)
55-64	11.5 (831)	12.1 (668)	13.5 (626)	11.6 (480)	12.7 (225)	11.2 (606)	15.2 (172)	13.0 (455)
65+	7.9 (569)	9.9 (548)	8.0 (372)	9.7 (403)	8.2 (145)	7.8 (424)	7.0 (80)	8.3 (291)
Gender %(n)								
Male	49.9 (3,588)	53.0 (2,933)	51.4 (2,382)	54.0 (2,237)	48.8 (863)	50.2 (2,725)	50.3 (571)	51.8 (1,811)
Female	50.1 (3,606)	47.0 (2,630)	48.6 (2,249)	46.0 (1,905)	51.2 (906)	49.8 (2,700)	49.7 (565)	48.2 (1,684)
Social-grade %(n)								
AB	15.2 (1,091)	15.3 (845)	16.4 (758)	15.7 (650)	16.8 (297)	14.6 (794)	16.5 (188)	16.3 (570)
C1	25.4 (1,828)	23.9 (1,322)	25.2 (1,169)	26.3 (1,091)	25.9 (459)	25.2 (1,369)	25.6 (291)	25.1 (878)
C2	24.3 (1,748)	25.6 (1,416)	25.3 (1,173)	23.8 (985)	23.6 (417)	24.5 (1,331)	25.6 (291)	25.3 (883)
D	22.7 (1,638)	22.6 (1,250)	19.3 (895)	20.7 (858)	21.3 (376)	23.2 (1,260)	17.5 (198)	19.9 (697)
E	12.4 (892)	12.7 (703)	13.7 (635)	13.5 (559)	12.4 (220)	12.4 (672)	14.8 (168)	13.4 (468)
Time to first cigarette %(n)								
>61 minutes	40.7 (2,919)	33.4 (1,844)	29.6 (1,366)	26.4 (1,087)	33.7 (97)	42.9 (2,323)	25.3 (287)	31.0 (1,079)
31-60 minutes	9.8 (701)	7.8 (430)	20.5 (945)	17.1 (702)	10.9 (192)	9.4 (509)	19.8 (224)	20.7 (721)
5-30 minutes	32.4 (2,325)	35.6 (1,964)	33.1 (1,529)	33.3 (1,370)	36.1 (639)	31.2 (1,686)	34.9 (396)	32.6 (1,134)
<5 minutes	17.4 (1,234)	23.3 (1,284)	16.8 (776)	23.3 (954)	19.3 (341)	16.5 (893)	20.0 (227)	15.8 (549)

Note: *SD*=Standard Deviation; M=mean; *n*=number; NRT=Nicotine Replacement Therapy; SR=smoking reduction; TA=temporary abstinence; SR(NRT)1=reporting attempts at smoking reduction (with NRT) among those in Group1; SR(NRT)2=reporting attempts at smoking reduction (with NRT) among those in Group2.
Data were weighted to match the 2001 census
[a] Group1: Participants recruited between November 2006 and June 2009
[b] Group2: Participants recruited between July 2009 and March 2011

Table 3: Association Between Smoking Reduction and the use of Nicotine Replacement Therapy for Smoking Reduction With Socio-Demographic Characteristics and Nicotine Dependence

	SR (SR1) vs no SR (Group1[a]) (*n*=7,195 vs *n*=5,540)		SR (SR2) vs no SR (Group2[b]) (*n*=4,630 vs *n*=4,144)		SR with NRT (SRNRT1) vs SR without NRT (Group1[a]) (*n*=1,769 vs *n*=5,426		SR with NRT (SRNRT2) vs SR without NRT (Group2[b]) (*n*=1,136 vs *n*=3,494)	
	OR	(CI 95%)	*OR*	(CI 95%)	*OR*	(CI 95%)	*OR*	(CI 95%)
Age (Reference category >65)								
16-24	0.92	(0.82-1.03)	0.97	(0.85-1.11)	0.77*	(0.62-0.96)	1.03	(0.82-1.28)
25-34	1.01	(0.90-1.12)	1.04	(0.91-1.19)	0.92	(0.75-1.12)	1.37**	(1.10-1.70)
35-44	1.01	(0.90-1.14)	1.00	(0.87-1.15)	1.02	(0.84-1.26)	1.40**	(1.12-1.74)
45-54	1.04	(0.91-1.18)	0.92	(0.79-1.07)	1.08	(0.87-1.33)	1.32*	(1.04-1.68)
55-64	1.40***	(1.23-1.60)	1.37***	(1.17-1.61)	1.08	(0.86-1.35)	0.96	(0.73-1.27)
Gender (Female=1)	1.13***	(1.06-1.22)	1.17***	(1.08-1.27)	1.05	(0.95-1.17)	1.10	(0.96-1.25)
Social-Grade (Reference category=E)								
AB	1.13	(0.99-1.29)	1.06	(0.91-1.23)	1.22*	(1.00-1.49)	0.98	(0.77-1.24)
C1	1.05	(0.95-1.17)	1.15*	(1.02-1.29)	1.12	(0.96-1.30)	1.01	(0.84-1.22)
C2	1.11*	(1.00-1.23)	1.03	(0.92-1.16)	0.99	(0.85-1.16)	0.96	(0.80-1.16)
D	1.03	(0.93-1.15)	1.12	(0.99-1.27)	0.93	(0.79-1.10)	0.87	(0.72-1.07)
Time to first cigarette of the day (Reference category=<5 minutes)								
>61 minutes	1.71***	(1.55-1.88)	1.65***	(1.46-1.86)	0.68***	(0.59-0.79)	0.68***	(0.55-0.82)
31-60 minutes	1.35***	(1.24-1.47)	1.16**	(1.04-1.29)	1.01	(0.82-1.24)	0.80*	(0.65-0.99)
5-30 minutes	0.97	(0.85-1.11)	0.94	(0.83-1.07)	1.00	(0.86-1.16)	0.86	(0.71-1.03)

Note: *n*=number; *OR*=Odds Ratio; CI=confidence interval; NRT=Nicotine Replacement Therapy; SR=smoking reduction; TA=temporary abstinence; SR(NRT)1=reporting attempts at smoking reduction (with NRT) among those in Group1; SR(NRT)2=reporting attempts at smoking reduction (with NRT) among those in Group2.
Significant difference between groups (***$p<0.001$, **$p<0.01$, *$p<0.05$)
Adjusted for age, gender, social-grade and time to first cigarette of the day
[a] Group1: Participants recruited between November 2006 and June 2009
[b] Group2: Participants recruited between July 2009 and March 2011

Table 4: Reports of Average Cigarette Consumption and Percentage of Previous Attempts to Quit Smoking Among Respondents as a Function of Smoking Reduction and the use of Nicotine Replacement Therapy for Smoking Reduction

	SR (SR1) vs no SR (Group1[a]) (*n*=7,195 vs *n*=5,540)		SR (SR2) vs no SR (Group2[b]) (*n*=4,630 vs *n*=4,144)		SR (SRNRT1) with NRT vs SR without NRT (Group1[a]) (*n*=1,769 vs *n*=5,426)		SR (SRNRT2) with NRT vs SR without NRT (Group1[b]) (*n*=1,136 vs *n*=3,494)	
	SR	No SR	SR	No SR	SR with NRT	SR without NRT	SR with NRT	SR without NRT
Quit attempt in the previous 12 months %(*n*)	50.8 (3,652)	21.6 (1,192)	45.8 (2,115)	18.0 (7,44)	72.7 (1,283)	43.7 (2,369)	68.6 (778)	38.3 (1,337)
Cigarette consumption per day M(*SD*)	12.7 (7.61)	14.8 (9.18)	11.8 (7.67)	14.0 (9.41)	13.1 (7.34)	11.9 (7.43)	12.3 (7.48)	11.7 (7.46)

Note: *SD*=Standard Deviation, M=mean; *n*=number; NRT=Nicotine Replacement Therapy; SR=smoking reduction; TA=temporary abstinence; SR(NRT)1=reporting attempts at smoking reduction (with NRT) among those in Group1; SR(NRT)2=reporting attempts at smoking reduction (with NRT) among those in Group2.
Data were weighted to match the 2001 census
[a] Group1: Participants recruited between November 2006 and June 2009 [b] Group2: Participants recruited between July 2009 and March 2011

Table 5: Association Between Smoking Reduction and the use of Nicotine Replacement Therapy for Smoking Reduction With Cigarette Consumption and Previous Attempts to quit smoking

	Unadjusted				[a] Adjusted			
	SR vs no SR (Group1[b]) (*n*=7,195 vs *n*=5,540)	SR vs no SR (Group2[c]) (*n*=4,630 vs *n*=4,144)	SR with NRT vs SR without NRT (Group1[b]) (*n*=1,769 vs *n*=5,426)	SR with NRT vs SR without NRT (Group2[c]) (*n*=1,136 vs *n*=3,494)	SR vs no SR (Group1[b]) (*n*=7,195 vs *n*=5,550)	SR vs no SR (Group2[c]) (*n*=5,530 vs *n*=4,144)	SR with NRT vs SR without NRT (Group1[b]) (*n*=1,769 vs *n*=5,426)	SR with NRT vs SR without NRT (Group1[c]) (*n*=1,136 vs *n*=3,494)
	OR β CI(95%)	*OR* (CI 95%)	*OR* CI(95%)	*OR* CI(95%)	*OR* CI(95%)	*OR* CI(95%)	*OR* CI(95%)	*OR* CI(95%)
Quit attempts in the previous 12 months	3.80*** 3.52-4.11)	3.91*** (3.55-4.30)	1.85*** (1.75-1.96)	1.84*** (1.72-1.97)	3.86*** (3.57-4.18)	3.96*** (3.60-4.36)	1.90*** (1.80-2.02)	1.86*** (1.73-1.99)
	β CI(95%)	β CI(95%)	β CI(95%)	β CI(95%)	β CI(95%)	β CI(95%)	β CI(95%)	β CI(95%)
Cigarette consumption per day	-2.71*** (-3.00-(-)2.41)	-2.37*** (-2.72-(-)2.02)	0.64*** (0.34-0.84)	0.29* (0.04-0.54)	-1.80*** (-2.06-(-)1.54)	-1.59*** (-1.89-(-)1.28)	0.33** (0.15-0.15)	0.02 (-0.20-0.23)

Note: *OR*=Odds Ratio; *n*=number; CI=confidence interval; β=beta coefficient; NRT=Nicotine Replacement Therapy; SR=smoking reduction; TA=temporary abstinence; SR(NRT)1=reporting attempts at smoking reduction (with NRT) among those in Group1; SR(NRT)2=reporting attempts at smoking reduction (with NRT]) among those in Group2.
Significant difference between groups (*** $p<0.001$, ** $p<0.01$, * $p<0.05$)
[a] Adjusted for age, gender, social-grade and time to first cigarette of the day
[a] Group1: Participants recruited between November 2006 and June 2009 [b] Group2: Participants recruited between July 2009 and March 2011

The comparison of those reporting attempts to cut down and the use NRT for smoking reduction in Group1 and Group2, showed that SR1 had a higher cigarette consumption (*U*=17890000.00, *p*=0.019; *r*=-0.02), but were more likely to have made a quit attempt compared to those categorised as SR2 (χ^2=30.381 (*df* 1), *p*=0.001; Odds Ratio (*OR*) 1.57; Confidence Interval (CI) 1.45-1.69). SRNRT1 also had a higher cigarette consumption (*U*=1066580.00, *p*=0.014; r=-0.04), and were more likely to report a previous quit attempt than SRNRT2 (χ^2=7.779 (*df* 1); *p*=0.005; *OR* 1.21; CI 1.03-1.43).

Discussion

A four per cent lower prevalence of smoking reduction was found amongst smokers who were asked if they were cutting down without an intention to quit smoking relative to those asked only if they were cutting down their cigarette consumption. In contrast, there was little difference in the prevalence of NRT use for smoking reduction amongst these two groups. Moreover, this slight variation in question format appeared to tap into different populations. Those reporting smoking reduction in response to the question asking only if they were attempting to cut down were more likely to be female, of a lower social-grade and nicotine dependency, and to have higher cigarette consumption and greater odds of a past attempt to quit smoking. Those reporting the use of NRT for smoking reduction were also found to differ depending on whether they were asked if they were cutting down or cutting down without a motivation to quit; the prior being of lower social-grade, smoking more cigarettes per day and being more likely to report an attempt to stop smoking. It is interesting, that smoking reduction, regardless of the way in which it was assessed, was associated with lower cigarette consumption, greater odds of an attempt to quit smoking in the previous year, a higher likelihood of being female and aged 55-64, and with a higher odds of being social-grade C1-C2 and of a lower nicotine dependency, than other smokers generally. Similarly, the use of NRT for smoking reduction was associated with higher odds of an attempt to quit smoking and greater nicotine dependency, regardless of whether smokers were asked if they were intending to quit. In contrast, those reporting NRT use in response to the question asking about smoking reduction only, were found to smoke more cigarettes per day, with some evidence that they were older and of higher socio-economic status; while those responding to the question also assessing intention to quit were found to smoke a similar number of cigarettes per day and to be younger than those not using NRT for such purposes.

In line with previous studies it appears that question format can impact on reports of the prevalence of smoking behaviour (Brener et al., 2004; Mullen et al., 1991; Suessbrick, Schober & Conrad, 2001). Where the question assessing smoking reduction was more general, a greater number of smokers reported that they were cutting down than when the pre-requisite that reduction must occur without an intention to quit was incorporated. If this is the case, future surveys assessing harm reduction need to ensure that smokers are only classified as cutting down if they are reducing as a goal in itself; not only will this prevent skewed prevalence data, but it will also ensure that those making policy decisions are correctly informed. Even a few percentage change in those reporting attempts at harm reduction could well be the difference in whether or not an approach reaches a threshold to be deemed worthy of consideration (Parrott, Godfrey, Raw, West & McNeill, 1998). However, this finding is highly confounded by the temporal nature of the study. Over the past few years there has seen a decline in the prevalence of smokers reporting attempts to cut down (see Chapter 7); thus the variation in the number of smokers attempting smoking reduction amongst Group1 and Group2 may well be attributed to this rather than question format. To resolve these issue future studies should aim to use a 'split-ballot' approach at the same point in time.

Interestingly, variations were found to exist amongst smokers reporting attempts at harm reduction in response to the question assessing smoking reduction only, and those reporting attempts to cut down in response to a question assessing smoking reduction without an intention to stop smoking. This is in line with previous research reporting that slight deviations in question format tap into different facets of the same phenomenon (Cantril, 1944; Payne, 1951). These differences may have occurred as a consequence of the smokers recruited, i.e. smokers reducing their smoking as a means to quit versus those reducing for harm reduction purposes, with the former only being excluded when intentions to quit are assessed. This is supported by the finding of disparities between the two groups in terms of nicotine dependence and attempts to quit, which coincide with findings reported previously amongst those reducing as a goal in itself and those attempting gradual cessation (Shiffman et al., 2007a; Peters et al., 2007). The current findings also appear to point towards the possibility that those reporting NRT use for smoking reduction without an intention to quit smoking may be of higher social-grades than those reporting NRT use as means to cut down but where intention to quit was not assessed. The one previous study to compare NRT use for abstinence and harm reduction did note that those using NRT for the latter tended to be of higher socio-economic status than those using NRT as a means to quit smoking (Hammond et al., 2008).

Consequently, it may be concluded that contradictory findings in previous surveys could be attributed to differences in the methodologies used to assess harm reduction (Bjorson et al., 1999; Hughes et al., 1999; Farkas, 1999; Godtfredsen et al., 2002; Meyer et al., 2003; Falba et al., 2004; Mooney et al., 2011; Hill et al., 1988; Hughes et al., 1999; Meyer et al., 2003; Farkas et al., 1999; Hyland et al., 2005; Hughes et al., 2004a; Falba et al., 2004; Hammond et al., 2008; Etter et al., 2002; Hughes et al., 2004b[a]; Hughes et al., 2004b[b]; Levy et al., 2007). This may apply particularly to cigarette consumption. It is rather counterintuitive that smoking reduction with NRT has sometimes been associated with higher cigarette intake, whereas it would be assumed that NRT would help to mitigate the tendency of smokers to compensate for the reduction in nicotine, resulting in a decline in cigarette consumption over time. Although partially due to the utilisation of cross-sectional data, it appears plausible that this may be attributed to the failure to restrict analyses to those not intending to quit smoking.

However, there is a concern that these differences may in part be due to characteristic changes of smokers over time. For example, those recruited in Group1 were more likely to be female, to smoke more cigarettes per day, and to be of lower dependency than those in Group2; as were those reporting smoking reduction in Group1 relative to those reporting smoking reduction without an intention to quit in Group2. Even if this were not the case, differences between groups were relatively small, and possibly detected due to the large sample size. Importantly, even when only those reducing with an intention to quit were included in the analysis, smoking reduction was still associated with an increased propensity to quit smoking relative to other smokers, and the use of NRT for smoking reduction with greater odds of a previous quit attempt compared to those reducing their intake without pharmacological help. This provides further endorsement for the provision of NRT for harm reduction purposes amongst those unable or unwilling to stop smoking, with the possibility that it may have beneficial effects on their motivation to quit. Moreover, such smokers do not appear to have higher cigarette consumption than other smokers generally, lending support to the negation of the concern of a negative impact of NRT use on smokers' cigarette intake. These findings also provide support for the view that females of a younger age and lower dependency have a greater interest in smoking reduction, while among this group, that those with higher dependency are more likely to opt to use NRT.

Taking this into consideration, it may be concluded that if question format does effect reported associations between harm reduction activities and smoking variables, and the prevalence of these activities, that this may only explain very small discrepancies, i.e. differences in a few cigarettes smoked per day. Consequently, previous variations between studies may be attributed more to differences in study design, i.e. recruitment method, choice of control group and study setting. The main implication of this, is that previous studies that have failed to ensure analyses were restricted to those unwilling or unable to quit smoking can still be used as evidence for a harm reduction approach; thus those involved in policy decisions can be re-assured. However, future researchers would be advised to adequately consider the questions they use, how they could affect responses, and perhaps develop a standardised taxonomy in order to allow accurate between study comparisons (Nielsen, Buckingham, Knoll, Marsh & Palen, 2008).

There are also a number of limitations with the current data which require consideration. First it is possible that other formatting differences than those investigated here, and which have been implicated in study variation, may have contributed to the reported discrepancies in harm reduction research (Brener et al., 2004; Mullen et al., 1991). Consequently, the impact of these needs to be assessed before firmer conclusions can be drawn. For example, questions with familiar words appear to be answered more accurately than questions with unfamiliar words (Blair, Sudman, Bradburn & Stocking, 1977). There is evidence that 'smoking reduction' is more proverbial among smokers as opposed to 'cutting down' (Richter et al., 2002), as such, consideration should be given to the use of the prior. Secondly, cigarette consumption and attempts to quit smoking were self-reported. However, it is hard to envisage how this would have resulted in the current findings. Thirdly, the data were cross-sectional in nature and so caution should be taken when drawing strong conclusions regarding cause and effect. For example, it is possible that those who reported smoking reduction in response to a question only asking if they were cutting down may have had higher odds of a past quit attempt, not because attempts to cut down induce motivation to quit, but because such individuals are more likely to relapse and consequently decided to reduce their cigarette consumption. This can only really be resolved with a prospective analysis. Fourthly, it is clear that the temporary nature of the study may have confounded the findings reported, with a need for split-ballot approaches occurring at one point in time. Finally, the current study failed to consider the potential misinterpretation of questions about temporary abstinence. It is possible that smokers may use NRT during periods of temporary abstinence either as means to tide them over, to reduce consumption, or as a practice quit attempt. It would be of interest to assess in what ways smokers interpret the term and whether this influences associations with smoking-related variables. Temporary abstinence is also clearly multi-faceted. Asking smokers if they have to abstain at work or when travelling may be interpreted differently to asking if they abstain at home or in the pub; the prior of which is likely to be enforced while the later voluntary.

Conclusion

Modification of the question used to assess smoking reduction, i.e. asking smokers if they were cutting down or if they were cutting down without an intention to quit smoking, appeared to tap into slightly different populations. Those reporting smoking reduction in relation to the former were more likely to have attempted to quit smoking in the past year and had a higher cigarette consumption. They were also more likely to be of lower social-grade, less likely to be male and were less nicotine dependent. In contrast, those reporting the use of NRT for smoking reduction without an intention to quit smoking were less likely to be of a high social-grade, had lower cigarette consumption, and lower odds of reporting a previous attempt to quit smoking, relative to those using NRT to cut down and whose intention to quit was not assessed. However, these differences were relatively small. Moreover, regardless of the question used, those reporting attempts at smoking reduction had a lower cigarette intake and greater odds of a quit attempt relative to other smokers generally. Those using NRT for smoking reduction, regardless of the question used, were also more likely to report a quit attempt than those cutting down without NRT. In contrast, whereas those responding to a question asking if they were cutting down without an intention to quit smoking reported a lower cigarette consumption than those attempting smoking reduction without NRT, those asked only if they were cutting down reported a higher consumption. Although this study is limited by its cross-sectional nature and temporal analysis, these findings point towards the possibility that variations between previous studies are only partially dependent on differences in question format.

Chapter 10: The use of Nicotine Replacement Therapy for Smoking Reduction and During Periods of Temporary abstinence: A Prospective National Survey of English Smokers

''Yesterday is not ours to recover, but tomorrow is ours to win or lose'' (Johnson, 1963)

Introduction

Clinical trials have consistently demonstrated that the use of NRT for smoking reduction results in significant decreases in cigarette consumption and can move smokers towards a successful quit attempt (Batra et al., 2005; Bolliger et al., 2000; Carpenter et al., 2003; Carpenter et al., 2004; Etter et al., 2004; Rennard et al., 2006; Wennike et al., 2003; Haustein et al., 200; Joseph et al., 2008; Wood-Baker, 2001; Tonnesen et al., 2005; Chan et al., 2011). It is important to determine whether the use of NRT for smoking reduction or to aid temporary abstinence has a similar effect at a population level. Studies which have assessed this so far have tended to be cross-sectional in nature, reporting that the spontaneous use of NRT for harm reduction purposes does not undermine cessation and may actually increase smokers' propensity to quit. In contrast, the reliable reductions in cigarette consumption appear to be confined to the highly controlled setting of the clinical trials, with those using NRT for harm reduction purposes smoking more cigarettes per day than other smokers (Etter et al., 2003; Hammond et al., 2008; Hughes et al., 2004b[a]; see Chapters 7-9).

A major issue with data such as these is that the associations could be for a number of reasons: it may be that NRT use for harm reduction does not induce reliable reductions; or that those who use NRT during attempts to cut down and periods of temporary abstinence are more nicotine dependent, which could preclude any determination of a decrease in cigarette intake. Similarly, associations with previous attempts to quit smoking could reflect NRT's ability to increase smokers' motivation to quit, or that those who relapse are more likely to opt to use NRT during an attempt to cut down. A better test is to examine how the far use of NRT for harm reduction purposes predicts quit attempts and cigarette consumption prospectively. Finding a positive association would not prove that the use of NRT for harm reduction results in an increased likelihood of cessation, but it would provide real-world evidence in support of the findings from the randomised controlled trials. It would also militate strongly against the view of any negative impact of NRT for harm reduction on cessation. Thus the current chapter aimed to ascertain the association between the use of NRT for smoking reduction and temporary abstinence with subsequent attempts to quit smoking, the success of those quit attempts, and cigarette consumption, in a general population sample of English Smokers. A secondary aim was to determine the stability of NRT use for such purposes, since a lack of stability may explain the failure to establish significant declines in cigarette intake in previous studies.

Although many studies have assessed the associations prospectively between cessation and cigarette consumption with unaided smoking reduction, reporting an increased propensity to quit smoking and reduced cigarette consumption among those attempting to cut down (for example:- Hughes et al., 2004a; Farkas, 1999; Hyland et al., 2005; Falba et al., 2004); only two small studies have examined the associations between cigarette intake and quit attempts with the use of NRT for temporary abstinence and/or smoking reduction. The first reported a significant decrease over time in the average number of cigarettes smoked per day among those using NRT for harm reduction purposes (Hughes et al., 2004a), while the other failed to find any association with a 50% reduction in cigarette consumption, quit attempts or smoking status, between baseline and two years follow-up (Levy et al., 2007). However, these studies were flawed in a number of ways: the selection of those formally taking part in a cessation intervention, which may have contributed to the reductions reported (Hughes et al., 2004a), and the measure of past ever use of NRT as opposed to the current use (Levy et al., 2007). A prospective study amongst those spontaneously reducing and who have not received any form of behavioural support for their habit is thus necessary.

Because many of those who attempt to reduce their cigarette consumption appear to enter a maintenance phase, whereby they continue smoking at their new reduced rate without further reductions (Farkas, 1999; Hughes et al., 1999; Hughes et al., 2004a; Hughes et al., 1981; Norregaard et al., 1992); the best method to establish whether declines in cigarette consumption occur, is to observe those who start or stop smoking reduction or the use of NRT for harm reduction purposes. This will eliminate from the analysis anyone who may have been reducing for an undetermined and extended amount of time. Indeed, even in the clinical trials, reductions in the initial stages were substantially larger (Batra et al., 2005; Bolliger et al., 2000; Carpenter et al., 2003; Carpenter et al., 2004; Etter et al., 2004; Rennard et al., 2006; Wennike et al., 2003; Haustein et al., 200; Joseph et al., 2008; Wood-Baker, 2001; Tonnesen et al., 2005; Chan et al., 2011), as are reductions which directly proceed the implementation of smoking restrictions (Owen & Borland, 1997).

Why such maintenance occurs, i.e. smokers reduce to a specific level and sustain this until they decide to quit, to begin the cycle of smoking reduction again, or go back to their previous smoking level, is unclear. It may be that they have reached their designated goal, with previous studies reporting that the majority of smokers who aim to reduce their cigarette consumption aspire for a reduction of 50% (Hughes, Callas & Peters, 2007). Alternatively, the behaviour of smoking reduction may be a sporadic process, with decreases in cigarette consumption being followed by a period of stability, which then leads to further reductions. Smoking itself is an erratic behaviour even when behaviour change is not in lieu, with a number of every day smokers switching for short periods of time to non-daily or occasional use (Mermelstein et al., 2002). Sporadic episodes are also noted among other health behaviours, for example, dieters often develop patterns of eating characterised by chronic reductions in calorific intake, followed by uncontrolled overindulgence (Herman & Policy, 1980).

When assessing the association between NRT use for harm reduction and cessation, it is of interest to consider both attempts to quit smoking and abstinence. This will allow for the determination as to whether the use of NRT for such purposes increases the likelihood of an attempt to quit, the success of a quit attempt when one is made, or both of these. To date such a comparison is difficult as the majority of survey-based studies have focussed solely on quit attempts, while the randomised controlled trials have focussed on abstinence. Those studies which have assessed both, appear to indicate at least some beneficial effect on attempts to quit smoking, but point more towards an effect on the success of a quit attempt when one is made (Carpenter et al., 2004; Carpenter et al., 2003; Etter et al., 2004; Levy et al., 2007). There are numerous measures of abstinence: point-prevalence, repeated point-prevalence, continuous and prolonged. In terms of survey-based research on harm reduction, point-prevalence may be deemed the most suitable, referring to the prevalence of abstinence during a time window immediately preceding follow-up. Although the latter two are perhaps the gold standards, use of point-prevalence cessation is universal (Fiore, Smith, Jorenby & Baker, 1994), and has the highest validity (Velicer & Prochaska, 2004). This is because it can capture delayed effects, which is particularly important when assessing smokers who are cutting down for harm reduction purposes. Since such individuals are unlikely to have an intention to quit smoking, a lapse in time may be required in order for the effects of their reduced cigarette consumption to impact on their propensity to quit. Previous clinical trials have reported that on average reductions occur over 3-4 weeks before any attempt to quit smoking is made (Hughes & Carpenter, 2006). Such sleeper effects are also well known among studies which have assessed the implementation of interventions for abrupt smoking cessation (Prochaska, DiClemente, Velicer & Rossi, 1993; Russell, Merriman, Stapleton & Taylor, 1983).

In order to help with the interpretation of the findings from a prospective study on the association between the use of NRT for harm reduction, attempts to quit smoking, and cigarette consumption, it is of interest to also examine the stability of smoking reduction and the use of NRT for harm reduction. Clearly, if smoking reduction or the use of NRT for such purposes is highly unstable, it would militate against them having any clinical benefit or impact on cessation. To date, the majority of research on the stability of smoking behaviours has examined how far smokers remain in or move between Stages of Change based on their motivation to quit (DiClemente et al., 1991). These studies generally class smoking reduction as preparation behaviour prior to action (Prochaska, DiClemente & Norcross, 1993; Crittenden, Manfredi, Lacey, Warnecke & Parsons, 1994), pointing to a lack of stability, with smokers over a six month period both progressing and regressing on a regular basis with at least two stage changes (Martin, Velicer & Fava, 1996). However, there are numerous issues with such a classification, including the definition of these stages and the inclusion of smokers in the preparation phase who are not just attempting to cut down (West, 2005).

More stable smoking behaviours have been reported in studies that grouped smokers not as a function of their motivation to quit, but in terms of the number of cigarettes they smoked per day (Mulder, Ranchor, Sanderman, Bouma & van den Heuve, 1998), or in terms of whether or not they were attempting to cut down their cigarette consumption (West et al., 2001a; Meyer et al., 2003). These latter two studies prospectively followed-up population-based cohorts, one year in English smokers and three years in German smokers respectively, and reported that those who were reducing their smoking at baseline were more likely to report trying to reduce their consumption at follow-up. What is unclear is whether such stability occurs over a shorter period of time and for the use of NRT for harm reduction purposes. Indirect evidence for a potential lack of stability in the use of NRT comes from the finding that few purchases of NRT lead to continuous monthly investments, with an average of eight weeks of use (Shiffman et al., 2003a; Shiffman et al., 2003b; Burns, Arnold & Levinson, 2008); while only 50% of those provided with NRT in clinical settings comply with the recommended length of treatment (Hajek et al., 1999; Alterman, Gariti, Cook & Cnaan, 1999; Wiggers et al., 2006). Speculated reasons for stopping the use of NRT have included inadequate mitigation of urges and withdrawal symptoms (Johnstone et al., 2004), adverse events attributed to NRT (Lam, Abdullah, Chan & Hedley, 2005; Fiore et al., 2004; Burns et al., 2008), aversive attitudes towards NRT/insufficient knowledge about it (Curry, Ludman & McClure, 2003; Etter & Perneger, 2001), and cost (Curry et al., 2003, Lam et al., 2005).

Methods

Study Design and Sampling

Baseline data for this study were obtained between February 2007 and July 2010, from the Smoking Toolkit Study. See methods section in Chapter 7 for more details.

Ethical Approval

Ethical approval was granted by the University College London Research Ethics Committee.

Measures

Smoking status was assessed by asking: ‘Which of the following best applies to you? – (I smoke cigarettes (including hand-rolled) every day; I smoke cigarettes (including hand-rolled), but not every day; I do not smoke cigarettes at all, but I do smoke tobacco of some kind (for example:- pipe or cigar); I have stopped smoking completely in the last year; I stopped smoking completely more than a year ago; I have never been a smoker (i.e. smoked for a year or more); don't know). Those who responded that they smoke cigarettes every day, or that they smoked but not every day, were coded as current cigarette smokers. Current smokers were asked questions about socio-demographic characteristics (i.e. gender, age & social-grade), cigarette consumption per day, and time to first cigarette of the day as a measure of nicotine dependence (Fagerstrom, 2003). Social-grade was classified as follows: AB=higher and intermediate professional/managerial; C1=supervisory, clerical, junior managerial/administrative/professional; C2=skilled manual workers; D=semiskilled and unskilled manual workers; E=on state benefit, unemployed, lowest grade workers.

Participants were also asked: 'Are you currently trying to cut down on how much you smoke' – (yes; no; don't know). In July 2009 this was changed to: 'Are you currently trying to cut down on how much you smoke but not currently trying to stop?' – (yes; no; don't know). If they answered 'yes' they were asked: 'Which, if any, of the following are you currently using to help you cut down the amount you smoke? – (nicotine patch; nicotine gum; nicotine lozenges/tablets; nicotine inhaler; nicotine nasal spray; I don't know; none of these; other). All smokers were asked: 'Do you regularly use any of the following in situations when you are not allowed to smoke? – (nicotine patch; nicotine gum; nicotine lozenges/tablets; nicotine inhaler; nicotine nasal spray; I don't know; none of these; other).

Following the baseline survey, participants who agreed to be contacted for follow-up were sent a postal questionnaire 6 months later, where they were again asked about their smoking status, if they were reducing their smoking and if they were using NRT for smoking reduction and/or temporary abstinence. Also assessed was whether an attempt to stop smoking between baseline and follow-up had occurred and cigarette consumption. Smokers were classified as being non-smokers at follow-up if they reported that they were not smoking and their quit attempt had started at least four weeks before the follow-up point. For further information on the measures used in the Smoking Toolkit Study see www.smokinginengland.info.

Analysis

Parametric Assumptions

For logistic regression analyses the assumption of 'non-multicollinearity' was assessed by calculating Tolerance Values and Variance Inflation Factors (Menard, 1995; Myers, 1990). There was no evidence that this assumption was violated. The assumption of 'normality' required for independent *t*-test analysis was assessed using the Kolmogorov-Smirnov (K-S) statistic, while 'homogeneity of variance' using Levene's statistic (Levene, 1960). Cigarette consumption and age were non-normal among responders ($D(3586)=0.154$, $p<0.001$ versus $D(3586)=0.041$, $p<0.001$) and non-responders ($D(13424)=0.148$, $p<0.001$ versus $D(13424)=0.074$, $p<0.001$). Variances in cigarette consumption were equal ($F=0.539$, $p>0.05$), although variances in age were not ($F=21.714$, $p<0.001$). Log and square root transformations were unsuccessful in correcting the heterogeneity and non-normality. Because the large sample size means that the K-S test may be significant even when the distribution only differs slightly from normal, histograms and P-P plots were also calculated. These confirmed the non-normality present in the data for cigarette consumption and age consumption. Consequently, non-parametric tests were sought. The assumption of 'normality' required for paired *t*-test analysis was assessed using P-P plots of the differences in cigarette consumption when smokers were and were not reducing their cigarette consumption; when smokers were and were not using NRT for smoking reduction; and when smokers were and were not using NRT for periods of temporary abstinence. All P-P plots showed that cigarette consumption was non-normally distributed. Because square root and log transformations failed to correct the non-normality present in the data, non-parametric tests were sought.

Finally, the assumptions of ‘normality’ and ‘homogeneity of variance’ inherent in repeated ANOVA analysis were assessed using the K-S and Levene’s statistic (Levene, 1960). Normality was violated for cigarette consumption at baseline and follow-up among those starting and stopping smoking reduction or NRT use for smoking reduction and/or temporary abstinence. Log and square root transformations were unsuccessful. Variances in cigarette consumption at baseline and follow-up were equal among those stopping and those starting smoking reduction ($F(1, 1048)=0.031$, $p>0.05$ versus $F(1, 1048)=1.907$, $p>0.05$) and starting and stopping the use of NRT for smoking reduction $F(1, 383)=0.001$, $p>0.05$ versus $F(1, 383)=1.406$, $p>0.05$). Although equal variances were found among those starting and stopping the use of NRT for periods of temporary abstinence at baseline ($F(1, 437)=0.541$, $p>0.05$) they were not at follow-up ($F(1, 437)=4.061$ $p<0.05$). Log and square root transformations were unsuccessful. P-P plots confirmed the non-normality present in the data for cigarette consumption. Consequently non-parametric tests were used (see Appendix D).

Statistical Analysis

STROBE guidelines for the reporting of epidemiological studies were followed throughout (von Elm et al., 2007), with missing data dealt with prior to analysis using the listwise deletion procedure. For the reporting of prevalence data, an iterative marginal weighting technique was used in order to maximise the reliability of the sample data and minimise any statistical bias. This was achieved by performing the least amount of weighting required to correct for sample disproportionalities that may have distorted estimates. The process works by setting separate nationally representative target profiles for gender, working status, prevalence of children in the household, age, social-grade and region, and the process repeated until all variables match the specified targets.

Differences in socio-demographic and smoking characteristics between responders and non-responders were assessed with Chi-squared analyses and Mann-Whitney tests. For Mann-Whitney tests corresponding effect sizes were also calculated (r=Z score/ $\sqrt{\text{total}}\,\text{sample size}$). In order to assess significance in the Chi-squared analyses, standardised residuals were compared to the critical values that correspond to an alpha of 0.05 (+/-1.96), an alpha of 0.01 (+/-2.58) or an alpha of 0.001 (+/-3.10). Odds Ratios were then calculated where significance was evident. Associations between smoking reduction and the use of NRT for smoking reduction and temporary abstinence at baseline, with reports of attempts to stop smoking and smoking status at follow-up were, assessed using logistic regression analyses. These were undertaken with and without adjustment for socio-demographic variables and time to first cigarette of the day as a measure of nicotine dependence (Fagerstrom, 2003); 95% confidence intervals were used unless otherwise stated. Stability of attempts at smoking reduction and in the use of NRT for smoking reduction and/or temporary abstinence were also assessed using logistic regression analyses to compare the odds of undertaking each activity at follow-up in those undertaking or not undertaking each activity at baseline.

The association between smoking reduction and use of NRT for harm reduction purposes with cigarette consumption was assessed in two separate analyses. These occurred only for those starting or stopping smoking reduction and or starting and stopping to use NRT for smoking reduction and/or temporary abstinence: 1) a repeated measures analysis using the Friedman's test to determine whether there was a change in cigarette consumption over time; and 2) an assessment of whether differences in cigarette consumption existed when smokers were reducing their smoking or using NRT for harm reduction and when the same smokers were not doing each of these. This was determined using the Wilcoxon Signed-Rank test. For all analyses SPSS version 18.0 was adopted.

Power

Post-hoc power analysis using G*Power 3 (Erdfelder, Faul & Buchner, 1996), revealed that for the assessment of the association between smoking reduction and the use of NRT for temporary abstinence with attempts to quit smoking, an Odds Ratio of 1.2 could be detected with 87% power using alpha 0.001, 97% power using an alpha of 0.01, while 99% power using an alpha of 0.05. For the assessment of the association between the use of NRT for smoking reduction and attempts to quit smoking, an Odds Ratio of 1.2 could be detected with 46% power using alpha 0.001, 75% power using an alpha of 0.01, while 91% power using an alpha of 0.05.

Results

Between February 2007 and July 2010, 69, 428 adults were surveyed; of whom, 16,326 reported that they were current smokers with a mean age [Standard Deviation (*SD*)] of 40.4 (16.08) years, and cigarette consumption of 13.2 (*SD* 8.43). Fifty-one per cent (*n*=8384) were male with percentages in each social-grade as follows: AB (14.5%; *n*=2,511), C1 (25.3%; *n*=4,123), C2 (24.6%; *n*=4,016), D (21.8%; *n*=3,558), E (13.0%; *n*=2,118). Thirty-four per cent (*n*=5,526) reported smoking a cigarette after 61 minutes of wakening, 12.5% (*n*=2,033) between 31 and 60 minutes after wakening, 33.8% (*n*=5,508) within 6 and 30 minutes of wakening and 19.9% (*n*=3,219) within 5 minutes of wakening. Thirty-six per cent (*n*=5,911) of smokers reported having made a quit attempt in the previous 12 months. Eighty-nine per cent (*n*=14,526) of smokers agreed to be re-contact; 22.9% (*n*=3,329) responded at 6 months follow-up (see Table 1 for characteristics of responders and non-responders). The differences between respondents and non-respondents were small but with the large sample size some were statistically significant. Respondents at follow-up were more likely to be female (χ^2=36.09 (*df* 1), *p*=0.001; Odds Ratio 1.25; Confidence Interval 1.17-1.35), of an older age (*U*=18450000.00, *p*=0.001; *r*=-0.17), and were more nicotine dependent (*U*=23350000.00, *p*=0.001; *r*=-0.02). Respondents also had a higher cigarette consumption than non-responders (*U*=22270000.00, *p*=0001; *r*=-0.06). No difference in social-grade was established (*U*=2423000.00, *p*=0.782).

Table 1: Socio-Demographic Characteristics and Nicotine Dependency of Responders and Non-Responders at Baseline

	Responders at follow-up (*n*=3,329)	Non-responders at follow-up (*n*=12,997)
Gender % (*n*)***		
Male	46.1 (1,540)	52.7 (6,844)
Female	53.9 (1,801)	47.3 (6,141)
Age M(*SD*)***	46.0 (15.40)	38.9 (15.94)
Social-grade %(*n*)		
AB	17.5 (585)	14.8 (1,927)
C1	24.5 (817)	25.5 (3,306)
C2	23.7 (791)	24.8 (3,325)
D	20.8 (696)	22.0 (2,863)
E	13.5 (452)	12.8 (1,666)
Cigarette consumption per day M(*SD*)***	14.1 (8.62)	13.0 (8.36)
Time to first cigarette of the day %(*n*)**		
>61 minutes	31.1 (1,035)	34.7 (4,491)
31-59 minutes	13.4 (446)	12.3 (1,587)
6-30 minutes	35.0 (1,166)	33.5 (4,342)
<5 minutes	20.5 (684)	19.6 (2,535)

Note: *SD*=Standard Deviation; M=mean; *n*=number
Significant difference between groups (**p*<0.05, ** *p*<0.01, ****p*<0.001)
Data were weighted to match the 2001 census

Twenty-eight per cent (*n*=932) of respondents reported that they had attempted to quit smoking between baseline and follow-up. Nine per cent (*n*=312) reported that they were no longer smoking at follow-up; 67.6% (*n*=211) of these had not smoked for the past four weeks. Fifty-one per cent (*n*=1711) of respondents reported that there were reducing their cigarette consumption, 12.8% (*n*=426) of smokers reported that they were cutting down with the aid of NRT, while thirteen per cent (*n*=418) reported that they were using NRT for periods of temporary abstinence. The most commonly used NRT product for smoking reduction and/or temporary abstinence was the nicotine patch (52.6% (*n*=224) versus 44.3% (*n*=185) respectively) followed by the gum (33.1% (*n*=141) versus 36.1% (*n*=151) respectively).

Table 2 shows the percentages of participants a) having attempted to stop smoking and b) having not smoked for 4 weeks at follow-up, as a function of their harm reduction activities at baseline. Table 3 shows the results of the regression analyses on this data. Those who reported attempting smoking reduction at baseline were more likely to report having attempted to stop smoking and less likely to be smoking at follow-up than those who did not. Those who used NRT for smoking reduction and/or temporary abstinence were also more likely to report having attempted to stop smoking and not to be smoking at follow-up than those attempting smoking reduction and/or temporary abstinence without NRT.

Three-thousand and sixteen smokers reported smoking at both time points. Among this sub-set of smokers, 72.7% of those reducing their cigarette consumption at baseline continued to do so at follow-up. In contrast, only 27.3% of those using NRT for smoking reduction and 25.7% of those using NRT for temporary abstinence at baseline were still using NRT for these purposes at 6 months. Table 4 shows this in more detail, with the percentage of participants attempting smoking reduction and using NRT for harm reduction at both time points, and those starting and stopping these activities. Those reporting smoking reduction at baseline were more likely to report smoking reduction at follow-up (Odds Ratio (*OR*) 3.26; Confidence Interval (CI) 2.81-3.79; *p*=0.001). The odds of those who were using NRT for smoking reduction and/or temporary abstinence at baseline using NRT at follow-up were also significantly greater than those who had not used NRT for either purpose at baseline (*OR* 5.32; CI 4.09-6.91; *p*=0.001 versus *OR* 6.23; CI 4.68-8.28; *p*=0.001).

Table 2: Reports of the Percentage of Respondents Attaining Four-Week Point Prevalence Cessation and Reporting an Attempt to Quit Smoking at 6 Months Follow-up as a Function of Smoking Reduction and the use of Nicotine Replacement Therapy for Smoking Reduction and/or Temporary abstinence

	SR vs not SR[a] (*n*=1,711 vs *n*=1,618)		Using NRT for SR vs SR without NRT[b] (*n*=426 vs *n*=1,285)		Using NRT for TA vs TA without NRT[c] (*n*=418 vs *n*=2,911)	
	SR	No SR	SR with NRT	SR without NRT	TA with NRT	TA without NRT
Quit attempt %(*n*)	36.5 (624)	19.0 (308)	45.6 (194)	33.5 (430)	39.7 (166)	26.3 (766)
Four-week point prevalence cessation %(*n*)	7.5 (82)	5.1 (128)	9.2 (39)	6.9 (89)	10.3 (43)	5.8 (168)

Note: *n*=number; SR=smoking reduction; NRT=Nicotine Replacement Therapy; TA=temporary abstinence
Data were weighted to match the 2001 census.

Table 3: Association Between Smoking Reduction and the use of Nicotine Replacement Therapy for Smoking Reduction and/or Temporary Abstinence With Attempts to Quit Smoking and Smoking Status at 6 Months Follow-up

	Unadjusted			[a] Adjusted		
	SR vs not SR[a] (*n*=1,711 vs *n*=1,618)	Using NRT for SR vs SR without NRT[b] (*n*=426 vs *n*=1,285)	Using NRT for TA vs TA without NRT[c] (*n*=418 vs *n*=2,911)	SR vs not SR[a] (*n*=1,711 vs *n*=1,618)	Using NRT for SR vs SR without NRT[b] (*n*=426 vs *n*=1,285)	Using NRT for TA vs TA without NRT[c] (*n*=418 vs *n*=2,911)
	OR CI (95%)	*OR* CI (95%)	*OR* CI (95%)	*OR* CI (95%)	*OR* CI (95%)	*OR* CI (95%)
Quit attempt %(*n*)	2.49*** 2.14-2.90	1.60*** 1.30-2.00	1.86*** 1.52-2.27	2.46*** 2.11-2.86	1.62*** 1.31-2.01	1.89*** 1.54-2.32
Four-week point prevalence cessation %(*n*)	1.42** 1.08-1.89	1.57* 1.08-2.29	2.10*** 1.50-2.93	1.36** 1.02-1.81	1.62** 1.11-2.37	2.25*** 1.60-3.16

Note: *n*=number; *OR*=Odds Ratio; CI=confidence interval; NRT=Nicotine Replacement Therapy; TA=temporary abstinence; SR=smoking reduction
[a] Adjusted for age, gender, social-grade and time to first cigarette of the day
Significant difference between groups (**p*<0.05, ***p*<0.01, ****p*<0.001)

Table 5 shows the mean daily cigarette consumption at baseline and follow-up among those who changed their smoking behaviour and/or NRT status. An NRT-use by time interaction was reported, with those stopping the use of NRT for smoking reduction (χ^2=22.56 (*df* 1), *p*=0.001), and for temporary abstinence (χ^2=16.99 (*df* 1), *p*=0.001) having a lower consumption at baseline. No significant difference was reported amongst those starting to use NRT for smoking reduction (χ^2=0.12 (*df* 1), *p*=0.726) or for periods of temporary abstinence (χ^2=0.09 (*df* 1), *p*=0.768). A smoking reduction by time interaction was also reported, with those stopping smoking reduction having a lower cigarette consumption at baseline than follow-up (χ^2=26.49 (*df* 1), *p*=0.001). However, no difference was reported amongst those starting to reduce their cigarette intake (χ^2=1.03 (*df* 1), *p*=0.310).

Table 4: Percentage of Smokers Reporting Smoking Reduction and the use of Nicotine Replacement Therapy for Smoking Reduction and/or Temporary Abstinence at Baseline and Follow-up

	Smoking reduction *n*(%)	Using NRT for smoking reduction *n*(%)	Using NRT for temporary abstinence *n*(%)
Not at any time point	27.8 (839)	82.2 (2,480)	83.9 (2,531)
Only at baseline	13.7 (413)	9.0 (272)	8.9 (269)
Only at 6 months follow-up	21.7 (654)	5.4 (162)	4.1 (123)
At baseline and 6 months follow-up	36.8 (1,110)	3.4 (102)	3.1 (93)

Note: *n*=number; NRT=Nicotine Replacement Therapy
Data were weighted to match the 2001 census
Table entries based on reports of smoking at baseline and follow-up (*n*=3,016)

After combing these two groups – those starting and stopping attempts at smoking reduction and those starting and stopping the use of NRT for harm reduction – the mean cigarette consumption [Standard Deviation (*SD*)] when smokers were cutting down their cigarette consumption was 14.8 (9.56) while the mean consumption when they were not cutting down was 15.4 (*SD* 9.30). This mean reduction of 3.9% was significant (Z=-3.36, *p*=0.01; *r*=-0.07). Similarly, among those starting and stopping to use NRT for smoking reduction, cigarette consumption when not using NRT for smoking reduction was higher than when smokers were using NRT for smoking reduction [15.5 (*SD* 9.33) v 14.2 (*SD* 9.83)], with a percentage change in consumption of 8.4%. This difference was significant (Z=-3.918, *p*=0.001; *r*=-0.12). Cigarette consumption was also significantly higher when not using NRT for temporary abstinence [17.0 (*SD* 11.31)] relative to when NRT was used for temporary abstinence (15.0 (*SD* 9.48); Z=-4.55, *p*=0.001; *r*=0.15); a percentage change of 11.8%.

Table 5: Reports of Average Cigarette Consumption at Baseline and Follow-up Among Respondents as a Function of Those Starting and Stopping Smoking Reduction and Starting and Stopping the use of Nicotine Replacement for Smoking Reduction and/or Temporary Abstinence

	Cigarette consumption at baseline M(*SD*)	Cigarette consumption at follow-up M(*SD*)
Smoking reduction		
Baseline only (*n*=413)	13.59 (8.09)	15.16 (9.67)***
Follow-up only (*n*=654)	15.46 (9.09)	15.49 (10.29)
Using NRT for smoking reduction		
Baseline only (*n*=272)	13.5 (7.94)	15.3 (8.79)***
Follow-up only (*n*=162)	16.1 (10.11)	15.7 (12.28)
Using NRT for temporary abstinence		
Baseline only (*n*=269)	15.5 (9.22)	17.2 (10.99)***
Follow-up only (*n*=123)	16.8 (10.84)	14.4 (10.72)

Note: M=mean; *SD*=Standard Deviation; *n*=number; NRT=Nicotine Replacement Therapy
Data were weighted to match the 2001 census
Significant difference are for the comparison of baseline and follow-up cigarette consumption using ANOVA controlling for age, gender and time to first cigarette of the day (*$p<0.05$, **$p<0.01$, ***$p<0.001$)

Discussion

Reports of smoking reduction and the use of NRT for smoking reduction and temporary abstinence were found to be positively associated with attempts to quit smoking and abstinence at 6 months follow-up. Although attempts at smoking reduction were quite stable over the six month period, the use of NRT for temporary abstinence and/or smoking reduction was only moderately stable. Change in NRT use for harm reduction purposes between baseline and 6 month follow-up, and in attempts at smoking reduction, were associated with significant but small reductions in cigarette consumption.

These findings support those of previous cross-sectional studies which have reported that those using NRT for harm reduction purposes have a higher rate of attempts to stop smoking relative to other smokers generally (Levy et al., 2007; Etter et al., 2003; Hughes et al., 2004b[a]). However, the only preceding prospective study did not find such a benefit (Levy et al., 2007). This may have been due to their assessment of past ever use of NRT rather than the current use, differences in comparison groups or disparities in recruitment methods. By themselves, these results could be interpreted in terms of NRT use for smoking reduction and cessation both stemming from a greater sustained motivation to stop smoking. However, taken together with the findings of the clinical trials, they strengthen the view that using NRT for smoking reduction enhances the chances of subsequent quitting and the success of those quit attempts at a population level. The rates of cessation reported here are similar to those commonly found in cessation interventions based on brief advice alone (Stead et al., 2008), suggesting that this is a viable strategy for many smokers who may be unable or unwilling to stop smoking, and that consideration should be given to providing NRT for harm reduction purposes alongside traditional tobacco control polices, such as abrupt cessation. These findings also support the recent changes in the licensing of NRT products to allow them to be marketed for use during attempts at smoking reduction and/or during periods of temporary abstinence (MHRA, 2010).

In line with previous research, attempts at smoking reduction were also associated with higher odds of reporting smoking abstinence and quit attempts than other smokers generally (for example:- Bjornson et al., 1999; Hughes et al., 1999; Farkas, 1999; Meyer et al., 2003; Hyland et al., 2005; Godtfredsen et al., 2002a; Mooney et al., 2011). However, the current study tried to eliminate one of their major methodological flaws, the failure to assess the reasons for the reductions. Asking if smokers were reducing their smoking without an intention to quit smoking affords the conclusion that smoking reduction may increase the propensity of smokers to quit even among those unable or unwilling to do so, i.e. where reduction is not part of a more complex attempt to quit smoking. Of course, it is also possible that both attempts to cut down and quit attempts reflect a strong tendency to curb the health consequences of smoking. This is something which is hard to resolve in survey data such as these. One potential method may be to determine whether those who cut down are more health conscious than other smokers generally. Previous studies have reported that many believe that smoking reduction will decrease harm from cigarettes and this may be a potent motivator to attempt to cut down (Joseph et al., 2008).

Nonetheless, caution should still be exercised since it remains possible that encouraging smoking reduction or providing NRT for harm reduction purposes could have unwanted consequences for the pool of smokers at large. This may include smokers who may otherwise have quit abruptly deciding instead to reduce their cigarette consumption. This issue could be addressed by observing population level quit rates before and after the introduction of marketing licences allowing the use of NRT for smoking reduction. Even then, there are clearly many factors that could come into play to affect those rates, making it difficult to disentangling any effect of smokers switching from the use of NRT for traditional cessation purposes to the use of NRT for smoking reduction. It may be noted that to date there is no evidence that marketing of NRT for smoking reduction has made any difference to the rate at which it has been used for this purpose (Shahab et al., 2008; see Chapter 7). This may be because the marketing activity has been very limited. It remains to be seen what will happen if and when the manufacturers engage in more vigorous marketing and the use of NRT increases. Moreover, the one trial which has offered reduction as an alternative to smoking cessation, reported similar quit rates among those who switched and stuck with the cessation programme (Glasgow et al., 1989).

The moderate stability in the use of NRT for smoking reduction and temporary abstinence coincides with previous research suggesting that only 2.3% of purchases of NRT lead to continuous monthly investments (Shiffman et al., 2003a; Shiffman et al., 2003b). In contrast, their appeared to be good stability in attempts at smoking reduction, which is in line with the findings established by others (Mulder et al., 1998; West et al., 2001a; Meyer et al., 2003). The early termination of NRT use could be due to the cost of purchasing NRT concurrently with cigarettes; although this cannot be the only explanation because many smokers continue to smoke despite the increased expense. It may be that smokers who are using NRT for temporary abstinence as a result of smoke-free laws find the current products ineffective (Etter et al., 2003). In line with this, previous studies have found that few smokers report that NRT helps them to resist urges to smoke in situations where smoking is not possible (Etter et al., 2001).

Although finding that a change in NRT-use status was associated with a change in cigarette consumption, this change was small. These findings are in line with previous population-based data (Hammond et al., 200; Levy et al., 2007; Hughes et al., 2004a; Hughes et al., 2004b[a]; Etter et al., 2003), but are in contrast to the significant reductions reported in the previous randomised controlled trials (Batra et al., 2005; Bolliger et al., 2000; Carpenter et al., 2003; Carpenter et al., 2004; Etter et al., 2004; Rennard et al., 2006; Wennike et al., 2003; Haustein et al., 200; Joseph et al., 2008; Wood-Baker, 2001; Tonnesen et al., 2005; Chan et al., 2011). It may be that NRT use is instead having an effect on the way smokers' smoke their cigarettes, consequently their toxin intake. Alternatively, it may be that the free provision of NRT and extensive behavioural support provided in the clinical trials was a potent motivator. Another explanation could be the lack of stability in NRT use; perhaps the length of time smokers had been using NRT for was not long enough to allow for reductions to be induced. In order to assess whether this could be the case, future studies should aim to ask smokers about how long they have been using NRT in particular ways, and to chart the trajectory of their NRT use and cigarette consumption over an extended period of time. Determining the amount of NRT used would also be of interest. If smokers underuse NRT, as previous population-based studies suggest (Shiffman et al., 2003b; Shiffman et al., 2002b), this may explain why reductions in cigarette consumption have not occurred in survey-based studies to the extent of those found in the previous clinical trials.

Reductions among those attempting smoking reduction were also significant but small, and substantially lower than those reported in many previous surveys (for example:- Bjornson et al., 1999; Hughes et al., 1999; Farkas, 1999; Meyer et al., 2003; Hyland et al., 2005; Godtfredsen et al., 2002a; Mooney et al., 2011). This could be for a number of reasons: the goal of smoking reduction which was assessed (harm reduction versus gradual cessation); sample recruitment; or length of follow-up. If it is the case and reductions are at the rate reported here, it may be assumed that few, if any, health benefits are likely to be reaped, with even reductions of 50% failing to reduce the risk of premature death (Tverdal & Bjartveit, 2006). Consequently, those interested in such an approach need to be made aware that improvements to health may only occur if they quit smoking. However, for firmer conclusion to be drawn it will be necessary to collect measures of actual toxin intake, with the possibility that smokers may instead be modifying how they smoke their cigarettes.

This study had several limitations. First there may be error or bias in the measurement of the key variables. For example, it has been found that smokers appear to forget previous attempts to quit smoking (Berg et al., 2010b). However, there is no reason to assume that the rate of forgetting would differ between reducers and non-reducers, and therefore, that this would have created spurious associations. Secondly, the follow-up rate was relatively low.

However, differences between responders and non-responders were small and it is not clear how self-selection bias could account for the effects observed. Nonetheless, care should be taken when generalising the findings to a population level. If further data are to be accumulated from the Smoking Toolkit Study it would be of use to consider ways in which the response rate could be increased. This may include providing more incentives, shortening the questionnaire, and/or contacting smokers to encourage participation (Edwards et al., 2002). Thirdly, there was no measure of the amount of NRT used. It could be that this played a significant role in any association with cessation or reduced cigarette consumption. Fourthly, it is unclear as to the continuity of behaviour between the baseline and 6 month surveys; it is quite probable that smokers started and stopped using NRT numerous times during this period. Further research on the topic of stability would need to adopt regular measures of NRT use. A fifth issue is that there is no agreed-upon definition of what constitutes a quit attempt and it is likely that respondents construed this in various ways; although this would have added noise to the data it would not have undermined the validity of the positive associations that were found. Finally, there was no biochemical verification of smoking status. Although in surveys of this kind there is very little deception, self-report can be influenced by social desirability (Prescott-Clarke & Primatesta, 1998).

Conclusion

Although the spontaneous use of NRT for smoking reduction and/or during periods of temporary abstinence is associated with only very modest reductions in cigarette consumption, it does appear to be predictive of attempts to stop smoking and abstinence 6 months later. This supports the conclusion from clinical trials that NRT use whilst smoking may help to promote cessation. The establishment of a lack of stability in NRT use may explain why sizable reductions in cigarette consumption were not found

Chapter 11: Analysis of Mediating Variables in the Association Between the use of Nicotine Replacement Therapy for Harm Reduction and Attempts to Quit Smoking: A National Survey of English Smokers

Introduction

If it is the case that the use of NRT for smoking reduction and/or during periods of temporary abstinence increases the propensity of smokers to quit at a population level, this might be for a number of reasons: by enhancing smokers' motivation to stop altogether; by bolstering a smokers' confidence in their ability to stop; and/or by weakening the rewarding effect of cigarettes. The current chapter aimed to establish the plausibility of these explanations by examining their mediating effects.

Statistical meditation analysis has a strong historical dominance in the social sciences, mainly as a result of the Stimulus-Organism-Response model developed in the early 1960s (Hebb, 1966). In this model, mediating mechanisms in the organism translate how a stimulus leads to a response. For example, a stimulus may trigger a memory mechanism that identifies the stimulus as a threat, thus resulting in avoidance. However, it wasn't until the 1970s to 1980s, that it gained recognition in the realm of health sciences, following the development of psychological theories of health behaviour. These claimed that attitudes, beliefs, and other social-environmental factors, only influence behaviour via the formation of intentions to act (Fishbein & Ajzen, 1975). A newer application is in prevention and treatment research, where interventions are designed to change the outcome of interest by targeting mediating variables that are hypothesised to be causally related to the outcome. A third reason for mediation analysis, and the raison d'être for the current chapter, is purely methodological, in that it allows the consideration of how a third variable affects the relationship between two other variables. Understanding the mechanisms via which the use of NRT for harm reduction purposes may increase the propensity of smokers to quit, could help to inform future interventions based on this topic and aid advances in theory development.

There are numerous examples of mediation analyses in the area of smoking initiation and continuation. For example, Cinciripini et al. (2003) assessed the mediating effect of self-efficacy, urges to smoke, nicotine withdrawal and coping behaviour, on the relationship between depressed mood and smoking abstinence in an intervention study. The strongest mediator was found to be smokers' confidence in their own ability to carry out specific tasks. In contrast, Willis, Sargent, Stoolmiller, Gibbons and Garrad (2008) assessed in a longitudinal study of 6,522 smokers, the mechanisms by which movie smoking exposure affected onset of adolescence smoking. Increases in positive expectations about smoking and increases in the affiliation with smoking peers, both appeared to be mediating factors. However, despite calls to do so, tobacco control researchers have neglected to determine the factors which may contribute to the association between the use of NRT for harm reduction and smoking cessation (Glasgow et al., 2008; Levinson et al., 2008; Asfar et al., 2011). This is perhaps a result of its only recent acceptance as a potential tobacco control strategy. Mediation analysis is of high importance in an area such as this, where numerous theories have been stipulated by which the use of NRT for smoking reduction and/or temporary abstinence may move smokers towards a quit attempt. For example, it might enhance motivation to stop; bolster a smokers' confidence in their ability to stop; or weaken the rewarding effect of cigarettes.

Increased Motivation to Quit

Past experiences have a huge impact on individuals' views about the effectiveness of treatment options (for example:- Kravitz et al., 1996). In general we have a tendency if an approach or method fails to associate low or negative expectations with it (Mezulis, Abramson, Hyde & Hankin, 2004). This may occur for abrupt cessation among smokers who have repeatedly failed to quit smoking. The concern with this is that treatment efficacy is often undermined as a result (Naegeli & Hayes, 2010). Providing such smokers instead with the option of smoking reduction, affords them the opportunity to try something that is not associated with previous failure, which if successful, may consequence in internal, stable, and global attributions, making them more motivated to discover whether giving up completely would be possible (Fagerstrom, 1999; Mezulis et al., 2004; Weiner, 1979). Motivation could be even greater when NRT is used for smoking reduction, as a result of withdrawal and craving reduction, encouraging smokers to believe that stopping smoking need not be uncomfortable (Fagerstrom et al., 1993). Indeed, the reason that many smokers resist trying to quit is often that they have tried before but found that abstinence symptoms were too strong to overcome (Fagerstrom, 1999). The same may also apply to periods of temporary abstinence, with NRT mounting smokers' relative comfort, thus increase their motivation to abstain for longer periods of time (ASH, 2005). There is evidence for an association between the ability to cope with smoking urges and smoking behaviour (Niaura et al., 2002).

Motivational variables have been consistently demonstrated to predict cessation attempts in different cultures (West et al., 2001a; Hagimoto et al., 2009; Fidler & West, 2011). There is also evidence that smoking reduction increases smokers' motivation to quit (Pisinger et al., 2005). In contrast, while some clinical trials have found an increase in motivation to quit among smokers using NRT to reduce their smoking relative to usual-care, no-treatment and motivational advice controls (Carpenter et al., 2003; Carpenter et al., 2004); a difference between placebo and active NRT conditions has generally not been established (Fagerstrom et al., 2000; Wennike et al., 2003). Trials have also failed to find an association between the use of NRT for smoking reduction and intention to quit (Bolliger et al., 2000;

Carpenter et al., 2003; Etter et al., 2002; Rennard et al., 2006). This could reflect the fact that the behavioural support and instructions provided in the clinical trials across the placebo and active groups diluted any effect of NRT. However, if this were the case we may not expect similar outcomes at a population level, where little or no additional support is provided. Studies to date which have assessed the spontaneous use of NRT for smoking reduction and/or temporary abstinence have also failed to report a positive association with intention to quit smoking (Levy et al., 2007; Hammond et al., 2008). Nonetheless, this may have been due to methodological issues with these population-based studies, including a reliance on the measurement of past ever use of NRT and the choice of comparison groups. Alternatively, it may simply be the case that the behaviour of reducing cigarette consumption increases motivation to quit, with little impact from pharmacological treatment, and that the influence of NRT on attempts to quit smoking acts via another mediating variable.

Traditional measures of motivation to quit among reduction studies have been based on the Stages of Change Model, which proposes a contemplation ladder of smokers' intention to quit smoking. This model argues that those in the 'preparation phase' do not intend to make changes, while those in the 'contemplation stage' are considering change. This latter group may be split according to future orientation, i.e. whether they intend to quit within the next month, six months or are as yet undecided (Prochaska & DiClemente, 1982). This method has subsequently been heavily criticised on a number of grounds (West, 2005), one of which is that measures of intention do not fully reflect one's motivation. Whereas intention involves what you plan to do, motivation involves an emotive element (hot cognitions) of effort and the energy that will be expended to attain the goal (Rhodes, Blanchard, Matheson & Coble, 2006). Mele (1992) provides a nice distinction of these: one can be motivated to do A without being settled on it, in contrast to intend to do something is, at least in part, to be settled on doing it. Conversely, one can intend to A but may not be motivated to do so. This may explain why behavioural intentions do not reliably lead to changes in behaviour, a phenomenon known as the intention-behaviour-gap (Sheeran, 2005). Better measures appear to be asking smokers how likely it is that they are going to quit and whether they want to quit (Sciamanna, Hoch, Duke, Fogle & Ford, 2000; Hymowitz et al., 1997). There also appears to be greater stability in these measures over time relative to intention formation, making them essentially more predictive (West et al., 2001a; Hughes et al., 2005a).

Increased Self-Efficacy

Smoking reduction may also increase the propensity of smokers to quit via increasing self-efficacy expectations, i.e. beliefs about how capable one is at performing certain behaviors. This is a major component of Bandura's Social Cognitive Theory (Bandura, 1977), which claims that performance accomplishments attained through personal experience are the most potent source of efficacy expectations. Consequently, because smoking reduction can be thought of as a step towards cessation, self-efficacy may be increased when accomplishing this goal. This coincides with the hypothesis made by the Stages of Change Model that the movement of reducers from the pre-contemplation stage towards contemplation, through preparation and action, results in a concurrent increase in self-efficacy levels (Proschaska & DiClemente, 1982). Smoking reduction also provides smokers with the opportunity to practice coping with smoking urges prior to complete abstinence (Cinciripini et al., 1995; Cinciripini et al., 1997; O'Connor & Langlois, 1998), and reduces negative affect, which thus may make these coping strategies more effective (Cinciripini et al., 1995). The use of NRT for smoking reduction and/or temporary abstinence may further increase self-efficacy levels as it helps smokers to learn that they can cope without tobacco for several hours without undue discomfort, and that NRT can act as an acceptable substitute for cigarettes. There is evidence that physiological cravings for nicotine affect smokers' confidence in their ability to quit (McIntyre, Mermelstein & Lichtenstein, 1980).

Although self-efficacy may be expected to be associated with cessation attempts, findings on this have been mixed (West et al., 2001a; Hyland et al., 2006; Hagimoto et al., 2009; Herd, Borland & Hyland, 2009; Yates & Thain, 1985). Nonetheless, there is consistent evidence that smoking reduction increases smokers' confidence in their ability to stop smoking (O'Connor & Langlois, 1998; Devins & Edwards, 1988). Randomised controlled trials have also revealed an increase in self-efficacy amongst those reducing their intake with NRT relative to no-treatment, motivational advice, and usual-care controls (Carpenter et al., 2004; Etter et al., 2002), but not relative to those reducing their cigarette consumption with placebo NRT (Etter et al., 2002). This again suggests that the behavioural support provided across placebo and active conditions may have affected self-efficacy levels, or that it is smoking reduction and not the use of NRT which increase smokers' confidence in their ability to quit. Indeed, Rennard et al. (2006) reported that perceived behavioural control, a similar variable to self-efficacy, increased among those reducing by 50% or more, irrelevant of assignment to active or placebo conditions.

Studies to data have generally used a domain specific measure of self-efficacy, an approach advocated by Social Cognitive Theory, since there does not appear to be an overall self-efficacy temperament, with confidence varying between tasks (Bandura, 1977). Domain specific self-efficacy measurements do appear to be more predictive of outcomes of interest (Wang & Richarde, 1988). Regarding the use of singular or multiple measures, it has been suggested that if a specific behaviour is to be predicted, as is the case with smoking cessation, single items are adequate. For example, Hoeppner, Kelly, Urbanoski and Slaymaker (2011) evaluated the validity and utility of a single item measure of self-efficacy in a clinical sample of young adults who had quit smoking. It proved to be a better predictor of relapse than a 20 item questionnaire. In contrast, multiple measures may be needed for more complex behaviours such as diabetes self-care, which includes medication adherence, blood glucose monitoring, diet control, exercise and foot-care (Lorig et al., 1999).

Decreased Rewarding Effects of Cigarettes

Finally, it is possible that the use of NRT for harm reduction purposes could promote cessation through reducing the rewarding effect of smoking. Obtaining nicotine from a source other than cigarettes could reduce smoking satisfaction because a smoker on NRT is already partly satiated with nicotine (Fagerstrom & Hughes, 2002). This is based on the foundations of operant conditioning, which state that behaviour becomes extinct when a lack of reinforcement follows performance (Skinner, 1953). Transdermal nicotine products do appear to produce a dose-related reduction in the subjective rewarding effects of smoking (Rose et al., 2001).

This dissociation between nicotine ingestion and smoking behaviour can be measured by assessing enjoyment of smoking (Jones & Simon. 2002; Pritchard, Robinson, Guy, Davis & Stiles, 1996; Rose, Behm, Westman & Coleman, 1999), which has been shown to be predictive of attempts to quit smoking and the success of those quit attempts when they are made (Fidler & West, 2009; McEwen et al., 2008). Larger declines in the pleasure of smoking and the positive benefits of smoking have been reported in clinical trials amongst those using NRT for smoking reduction relative to no-treatment controls, but not relative to placebo controls (Etter et al., 2002). This is counterintuitive, since it may be assumed that smoking reduction without the aid of NRT would increase the rewarding effects of cigarettes due to nicotine withdrawal relief. However, it is possible that decreased enjoyment among those not using NRT could occur if smoking reduction results in reduced nicotine dependency

(McEwen et al., 2008). Previous clinical trials and population-based studies have reported a reduction in nicotine dependence among those attempting smoking reduction (Etter et al., 2002; Joseph et al., 2008; Mooney et al., 2011). However, these data were confounded by the use of the Fagerstrom Test for Nicotine Dependence (Fagerstrom & Schneider, 1989), a central measure of which is cigarette consumption; thus lower scores may simply reflect reductions in the number of cigarettes smoked per day. Because smokers have a tendency to compensate during attempts at smoking reduction by smoking each cigarette harder, other measures may not show such an effect (Sutton et al., 1982). An alternative means by which enjoyment may be reduced is via the extinction of cue-cigarette pairings, i.e. decreasing the occurrence of smoking could concurrently decrease the frequency at which it is associated with environmental cues, thus reducing the elicitation of urges to smoke and ultimately the pleasure of smoking. The strength of smoking urges has been demonstrated to be positively correlated with reports of smoking pleasure (McEwen et al., 2008).

Methods

Study Design and Sampling

Data for this study were obtained between April 2009 and February 2010 from the Smoking Toolkit Study. See methods section in Chapter 7 for more details.

Ethical Approval

Ethical approval was granted by the University College London Research Ethics Committee.

Measures

Smoking status was assessed by asking: 'Which of the following best applies to you? – (I smoke cigarettes (including hand-rolled) every day; I smoke cigarettes (including hand-rolled), but not every day; I do not smoke cigarettes at all, but I do smoke tobacco of some kind (for example:- pipe or cigar); I have stopped smoking completely in the last year; I stopped smoking completely more than a year ago; I have never been a smoker (i.e. smoked for a year or more); don't know). Those who responded that they smoke cigarettes every day or that they smoked but not every day were coded as current cigarette smokers. Current smokers were asked questions about socio-demographic characteristics (i.e. gender, age & social-grade), cigarette consumption per time, and time to first cigarette of the day as a measure of nicotine dependence (Fagerstrom, 2003). Social-grade was classified as follows: AB=higher and intermediate professional/managerial; C1=supervisory, clerical, junior managerial/administrative/professional; C2=skilled manual workers; D=semiskilled and unskilled manual workers; E=on state benefit, unemployed, lowest grade workers.

Participants were asked: 'Are you currently trying to cut down on how much you smoke' – (yes; no; don't know). In July 2009 this was changed to: 'Are you currently trying to cut down on how much you smoke but not currently trying to stop?' – (yes; no; don't know). If they answered 'yes' they were asked: 'Which, if any, of the following are you currently using to help you cut down the amount you smoke? – (nicotine patch; nicotine gum; nicotine lozenges/tablets; nicotine inhaler; nicotine nasal spray; I don't know; none of these; other). All smokers were asked: 'Do you regularly use any of the following in situations when you are not allowed to smoke? – (nicotine patch; nicotine gum; nicotine lozenges/tablets; nicotine inhaler; nicotine nasal spray; I don't know; none of these; other). They were also asked: 'How many serious attempts to stop smoking have you made in the last 12 months?'

Those reporting one or more quit attempts were classified as having made a quit attempt in the past year.

Finally, questions regarding their intentions to stop smoking, desire to stop smoking, self-efficacy for stopping smoking, and enjoyment of smoking, were assessed by asking whether the following applied to them: ‘I intend to stop smoking soon’; ‘I want to stop smoking’; ‘I am confident I could stop smoking if I tried’; and ‘I enjoy (smoking)’ – (Yes; No). For further information on the measures used in the Smoking Toolkit Study see www.smokinginengland.info.

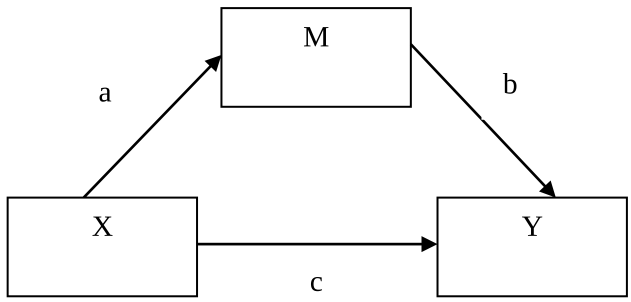


Figure 1: Causal Steps Model Showing the Direct Effect of X on Y (c), and the Indirect Effect of X on Y (a-b) (Baron & Kenny, 1986)

Analysis

Although there are many methods available for testing hypotheses about intervening variable effects, the most widely-used method is the ‘causal steps approach’ popularised by Baron and Kenny (1986). This model assumes three steps in establishing mediation: 1) demonstrate a correlation between the initial variable (X) with the outcome (Y), i.e. the direct effect (path c); 2a) demonstrate a correlation between the initial variable (X) and the mediating variable [(M); path a], and 2b) demonstrate a correlation between the mediating variable (M) and the outcome variable [(Y); path b], i.e. the indirect effect; and 3) demonstrate that after controlling for the mediating variable (M) the relationship between the initial variable (X) and outcome variable (Y) is either reduced in partial mediation or is zero in complete mediation (see Figure 1).

However, in recent years this approach has been heavily criticised. For one, the significance of the indirect pathway is never tested, i.e. that X affects Y through the compound pathway of a and b. A second problem is that the Barron and Kenny approach tends to miss some true mediation effects because of its low power and fallible principles (Fritz & MacKinnon, 2007; MacKinnon, Lockwood, Hoffman, West & Sheets, 2002). For example, there are cases of mediation in the absence of a statistically significant total effect of X on Y (Shrout & Bolger, 2002). This often occurs due to a phenomenon known as suppression, whereby the mediating effect of a competing process has the opposite sign of the mediating effect of interest; the two effects thus cancel out what would otherwise have been a significant direct effect. Attempts have been made to rectify these issues, including the conjunctive use of the Product of Coefficients Approach, most well known as the Sobel test (Sobel, 1982). However, this is also problematic in that it assumes that the sampling distribution of the indirect effect is normally distributed (Bollen & Stine, 1990).

As a consequence, in more recent years there has been a move away from the causal steps approach towards methods such as structural equation modelling in conjunction with bootstrapping. This approach is advocated for testing mediation as it does not impose the assumption of normality of the sampling distribution (Preacher & Hayes, 2008), and has high power to detect differences while maintaining reasonable control over Type 1 error rates (MacKinnon, Lockwood & Williams, 2004). Bootstrapping generates an empirical representation of the sampling distribution of the indirect effect by treating the obtained sample of size *n* as a representation of the population in miniature, which is repeatedly re-sampled during analysis as a means of mimicking the original sampling process. This procedure is now included in a number of structural equation modelling programs including AMOS and Mplus (Arbuckle & Wothke, 1999; Muthen & Muthen, 2004); the latter of which allows dichotomous X, Y and M variables to be inputted by using probit distributions (Muthen & Muthen, 2004). Consequently, due to the dichotomous nature of the independent (IV), dependent (DV) and mediating (MV) variables, mediation analysis was conducted using the statistical package Mplus (v 6.1), with bootstrapping to estimate 95% confidence intervals. One thousand Bootstrap draws were completed for each analysis. Estimates of the indirect effect, i.e. mediated effect of the IV on the DV, direct effect, i.e. unmediated effect of the IV on the DV, and total effect, i.e. unmediated and mediated effects of the IV on the DV, are given. Single mediator models, as opposed to multi-mediator models, were used due to the high correlation between the MVs. Because probit coefficients (β) may be unfamiliar they were transformed to approximate logistic coefficients [Odds Ratio (*OR*)] with *OR* ~exp $^{1.81B}$.

STROBE guidelines for the reporting of epidemiological studies were followed throughout (von Elm et al., 2007), with missing data dealt with prior to analysis using the listwise deletion procedure. For the reporting of prevalence data, an iterative marginal weighting technique was used in order to maximise the reliability of the sample data and minimise any statistical bias. This was achieved by performing the least amount of weighting required to correct for sample disproportionalities that may have distorted estimates. The process works by setting separate nationally representative target profiles for gender, working status, prevalence of children in the household, age, social-grade and region, and the process repeated until all variables match the specified targets.

Power

Post-hoc power analysis using G*Power 3 (Erdfelder, Faul & Buchner, 1996), revealed that for the assessment of the association between smoking reduction and attempts to quit smoking, a probit regression coefficient of 0.1 could be detected with 100% power using an alpha 0.001, 100% power using an alpha of 0.01, while 100% power using an alpha of 0.05. For the assessment of the association between the use of NRT for smoking reduction and attempts to quit smoking, a probit regression coefficient of 0.1 could be detected with 100% power using an of 0.001, 100% power using an alpha of 0.01 and 100% using alpha of 0.05.

Results

Between April 2009 and February 2010, 19,516 adults were surveyed; of whom, 4,178 reported that they were current smokers. Fifty-two per cent of respondents were male (*n*=2,161) and 48% female (*n*=2,017), with a mean age [Standard Deviation (*SD*)] of 41 (16) years. The percentages of participants in each social-grade were as follows: AB (16%; *n*=653), CI (26%; *n*=1,096), C2 (24%; *n*=1,011), D (21%; *n*=872), E (13%; *n*=546). The mean number of cigarettes smoked per day was 13 (*SD* 8), with 28% of smokers (*n*=1,162) reporting smoking a cigarette after 61 minutes of waking, 19% (*n*=774*)* between 31 and 60 minutes after wakening, 35% (*n*=1,448) within 6-30 minutes of wakening, and 19% (*n*=794) within 5 minutes of wakening. Table 1 shows the socio-demographic and smoking characteristics of smokers as a function of the cohorts of interest.

Fifty-five per cent (*n*=2,276) of participants reported that they were currently reducing their cigarette smoking, with 13% (*n*=537) using NRT during attempts to cut down. Twelve per cent (*n*=488) of the sample also reported using NRT for periods of temporary abstinence.

The most commonly used product was the nicotine patch for smoking reduction and temporary abstinence (47% (*n*=255) v 39% (*n*=208), respectively), followed by the nicotine gum (40% (*n*=195) v 37% (*n*=180), respectively).

Table 1: Socio-Demographic Characteristics and Nicotine Dependency of Respondents as a function of Smoking Reductions and the use of Nicotine Replacement Therapy for Smoking Reduction and/or Temporary Abstinence

	SR vs not SR (*n*=2,276 vs *n*=1,902)		NRT for SR vs SR without NRT (*n*=537 vs *n*=1,739)		NRT for TA vs TA without NRT (*n*=488 vs *n*=3,690)	
	SR	Not SR	NRT for SR	SR without NRT	NRT for TA	TA without NRT
Gender %(*n*)						
Male	50 (1,146)	53(1,015)	48(258)	888(51)	46(222)	53(1,939)
Female	50 (1,130)	47(885)	52(279)	851(49)	54(266)	48(1,751)
Age M(*SD*)	40(16)	41(16)	41(16)	40(16)	41(15)	41(16)
Social-Grade %(*n*)						
AB	16(363)	15(291)	17(92)	16(271)	17(84)	15(569)
C1	26(592)	27(503)	23(121)	27(471)	26(127)	26(969)
C2	25(565)	24(446)	29(158)	23(407)	27(133)	24(877)
D	20(458)	22(414)	16(88)	21(369)	15(74)	22(798)
E	13(299)	13(247)	15(78)	13(221)	14(70)	13(476)
Cigarettes per day M(*SD*)	12(7)	14(9)	13(7)	12(7)	14(8)	12(8)
Time to first cigarette of the day %(*n*)						
61> minutes	30(671)	26(491)	24(128)	31(542)	18(87)	29(1,076)
31-60 minutes	21(484)	15(290)	21(111)	22(373)	22(106)	18(669)
6-30 minutes	34(763)	36(673)	37(198)	33(565)	37(180)	34(1,256)
<5 minutes	16(353)	23(441)	19(100)	15(253)	24(116)	19(679)

Note: NRT=Nicotine Replacement Therapy; SR=smoking reduction; TA=temporary abstinence; *SD*=Standard Deviation; M=Mean; *n*=number
Data were weighted to match the 2001 census

Table 2: Percentage of Respondents Reporting Motivation to Quit Smoking, Intention to Quit Smoking, Self-Efficacy in their ability to Quit and Enjoyment of Smoking, as a function of Smoking Reduction and the use of Nicotine Replacement Therapy for Smoking Reduction and/or Temporary Abstinence

	SR vs not SR (*n*=2,276 vs *n*=1,902)		NRT for SR vs SR without NRT (*n*=537 vs *n*=1,739)		NRT for TA vs TA without NRT (*n*=488 vs *n*=3,690)	
	SR	Not SR	NRT for SR	SR without NRT	NRT for TA	TA without NRT
Intend to stop smoking soon %(*n*)	35(800)	12(231)	39(208)	34(593)	33(161)	24(870)
Want to stop smoking %(*n*)	43(978)	16(305)	49(266)	41(712)	40(192)	30(1,090)
Self-efficacy for cessation %(*n*)	23 (522)	20 (42)	20(107)	24(415)	18(88)	22(820)
Enjoyment of smoking %(*n*)	42(955)	57(1,075)	39(207)	43(749)	41(198)	50(1,833)

Note: NRT=Nicotine Replacement Therapy; *n*=Number
Data were weighted to match the 2001 census

A total of 31% (n=1,282) of respondents reported that they wanted to stop smoking, 25% (n=1,031) that they intended to stop smoking soon, and 22% (n=908) that they were confident that they could stop smoking if they tried. The percentage reporting that they wanted to stop was lower than typically reported in the literature but reflects the fact that respondents were allowed to distinguish this from 'ought' to stop smoking – 'wanting' to stop has been found to predict quit attempts whereas 'ought' to stop has not (Smit, Fidler & West, 2011). Forty-nine per cent (n=2,031) of respondents reported that they also enjoyed smoking. Table 2 shows the prevalence of these variables as a function of the cohorts of interest.

Table 3: Mediation Analysis of the Association Between Smoking Reduction and Previous Attempts to Quit Smoking

	Estimate	S.E	*p* value	95% CI	Approx. *OR*
Want to quit smoking					
Smoking reduction → quit attempts	0.54	0.05	0.001	0.45-0.63	2.66
Want to quit → quit attempts	0.27	0.03	0.001	0.22-0.32	1.63
Smoking reduction → want to quit	0.83	0.04	0.001	0.74-0.91	4.49
Total effect	0.77	0.04	0.001	0.68-0.85	4.03
Direct Effect	0.54	0.05	0.001	0.45-0.63	2.66
Indirect Effect	0.22	0.02	0.001	0.18-0.27	1.49
Intention to quit smoking					
Smoking reduction → quit attempts	0.60	0.05	0.001	0.51-0.69	2.96
Intention to quit → quit attempts	0.21	0.03	0.001	0.16-0.27	1.46
Smoking reduction → intention to quit	0.80	0.05	0.001	0.70-0.88	4.25
Total effect	0.77	0.04	0.001	0.68-0.85	4.03
Direct Effect	0.60	0.05	0.001	0.51-0.69	2.96
Indirect Effect	0.17	0.02	0.001	0.12-0.21	1.36
Self-efficacy for smoking cessation					
Smoking reduction → quit attempts	0.76	0.04	0.001	0.68-0.85	3.96
Self-efficacy → quit attempts	0.02	0.03	0.593	-0.04-0.07	1.04
Smoking reduction → self-efficacy	0.11	0.04	0.017	0.02-0.19	1.22
Total effect	0.77	0.04	0.001	0.68-0.85	4.03
Direct Effect	0.76	0.04	0.001	0.68-0.85	3.96
Indirect Effect	0.01	0.00	0.628	-0.01-0.01	1.02
Enjoyment of smoking					
Smoking reduction → quit attempts	0.70	0.04	0.001	0.62-0.79	3.55
Enjoyment of smoking → quit attempts	-0.17	0.03	0.001	-0.22-(-)0.19	0.74
Smoking reduction → enjoyment of smoking	-0.39	0.04	0.001	-0.46-(-)0.31	0.49
Total effect	0.77	0.04	0.001	0.68-0.85	4.03
Direct Effect	0.70	0.04	0.001	0.62-0.79	3.55
Indirect Effect	0.07	0.01	0.001	0.04-0.09	1.14

Note: Estimate=probit regression coefficient; SE=standard error; CI=confidence interval; *OR*=Odds Ratio

Table 3 shows the regression weights for the mediation analysis of smoking reduction with quit attempts, along with the associated total, indirect and direct effects. Those engaging in smoking reduction were more likely to report that they wanted to quit and intended to quit smoking soon, than those not engaging in smoking reduction. Reducers were also less likely to report enjoyment of cigarettes, but were more likely to report that they felt confident that they could stop smoking. A strong positive association was reported between smoking reduction and all mediating variables with attempts to quit smoking, with the exception of self-efficacy. These results translated into three indirect effects: wanting to quit smoking, intention to quit and enjoyment of smoking, all partially mediated the association between smoking reduction and attempts to stop. Self-efficacy was not found to be a mediator.

Table 4: Mediation Analysis of the Association Between Smoking Reduction With Nicotine Replacement Therapy and Previous Attempts to Quit Smoking

	Estimate	S.E	*p* value	95% CI	Approx. OR
Want to quit smoking					
Smoking reduction with NRT → quit attempts	0.61	0.06	0.001	0.49-0.73	3.02
Want to quit → quit attempts	0.19	0.03	0.001	0.13-0.25	1.41
Smoking reduction with NRT → want to quit	0.23	0.06	0.001	0.11-0.35	1.52
Total effect	0.65	0.06	0.001	0.53-0.77	3.24
Direct Effect	0.61	0.06	0.001	0.49-0.73	3.02
Indirect Effect	0.04	0.01	0.001	0.02-0.07	1.08
Intention to quit smoking					
Smoking reduction with NRT → quit attempts	0.63	0.06	0.001	0.52-0.75	3.13
Intention to quit → quit attempts	0.18	0.03	0.001	0.12-0.25	1.39
Smoking reduction with NRT → intention to quit	0.11	0.06	0.088	-0.02-0.23	1.22
Total effect	0.65	0.06	0.001	0.53-0.77	3.24
Direct Effect	0.63	0.06	0.104	0.52-0.75	3.13
Indirect Effect	0.02	0.01	0.104	-0.01-0.04	1.03
Self-efficacy for smoking cessation					
Smoking reduction with NRT → quit attempts	0.65	0.07	0.001	0.53-0.77	3.24
Self-efficacy → quit attempts	0.01	0.04	0.916	-0.07-0.08	1.02
Smoking reduction with NRT → self-efficacy	-0.14	0.07	0.046	-0.27-(-)0.01	0.78
Total effect	0.65	0.06	0.001	0.53-0.77	3.24
Direct Effect	0.65	0.06	0.001	0.53-0.77	3.24
Indirect Effect	-0.00	0.01	0.926	-0.01-0.01	1.00
Enjoyment of smoking					
Smoking reduction with NRT → quit attempts	0.64	0.06	0.001	0.52-0.76	3.18
Enjoyment of smoking → quit attempts	-0.15	0.03	0.001	-0.22-(-)0.09	0.76
Smoking reduction with NRT → enjoyment of smoking	-0.08	0.06	0.165	-0.20-0.04	0.87
Total effect	0.65	0.06	0.001	0.53-0.77	3.24
Direct Effect	0.64	0.06	0.001	0.52-0.76	3.18
Indirect Effect	0.01	0.01	0.209	-0.01-0.03	1.02

Note: Estimate=probit regression coefficient; SE=standard error; CI=confidence interval; *OR*=Odds Ratio

Table 4 shows the regression weights for the mediation analysis of the use of NRT for smoking reduction with attempts to quit smoking, along with the associated total, indirect and direct effects. Those using NRT for smoking reduction were more likely to report wanting to quit smoking and were less likely to report self-efficacy in their ability to quit than those reducing their cigarette intake without NRT. No associations with enjoyment of smoking or intention to quit were established. The use of NRT for smoking reduction, wanting to quit smoking, intention to quit smoking and enjoyment of smoking, were strongly associated with attempts to quit smoking. Only a significant mediating effect of wanting to quit smoking was established.

Table 5: Mediation Analysis of the Association between Temporary Abstinence With Nicotine Replacement Therapy and Previous Attempts to Quit Smoking

	Estimate	S.E	*p* value	95% CI	Approx. OR
Want to quit smoking					
Temporary abstinence with NRT → quit attempts	0.73	0.60	0.001	0.61-0.85	3.89
Want to quit → quit attempts	0.35	0.03	0.001	0.31-0.40	1.88
Temporary abstinence with NRT → want to quit	0.39	0.06	0.001	0.17-0.41	2.03
Total effect	0.83	0.06	0.001	0.71-0.95	4.49
Direct Effect	0.73	0.06	0.001	0.61-0.85	3.89
Indirect Effect	0.10	0.02	0.001	0.06-0.15	1.20
Intention to quit smoking					
Temporary abstinence with NRT → quit attempts	0.75	0.06	0.001	0.63-0.87	3.89
Intention to quit → quit attempts	0.30	0.03	0.001	0.25-0.35	1.72
Temporary abstinence with NRT → intention to quit	0.27	0.06	0.001	0.14-0.39	1.63
Total effect	0.83	0.06	0.001	0.71-0.95	4.49
Direct Effect	0.75	0.06	0.001	0.63-0.97	3.89
Indirect Effect	0.08	0.02	0.001	0.04-0.12	1.16
Self-efficacy for smoking cessation					
Temporary abstinence with NRT → quit attempts	0.84	0.06	0.001	0.72-0.96	4.57
Self-efficacy → quit attempts	0.05	0.03	0.097	-0.01-0.10	1.09
Temporary abstinence with NRT → self-efficacy	-0.16	0.07	0.026	-0.30-(-)0.02	0.75
Total effect	0.83	0.06	0.001	0.71-0.95	4.49
Direct Effect	0.84	0.06	0.001	0.72-0.96	4.57
Indirect Effect	-0.01	0.001	0.223	-0.02-0.01	0.98
Enjoyment of smoking					
Temporary abstinence with NRT → quit attempts	0.78	0.06	0.001	0.66-0.90	4.10
Enjoyment of smoking → quit attempts	-0.21	0.02	0.001	-0.27-(-)0.16	0.68
Temporary abstinence with NRT → enjoyment of smoking	-0.24	0.06	0.001	-0.35-(-)0.13	0.65
Total effect	0.83	0.06	0.001	0.71-0.95	4.49
Direct Effect	0.78	0.06	0.001	0.66-0.90	4.10
Indirect Effect	0.05	0.01	0.001	0.02-0.08	2.09

Note: Estimate=probit regression coefficient; SE=standard error; CI=confidence interval; *OR*=Odds Ratio

Table 5 shows the regression weights for the mediation analysis of the use of NRT for temporary abstinence with attempts to quit smoking, along with the associated total, indirect and direct effects. Those using NRT for temporary abstinence were more likely to report that they wanted to quit, and that they intended to quit, than those not using NRT for temporary abstinence. They were also less likely to report that they enjoyed smoking and that they were confident in their ability to quit. The use of NRT for temporary abstinence, intention to quit, wanting to quit, and enjoyment of smoking, were all associated with quit attempts in the previous 12 months. No association between self-efficacy and attempts to quit smoking was reported. Significant indirect effects were established for wanting to quit smoking, intending to quit smoking, and enjoyment of smoking, but not self-efficacy in one's ability to quit.

Discussion

Wanting to quit smoking, enjoyment of smoking and intention to quit smoking, all partially mediated the relationship between smoking reduction and the use of NRT for temporary abstinence with attempts to quit smoking. No mediating effect of self-efficacy was established. This seemed to reflect the fact that self-efficacy was unrelated to smokers' reports of whether or not they had attempted to quit smoking in the previous 12 months. Of interest, is that while smoking reduction was associated with increased odds of reporting self-efficacy, the use of NRT for harm reduction purposes was associated with lower odds. Wanting to quit smoking was also found to be a partial mediator between the use of NRT for smoking reduction and reports of a previous attempt to quit smoking. The use of NRT for this purpose was not related either to enjoyment of smoking or intention to quit smoking, while it was negatively associated with self-efficacy in one's ability to quit.

The finding of a positive association between attempts to quit smoking with wanting and intending to quit smoking, while a negative association with enjoyment of smoking, is in line with previous research (West et al., 2001a; Hagimoto et al., 2009; Fidler & West, 2011; Fidler & West, 2009; McEwen et al., 2008). The failure to unearth an association with self-efficacy is not surprising, as although many researchers assume that it plays an important role in the process of quitting, findings are inconsistent (West et al., 2001a; Hyland et al., 2006; Herd et al., 2009; Yates & Thain, 1985; Hagimoto et al., 2009). This may be a consequence of smokers possessing an external locus of control (Chambliss & Murray, 1979), perhaps due to the dominance of external treatment for nicotine addiction heightening smokers' perception that smoking is difficult to change on their own (Clarke, MacPherson & Holmes, 1982).

Consequently, it has been suggested that perceived behavioural control may be a more important factor, which is the perceived ease or difficulty of performing a task. There is evidence for a consistent relationship between perceived behavioural control and smoking cessation (for example:- Godin, Valois, Lepage & Desharnais, 2006; Kovac, Rise & Moan, 2009; Armitage & Conner, 2001). Moreover, whereas levels of perceived behavioural control have been demonstrated to influence actual behaviour, efficacy expectancies appear to influence behavioural intentions and maintenance of behaviour (Terry & O'Leary, 1995; White, Terry & Hogg, 1994; Stuart, Borland & McMurray, 1994; Marlatt & Gorden, 1985). Thus although self-efficacy may not interact with a smoker's propensity to quit, it may impact on the success of a quit attempt when one is made. Interestingly motivational variables have little impact at this stage (Borland et al., 2010). This may be because motivation has a threshold-related effect, where if there is enough to generate an attempt, i.e. it is above the threshold, then additional motivation makes no difference to the outcome of the attempt (West, 2006). Alternatively, smokers may rely too much on motivation to see them though a quit attempt, resulting in them neglecting other effective coping strategies, and thus leading to a negative association of motivation with sustained abstinence. Anxiety and physiological arousal have also been proposed to undermine the effects of self-efficacy on outcomes

(Bandura et al., 1977). Consequently, another possible explanation for the lack of an association between confidence in one's ability to quit and actual attempts to quit smoking, is the significant number of smokers who suffer from psychiatric disorders (West & Jarvis, 2005).

This has substantial practice implications. The re-evaluation of interventions used by smoking cessation counsellors which aim to bolster confidence in one's ability to quit may be required, or a focus needs to be given to shifting smokers' locus of control internally. Because an internal locus of control is associated with higher odds of smoking cessations and larger reductions in cigarette consumption, this may be the most suitable option (Segall & Wynd, 1990; Kaplan & Cowles, 1978). Programmes which train internality have demonstrated efficacy (Tobias & McDonald, 1977; Green, Levine & Deeds, 1975). For smoking, this may involve adaptations to smokers' beliefs so that smoking is viewed to be at least partially under their control.

The finding that smoking reduction was positively associated with wanting to quit, intending to quit, and self-efficacy, is in line with previous research (Pisinger et al., 2005; O'Connor & Langlois, 1998; Devins & Edwards, 1988); of which, the prior two were found to be partial mediators of the relationship between smoking reduction and attempts to stop smoking. This could occur because many of those who opt for a harm reduction approach may have struggled with smoking cessation in the past, with smoking reduction affording them the opportunity to try something which is not associated with previous failure. Through repeated success with cutting down they may become motivated to discover whether giving up completely could be an option (Fagerstrom, 1999; Mezulis et al., 2004; Weiner, 1979). The finding that smoking reduction may also promote cessation through enjoyment of smoking in contrast is rather counterintuitive, as it might be expected that reducing smoking would lead to each cigarette becoming effectively more rewarding. Although it is possible that urges to smoke and nicotine dependence decrease as smokers adjust to lower nicotine levels, which could make smoking much less pleasurable; a more likely explanation is that enjoyment of smoking plays a causal role in attempts at smoking reduction. That is, smokers who do not enjoy smoking are more likely to try to reduce. This latter explanation is more probable on the basis that smokers who are reducing do not have significantly lower cigarette consumptions and are unlikely to have reduced nicotine intake relative to other smokers (see Chapters 8-10 & 12; Fagerstrom & Hughes, 2002).

Interestingly, whereas smoking reduction was associated with higher odds of reporting self-efficacy, the use of NRT for smoking reduction and during periods of temporary abstinence was not, with those using NRT for such purposes being less likely than those reducing or temporarily abstaining without pharmacological help to report confidence in their ability to quit. Taken together with the finding that self-efficacy does not appear to mediate the relationship between the use of NRT for harm reduction and attempts to quit smoking, this suggests that it is very unlikely that any effect of NRT use for smoking reduction or during periods of momentary abstinence on cessation is the result of increased self-efficacy in one's ability to stop smoking. The negative association may be for many reasons. The most likely, due to the cross-sectional nature of the study, is that those using NRT for temporary abstinence and smoking reduction were a priori less confident in their ability to quit smoking, while those attempting smoking reduction may be a priori more confident (Godding & Glasgow, 1985). Alternatively, attributions of success may play a role; whereas smokers not using NRT may attribute any success internally, those using NRT may attribute success with temporary abstinence or smoking reduction externally to medication, ultimately lowering their internal attributions of success (Bandura, 1977). It has been demonstrated that removing the responsibility of control from individuals diminishes their confidence in their ability to perform a task (Clifford, 1983; Chambliss & Murray, 1979). Of interest, is that these studies established a concurrent decline in clinical outcomes as a result. For example, Chambliss and Murray (1979) reported that smokers given a self-efficacy communication to internalise their success at smoking reduction, reduced their smoking significantly more than those smokers who attributed their success to a placebo drug. If this is the case, it has a number of therapeutic implications, including the possibility of offering behavioural counselling alongside the use of NRT for harm reduction purposes to focus on increasing internal attributes among smokers. There is evidence that attributions can be modified in a favourable direction during treatment (Firth-Cozens & Brewin, 1988; Brewin. 1988; Forsterling, 1985). However, although internal attributions may help with smoking cessation and reductions in cigarette intake (Schoeneman, Stevens, Hollis, Cheek & Fischer 1988), such attributions during relapse could promote feelings of guilt. Accordingly more external attributions may be optimal once a quit attempt has occurred (Curry, Marlatt & Gordon, 1987; Marlatt & Gordon, 1985).

The finding that wanting to quit smoking was a partial mediator of the association between the use of NRT for smoking reduction and attempts to stop smoking is inconsistent with previous clinical trials, which reported greater odds of a desire to quit smoking among active NRT groups relative to usual-care but not placebo NRT controls (Carpenter et al., 2003; Carpenter et al., 2004; Fagerstrom et al., 2000; Wennike et al., 2003). This may because the behavioural support provided in the clinical trials across the placebo and active groups diluted any effect of NRT. Previous survey-based studies have also failed to report such associations, but this may reflect methodological issues (Levy et al., 2007; Hammond et al., 2008). Thus it may be argued that if the use of NRT for smoking reduction does increase smokers' propensity to quit, it may do so via increasing their motivation to stop. However, because a cross-sectional study and statistical mediation does not necessarily imply causal mediation, it could be that smokers who are more motivated to stop are also more motivated to use NRT.

In contrast, the failure to find an association between the use of NRT for smoking reduction and intention to quit is in line with previous findings (Bolliger et al., 2000; Carpenter et al., 2003; Etter et al., 2002; Rennard et al., 2006). In the current study this most likely reflects the sample that was recruited, with those using NRT for smoking reduction holding a desire to quit, but perhaps not intending to do so in the near future. Previous studies have reported that there are a number of smokers who want to quit smoking but have no intention to do so (Sargent, Mott & Stevens, 1998). According to Heckhausen and Kuhl (1985) this is because a temporal sequence to motivational decision making exists, from 'wishing' (wants) related to value and which are removed from goal action, through 'intentions' which are closer to action and based on decisions about behaviour. Moreover, as those partaking in harm reduction may be more likely to make unplanned, impromptu quit attempts (Ferguson et al., 2009), it is plausible that the failure to report a mediating effect of intention to stop smoking is because smokers' intentions to quit only arises at the moment they actually stop smoking.

However, the failure to find an association with enjoyment of smoking is rather counterintuitive. It may have been assumed that obtaining nicotine from a source other than cigarettes would reduce smoking satisfaction, as the smoker would already be partly satiated with nicotine (Fagerstrom & Hughes, 2002). Of course, this finding may simply reflect the cross sectional nature of the study, with those who enjoy smoking the most being more likely to opt to use NRT. Consequently, even if a reduction in enjoyment did occurred, it would not be detected unless it was to a level lower than that of non-smokers. To understand this process better it will be important to undertake studies examining mediation using prospective and experimental designs. An alternative explanation may be that smokers use insufficient amounts of NRT for enjoyment to be affected. There is evidence that smokers have a tendency to underuse and incorrectly use NRT at a population level (Shiffman et al., 2002b; Shiffman et al., 2003a; Shiffman et al., 2003b). Moreover, enjoyment of smoking is not just dependent on nicotine but also non-nicotine factors, including cigarettes distinctive smell and taste. Because NRT does not eliminate these whilst used concurrently with cigarettes, it is perhaps of little surprise that smokers continue to report the enjoyment of smoking (Etter et al., 2002). Perkins et al. (2001) have shown that attenuating these olfactory/taste cues of smoking, diminishes the pleasure and behaviourally reinforcing effects of cigarette smoke. Whichever the explanation, it may be concluded from the current findings that it appears unlikely that enjoyment of smoking is causally implicated in the association between the use of NRT for smoking reduction and cessation, if such a relationship exists.

Finally, the finding that the association between NRT use for periods of temporary abstinence and attempts to quit smoking may be mediated by enjoyment of smoking, wanting to quit smoking and intention to quit smoking, is of interest; particularly as this is the first time an association between NRT use to tide one over and the rewarding effects of cigarettes has been reported. It is possible that this occurs as a result of NRT use diminishing the impact cigarettes have on urges to smoke and withdrawal symptoms following periods of momentary abstinence. However, as with the other associations, it is also quite probable that those who enjoy smoking less are more likely to opt to use NRT. Similarly, it is quite plausible that those using NRT for temporary abstinence were a priori more motivated to quit smoking.

Prior to drawing firmer conclusions a number of limitations need to be considered. First the measures of the psychological variables of interest were dichotomous, which may have limited their measurement efficacy and led to some associations being missed. However, the large sample size meant we were able to detect even modest associations. Secondly, this study was concerned with smokers' reports of their behaviour, which may be subject to recall or other biases and errors. Thirdly, there are issues with using cross-sectional data for mediation analysis. Gollob and Reichardt (1985) claim that testing mediational hypotheses with cross-sectional data will be accurate only under fairly restrictive conditions, and that when these do not pertain, cross-sectional studies provide biased and potentially very misleading estimates of temporal processes. One of these conditions is that of complete mediation, which did not occur in the current analysis. Moreover, in cross-sectional analyses we cannot be sure that X precedes M and M precedes Y, unlike longitudinal designs which yield the advantage of providing information about temporal precedence (Maxwell & Cole, 2007). Additionally, if unknown Ms are uncontrolled for, then any paths may be spuriously inflated, i.e. true mediating variables may result in variables correlated to these being demonstrated to mediate associations. This is often difficult in cross-sectional analyses and surveys such as this, which do not specifically focus on the questions at hand, and therefore fail to assess all confounding variables of interest. Fourthly, there was only evidence for partial mediation, thus future studies should aim to assess other variables, including changes in attentional bias and quality of life, which may be stronger mediators. Finally, these data provide evidence of mediation only for quit attempts. It is quite plausible that different variables may mediate between attempts at harm reduction and the success of a quit attempt. This would be an interesting area for future research.

Conclusion

A number of hypotheses have been made as to the factors which may mediate the relationship between the use of NRT for smoking reduction and/or temporary abstinence and attempts to quit smoking. These include increased motivation to quit; reduced enjoyment of smoking; and increased self-efficacy in one’s ability to quit. This study found that while the first two explanations remain plausible, increased self-efficacy can largely be ruled.

Chapter 12: The Association Between the use of Nicotine Replacement for Harm Reduction and Cotinine Levels: A National Survey of English Smokers

Introduction

The nicotine regulation hypothesis proposes that smokers smoke in order to regulate their blood nicotine levels and that they will decrease their smoke intake when extra nicotine is received from another route [know as down-regulation; (Russell, 1978)]. This model has been tested numerous times in experimental studies, which have demonstrated that the use of medicinal nicotine during *ad libitum* smoking results in partial compensation, at least in some smokers (Benowitz et al., 1998; Russel, 1990; Foulds et al., 1992; Pickworth, Bunker & Henningfield, 1994). This chapter provides preliminary evidence on whether those using NRT for harm reduction also have a tendency to compensate for the additional nicotine attained from NRT, by examining salivary cotinine concentrations among smokers spontaneously using NRT for smoking reduction and/or during periods of temporary abstinence. Cotinine is a major metabolite of nicotine and gives a reasonable indication of the amount of smoke and medicinal nicotine intake over the past few days (Apseloff, Ashton, Friedman & Gerber, 1994).

Previous clinical trials assessing the efficacy of NRT for smoking reduction have shown that cotinine levels reside below or at the same level of smokers reducing their cigarette consumption without pharmacological help, and do not reach above baseline rates (Batra et al., 2005; Wennike et al., 2003; Fagerstorm et al., 2002; Rennard et al., 2006; Joseph et al., 2008). This appears to materialise from smokers’ ability to significantly reduce their cigarette consumption. One exception to this rule was a cross-over study by Tidey et al. (2002) who reported higher cotinine levels among patients diagnosed with schizophrenia when they received the nicotine patch for smoking reduction, as opposed to placebo NRT. This appeared to be consequence not only of their inability to significantly reduce their cigarette intake, but also to regulate NRT use. Previous studies have reported that those diagnosed with schizophrenia find it substantially harder to change their smoking behaviour (Hasnain, Victor & Vieweg, 2011), and that they experience a breakdown of self-regulatory processes, making it difficult to regulate medication use (Ownsworth, McFarland & Young, 2002). This is presumed to result from the collapsing of attentional filters leading to sensory and cognitive overload in demanding situations (Broadbent, 1970). Those with psychiatric disorders also tend to self-medicate, with nicotine use being a means to reduce a number of psychological symptoms, including dysphoria (Khantzian, 1997). This may consequently lead to the overuse of NRT. There is evidence that patients with schizophrenia have increased levels of nicotine relative to other smokers, proposed to be due to higher doses activating low-affinity α-7 nicotinic receptors, which are associated with deficits in sensory inhibition (Olincy, Young & Freedman, 1997). Moreover, results show that although smokers' titration of their nicotine levels with acute NRT forms is reasonable good, they are relatively inept at doing so with nicotine patches (Fagerstrom & Hughes, 2002). This is possibly because patches do not give a nicotine boost that can be felt subjectively and do not naturally replace the subjective effect of a cigarette. If nicotine is delivered slowly this gives the body time to adapt increasing tolerance with a parallel increase in nicotine concentrations. Acute systems also directly interfere with smoking behaviour, with the concurrent chewing of nicotine gum and smoking being fairly uncommon.

If it is the case that smokers are unable to regulate their nicotine levels with transdermal products, the concern arises that smokers spontaneously using NRT during attempts at smoking reduction and momentary abstinence may experience increased nicotine intake; not only because the nicotine patch is the most commonly used NRT product for such purposes (see Chapters 6 & 7; Carpenter et al., 2003; Carpenter et al., 2004; Etter et al., 2002; Chan et al., 2011), but since the use of NRT in these ways is associated with declines in cigarette consumption in the range of only one to two cigarettes per day (see Chapter 10; Levy et al., 2007; Hammond et al., 2008; Etter et al., 2003). Of course, compensation does not have to occur by reducing actual cigarette consumption, but could also do so via the modification of the way in which cigarettes are smoked (Foulds et al., 1992). Adaption of smoking style does appear to be a common behaviour among smokers (Johnson et al., 2004), with previous studies reporting that those spontaneously reducing their cigarette consumption often attempt to inhale less and put their cigarettes out early (Okuyemi et al., 2002). Moreover, reductions in the intensity of smoking and the total quantity of smoke inhaled have been noted among those using NRT as part of a smoking reduction intervention (Etter et al., 2002).

If compensation is shown to occur among those spontaneously using NRT for smoking reduction and/or during periods of temporary abstinence, this will reassure regulatory authorities who may be concerned about smokers being exposed to increased levels of nicotine. This concern was a major hindrance to the change in the licensing of NRT in the UK so that it could be used for harm reduction purposes (MHRA, 2010); currently limits NRT regulation in the US (Association for the Treatment of Tobacco Use & Dependence & the Society for Research on Nicotine and Tobacco, 2010); and could hamper the application the use of NRT for smoking reduction in stop smoking services (Croghan & Chambers, 2011; Borreli & Novak, 2007). Currently, the US Food and Drug Administration under the red-lettered 'warnings' section of NRT cautions: *''Do not use if you continue to smoke . . .''* On nicotine patch products the warning is even harsher: *''When using this product, do not smoke* *even when not wearing the patch. The nicotine in your skin will still be entering your blood stream for several hours after you take off the patch.''* This is despite the American Council on Science and Health endorsing tobacco harm reduction approaches and calling for change (Rodu & Godshall, 2006).

Evidence for compensation could also point towards the possibility of a reduction in harm, since smokers in the process of reducing nicotine intake from cigarettes are likely to reduce their intake of other toxic substances as well. However, reductions in toxin intake may be small, since the current NRT products, unless adhered to and taken in large quantities, have only minimal effects on cotinine levels (Foulds et al., 1992). This is because they are designed to weaken and minimise nicotine dependency, offering a much lower dose of nicotine and at a slower rate than the traditional cigarette (Hurt et al., 2003). For example, plasma nicotine levels equivalent to those following a cigarette can only be obtained by chewing at least 10 pieces of 4mg nicotine gum daily for about 30 minutes, while even excessive dosages of 2mg gum do not produce an adequate plasma nicotine level (Russell, Feyerbend & Cole, 1976). In relation to the nicotine patch, dosages less than 22mg fail to produce cotinine levels in the range of cigarette smoking; this is only achieved by dosages of 44mgs or more (Lawson et al., 1998). Moreover, at a population level, smokers have a tendency to underuse and incorrectly use medicinal nicotine products, resulting in peak cotinine concentrations far below those found in experimental trials (Shiffman et al., 2002b; Shiffman et al., 2003a; Shiffman, et al., 2003b; Hughes et al., 2011; Cartwright, May & Polisky, 2007; Etter & Perneger, 2001; Cummings & Hyland, 2005; Hammond et al., 2004; Schneider et al., 2005; Mooney, Leventhal & Hatsukami, 2006; Paul, Walsh & Girgis, 2003). This may be a result of smokers fearing that the use of NRT, especially the nicotine patch, while continuing to smoke is dangerous and may cause a heart attack (Balch et al., 2004; Cartwright et al., 2007; Etter et al., 2003; Zwar, Bell, Peters, Christie & Mendelsohn, 2006).

Even if the opposite is the case, and smokers show clear evidence of an increase in nicotine intake when they smoke and use NRT concurrently, this would not necessarily be cause for concern, since even substantially increased nicotine concentrations (for example:- up to three times the approved dose), do not appear to cause any serious adverse reactions (Fagerstrom & Hughes, 2002). Nonetheless, some may still be concerned about the possible effects of increased nicotine intake on smokers' reliance on cigarettes; increasing plasma nicotine may result in smokers becoming more dependent through neuroadaptation, which includes receptor inactivation and desensitisation and an increase or up-regulation in receptor number, thus making it harder for them to quit smoking (Benowitz, 1999). Many smokers do appear to believe that the concomitant use of NRT and cigarette will increase their levels of dependence on tobacco products (Etter et al., 2003).

Methods

Study Design and Sampling

Baseline data for this study were obtained between February 2007 and April 2010 from the Smoking Toolkit Study. See methods section in Chapter 7 for more details.

Ethical Approval

Ethical approval was granted by the University College London Research Ethics Committee.

Measures

Smoking status was assessed by asking: 'Which of the following best applies to you? – (I smoke cigarettes (including hand-rolled) every day; I smoke cigarettes (including hand-rolled), but not every day; I do not smoke cigarettes at all, but I do smoke tobacco of some kind (for example:- pipe or cigar); I have stopped smoking completely in the last year; I stopped smoking completely more than a year ago; I have never been a smoker (i.e. smoked for a year or more); don't know). Those who responded that they smoke cigarettes every day or that they smoked but not every day were coded as current cigarette smokers. Current smokers were asked questions about socio-demographic characteristics (i.e. gender, age & social-grade), cigarette consumption per day, and time to first cigarette of the day as a measure of nicotine dependence (Fagerstrom, 2003). Social-grade was classified as follows: AB=higher and intermediate professional/managerial; C1=supervisory, clerical, junior managerial/administrative/professional; C2=skilled manual workers; D=semiskilled and unskilled manual workers; E=on state benefit, unemployed, lowest grade workers.

Participants were also asked: 'Are you currently trying to cut down on how much you smoke' – (yes; no; don't know). In July 2009 this was changed to: 'Are you currently trying to cut down on how much you smoke but not currently trying to stop?' – (yes; no; don't know). If they answered 'yes' they were asked: 'Which, if any, of the following are you currently using to help you cut down the amount you smoke? – (nicotine patch; nicotine gum; nicotine lozenges/tablets; nicotine inhaler; nicotine nasal spray; I don't know; none of these; other). All smokers were asked: 'Do you regularly use any of the following in situations when you are not allowed to smoke? – (nicotine patch; nicotine gum; nicotine lozenges/tablets; nicotine inhaler; nicotine nasal spray; I don't know; none of these; other).

Following the baseline survey, participants who agreed to be contacted for follow-up were sent postal questionnaires 3 and 6 months later, where they were asked about their cigarette consumption, if they were cutting down, and if they were using NRT for smoking reduction and/or temporary abstinence. Half of these were also asked to provide cotinine swabs for analysis at both follow-up points. Saliva samples were sent to ABS laboratories where cotinine was assayed using a gas chromatographic method with a detection limit of 0.1 ng/ml (Feyerabend & Russell, 1990). For further information on the measures used in the Smoking Toolkit Study see www.smokinginengland.info.

Analysis

Parametric Assumptions

The assumption of 'normality' required for independent *t*-test analysis was assessed using the Kolmogorov-Smirnov (K-S) statistic, while 'homogeneity of variance' using Levene's statistic (Levene, 1960). Age and cigarette consumption were non-normal among responders (D(604)=0.050, $p<0.001$ versus D(604)=0.182, $p<0.001$) and non-responders (D(15214)=0.065, $p<0.001$ versus D(15214)=0.145, $p<0.001$). Variances in cigarette consumption were equal ($F=0.143$, $p>0.05$), although variances in age were not ($F=6.625$, $p<0.01$). Log and square root transformations were unsuccessful for correcting these issues with non-normality and heterogeneity. Because the large sample size means that the K-S test may be significant even when the distribution only differs slightly from normal, histograms and P-P plots were also calculated. These confirmed the non-normality present in the data for cigarette consumption and age. Consequently, non-parametric tests were sought to assess differences among responders and non-responders. The assumption of 'normality' required for paired *t*-test analysis was assessed using P-P plots of the differences in cigarette consumption and cotinine when smokers were and were not reducing their cigarette consumption; and when smokers were and were not using NRT for smoking reduction and/or temporary abstinence. All P-P plots showed that cigarette consumption and cotinine were non-normally distributed. Because square root and log transformations were unsuccessful at correcting these issues with non-normality, non-parametric tests were used.

Finally, the assumptions of 'normality' and 'homogeneity of variance' inherent in repeated ANOVA analysis were assessed using the K-S and Levene's statistic (Levene, 1960). Cigarette consumption at baseline and follow-up were both significantly non-normal among those only reporting NRT use at baseline (D(29)=0.209, $p<0.01$ versus D(29)=0.172, $p<0.05$); among those only reporting smoking reduction at baseline (D(57)=0.181, $p<0.001$ versus D(57)=0.211, $p<0.001$); and among those only reporting smoking reduction at follow-up (D(49)=0.256, p<0.001 versus D(29)=0.263, $p<0.001$). In contrast, whereas cigarette consumption among those only reporting NRT use at follow-up was non-normal at baseline (D(29)=0.274, $p<0.001$), it was normal at follow-up (D(29)=0.150, $p>0.05$). Cotinine levels at follow-up and baseline were also non-normally distributed among those reporting NRT use only at follow-up (D(29)=0.170, $p<0.05$ versus D(29)=0.165, $p<0.05$). In contrast, at baseline and follow-up there was no evidence of non-normality among those only reporting NRT use at baseline (D(29)=0.100, $p>0.05$ versus D(29)=0.112, p>0.05). Cotinine levels at both baseline and follow-up were also established to be normally distributed among those reporting smoking reduction only at baseline (D(57)=0.074, $p>0.05$ versus D(57)=0.077, $p>0.05$) and only at follow-up (D(49)=0.104, $p>0.05$ versus D(49)=0.101, $p>0.05$). Square root transformations were successful for correcting issues with normality for cotinine levels. The assumption of homogeneity of variance was not violated either for cigarette consumption at baseline or follow-up (F=(1,119)=3.486, $p>0.05$ versus F(1, 119)=0.096, $p>0.05$) or cotinine between baseline and follow-up (F=(1,119)=0.182, $p>0.05$ versus F(1, 119)=0.002, $p>0.05$) among those starting and stopping smoking reduction. Neither was the assumption violated for cigarette consumption at baseline or follow-up (F=(1,63)=0.013, $p>0.05$ versus F(1, 63)=0.013, $p>0.05$) or cotinine between baseline and follow-up (F(1,63)=1.183, $p>0.05$ versus F(1, 63)=0.489, $p>0.05$), among those starting and stopping the use of NRT. P-P plots confirmed the non-normality present in the data. Consequently, non-parametric tests were sought for the assessment of any change in cigarette consumption (see Appendix E).

Statistical Analysis

STROBE guidelines for the reporting of epidemiological studies were followed throughout (von Elm et al., 2007), with missing data dealt with prior to analysis using the listwise deletion procedure. For the reporting of prevalence data, an iterative marginal weighting technique was used in order to maximise the reliability of the sample data and minimise any statistical bias. This was achieved by performing the least amount of weighting required to correct for sample disproportionalities that may have distorted estimates. The process works by setting separate nationally representative target profiles for gender, working status, prevalence of children in the household, age, social-grade and region, and the process repeated until all variables match the specified targets.

Differences among responders and non-responders were assessed using Chi-squared analysis and Mann-Whitney tests. For Mann-Whitney tests corresponding effect sizes were calculated (r=Z score/$\sqrt{\text{total}}$ sample size). To assess significance in the Chi-squared tests, standardised residuals were compared to the critical values that correspond to an alpha of 0.05 (+/-1.96), an alpha of 0.01 (+/-2.58) or an alpha of 0.001 (+/-3.10). Odds Ratios were then calculated where significance was evident. In order to determine whether the use of NRT for harm reduction was associated with reduced cigarette consumption and cotinine levels, those who were smokers at both three and six months follow-up and who on one occasion were using NRT and on the other occasion were not, were identified. Comparisons were made in the reported daily consumption and cotinine between these two instances, irrespective of the order in which they occurred, using the Wilcoxon Signed-Rank test. The same analysis was then conducted for those who reported smoking reduction on one occasion and not the other, and who were not using NRT. Corresponding effect sizes were also calculated (r=Z score/$\sqrt{\text{total}}$ sample size). A secondary analysis was undertaken to assess whether there was a change in cigarette consumption and cotinine over time. The Friedman test was used to assess alterations in cigarette consumption and repeated measures ANOVA to assess alterations in cotinine levels; controlling for potential confounding variables as appropriate (i.e. age, gender, socio-grade & time to first cigarette of the day). SPSS version 18.0 was used for all analyses.

Power

Post-hoc power analysis using G*Power 3 (Faul, Erdfelder, Buchner & Lang, 2009), revealed that for the assessment of differences in cotinine levels when attempting smoking reduction and not attempting smoking reduction, an effect size of 0.5 could be detected with 100% power using an alpha of 0.05, 99.7% power using an alpha 0.01, while 97.5% power using an alpha of 0.001. For the assessment of differences in cotinine levels when using NRT for harm reduction and not using NRT for harm reduction, an effect size of 0.5 could be detected with 94.3% power using an alpha of 0.05, 81.9% power using an alpha 0.01, while 54.9% power using an alpha of 0.001.

Results

Between February 2007 and April 2010, 67,690 adults were surveyed; of whom, 15,189 reported that they were current smokers. Ninety per cent (*n*=13,622) agreed to be re-contacted at follow-up. Twenty-seven per cent (*n*=3,730) of these completed the questionnaire at 3 months (T1) and 22% (*n*=3058) completed the questionnaire at 6 months (T2). Seventeen per cent (*n*=2,258) of respondents completed both the T1 and T2 questionnaires. Forty-one per cent (*n*=930) of respondents provided a cotinine sample at T1 and 41% (*n*=917) at T2. Of the T1 saliva samples, 79% (*n*=734) were valid (153 contained insufficient volume for analysis, 43 were contaminated/missing). Seventy-nine per cent (*n*=723) of the saliva samples were also valid at T2 (146 contained insufficient volume for analysis, 48 were contaminated/missing).

Table 1: Socio-Demographic Characteristics and Nicotine Dependency of Respondents in the Baseline Survey and Those With Valid Cotinine at Both Follow-up Time Points

	Sample at baseline[a] (*n*=14,638)	Sample with valid cotinine at both time points (*n*=551)
Age M(*SD*)	40.4 (16.10)	46.1 (15.22)
Gender *n*(%)		
Male	51.2 (7,770)	45.7 (251)
Female	48.8 (7,418)	54.3 (299)
Cigarettes smoked per day M(*SD*)	13.2 (8.44)	14.9 (8.82)
Social-grade *n*(%)		
AB	15.3 (2,326)	16.3 (90)
C1	25.3 (3,843)	24.1 (133)
C2	24.4 (3,713)	24.1 (133)
D	22.0 (3,335)	21.8 (120)
E	13.0 (1,972)	13.6 (75)
Time to first cigarette of the day *n*(%)		
>61 minutes	34.5 (5,031)	29.8 (164)
31-60 minutes	12.0 (1,752)	10.4 (57)
6-30 minutes	33.8 (4,939)	36.5 (201)
<5 minutes	19.7 (2,878)	23.3 (128)

Note: M=mean; *SD*=Standard Deviation; *n*=number
Data were weighted to match the 2001 census.
[a]Excluding those followed-up with valid cotinine at both time points

Six hundred and thirty-two (28%) respondents provided valid cotinine samples at both time points. For four participants cotinine values were above 1,000ng/ml; these cases were removed from the analysis, as were those smokers who reported that they were no longer smoking at follow-up. This resulted in a final sample of 551 smokers. Table 1 shows the socio-demographic and baseline smoking characteristics of these smokers, as well as for the sample of smokers eligible to be included in the postal survey. No differences between those followed-up with valid cotinine and the original sample were found in relation to social-grade (*U*=3972194.00, *p*=0.996). The sample followed-up and who provided usable saliva specimens were slightly older (*U*=3698667.0, *p*=0.001; r=-0.07), reported smoking more cigarettes per day (*U*=4015564.0, *p*=0.001; *r*=-0.04), were less likely to be male (χ^2=7.0, *df*=1, *p*=0.001; Odds Ratio 1.14; Confidence Interval 1.00-1.35), and were more nicotine dependent (*U*=4296879.00, *p*=0.003; *r*=-0.02), than those not followed-up.

Table 2: Socio-Demographic Characteristics and Nicotine Dependency of Respondents as a Function of Those Starting and Stopping Smoking Reduction and Those Starting and Stopping the use of Nicotine Replacement Therapy for Harm Reduction

	Starting or stopping smoking reduction (*n*=116)	Starting or stopping use of NRT for harm reduction (*n*=52)
Gender %(*n*)		
Male	44.9 (52)	39.5 (21)
Female	55.1 (64)	60.5 (32)
Age M(*SD*)	43.8 (16.53)	45.7 (13.00)
Cigarettes per day M(*SD*)	14.4 (9.12)	15.7 (6.93)
Social-grade %(*n*)		
AB	11.6 (13)	14.2 (7)
C1	19.9 (23)	25.5 (13)
C2	25.3 (29)	26.5 (14)
D	33.6 (39)	15.4 (8)
E	9.7 (11)	19.3 (10)
Time to first cigarette of the day *n*(%)		
>61 minutes	32.8 (38)	26.2 (14)
31-60 minutes	7.0 (8)	11.2 (6)
6-30 minutes	37.1 (43)	34.6 (18)
<5 minutes	23.1 (27)	28.0 (15)

Note: M=mean; *SD*=Standard Deviation; *n*=number; NRT=Nicotine Replacement Therapy
Data were weighted to match the 2001 census

Of the 511 participants who were followed-up with valid cotinine, 187 were identified who were reducing their smoking at both time-points (without the aid of NRT), 172 who were not reducing at either time point, and 116 who had started or stopped attempting to reduce their smoking. Twenty-three were also identified who were using NRT for smoking reduction or temporary abstinence at both follow-up points, 475 who did not use NRT at either time point, and 52 who reported using NRT for smoking reduction and/or during periods of temporary abstinence at one time point but not the other. Smokers were more likely to report using the nicotine patch (38.3% (*n*=18) at T1 and 44.2% (*n*=23) at T2) and nicotine gum (38.3% (*n*=18) at T1 and 40.2% (*n*=21) at T2). Socio-demographic characteristics of those smokers of interest, i.e. those starting or stopping smoking reduction and those starting or stopping the use of NRT for harm reduction, are shown in Table 2.

Table 3: Reports of Average Cigarette Consumption and Cotinine Levels Among Respondents at Three and six Months Follow-up as a Function of Those Starting and Stopping Smoking Reduction and Those Starting and Stopping the use of Nicotine Replacement Therapy for Harm Reduction

	Cigarettes per day T1 M(*SD*)	Cigarettes per day T2 M(*SD*)	Cotinine T1 (ng/ml) M(*SD*)	Cotinine T2 (ng/ml) M(*SD*)
Smoking reduction at T1 not T2 (*n*=62)	16.2 (9.34)	16.8 (10.17)	286.7 (193.75)	293.7 (185.89)
Smoking reduction at T2 not T1 (*n*=54)	16.5 (12.03)	14.0 (10.14)	276.7 (213.07)	270.6 (197.75)
Concurrent use of NRT and cigarettes at T1 not T2 (*n*=24)	16.6 (8.1)	16.4 (7.4)	324.5 (140.0)	373.4 (168.40)
Concurrent use of NRT and cigarettes at T2 not T1 (*n*=28)	16.6 (9.0)	13.3 (8.1)*	345.9 (164.8)	339.4 (185.3)

Note: *n*=number; M=mean; *SD*=Standard Deviation; NRT=Nicotine Replacement Therapy T1=3 months follow-up/time 1; T2=6 months follow-up/time 2
Data were weighted to match the 2001 census
Significant difference between T1 and T2 (*p<0.05, ** p<0.01, ** p<0.001)

The mean [Standard Deviation (*SD*)] cotinine concentration when smokers were reducing their cigarette consumption was 275.2ng/ml (185.38); the mean cotinine concentration when smokers were not reducing their consumption was higher at 284.8ng/ml (*SD* 195.62), but not significantly (Z=-0.01, p=0.996). In contrast, a significant difference in cigarette consumption was reported (Z=-2.33, p=0.02; r=-0.15), with a mean of 15.0 (*SD* 9.24) while reducing smoking, compared with 16.3 (*SD* 10.25) when not reducing smoking. The mean cotinine concentration when smokers were using NRT was 325.5ng/ml (*SD* 169.69); the mean cotinine concentration when smokers were not using NRT was higher at

360.1ng/ml (*SD* 167.65), but not significantly (Z=-1.92, *p*=0.055). In contrast, there was a significant difference in cigarette consumption (Z=-1.97, *p*=0.049; *r*=-0.17), with a mean of 14.4 (*SD* 8.30) while using NRT, compared with 16.5 (*SD* 9.62) when not using NRT.

Table 3 shows the mean cotinine concentrations and daily cigarette consumption of the study sample at the two follow-up points. After controlling for potential confounding variables, no significant interaction was reported between smoking reduction and follow-up point in terms of cotinine (*F*(*df* 1,115)=0.29, *p*=0.594); nor was there any differ in consumption at T1 and T2 among those only reducing at T1 (χ^2=0.01 (*df* 1), *p*=1.000) or T2 (χ^2=3.00 (*df* 1), *p*=0.083). The interaction between the use of NRT and follow-up point for cotinine was also non-significant (*F*(*df* 1,59)=1.845, *p*=0.180). There was also no difference in cigarette consumption at the two time points among those only using NRT at T1 (χ^2=0.25 (*df* 1), *p*=0.617), although those only using NRT at T2 had a lower cigarette consumption at T2 (χ^2=3.85 (*df* 1), *p*=0.050).

Discussion

The use of NRT for harm reduction purposes was not associated with any detectable increase in nicotine intake, despite smokers failing to reduce their cigarette consumption by significantly large amounts. In fact, a trend towards a decrease in cotinine levels when using NRT was established. Attempts at smoking reduction were also not associated with reduced cotinine levels or large reductions in cigarette consumption.

These findings imply that smokers who are spontaneously using NRT for harm reduction purposes at a population level may be changing the way they smoke their cigarettes to compensate for the additional nicotine obtained. If this is the case, it would support not only one of the most prominent concepts in nicotine addiction, that of the nicotine regulation hypothesis (Russell, 1978), but also previous studies on the concurrent use of NRT with *ad libitum* smoking (Benowitz et al., 1998; Russell, 1990; Foulds et al., 1992; Pickworth et al., 1994). Consequently, future studies should rely more on measures of actual toxin exposure when assessing the efficacy of the use of NRT for smoking reduction and/or during periods at a population level. However, the failure to establish any change in cotinine levels among those spontaneously using NRT for harm reduction purposes, also points towards the possibility that significant reductions in the harm caused to smokers may not result from such activities. As current NRT products have only minimal effects on nicotine levels (Foulds et al., 1992), stability in cotinine pre- and post- NRT use would point towards only a small decline in toxin intake from cigarettes. However, Fagerstrom and Hughes (2002) have noted that stability of cotinine following NRT use is associated with reductions of up to 30% in carbon monoxide intake, which could be indicative of reduced harm (Vogt, Selvin & Hulley, 1979). Thus to draw firmer conclusions it will be necessary to assess changes in disease biomarkers, such as carbon monoxide, among those using NRT for harm reduction purposes at a population level. Nonetheless, in the meantime, we should perhaps err on the side of caution and inform smokers that health benefits may only be reaped if they quit smoking.

Previous clinical trials assessing the use of NRT for smoking reduction have also reported that smokers attempt to modify how they smoke their cigarettes (Etter et al., 2002). However, in contrast they also established significant declines in cotinine levels. This potentially signifies that compensation for the additional nicotine attained form NRT may occur through the modification in the way cigarettes are smoked, but that actual reductions in nicotine intake may only materialise if concurrent declines in cigarette consumption of over 50% transpire (Batra et al., 2005; Wennike et al., 2003; Fagerstorm et al., 2002; Rennard et al., 2006; Joseph et al., 2008). The significant reductions in cigarette consumption present in the clinical trials may partially be due to social pressure, i.e. the awareness that the study was looking at smoking reduction, in addition to the extensive behavioural support that was provided and the extended treatment lengths. In the current study it is unclear when attempts to reduce smoking intake or the use of NRT commenced, with the findings perhaps being biased as a consequence of those who had started to cut down or to use NRT only a few days prior to follow-up. Future studies are warranted which assess changes in cigarette consumption and cotinine levels amongst those reducing their cigarette consumption or temporarily abstaining with NRT over longer periods of time.

However, rather than the failure to find an increase in cotinine levels being the result of smokers compensating for the additional nicotine attained from NRT through the adaption of their smoking style, while the failure to find a decrease due to a lack of significant reductions in cigarette consumption; these findings may also reflect the fact that NRT use was so minimal as to not to have any detectable effect on cotinine levels. There is evidence that smokers do not use enough NRT, incorrectly use NRT, and do not adhere to its use for substantial periods of time (Shiffman et al., 2003a; Shiffman et al., 2003b; Hughes et al., 2011; Cartwright et al., 2007; Etter & Perneger, 2001; Cummings & Hyland, 2005; Hammond et al., 2004; Mooney et al., 2006; Paul et al., 2003). Studies have also observed that the greater the dose of exogenous nicotine, the lower the cigarette nicotine intake (Hatsukami et al., 2007; Benowitz et al., 1998). However, such concerns may apply more so to non-transdermal products where the bio-available doses of nicotine are reliant on behavioural usage. Since it appears that smokers hold a preference for the nicotine patch, adequate nicotine levels may thus be attained, being restricted only by the strength of the product used. The extent of NRT use thus needs to be explored further.

The finding that cotinine levels did not decrease among those starting and stopping attempts at smoking reduction is perhaps unsurprising, since it may be assumed that without pharmacological help smokers will smoke each remaining cigarette harder in order to maintain a steady nicotine intake. Previous population-based studies have also reported little reduction in cotinine and other biological measures over time among those cutting down (Godtfredsen, Prescott, Vestbo & Osler, 2006). Moreover, clinical trials have noted reductions in nicotine intake only amongst those reducing their cigarette consumption considerably by 50% or more (Bolliger et al., 2002; Riggs et al., 2001). However, the picture is not that clear cut. Others have established that smoking reduction results in the decreased risk of cardiovascular disease (Eliasson et al., 2001), respiratory conditions (Godtfredsen et al., 2002a), and improves immune system recovery (Pulera et al., 1997). This may be explained by the recruitment of those reducing with an aim to quit, the participation of lighter smokers, and long-term follow-up. Many of these studies also occurred more than a decade ago when cessation was the only recommended treatment option, consequently similar findings may not apply to those attempting smoking reduction today. It is also perhaps difficult to infer about disease risk from biomarkers such as cotinine, because it is currently unclear how much of a reduction is needed in a given biomarker for it to produce a reduction in subsequent disease risk.

However, this study did suffer from a number of limitations that require consideration. First the sample size was relatively small. Although, using a within-subject comparison means that it would have had the sensitivity to detect a meaningful change. Secondly, the sample that responded to both follow-up questionnaires and provided valid cotinine differed to a small but significant extent from the baseline sample, and so was not wholly representative. However, the difference was not large and it is difficult to conceive how any self-selection bias could have influenced the findings. Thirdly, cigarette consumption was self-reported which may have biased the outcomes. Fourthly, we did not have a sufficiently large sample to be able to determine whether the usage of different NRT products might have different effects, or to separate the influence of the use of NRT for temporary abstinence and smoking reduction.

Even with an original sample of more than 15,000 smokers there were only 52 who met the criteria for the study, so accumulating a sample of sufficient size to be able to address the question of differential effects of the various NRT products and harm reduction behaviours could take many years. In the meantime, our findings should provide reassurance to regulators that the concurrent use of NRT and smoking as presently practised poses no significant risk arising from an increase in overall nicotine intake.

Conclusion

Smokers who use NRT for harm reduction purposes appear to obtain similar overall levels of nicotine to when they are not using NRT, without significantly large reductions in cigarette consumption. Although this study is limited by its small sample size, these findings suggest that smokers are either compensating for the additional nicotine attained from NRT by changing the way they smoke their cigarettes, i.e. not inhaling as much or putting them out early, or they are not using enough NRT for it to have a significant effect on nicotine levels. Either way, we can be reassured that the concurrent use of NRT and cigarettes does not pose a significant risk arising from an overall increase in nicotine intake.

Chapter 13: Association Between the use of Nicotine Replacement Therapy During Various Periods of Temporary Abstinence and Attempts to Quit Smoking: A National Survey of English Smokers

Introduction

There is a commonly held belief that relieving smokers' discomfort during periods of temporary abstinence with the use of NRT may undermine attempts at cessation, with motivation to quit only occurring if smokers suffer withdrawal and experience the stigma or inconvenience of leaving home or work to smoke (Serra, Cabezas, Bonfill, Pladevall-vila, 2000). Despite data discrediting this view (see Chapters 7-11; Levy et al., 2007), many countries still oppose the use of NRT for periods of momentary abstinence. One reason being, that research to date has failed to view temporary abstinence as multi-faceted, presuming instead that it is a unified concept. For example, smokers may be unable to smoke in the pub or at work, and in more recent years in the home; with many households adopting smoke-free homes as a means of protecting children from the passive effects of smoking (Ashley et al., 1998; Borland et al., 2006). The argument is that these varying 'situations' requiring temporary abstinence may mediate the association between NRT use and attempts to quit smoking.

The failure to consider the various situations in which a smoker may have to abstain for a designated period of time each day may also explain the lack of established reductions in cigarette consumption among those using NRT for such purposes at a population level (see Chapters 7-10; Levy et al., 2007). Many had hypothesised that NRT would mitigate the tendency of smokers to compensate prior to or following smoking restrictions, resulting in a decrease in the number of cigarettes smoked per day. It is possible that the use of NRT during certain periods of momentary abstinence results in declines in the number of cigarettes smoked per day, but that these are masked when combined with the use of NRT for other periods in which reduced intake fails to materialise. Of course, the failure to report reliable reductions in cigarette consumption could also be due to the ineffectiveness of the currently marketed NRT products, which as a consequence of their design and underuse offer a much lower dose of nicotine than the traditional cigarette. There does appear to be widespread scepticism among smokers about whether NRT actually helps to resist the need to smoke in situations where it is not possible (Etter & Perneger, 2001).

The current chapter attempted to address these issues by assessing the prevalence of NRT use in various temporary abstinence situations, i.e. at work, at home, in a restaurant, in a pub and whilst travelling; the association between the use of NRT in these various situations with attempts to quit smoking and the average number of cigarettes smoked per day; how helpful smokers reported finding NRT in these situations; if differences existed in reports of the helpfulness of NRT as a function of the NRT product which was used; and whether reports of the helpfulness of NRT were associated with attempts to stop smoking and cigarette intake.

It is of interest to know the prevalence of NRT use in specific types of situations that require smokers to abstain from smoking for a designated period of time, and of further interest to determine whether those using NRT in these various situations differ as a function of nicotine dependence and socio-demographic characteristics. Although data suggests that the majority of smokers now abstain in pubs and restaurants in the UK, whilst almost 60% do so in their own home (Lee, Glantz & Millet, 2011), it is currently unclear how many use NRT in these situations. Moreover, the only data outside of the UK consists of an unpublished study on a small sample of Swedish smokers. This study reported that amongst those using

NRT for periods of temporary abstinence, 50% used NRT at work, 50% whilst travelling, 45% at home, and only 18% in restaurants (Etter, 2003). This may have been hypothesised since those temporarily abstaining at home are perhaps more motivated to try and mitigate the harmful effects of smoking, while high levels of use may occur at work where restrictions are enforced and smokers are unable to leave until their designated break. In contrast, prevalence may be lower in pubs and restaurants due to the stigma and embarrassment of NRT use and ease of smoking outside (Hajek, West, Foulds, Nilsson, Burrows, Meadow, 1999).

Data are also lacking on the socio-demographic and smoking characteristics of those using NRT in these various situations, and whether those using NRT in only one situation differ to those using NRT in multiple situations. The latter of which is of particular importance, due to the possibility that greater NRT use may occur among those using NRT in numerous situations requiring momentary abstinence, and that this may lead to improved clinical outcomes (Hatsukami et al., 2007). It may be theorised that higher socio-economic status will be associated with NRT use at work, due to the greater disposal incomes among these individuals and since it is likely that they will experience longer periods of abstinence. The use of NRT while in pubs may be more common among lower nicotine dependent smokers who may use NRT instead of going outside to smoke (Emmons et al., 2000). Because females appear to be less embarrassed about using NRT they may also be more inclined to opt for its use in public places (Zhu et al., 2000). Regarding the multiple use of NRT, it may be hypothesised that those of higher social-grades will be more inclined to use NRT in various situations requiring temporary abstinence because they can afford concurrent NRT and cigarette purchases. Older women tend to be more conscious about their well-being, which may lead them to use NRT more often as a means to reduce harm (Allgower et al., 2001; Nurmi, 1992). Favourable attitudes towards NRT may also play a part, appearing to exist among older more dependent male smokers (Shiffman, Di Marino & Sweeney, 2005).

It is of additional interest to know how helpful smokers report finding NRT in these different situations, and whether reports differ as a function of the NRT product which is used. Such information could help shape the advice smokers receive so that benefits from the products are maximised. Smokers may find NRT more helpful at work because of the extended periods they have to manage without smoking, or because they use it, as they see it, to help with the stress of the working environment. The faster acting products (i.e. the nicotine inhalator, lozenges & gum), may be hypothesised to be more effective than the nicotine patch, despite its use being more prevalent, because they provide behavioural substitution and allow the accurate titration of nicotine levels when urges to smoke present (Fagerstrom & Hughes, 2002). However, previous studies have failed to reported differences in the perceived helpfulness of the nicotine patch, inhalator, gum and nasal spray for smoking cessation (Hajek et al., 1999). Moreover, 90% of smokers using the patch ad hoc whilst smoking, report it to be very or moderately helpful (Jaen, Cummings, Shah & Aungst, 1997).

It may also be hypothesised that the extent of any promotion in quit attempts as a result of NRT use may vary as a function of the temporary abstinence situation. There is data to suggest that smoke-free homes and smoking restrictions increase the propensity of smokers to quit (Farkas et al., 1999; Pizacani et al., 2004). However, data are wanting on whether the use of NRT in these situations promotes quit attempts to a larger extent than the use in other situations, and the effect during shorter more intermittent terms of abstinence, such as in the pub and while in a restaurant. It maybe hypothesised that where the use of NRT is more internally motivated – such as the use of NRT to abstain in the home in order to protect other inhabitants – as opposed to externally motivated – such as the use of NRT as a result of public smoking restrictions – that a higher odds of an attempt to quit smoking will prevail (Curry, Wagner & Grothaus, 1990; Curry, McBride, Grothaus, Lando & Pirie, 2001). Similarly, where the option to smoke is readily available, i.e. going outside to smoke when in a pub, an increase in the propensity of smokers to quit could occur as a consequence, because the smoker using NRT during such situations has the opportunity to develop feelings of self-control and self-efficacy over their behaviour (Bandura, 1977). The odds of a quit attempt may also be envisaged to be greater amongst those using NRT in multiple situations. This is based on the assumption that they will use larger amounts of NRT (Hatsukami et al., 2007; Okuyemi et al., 2002). Previous research has also demonstrated that the use of multiple harm reduction strategies is associated with reports of smoking cessation and reduced cigarette consumption (Levy et al., 2007).

Such an analysis may also help to resolve the issue of causality with previous cross-sectional data. If the association between the use of NRT for temporary abstinence and attempts to quit smoking is not causal, but due to smokers who use NRT for temporary abstinence being more motivated to stop smoking, one might expect to see a stronger association between quitting and NRT use in situations of voluntary temporary abstinence. This may also occur if the association is because attempts to stop and NRT use are both manifestations of an attempt to mitigate the harmful effects of smoking. Voluntary temporary abstinence may include NRT use at home where personal choice or social pressure, rather than legislation, has led to a smoking ban. In contrast, if there is a causal association so that NRT use during temporary abstinence enhances smokers' propensity to quit by boosting their confidence in quitting, one would expect that the use of NRT during enforced periods would also be associated with attempts to stop (Stratton et al., 2001).

The failure to identify temporary abstinence as a multi-faceted construct could also explain why previous studies have failed to establish a significant difference in cigarette consumption amongst those using and not using NRT for temporary abstinence (see Chapters 7-11; Levy et al., 2007). Significant reductions may be hypothesised amongst those using NRT with an aim to mitigate the health consequences of smoking, and in situations which require abstinence for some designated period each day, such as at home. In contrast, reductions may not occur if smokers only use NRT in situations which occur intermittently or which are enforced, resulting in an increased consumption in anticipation.

Another unanswered question is whether smokers who report NRT to be more helpful during temporary abstinence are more likely to have tried to quit and experience lower cigarette consumption. If such associations exist, it would suggest that the perception of the benefits of NRT might mediate between its use and attempts to stop smoking and cigarette intake. In the general medication literature, attitudes and beliefs about medications have been shown to predict treatment adherence and clinical outcomes (Horne & Weinman, 1999). In contrast, if it is the case and reports of the helpfulness of NRT are not associated either with attempts to stop smoking or cigarette consumption, this would suggest that it is not an important mediating factor. This might be for a number of reasons: perceptions of the helpfulness of NRT may not influence the extent of use (Mooney et al., 2006), or smokers may attribute any success with momentary abstinence to their own actions, thus underestimating its effectiveness (Weiner, 1992).

Methods

Study Design and Sampling

Data for this study were obtained between July 2009 and April 2010 from the Smoking Toolkit Study. See methods section in Chapter 7 for more details.

Ethical Approval

Ethical approval was granted by the University College London Research Ethics Committee.

Measures

Smoking status was assessed by asking: ‘Which of the following best applies to you? – (I smoke cigarettes (including hand-rolled) every day; I smoke cigarettes (including hand-rolled), but not every day; I do not smoke cigarettes at all, but I do smoke tobacco of some kind (for example:- pipe or cigar); I have stopped smoking completely in the last year; I stopped smoking completely more than a year ago; I have never been a smoker (i.e. smoked for a year or more); don’t know). Those who responded that they smoke cigarettes every day or that they smoked but not every day were coded as current cigarette smokers. Current smokers were asked questions about socio-demographic characteristics (i.e. gender, age & social-grade), cigarette consumption per day, and time to first cigarette of the day as a measure of nicotine dependence (Fagerstrom, 2003). Social-grade was classified as follows: AB=higher and intermediate professional/managerial; C1=supervisory, clerical, junior managerial/administrative/professional; C2=skilled manual workers; D=semiskilled and unskilled manual workers; E=on state benefit, unemployed, lowest grade workers.

Participants were also asked: ‘Do you regularly use any of the following in situations when you are not allowed to smoke? – (nicotine patch; nicotine gum; nicotine lozenges/tablets; nicotine inhaler; nicotine nasal spray; I don’t know; none of these; other). Those reporting the use of NRT were additionally asked: ‘In which of the following situations does this apply to?’ – (In an office; at home; in a pub or bar; in a restaurant; whilst travelling; other). The helpfulness of NRT was assessed by asking: ‘How helpful do you find using NRT in situations where you are not allowed to smoke?’ – (not at all; slightly; moderately; very; don’t know). Finally, smokers were asked: ‘How many serious attempts to stop smoking have you made in the last 12 months?’ Those reporting one or more quit attempts were classified as having made a quit attempt in the past year. For further information on the measures used in the Smoking Toolkit Study see www.smokinginengland.info

Analysis

Parametric Assumptions

For regression analyses the assumption of 'non-multicollinearity' was assessed by calculating Tolerance Values and Variance Inflation Factors (Menard, 1995; Myers, 1990). A further four assumptions were assessed for least-squares regression: 'independent errors' using the Durbin-Watson test (Durbin & Watson, 1951); 'normality' using histograms and normal probability plots; and 'homoscedasticity' and 'linearity', using plots of the standardised residuals against predicted values (Levene, 1960). There was no evidence that these assumptions were violated. The assumption of 'normality' required for *t*-test analysis was assessed using the Kolmogorov-Smirnov (K-S) statistic, while 'homogeneity of variance' using Levene's statistic (Levene, 1960). Age and cigarette consumption were non-normal among those using NRT in only one situation (D(380)=0.049, $p<0.05$ versus D(380)=0.160, $p<0.001$) and those using NRT in multiple situations (D(129)=0.102, $p<0.01$ versus D(129)=0.135, $p<0.001$). There was no evidence for heterogeneity among these two groups in either cigarette consumption or age (F=713, $p>0.05$ versus F=0.001, $p>0.05$). Log and square root transformations were unsuccessful at correcting issues with normality. Because the large sample size means that the K-S test may be significant even when the distribution only differs slightly from normal, histograms and P-P plots were also calculated. These confirmed the non-normality present in the data. Consequently, non-parametric tests were sought.

Finally, the assumptions of 'normality' and 'homogeneity of variance' inherent in ANOVA analyses were tested using the Kolmogorov-Smirnov (K-S) statistic and Levene's statistic (Levene, 1960). Age was established to be non-normally distributed only among those using NRT for temporary abstinence at home (D(159)=0.083, $p<0.01$). In contrast, cigarette consumption was significantly non-normal among those using NRT in the office (D(30)=0.193, $p<0.01$), at home (D(159)=0.183, $p<0.001$), in the pub (D(35)=0.156, $p<0.05$), whilst travelling (D(108)=0.167, $p<0.001$), and in other situations (D(35)=0.154, $p<0.05$). Square root transformations corrected issues with non-normality for age (D(159)=0.046, $p>0.05$), and for cigarette consumption in relation to the use of NRT in the office (D(30)=0.125, $p>0.05$), pub (D(35)=0.129, $p>0.05$) and in other situations (D(35)=0.098, $p>0.05$), but not in relation to use in the home or whilst travelling. Log transformations also corrected non-normality in cigarette consumption for use of NRT in the office (D(30)=0.146, $p>0.05$). No evidence of heterogeneity for cigarette consumption was established among those using NRT in various situations requiring temporary abstinence ($F(5, 374)=0.616$, $p>0.05$), although variances appeared to be somewhat unequal in terms for age ($F(5, 375)=2.260$, $p<0.05$). This was rectified with square root ($F(5, 375)=1.612$, $p>0.05$) and log transformations ($F(5, 375)=1.264$, $p>0.05$). P-P plots confirmed the non-normality present in the data, thus non-parametric tests were used for the assessment of differences in cigarette intake (see Appendix F).

Statistical Analysis

STROBE guidelines for the reporting of epidemiological studies were followed throughout (von Elm et al., 2007), with missing data dealt with prior to analysis using the listwise deletion procedure. For the reporting of prevalence data, an iterative marginal weighting technique was used in order to maximise the reliability of the sample data and minimise any statistical bias. This was achieved by performing the least amount of weighting required to correct for sample disproportionalities that may have distorted estimates. The process works by setting separate nationally representative target profiles for gender, working status, prevalence of children in the household, age, social-grade and region, and the process repeated until all variables match the specified targets.

Differences among those using NRT in various situations requiring periods of temporary in terms age, time to first cigarette of the day, socio-economic status and gender, were assessed with ANOVA, Chi-squared and Kruskal-Wallis tests. In contrast, differences in age, gender, time to first cigarette and social-grade among those using NRT in multiple situations requiring temporary abstinence compared to those using NRT in only one situation, were determined using Chi-squared and Mann-Whitney tests. Corresponding effect sizes were calculated for the later (r=Z score/$\sqrt{\text{total}}$ sample size). To assess significance following the Chi-squared analysis, standardised residuals were compared to the critical values that correspond to an alpha of 0.05 (+/-1.96), an alpha of 0.01 (+/-2.58) or an alpha of 0.001 (+/-3.10). Odds Ratios were then calculated where significance was evident. Kruskal-Wallis tests were also used to assess if differences exited in reports of the helpfulness of NRT as a function of the various temporary abstinence situations, and as a function of the NRT product which was used. Post-hoc analysis was conducted with multiple Mann-Whitney tests with the Bonferroni correction applied (effects are reported at 0.003 level of significance).

The comparison of past quit attempts and cigarette consumption among those using NRT in various situations compared to smokers temporarily abstaining without pharmacological help, were assessed by logistic and linear regression analyses. Associations between reports of the helpfulness of NRT, quit attempts and cigarette consumption, were also assessed using logistic and linear regression analyses. These were undertaken with and without adjustment for socio-demographic variables and time to first cigarette of the day as a measure of dependence (Fagerstrom, 2003); 95% confidence intervals were used unless otherwise stated. Due to sample size restrictions it was not possible to assess if reports of the helpfulness of the various NRT products differed as a function of the situation they were used in. All analyses were undertaken using SPSS version 18.0.

Power

Post-hoc power analysis using G*Power 3 (Faul, Erdfelder, Buchner & Lang, 2009), revealed that for the assessment of differences in cigarette consumption among those using NRT at work, at home, in a pub, in a restaurant, whilst travelling and in other situations, an effect size of 0.2 could be detected with 94% power using an alpha of 0.05, 82% power using an alpha 0.01, while 59% power using an alpha of 0.001.

Results

Between July 2009 and April 2010, 17,803 adults surveyed; of whom, 3,775 (21.2%) reported that they were current smokers. Fifty-one per cent were male with a mean [Standard Deviation (*SD*)] age of 40.6 (16.08) years. The percentages of participants residing in each social-grade were as follows: AB (15.8%; *n*=597), C1 (26.5%; *n*=1,002), C2 (24.0%; *n*=904), D (20.0%; *n*=755), E (13.7%; *n*=517). The mean daily consumption was 13.1 cigarettes (*SD* 8.43), with 28.1% (*n*=1058) reporting smoking a cigarette after 61 minutes of wakening, 18.0% (*n*=677) between 31 and 60 minutes after wakening, 34.3% (*n*=739) within 6-30 minutes of wakening and 19.6% (*n*=517) within 5 minutes of wakening. Sixty-eight per cent (*n*=2573) of smokers reported having made a quit attempt in the previous 12 months.

Thirteen per cent (*n*=473) of smokers were using NRT for periods of temporary abstinence. The most commonly used product was the nicotine patch (36.2%; *n*=171), followed by the nicotine gum (32.0%; *n*=152), inhalator (22.2%; *n*=105), lozenges (8.4%; *n*=105) and nasal spray (2.5%; *n*=12). Twelve per cent (*n*=57) of smokers used a combination of NRT products; 11.0% failed to report which NRT products they used (*n*=52). Of those using NRT for temporary abstinence, 41.2% (*n*=195) reported using NRT at home, 40.2% (*n*=190) whilst travelling, 22.4% (*n*=106) in a pub or bar, 20.1% (*n*=95) in the office, 16.3% (*n*=77) in a restaurant, and 9.7% (*n*=46) for ‘other’ reasons. Twenty-eight per cent were using

NRT in multiple situations requiring momentary abstinence (n=130), while 72.5% cited only one situation in which they used NRT (n=343). Table 1 shows the socio-demographic and smoking characteristics of respondents as a function of the situation they were using NRT in.

No differences in gender (χ^2=3.56 (df 5), p=0.615), nicotine dependence (χ^2=9.56 (df 5), p=0.087), or age (F(df 5,380)=1.38, p=0.231), were reported among those using NRT in the various situations requiring temporary abstinence. However, they did differ as a function of social-grade (χ^2=40.67 (df 5), p=0.001), with those using NRT in the office or whilst travelling more likely to report being of a higher social-grade than those using NRT at home (U=1264.00, p<0.01; r=-0.31, versus U=5525.5, p<0.01; r=-0.32), or in the pub (U=268.50, p<0.01; r=-0.43, versus U=1178.50, p<0.01; r=-0.29). Those using NRT in only one situation also did not differ to those using NRT in multiple situations in terms of gender (χ^2=0.25 (df 1), p=0.621), nicotine dependence (U=22995.00, p=0.255), or age (U=22162.00, p=0.095); however, they were less likely to be of a higher social-grade (U=21671.50, p=0.039; r=-0.09).

Overall, 25.2% (n=115) of smokers reported that NRT was very helpful, 30.6% (n=140) that it was moderately helpful, 28.9% (n=132) that it was slightly helpful, and 15.3% (n=70) that it was not at all helpful. Table 2 shows reports of the helpfulness of NRT as a function of the situation NRT was used in. A significant difference was reported between groups (χ^2=25.01 (df 5), p=0.001). Those using NRT at home were less likely to report it was helpful than those using NRT while travelling (U=6472.00, r=-0.22) and in ‘other’ situations (U=1708.50, r=-0.24). Moreover, the use of NRT for multiple reasons was rated as more helpful than the use of NRT in only one situation (U=21837.5, p=0.050, r=-0.09).

Table 1: Socio-Demographic Characteristics and Nicotine Dependency of Respondents as a Function of Nicotine Replacement Therapy use in Various Situations Requiring Temporary Abstinence

	Type of TA						Multiple vs single use of NRT for TA	
	Office (*n*=95)	Home (*n*=195)	Pub (*n*=106)	Restaurant (*n*=77)	Travel (*n*=190)	Other (*n*=46)	Multiple (*n*=130)	Single (*n*=343)
Gender % (*n*)								
Male	47.4 (45)	45.6 (89)	48.1 (51)	44.2 (34)	46.3 (88)	34.8 (16)	48.5 (63)	44.6 (153)
Female	52.6 (50)	54.4 (106)	51.9 (55)	55.8 (43)	53.7 (102)	65.2 (30)	51.5 (67)	55.4 (190)
Age M(*SD*)	38.4 (14.70)	40.5 (16.58)	37.8 (15.99)	41.2 (17.13)	41.7 (14.69)	42.8 (17.09)	38.9 (15.97)	41.3 (15.84)
Social-grade %(*n*)								
AB	22.9 (22)	14.4 (28)	15.2 (16)	19.2 (15)	24.2 (46)	23.9 (11)	23.7 (31)	15.7 (54)
C1	34.3 (33)	21.0 (41)	22.9 (4)	26.9 (21)	30.0 (57)	28.3 (13)	25.2 (33)	26.5 (91)
C2	18.8 (18)	22.1 (43)	31.4 (33)	24.4 (19)	23.7 (45)	30.4 (14)	24.4 (32)	24.8 (85)
D	19.9 (19)	22.6 (44)	13.3 (14)	16.7 (13)	10.5 (20)	2.2 (1)	14.5 (19)	16.3 (56)
E	4.2 (4)	20.0 (39)	17.1 (18)	12.8 (10)	11.6 (22)	15.2 (7)	12.2 (16)	16.6 (57)
Time to first cigarette %(*n*)								
> 61 minutes	33.7 (32)	22.1 (43)	23.6 (25)	28.6 (22)	17.4 (33)	30.4 (14)	29.2 (38)	17.8 (61)
31-60 minutes	22.1 (21)	16.4 (32)	15.1 (16)	16.9 (13)	26.8 (51)	13.0 (6)	16.9 (22)	22.2 (76)
6-30 minutes	28.4 (27)	38.5 (75)	33.0 (35)	31.2 (24)	33.7 (64)	34.8 (16)	28.5 (37)	38.9 (133)
<5 minutes	15.8 (15)	23.1 (45)	28.3 (30)	23.4 (18)	22.1 (42)	21.7 (10)	25.4 (33)	21.1 (72)

Note: *n*=number; M=mean; *SD*=Standard Deviation; TA=temporary abstinence; NRT=Nicotine Replacement Therapy
Data were weighted to match the sample to the 2001 census

Table 2: Reports of the Helpfulness of Nicotine Replacement Therapy Among Respondents as a Function of the Situation Requiring Temporary Abstinence

	NRT use in different situations[a]						Multiple vs single use of NRT for TA	
	Office (*n*=31)	Home (*n*=129)	Pub (*n*=30)	Restaurant (*n*=12)	Travel (*n*=106)	Other (*n*=34)	Multiple (*n*=130)	Single (*n*=343)
NRT helpful %(*n*)								
Not at all	19.4 (6)	25.6 (33)	20.0 (6)	25.0 (3)	5.7 (6)	5.9 (2)	14.7 (19)	16.4 (56)
Slightly	32.3 (10)	29.5 (38)	26.7 (8)	50.0 (6)	29.2 (31)	20.6 (7)	22.5 (29)	28.9 (99)
Moderately	25.8 (8)	24.8 (32)	33.3 (10)	16.7 (2)	34.9 (37)	32.4 (11)	28.7 (37)	29.2 (100)
Very	22.6 (7)	20.2 (26)	20.0 (6)	8.3 (1)	30.2 (32)	41.2 (14)	34.1 (44)	25.4 (87)

Note: *n*=number; TA=temporary abstinence; NRT=Nicotine Replacement Therapy
Data weighted to match the sample to the 2001 census
[a]Excluding those using NRT in multiple situations

Sixteen per cent (*n*=19) of gum users, 20.0% (*n*=6) of lozenge users, 30.8% (*n*=41) of patch users, 44.0% (*n*=33) of inhalator users and 37.5% (*n*=3) of nicotine nasal spray users, reported that they found NRT very helpful during periods of time when they were unable to smoke (see Table 3). Reports of the helpfulness of NRT differenced as a function of the NRT product which was used (χ^2=21.91 (*df* 4), *p*=0.001). Those using the nicotine gum were less likely to report that NRT was helpful than those using the nicotine patch (*U*=6897.50, *p*=0.002; *r*=-0.19), or the nicotine inhalator (*U*=3373.00, *p*=0.001; *r*=-0.29). Helpfulness of NRT did not differ among those using only one NRT product compared to those using a combination of NRT products (*U*=11903.50, *p*=0.994).

Table 3: Reports of the Helpfulness of Nicotine Replacement Therapy Among Respondents Using Nicotine Replacement Therapy for Temporary Abstinence as a Function of the Product Used

	NRT product[a]					Use of Combined NRT	
	Gum (*n*=118)	Lozenges (*n*=30)	Patch (*n*=133)	Inhalator (*n*=75)	Nasal spray (*n*=8)	Combined (*n*=57)	Single (*n*=364)
NRT helpful %(*n*)							
Not at all	19.5 (23)	16.7 (5)	9.8 (13)	5.3 (4)	50.0 (4)	19.3 (11)	13.7 (50)
Slightly	33.9 (40)	20.0 (6)	27.1 (36)	29.3 (22)	0 (0)	21.1 (12)	28.6 (104)
Moderately	30.5 (36)	43.3 (13)	32.3 (43)	21.3 (16)	12.5 (1)	31.6 (18)	29.7 (108)
Very	16.1 (19)	20.0 (6)	30.8 (41)	44.0 (33)	37.5 (3)	28.1 (16)	28.0 (102)

Note: *n*=number; TA=temporary abstinence; NRT=Nicotine Replacement Therapy; TA=temporary abstinence
Date are weighted to match the sample to the 2001 census
[a]Excluding those using combination NRT

Table 4 shows the average number of cigarettes smoked per day and percentage of smokers reporting a quit attempt in the past 12 months among those using NRT in various situations requiring temporary abstinence. Table 5 shows the results of the regression analyses on this data. After adjusting for socio-demographic variables and nicotine dependency, the use of NRT in all situations was associated with greater odds of an attempt to quit smoking relative to other smokers generally. Although the use of NRT whilst travelling was associated with smoking around 1.35 cigarettes more per day than other smokers before adjustment, after adjustment no associations were found between the use of NRT for momentary abstinence and cigarette intake.

Table 4: Reports of Average Cigarette Consumption and Percentage of Previous Attempts to Quit Smoking Among Respondents as a Function of Nicotine Replacement Therapy use in Various Situations Requiring Temporary Abstinence

	Not using NRT for TA (*n*=3,354)	Type of TA					
		Office (*n*=95)	Home (*n*=195)	Pub (*n*=106)	Restaurant (*n*=77)	Travel (*n*=190)	Other (*n*=46)
Cigarette consumption per day M(*SD*)	12.9 (8.42)	12.3 (9.08)	13.6 (8.54)	14.8 (10.00)	13.2 (8.44)	15.1 (8.72)	12.6 (8.00)
Quit attempt in the previous 12 months %(*n*)	28.5 (955)	64.2 (61)	62.4 (121)	65.1 (69)	58.4 (45)	49.2 (94)	65.2 (30)

Note: *n*=number; M=mean; *SD*=Standard Deviation; TA=temporary abstinence; NRT=Nicotine Replacement Therapy
Data were weighted to match the sample to the 2001 census

Reports of an attempt to quit smoking in the past year were more likely amongst those using NRT in multiple situations (69.5%; *n*=91), than those using NRT in only one situation [(51.5%; *n*=176); χ^2=12.618 (*df* 1), *p*=0.001; Odds Ratio (*OR*) 2.15; Confidence Interval (CI) 1.40-3.31]. Average cigarette consumption [Standard Deviation (*SD*)] did not differ among these two groups (13.5 (*SD* 9.43) versus 14.3 (*SD* 8.35); *U*=222308.50, *p*=0.122). After the removal of those using NRT in multiple situations, 64.5% (*n*=20) of those using NRT in the office, 60.2% (*n*=77) of those using NRT at home, 53.3% (*n*=16) of those using NRT in the pub, 45.2% (*n*=5) of those using NRT in a restaurant, 34.9% (*n*=37) of those using NRT whilst travelling, and 63.6% (*n*=21) of those using NRT in 'other' situations, reported a quit attempt in the previous 12 months. Corresponding values for the mean daily cigarette consumption were as follows: in the office 11.7 (*SD* 8.08), at home 13.9 (*SD* 8.40), in the pub 16.3 (*SD* 9.85), in a restaurant 10.5 (*SD* 6.36), whilst travelling 16.1 (*SD* 7.93) and 12.1 (*SD* 7.55), among those using NRT in 'other' situations.

Table 5: Association Between the use of Nicotine Replacement Therapy in Various Situations Requiring Temporary Abstinence With Cigarette Consumption and Previous Attempts to Quit Smoking

	NRT use in the office vs other smokers (*n*=95 vs *n*=3,680)		NRT use at home vs other smokers (*n*=195 vs *n*=3,580)		NRT use in pub/bar vs other smokers (*n*=106 vs *n*=3,669)		NRT use in restaurant vs other smokers (*n*=77 vs *n*=3,698)		NRT use whilst travelling vs other smokers (*n*=190 vs *n*=3,585)		NRT use in 'other' situations vs other smokers (*n*=46 vs *n*=3,729)	
Unadjusted	*OR*	CI 95%	*OR*	CI 95%	*OR*	CI 95%	*OR*	CI 95%	*OR*	CI 95%	*OR*	CI 95%
Quit attempts	3.62 ***	2.33-5.62	4.09 ***	3.09-5.41	4.23 ***	2.86-6.26	3.75 ***	2.37-5.93	2.41 ***	1.80-3.23	3.70 ***	2.06-6.67
	β	CI 95%	β	CI 95%	β	CI 95%	β	CI 95%	β	CI 95%	β	CI 95%
Cigs per day	-0.79	-2.66-1.08	0.49	-0.68-1.68	1.56	-0.07-3.19	0.13	-1.81-2.07	1.35*	0.08-2.61	-0.10	-2.59-2.39
Adjusted	*OR*	CI 95%	*OR*	CI 95%	*OR*	CI 95%	*OR*	CI 95%	*OR*	CI 95%	*OR*	CI 95%
Quit attempts	3.65 ***	2.34-5.60	4.25 ***	3.20-5.64	4.17 ***	2.81-6.19	3.86 ***	2.43-	2.49 ***	1.86-3.35	3.95 ***	2.18-7.16
	β	CI 95%	β	CI 95%	β	CI 95%	β	CI 95%	β	CI 95%	β	CI 95%
Cigs per day	0.45	-1.11 – 2.02	-0.40	-1.39-0.58	0.95	-0.41-2.31	-0.15	-1.77-1.47	0.85	-0.21-1.92	-0.66	-2.74-1.42

Note: *n*=number; *OR*=Odds Ratio; CI=confidence interval; β=beta coefficient; TA=temporary abstinence; NRT=Nicotine Replacement Therapy
Significant difference between groups *** p<0.001, **p<0.01 * p<0.05
Adjusted for age, gender, social-grade and time to first cigarette of the day

The percentage of smokers reporting a quit attempt differed as a function of the situation smokers used NRT in (χ^2=13.91 (*df* 5), *p*=0.016). This seemed to represent the fact that those using NRT in the office (Odds Ratio (*OR*) 2.39; Confidence Interval (CI) 1.05-5.47; *p*<0.05), at home (*OR* 2.41; CI 1.46-4.00; *p*<0.001), and in 'other' situations (*OR* 2.39; CI 1.10-5.21; *p*<0.01), were more than twice as likely to report a quit attempt as those using NRT whilst travelling. Cigarette consumption was also reported to differ as a function of the situation smokers used NRT in (χ^2=13.76 (*df* 5), *p*=0.017); those using NRT whilst travelling had a higher cigarette consumption than those using NRT in the office (*p*<0.05).

Fifty-five per cent (*n*=43) of those reporting that NRT was 'not at all' helpful had attempted to quit smoking in the previous 12 months and reported an average cigarette consumption per day of 14.2 (Standard Deviation (*SD*) 8.55); while 50.4% (*n*=66) of those reporting that NRT was ‘slightly’ helpful reported a quit attempt in the previous 12 months and a cigarette consumption per day of 13.2 (*SD* 7.90). Corresponding values for those reporting that NRT was ‘moderately’ helpful were 54.2% (*n*=78) and 14.4 (*SD* 8.70), and for those reporting it was ‘very’ helpful were 63.7 (*n*=86) and 14.7 (*SD* 9.20). No association between cigarette consumption and the helpfulness of NRT was reported either before (Beta coefficient (β)=0.65; Confidence Interval (CI) -0.85-2.15; *p*=0.392) or after adjustment for potential confounding variables (β=0.78; CI -0.53-2.09; *p*=0.241); nor was there any association between quit attempts and reports of the helpfulness of NRT before (Odds Ratio (*OR*) 1.30; Confidence Interval (CI) 0.92-1.84; *p*=0.137) or after adjustment (*OR*=1.37; CI 0.96-1.95; *p*=0.083).

Discussion

Those using NRT during periods of temporary abstinence were more likely to report having done so at home and whilst travelling. Prevalence did not appear to differ as a function of smokers’ age, gender or nicotine dependence. However, those using NRT at work and whilst travelling tended to be of a higher social-economic status than using NRT at home or in the pub. The use of NRT in multiple situations was also associated with higher social-grade. Fifty-six per cent of NRT users reported that NRT was moderately or very helpful during these periods. The use of NRT to tide one over whilst travelling was deemed more helpful than the use of NRT at home, while the nicotine inhalator and patch received higher helpfulness ratings the nicotine gum. NRT was also deemed more helpful when used in multiple situations of momentary abstinence. The use of NRT in all situations requiring temporary abstinence was associated with increased odds of a prior attempt to quit smoking, but similar cigarette consumption to smokers not using NRT for such purposes. Those using NRT in the office and at home were more likely to have attempted to stop smoking in the previous 12 months, as were those using NRT in multiple situations. No association was reported between the helpfulness of NRT and either quit attempts in the past year or cigarette consumption.

It is unclear why those using NRT during periods of temporary abstinence were more likely to report doing so at home and whilst travelling. Hypotheses can nonetheless be made. It could be that those opting to use NRT for momentary abstinence are more concerned about the effects of smoking on the health of those around them, thus leading them to use NRT in the presence of significant others; it could also be that opportunities to break abstinence are less common whilst travelling, resulting in the use of NRT to keep withdrawal symptoms at bay; or NRT could simply be more accessible and less embarrassing to use in these contexts. Moreover, these findings are at least partially in line with a previously unpublished study, which reported greater NRT use among Swedish smokers whilst in the office, at home and when travelling by train, car or plane (Etter, 2003).

Of interest, is that the use of NRT in various situations requiring brief abstinence was dependent on socio-economic status, but not demographic characteristics. This identifies one way in which the social inequalities in achievements of abstinence may be tackled (Kotz & West, 2009). It is of little surprise that those using NRT at work and whilst travelling tended to be of higher social-grades than those using NRT in the pub and at home, if we assume that NRT is used only during the longest or more sustained periods of abstinence. Similarly, those using NRT in multiple situations would be hypothesised to be of higher social-grades due to their greater disposal incomes (Curry et al., 1998). Alternatively, this may simply reflect more favourable attitudes towards NRT amongst those of a higher socio-economic status (Bansal et al., 2004). What is surprising is that the decision to use NRT did not appear to be reliant on nicotine dependency; one may have assumed that more dependent smokers would require NRT during longer periods of abstinence, such as in the office, to keep urges to smoke at bay, but that these individuals may be less likely to use NRT where they have the opportunity to smoke outside. Moreover, it may have been theorised that highly dependent smokers would opt to use NRT in multiple situations, with less dependent smokers experiencing fewer withdrawal symptoms and having the ability to abstain without pharmacological help.

As may have been hypothesised, the inhalator received one of the highest helpfulness ratings, which possibly materialises from its cigarette-like appearance and ritual elements associated with its use (Schneider, Olmstead, Franzon & Lunell, 2001). It is unclear therefore, why few smokers opt to use it during periods of temporary abstinence. The nicotine patch, the preferred product of choice, also received high ratings of helpfulness. This is counterintuitive, since the patch does not provide an instant nicotine hit or allow the accurate titration of nicotine levels, which may be deemed necessary characteristics for a product being used during momentary abstinence. However, there is a tendency for smokers to attain more nicotine from transdermal forms of NRT, unlike the gum where the bio-available dose of nicotine is dependent on the method of use (Fagerstrom & Hughes, 2002)

These findings also suggest that the association reported previously between past attempts to quit smoking and use of NRT for temporary abstinence (see Chapters 7-11; Levy et al., 2007), is unlikely to be due to smokers who are more motivated to quit smoking opting to use NRT when they are unable to smoke; or the result of quit attempts and the use of NRT both stemming from a tendency to try and mitigate the harmful effects of smoking. If this were the case, we may not expect any association between the use of NRT during enforced periods of temporary abstinence and attempts to stop smoking. This supports the indication of NRT for harm reduction purposes (Shiffman et al., 2005; Stratton et al., 2001). Those which have yet to change their licensing of NRT should take this on-board, with the possibility that the use of NRT during periods of temporary abstinence may increase the propensity of smokers to quit. It is of interest that the odds of reporting a previous quit attempt were highest among those using NRT in the office and one's own residence, which provides support for the claim that smokers should be encouraged to utilise NRT as a means of attaining smoke-free homes (Atkinson, McNeill & Jones, 2011). This may partially be due to smokers having to abstain for longer periods of time during these situations, increasing smokers' self-efficacy in their ability to cope without cigarettes (Bandura, 1977). It is of further interest that reports of a previous attempt to quit smoking were more common among those using NRT in multiple situations requiring momentary abstinence. This could result from greater NRT use; more extensive periods of brief abstinence; or a stronger prior motivation to at least partially eliminate the harmful effects of smoking. Although prospective analyses are required to disentangling these explanations, previous studies have also reported higher odds of smoking abstinence among those using multiple harm reduction techniques (Okuyemi et al., 2002); thus consideration is required as to whether smokers are actively encouraged to use NRT during both voluntary and enforced smoking restrictions.

The lack of an association between the use of NRT for temporary abstinence and cigarette consumption is rather counterintuitive. Although one may have assumed that not all situations requiring temporary abstinence would lead to a reduction in cigarette consumption, reductions may have been envisaged in situations where NRT was used for extended periods of time, i.e. at home or work. Consequently, it could be concluded that the use of NRT for temporary abstinence fails to mitigate the tendency of smokers to compensate prior to and following smoking restrictions. However, it is possible that the cross-sectional nature of the study precluded the determination of a reduction in cigarette consumption, if it is the case that smokers with a higher nicotine dependency are more likely to use NRT. Alternatively, smokers may instead be modifying how they smoke their cigarettes, such as reducing the amount of smoke inhaled or putting their cigarettes out early, or may not be using enough NRT to result in reliable reductions in cigarette consumption. This latter hypothesis appears unlikely, on the basis that the use of NRT in multiple situations was not associated with lower consumption, despite assuming greater NRT use would have occurred. If it is the case and the use of NRT during momentary abstinence does not induce significant reductions in cigarette intake, smokers need to be aware that decreased harm to their health may only occur if smoking cessation is attained; otherwise consideration should be given to the development of interventions aimed at inducing reliable reductions, and analyses conducted on whether declines in the risk of mortality and morbidity result.

Finally, the failure to find an association between reports of the helpfulness of NRT and attempts to quit smoking, suggests that perceptions of the effectiveness of NRT are unlikely to mediate the relationship between the use of NRT for periods of temporary abstinence and attempts to quit smoking. There are several possible reasons for this: it may be that perceptions of the helpfulness of NRT do not influence extent of use (Mooney et al., 2006), or that smokers have a tendency to attribute any success with temporary abstinence to their own actions rather than medicinal nicotine, thus underestimating its effectiveness. This may be a beneficial technique in the long-term, with internal attributions increasing smokers' confidence in their own ability to cope without cigarettes for several hours (Weiner, 1992).

However, this study suffers from a number of limitations which need to be considered. First its reliance on self-report to assess smoking status, quitting behaviour and NRT use, may have resulted in some recall bias or misreporting. However, it is difficult to envisage that these biases would have led to the specific patterns of findings observed. Secondly, it should also be noted that a substantial number of participants reported using NRT for temporary abstinence in 'other' situations. It is unclear what smokers meant by this, which limits the conclusions that can be drawn. Thirdly, due to the cross-sectional nature of this study, the positive associations between the use of NRT in various temporary abstinence situations and attempts to stop smoking, could either reflect NRT's ability to increase smokers' motivation to quit, or the use of NRT being an after effect of a failed quit attempt. This can only truly be resolved with a prospective analysis. Finally, our measure of the helpfulness of NRT was rather limited. It would be of interest to replicate these particular findings with a multifaceted instrument, i.e. one which assesses NRT's ability to relieve urges to smoke and withdrawal symptoms.

Conclusion

Those using NRT during periods of temporary abstinence appeared to be more likely to report doing so at home and whilst travelling, with just over half of smokers finding NRT helpful in these situations. Smokers found NRT the most helpful during periods of enforced as opposed to voluntary abstinence, and reported the patch and inhalator to be more helpful than the nicotine gum. Although the use of NRT in all situations requiring momentary abstinence was associated with increased odds of a prior attempt to quit smoking, odds were greatest amongst those using NRT in the office and at home, and in multiple situations as opposed to only one situation. Interestingly, reports of the helpfulness of NRT were not related to either cigarette intake or attempts to quit smoking in the previous year. These findings provide further support for the argument that the use of NRT during momentary abstinence may increase the propensity of smokers to quit.

Chapter 14: The use of Nicotine Replacement Therapy for Smoking Reduction and During Periods of Temporary Abstinence: An Interview Study

Introduction

Survey-based studies appear to point towards the possibility that significant reductions in cigarette consumption may not occur amongst those spontaneously using NRT for harm reduction purposes (see Chapters 7-11; Levy et al., 2007). It is of interest to determine the factors which may account this for two reasons: inducing significant reductions in cigarette consumption may concurrently lessen the harm caused to continuing smokers by cigarettes (Eliasson et al., 2001; Simmons et al., 2005; Pulera et al., 1997), and with a positive association reported previously between the extent of reductions in cigarette intake and attempts to quit smoking, could future augment the odds of smokers achieving abstinence (Etter et al., 2004 & Carpenter et al., 2004). Smokers who are spontaneously reducing their cigarette intake also demonstrate a preference for the nicotine patch, which until recently was not licensed for harm reduction purposes (see Chapters 6-11). The patch may be less suitable as a smoking substitute than the other NRT products, because it does not involve a replacement activity and cannot provide a relatively rapid increase in nicotine when required; thus making it difficult for smokers to titrate their nicotine levels (Hatsukami et al., 2007). Understanding the reasons for this choice may help in the manufacturing of newer NRT products which are more in line with consumer needs, and point to ways in which smokers may be encouraged to use those products which are non-transdermal in nature.

Consequently, the current chapter, using an interview methodology, aimed to determine (i) the factors which may account for the lack of reliable reductions in cigarette consumption amongst those using NRT for smoking reduction and/or during periods of temporary abstinence at a population level, and (ii) the reasons for smokers' preference for the nicotine patch. Although qualitative studies cannot enlighten us about the behaviour of the entire smoking population, it is hoped that these findings may inform future surveys as to the variables of interest; the outcomes of which can be used during the development of interventions aimed at increasing the rates of reductions in cigarette intake and may also be used to instruct medicinal nicotine product design. In order to address these objectives, a sample of smokers were questioned about 1) their understanding of 'smoking reduction' and what it entailed; 2) the methods they used to reduce their cigarette consumption and/or to temporarily abstain; 3) how they used NRT for these purposes; 4) their views on the various NRT products including their advantages and disadvantages; and 5) their knowledge of the regulations surrounding the use of NRT for harm reduction purposes.

There are several possible reasons why NRT may not be associated with significant reductions in cigarette consumption in the population. Smokers may not use enough NRT or use it incorrectly (Shiffman et al., 2003a; Shiffman et al., 2003b), with higher levels of NRT use being associated with greater reductions in cigarette consumption (Hatsukami et al., 2007). Smokers may also hold unrealistic expectations about what NRT can achieve, and as a consequence, underestimate the effort they need to expend in order to abstain from smoking. It is now evident that many smokers are overly optimistic about their ability to change their smoking behaviour and hold idealistic expectations about NRT's efficacy independent of human effort (Weinstein, Slovic & Gibson, 2004; Yerger et al., 2008). Previous behaviour change research has also emphasised the pivotal role of 'goal setting' and the importance of formulating 'structured rules' to achieve these goals (Borrelli & Mermelstein, 1994; Strecher et al., 1995; Riggs et al., 2001; Riley et al., 2002; Michie et al., 2009). Smokers may be failing to establish firm goals concerning the extent of reduction they want to attain, may not be establishing a clear set of rules for attaining such goals, or the rules they adopt may not be effective. Alternatively, it may be that smokers are seeking to reduce their intake by means other than reducing their cigarette consumption. Previous studies of *ad libitum* smoking have demonstrated at least partial compensation for the additional nicotine attained from NRT though the adaptation of puff frequency (Benowitz et al., 1998; Foulds et al., 1992; Pickworth et al., 1994).

Possible reasons for the popularity of the nicotine patch include its ease of use and long established history as a medicinal nicotine product (Schneider et al., 2006). Smokers' mental representations of nicotine cravings may also account for this preference. A representation that is based on depleted brain nicotine concentrations is likely to favour the nicotine patch over other nicotine products, since the patch provides a steady release of nicotine throughout the day (Shiffman, 1989). In contrast, a representation that is based on smoking-cues is likely to favour nicotine gum, lozenges and the inhalator, due to their speed of delivery and active application (Fiore, Jorenby, Baker & Kenford, 1992; West, 2009). Another factor may be that smokers are largely unaware of which products are and are not licensed for this kind of use; with smokers opting for the nicotine patch simply because they had utilised it previously during an attempt to stop smoking.

Methods

Design and Procedure

Participants were recruited via a newspaper advertisement seeking smokers who were using NRT during attempts at smoking reduction and/or during periods of temporary abstinence, but who were not currently trying to quit or were unable to do so. Participants had to be aged 18+ and to speak English fluently. Interviews were conducted over the telephone using open-ended questions to ensure that participants freely reported their experiences of using NRT products for harm reduction purposes. Data on socio-demographic and smoking characteristics were also collected. The interviews lasted approximately 20 minutes and were tape-recorded. Following the interview, participants were offered information regarding NHS stop smoking services and were given £20 of high-street vouchers to compensate them for their time. Interview topics that were covered were 1) smokers current smoking behaviour; 2) what smokers meant when they said that they were cutting down or temporarily abstaining; 3) how they were cutting down or temporarily abstaining; 4) their current goals; 5) which NRT products they were using and how they were using them; 6) why they were using NRT and if they found it helpful; 7) their experiences with previous attempts to quit smoking and smoking reduction; 8) whether they were recommended to cut down and to use NRT for smoking reduction and/or during momentary abstinence; and 9) their knowledge of the regulations surrounding the use of NRT for harm reduction purposes. See appendix H for the full interview schedule.

Ethical Approval

Ethical approval was granted by the University College London Research Ethics Committee.

Participants

Eighty-one smokers responded to the advertisement; of whom, 36 did not meet the inclusion criteria and nine could not be contacted. This resulted in a final sample of 36 smokers. Sixteen were male and twenty female, with an average age [Standard Deviation (*SD*)] of 42 (14.7). Thirty-three identified themselves as White British, one Afro-Caribbean, one White South African and one North African. Twenty were single, thirteen were married or living with their partner, and three divorced. Participants reported smoking for an average of 23 years (*SD* 14.1) and a current cigarette consumption of 11 cigarettes per day (*SD* 11.0).

Nine participants were using NRT in an attempt to reduce their cigarette consumption, five were using NRT during periods of temporary abstinence, and twenty-two were using NRT for both purposes. Nineteen smokers reported using either nicotine patches (*n*=10), nicotine gum (*n*=8) or nicotine lozenges (*n*=1). The other seventeen participants used a combination of NRT products: nicotine patches and gum (*n*=6), nicotine patches and inhalator (*n*=6), lozenges and gum (*n*=2), inhalator and gum (*n*=2) or gum, inhalator and nicotine nasal spray (*n*=1). Participants had been attempting to reduce their cigarette consumption for an average of 13 months (*SD* 10.8).

Data Analysis

Interviews were transcribed and analysed using a variant of Framework Analysis (Ritchie & Lewis, 2003). This method of qualitative analysis was chosen because it aims to preserve the integrity of individual accounts and is appropriate for studies in which research questions are predetermined. Four key stages were followed: familiarisation, identification of the thematic framework, indexing, and mapping/interpretation. Familiarisation involved re-reading the interview transcripts to achieve immersion in the data. Following initial familiarisation, a thematic framework was developed by identifying key themes and sub-themes. The framework was then systematically applied to all the data and concurrently modified and refined. The final processes of mapping and interpretation involved exploring patterns by making comparisons and developing explanations that were grounded in the data. COREQ guidelines for the reporting of qualitative interviews were followed throughout the analysis process (Tong, Sainsbury & Craig, 2007).

Reflexivity

This study was motivated by a sense of commitment to uncover the experiences and beliefs of smokers using NRT for smoking reduction and/or during periods of temporary abstinence, who sometimes have no voice regarding tobacco harm reduction policies; this is partially due to the historically reliance of policy makers on quantitative research when deciding which treatment options smokers should receive. As the main coder had worked with smokers previously and was well read on the topic of harm reduction, it is possible that their preconceived ideas about the use of NRT for such purposes may have biased interpretations; however, attempts were made to prevent this. Throughout the analysis process the main coder reflected on the possible influences their beliefs may be having on the themes that emerged. Two external validity checks recommended by Ritchie and Lewis (2003) were also used: 1) a sample of eighteen randomly selected transcripts was re-coded by two additional researchers, who confirmed that the transcripts were coded consistently and that they included data that supported the key findings of the study; and 2) respondent validation was undertaken by sending a brief summary of the main findings to participants to check that the overall interpretation was correct. Internal validity was also addressed using the ‘constant comparative method’ and by ‘deviant case analysis’.

Results

Themes

Of the twenty-one themes which were identified, sixteen were judged to be major themes addressing the questions at hand. These sixteen themes are discussed below, followed by the additional five themes.

Theme 1: Interpretation of the Term 'Smoking Reduction'

Few smokers used the term 'smoking reduction', instead they opted for variations such as 'windle down' or terminology which was almost synonymous to smoking cessation: 'on the way out' and 'cut out' (sub-theme 1.1). Smokers also held differing conceptions of what 'smoking reduction' means: reducing the number of cigarettes smoked per day; not smoking during periods of temporary abstinence; having attempted but failed to quit smoking; and having quit smoking recently but there being a possibility that relapse could occur (sub-theme 1.2; see Table 1).

Theme 2: Goals

The goals set by smokers ranged from a specific reduction in cigarette consumption (sub-theme 2.1), to smoking cessation (sub-theme 2.2), switching to social or occasional smoking (sub-theme 2.3), and the complete substitution of cigarettes with the long-term use of NRT (sub-theme 2.4). These goals were often unrealistic and rarely specific, with arbitrary rates of reduction and no indication as to whether sub-goals were set. There was also a general failure to indicate the time-line over which they should be attained, and when this was mentioned, smokers set goals which needed to be achieved within a relatively short period of time (see Table 1).

Theme 3: Methods of Smoking Reduction

Smokers revealed that they used a variety of methods to try and reduce their cigarette consumption (see Table 1): increasing the interval between their cigarettes (sub-theme 3.1); stopping chain smoking (sub-theme 3.2); limiting when they smoked either by designating time periods, i.e. only smoking in the mornings or the evenings, specifying specific activities, i.e. only smoking after eating, or restricting smoking to specific locations, i.e. only smoking in one room of their home (sub-theme 3.3); switching to occasional smoking which included social or non-daily smoking (sub-theme 3.4); limiting the number of cigarettes smoked (sub-theme 3.5); not smoking when they normally would (sub-theme 3.6); and using periods of temporary abstinence (sub-theme 3.7). None of these were implemented in a structured manner, with intervals between cigarettes rarely being specified. Some methods also appeared to be rather counterproductive. For example, those who limited themselves to a specified number of cigarettes per day would consume their daily allowance whether or not they had the urge to smoke.

Theme 4: Use of Non-Medical Aids

Smokers used a number of non-medical aids and techniques to help them cut down. These included relaxation techniques, such as using acupuncture, exercising and reading books (sub-theme 4.1); substituting their cigarettes with normal chewing gum or drinks (sub-theme 4.2); distracting themselves (Sub-theme 4.3); avoiding other smokers and smoking paraphernalia (sub-theme 4.4); and using periods of enforced temporary abstinence (Sub-theme 4.5; see Table 1).

Theme 5: Feelings and Emotions Associated With Smoking Reduction

The current sample of smokers were ‘chronic reducers’, having attempted to cut down their consumption in the past. These attempts were generally half-hearted and without the aid of NRT (sub-theme 5.2). There was a general view that they would have been more successful had they utilised medicinal nicotine. Nonetheless, smoking reduction even with the aid of NRT was extremely difficult, more so than was anticipated (sub-theme 5.1). These difficulties were coupled with general feelings of under-achievement. Although a few smokers did report that they were pleased with what they had achieved (sub-theme 5.3), and noted positive effects on their general health as a result (sub-theme 5.4; see Table 1).

Theme 6: Factors Affecting Smoking Reduction

Smokers found it difficult to report the number of cigarettes they smoked per day. Reports also varied substantially throughout the interview with one smoker reporting that they smoked ten cigarettes at the start of the interview and seven cigarettes later on (sub-theme 6.1). This confusion may have been partially due to day to day fluctuations in cigarette consumption caused by a number of environmental and personal factors. These included boredom and a lack of structure to their day (sub-theme 6.2); being around other smokers (sub-theme 6.3); when taking other drugs or eating (Sub-theme 6.4); and when stressed, anxious or in a bad mood (sub-theme 6.5; see Table 1).

Theme 7: Types of Temporary Abstinence

Three types of temporary abstinence were reported: forced [(i.e. on aeroplanes & at work); sub-theme 7.1]; semi-forced [(i.e. in pubs & restaurants); sub-theme 7.2]; and those involving an element of choice [(i.e. at home); sub-theme 7.3]. Most smokers found that they had to abstain at some point during forced periods and to a lesser extent during semi-forced periods. Few of the smokers abstained out of choice, with many reporting that they had not thought about using NRT at home and that often decided to smoke outside when they had the opportunity to do so (see Table 1).

Table 1: Themes Associated With the Behaviour of Smoking Reduction and Temporary Abstinence

Theme	Sub-theme	Example
1. Interpretation of the term 'smoking reduction'	1.1 Terminology	'reduce', 'wean it off', 'cut it off', 'cut out', 'keep it down', 'cut back', 'windle down', 'get down', 'cut up', 'on the way out', 'slowed down', 'get right down', and 'drop back'.
	1.2 Definition	'Gradually trying to wean it off really. Basically trying to give up' (PC, 40 year old male). 'That I've almost stopped smoking apart from having the odd couple if my daughter has a cigarette every now and again' (KG, 76 year old male) 'I have cut down completely. I'm on my seventh week of just using patches and the Nicorette inhalator . . . .yes, yes I have cut down for three months when I was actually pregnant with my son, and didn't smoke at all' (MD, 30 year old female)' 'Um I suppose it means just reducing the amount you smoke. So I sort of cut out a few, so I suppose I'm cutting down as I'm not smoking what I used to' (LW, 24 year old female). '. . . to not smoke at all during the day' (SS, 44 year old female).
2. Goal setting	2.1 Percentage reduction	'I do cut down, but I want to try and get down to five or six a day rather than, um, 10 a day' (LW, 24 year of female). 'Um, yeah I'd like to go down to about two fags every other day maybe. But obviously I know it ain't going to happen overnight . . . but two fags a day . . . well considering I was smoking 20 a day. It helps out' (DB, 32 year old male).
	2.2 Cessation	'Well, I've managed to cut it down to 50% and hopefully I'm going to cut it out completely by the end of the year' (PC, 40 year old male) 'Well, over the last week I've managed to have only one cigarette, um I want to get, well I'm not having a cigarette at the moment, get rid of them completely' (KG, 76 year old male).
	2.3 Switch to social smoking	'Well to get down to socially I think, just now and again' (TM, 19 year old female)
	2.4 Complete Nicotine Replacement Therapy substitution	'Well, my obvious goal is to cut back, cut down and eventually moving on to the nicotine patches. So obviously so I don't have that urge to smoke. That is the plan basically' (BM, 35 year old male).
3. Methods of reduction	3.1 Increasing the interval between cigarettes	'I'm cutting down in terms of not smoking as frequently and increasing the time between each' (PC, 40 year old male).
	3.2 Stopping chain smoking	'One thing I used to do sometimes, especially if I was out and about, was as soon as I had put one out I was sparking up another one and I don't do that anymore. If I smoke one that is enough for a little bit . . . like I said I no longer light up a cigarette straight after another one' (JB, 22 year old male).
	3.3 Limiting when smoke	'. . . and when I do smoke it is usually after a meal, rather than kind of all during the whole of the day really' (PC, 40-year old male). '. . .I only smoke in one room. In the kitchen' (LE, 62 year old female).
	3.4 Occasional smoking	'Yes, yes, now it's more social than just habit forming' (MF, 55 year old female). 'Like yesterday I didn't smoke up till now. Then maybe there are some days when I will have one or two I would say' (H, 60 year old male).

Table 1: Themes Associated With the Behaviour of Smoking Reduction and Temporary Abstinence (Continued)

Theme	**Sub-theme**	**Example**
	3.5 Not smoking when normally would	'Well I try not to have a cigarette when I normally have them, like when I pick the telephone up, or after a cup of coffee, or when I'm particularly stressed and when I'm bored' (JK, 61 year old male).
	3.6 Limiting the number of cigarettes	'I have, um, not using anything else, um, just trying to limit the amount I smoke per day by buying boxes of 10 and promising myself I won't buy anymore' (LG, 27 year old female).
	3.7 Using temporary abstinence	'One good thing is my job that I can't really smoke. That made it easier . . . but yeh I think, yeh it really helped when I started this job, and knowing that you can go seven hours without a cigarette makes it easier to try and go longer between cigarettes, and I do think I smoke a lot less because I have had the breaks at work because of the job.' (JB, 32 year old male).
4. Use of non-medical aids	4.1 Relaxation	'I started doing, um, needles and stuff. Acupuncture and sort of yoga for stress and some herbal remedies' (PC, 40 year old male).
		'Yes. I try to relax. Yes I try to listen to music or something like that, yep that does tend to work' (CH, 41 year old female).
		'Sort of that and sort of exercise' (LW, 24 year old female).
	4.2 Substitution	'I'm having cold drinks, well cold fizzy drinks, well cold fizzy water. That helps as it gives a tingling on the tongue. Cold fizzy drinks and there is always a bowl of grapes, red grapes in the kitchen which helps or seeds (LE, 62 year old female).
		'Other than normal chewing gum if I don't have the Nicorette gum, instead of the cigarette I try to wean myself off the Nicorette gum and have a normal one. Yes, some extra mint gum or something' (SL, 40 year old male).
	4.3 Distraction	'I know a number of my friends who have done it and when I am with them I can have a glass of wine and not really, not really miss a cigarette, um, so I try to spend more time with them. I force myself into difficult situations' (LE, 62 year old female).
		'Yeh, yeh, during the day just trying to do different things. Mainly having a coffee or going for a walk, that sort of thing . . . I suppose I go on the internet and just try to keep busy. Read a book. It's difficult and the habit lights up when you're relaxing' (MZ, 59 year old male).
	4.4 Avoidance	'. . . if you're with other smokers sometimes it's best to leave, you know and whatever, and I work in the city where a lot do it' (BM, 35 year old male).
		'Um, um, um, I didn't go outside much, and there was this one job after the shift which was changing the ashtrays and stuff and I always made sure I was busy washing up . . . I'd have to eat as I was literally hungry I think. Yeh, so eating and not doing the jobs I was supposed to be doing' (HM, 23 year old female).
	4.5 Temporary abstinence	'I find when I go home to my mum's I just don't smoke, but then I come back and it's more difficult, as me and my mum don't get on, um, that well. For three days I'm like desperate for a cigarette. I find that's a good thing to go home as I can't smoke in any of my families houses so um, but she makes me so tense that I feel I like need one (DR, 50 year old female).

Table 1: Themes Associated With the Behaviour of Smoking Reduction and Temporary Abstinence (Continued)

Theme	**Sub-theme**	**Example**
5. Feelings and emotions associated with smoking reduction	5.1 Difficulties with their current attempt	'I'm trying to cut down but it's difficult, you know . . . my boyfriend who I live with smokers and it's hard when you want one and you're trying to give up and their still smoking . . . I mean I guess when I was trying to cut down over the summer I didn't realise how difficult it was going to be, and the fact that my smoking continued is a bit shocking really, if I'm honest with you' (LW, 24 year old female). 'I think a lot of it is willpower you see when you have to miss some, and I don't seem to have a lot of willpower. But I suppose after 40 years it is hard' (BC, 80 year old man).
	5.2 Difficulties with previous attempts	'I tried before about five years ago, but it wasn't as serious as it is now. It didn't really last long. It was kind of a new year resolution sort of thing'' (PC, 40 year old male) 'Yeh, I have done on several occasions over say the past five years and again not with an awful amount of success' (GH, 45 year old male).
	5.3 Achievement	'I'm smoking less, but it is not enough as I so really want to give up' (JK, 61 year old male). 'Ah, well I used to smoke 20-30 a day and a, I'm down to about three or four, which is pretty good' (MZ, 59 year old male).
	5.4 Benefits	'. . . I know it's benefiting me and I can feel the benefits already so hopefully um, I'll try to get down to 10 . . . I'm smoking maybe three quarters of it, um, I think that's good' (RG, 22 year old male).
6. Factors affecting smoking reduction	6.1 Uncertainty about the number smoked	' Um, well, um I smoke about 10 a day, maybe a bit more at times, um, probably about half a pack . . . I think I have cut down by two or three so I'm on about sort of seven or eight a day' (LW, 24 year old female).
	6.2 Boredom/structure	'If a person is a bit busy with something then you won't think about the smoke, but if somebody is bored, then you'll get the feeling to smoke, you know' (H, 60 year old male).
	6.3 Other smokers	'I'm living with a heavy smoker, my daughter, um, so I tend to occasionally fall off my perch and have a cigarette . . . I think if she hadn't been here I think it probably would have been a lot easier. But she comes in from work and promptly lights a cigarette, you know what I'm saying. She does smoke a lot at home as she can't smoke in her job. So that sort of sends the flash bulb going oh cigarettes, cigarettes, cigarettes, you know.' (KG, 76 year old male). 'At weekends it's obviously a lot more difficult with going out and stuff. The number I smoke may increase on Saturday or Friday night or Sunday or whatever. . . if you're a smoker it depends on your social circumstance and if you're with other smokers sometimes it's best to leave, you know and whatever and I work in the city where a lot do it' (BM, 35 year old male).
	6.4 Other drugs/eating	'I smoke more when I'm drinking alcohol to be quite honest' (SL, 40 year old male). 'I smoke generally after eating really. If I have a meal I'd probably have a fag afterwards really' (DB, 31 year old male).
	6.5 Stress/bad mood	'Well, sometimes I have a good day, but if I feel stressed and things like that I find it harder, but if I have a good day I find it a lot easier, yeh. If I'm stressed it's a cigarette or food or something like that.' (BC, 40 year old male).

Table 1: Themes Associated With the Behaviour of Smoking Reduction and Temporary Abstinence (Continued)

Theme	Sub-theme	Example
		'So I smoke if I've got the hump. I might stretch to like 10 a day if I've got a right hump that day. If I've had a c*** day at work and things like that' (DB, 31 year old male).
7. Types of temporary abstinence	7.1 Forced	'Yeh, if I'm on a long train journey, but I'm not sort of noticing it as much now I suppose. But yeh, usually I take some if I like travel down to South End or something. Obviously you can't smoke on the stations or anything like that. I'll probably have one while I'm travelling' (SL, 40 year old male)
		'Yes, if I'm in a meeting I eat chewing gum all the time so they don't get the hump with me. They are alright with that' (DB, 31 year old male).
		'If I was able to go outside at work I probably would go outside and have a cigarette' (JB, 32 year old male).
		'Um, generally no, it's a bit of a strange psychology one I have. I know there are certain times when I can't smoke so I don't need to replace them as I know I can't' (GH, 45 year old male).
	7.2 Semi-forced	'So obviously the hassle of going out of the building and all that kind of stuff. So it is easier. It's convenient at home or in the pub where you have to go outside, obviously it helps' (BM, 35 year old male).
		'Things like social occasions, when um, the main thing is that I am very conscious of the fact when you first smoke, when you have a cigarette and you come in that the initial smell is so strong that, so I try not to smoke in social circumstances because I'm very conscious of the smell' (LG, 27 year old female).
	7.3 Choice	'No, not really. My husband doesn't mind and understands. I think it's my right to smoke in my own home and no one can tell me there' (AM, 45 year old female).
		'Oh, yes I try not to smoke at home as I don't like the smell of it in the house. . . sometimes I find myself going outside and having a cigarette' (RW, 29 year old female).
		'. . . before you mentioned it I hadn't really thought about using outside work hours really' (JB, 32 year old male).
8. Modified smoking behaviour	8.1 Smoking part of the cigarette	'I snub it out half way through it rather than smoke the whole thing, whereas I did smoke the whole thing and then light another one. Whereas now when I have one it's mainly just half and I snub it out and I usually don't need another one for a while' (PC, 40 year old male).
		'Um, no. Um, I always sort of leave about quarter of an inch at the end anyway' (MM, 70 year old female).
		'Yeh, but I have to say that I sometimes take the fag end out of the ash tray and have a puff. That's it, it's gone. Yeh, sometimes I only have a couple of drags. Normally it's a cigarette end in the ash tray and I have sort of run over and dumped them in the bin, but I don't always do that.' (KG, 76 year old female).
	8.2 Inhaling less	'Um, I'm trying not to inhale as much and I just leave longer stubs I suppose . . . it just doesn't get me as high (if inhales less)' (GH, 45 year old male).
	8.3 Not inhaling	'Well, I try not to inhale you know, like put it in my mouth. But there is always that temptation.' (NK, 45 year old male).

Theme 8: Modified Smoking Behaviour

Smokers were not only attempting to reduce their cigarette intake but were also modifying how they smoked their cigarettes. This included smoking only part of the cigarette (sub-theme 8.1), trying to inhale less (sub-theme 8.2), or not inhaling at all (sub-theme 8.2; see Table 1).

Theme 9: Reasons for Using Nicotine Replacement Therapy

A range of reasons were stated for the use of NRT: to prevent withdrawal symptoms and cravings (sub-theme 9.1); because it was recommended or free of charge (sub-theme 9.2); and because they had used it in the past (sub-theme 9.4). The history and advertisement of the products was also mentioned, with smokers opting for those which were more extensively promoted and had a longer reputable history. Smokers also appeared to be largely unaware of some of the newer products (sub-theme 9.3; see Table 1).

Theme 10: Benefits of Specific Products

Smokers liked the nicotine gum because it acted as a form of distraction, involved active participation, was similar to normal gum, was easy to carry, and felt that the taste was indicative of a pharmacological effect (sub-theme 10.1). In contrast, the patch could be forgotten about, was discreet, provided a prolonged nicotine dose, and was seen as safer than other medicinal nicotine products (sub-theme 10.2). Smokers who preferred the nicotine nasal spray reported that this was because it gave them a quick hit (sub-theme 10.3), while for the inhalator it was the similarity to the action of smoking that was important (sub-theme 10.4; see Table 2).

Theme 11: Disadvantages of Specific Products

The main disadvantage of the nicotine gum was its taste and side-effects, which included sore gums and acid reflux. Some of the older smokers believed it was not an acceptable product to be using at their age, and there were worries about its addictive potential (sub-theme 11.1). Smokers also reported a number of what they believed were side-effects from the nicotine patch, including nightmares, score skin and mood swings. There was a concern about putting a patch containing a drug on their skin and that the patch may be too strong. Some of the smokers also reported that they disliked the lack of substitution for the act of smoking (sub-theme 11.2). The inhalator was deemed by some as embarrassing (sub-theme 11.3), the nasal spray was disliked due to the fact that it involved placing it in the nose (sub-theme 11.4), while the lozenges effect was judged by some as too fast (sub-theme 11.5; see Table 2).

Theme 12: Use of Nicotine Replacement Therapy

Smokers reported using a combination of NRT products, although rarely at the same time. Generally one product was used as the main source of nicotine and the other as a backup (sub-theme 12.1). Smokers also appeared to be under-using NRT due to its cost, concerns about overdose or because they forgot (sub-theme 12.2). Although smokers were unaware of how to use the nicotine patch, leaving it for too long or short a period, they used the non-transdermal products largely in the manner that is directed (sub-theme 12.3; see Table 2).

Theme 13: Views of Nicotine Replacement Therapy

NRT was deemed helpful by smokers because it prevented cravings, took the edge off withdrawal symptoms, calmed them down, and boosted their willpower (sub-theme 13.1).

Nevertheless, medicinal nicotine products did not live up to their expectations: their effects were too short lived; they were viewed as only a partial substitute for cigarettes; were deemed to be too weak; and were seen as effective only during enforced periods of temporary abstinence (sub-theme 13.2; see Table 2).

Theme 14: Misperceptions About Nicotine Replacement Therapy and Cigarettes

Smokers were concerned that they would become addicted to NRT and held the belief that NRT could not be used whilst smoking at exactly the same time. The belief that NRT products were only for smoking cessation purposes was also prevalent, with some smokers viewing them to be as dangerous as cigarettes or chewing tobacco, while others were dubious about whether NRT products contained an active ingredient (see Table 2).

Theme 15: Advice From Healthcare Professionals

Healthcare professionals had largely advised against smoking reduction, instead emphasising smoking cessation. Those who did recommend smoking reduction often encouraged smokers to cut down by as much as possible (see Table 3).

Theme 16: Knowledge of Regulations

Smokers were unaware of which NRT products were licensed for smoking reduction and/or periods temporary abstinence; although some were aware that you could use NRT concurrently with cigarettes (sub-theme 16.1). Smokers reported that they would be interested in knowing which products were recommended for harm reduction purposes (sub-theme 16.2), and that being informed about NRT regulations may affect their choice of product, but that they would not switch to one they disliked (sub-theme 16.3; see Table 3).

Table 2: Themes Associated With the use of Nicotine Replacement Therapy for Smoking Reduction and Temporary Abstinence

Theme	Sub-theme	Example
9. Reasons for using Nicotine Replacement Therapy	9.1 Psychological reasons	‘Well, basically it’s um. I find it more of a habit forming thing than anything else, well the gum helps to put the nicotine intake into you’ (JR, 49 year old male).
		‘I thought it would give me the edge. I thought it would stop that need a bit and help me cut down’ (SG, 42 year old male).
		‘Well, I don’t have the willpower to go cold turkey and um I don’t think my work mates want to put up with my temper, so out of the kindness to them I decided to wear patches and I find they work’ (MM, 70, year old female).
		‘. . . with the smoking tool I find that that is just a habit using thing. So it sort of cuts out the habit as well (JR, 49 year old male).
	9.2 Recommendation/ free of charge	‘I remember being told by the pharmacist that um, gum was good as it would replace some of the actions involved in smoking’ (LW, 24 year old female).
		‘Um, well I have been aware of it for quite some time and as I said my kids have been badgering me. In fact, they brought me round the patches and the inhaler, so’ (JK, 61 year old male).
		‘I haven’t tried the gum. I’ve tried the patches as I was getting them free with the chemist and somebody else I know gives me the inhalators as they are trying to stop smoking, and that’s really why I am using them. Because they are free’ (CS, 39 year old female).
	9.3 History/ advertisement	‘Well, firstly, I didn’t know there were any others [other NRT products]’ (JK, 61 year old male).
		‘Well, um, I don’t know, maybe they [gum and patch] have been around longer, I think’ (SG, 24 year old male).
		‘I mean I used the gum and the patches as that’s what you see on tele and advertisements’ (LW, 24 year old female).
	9.4 Past use	‘Well, to be honest the gum and patches have been around longer. When I was young and I tried to stop it was always the gum and patches that I’d. I know that there are other sorts of therapy available now, but um, the patches and the gum were the ones I knew about and had used before. So it’s using the same as before (LG, 27 year old female).
10. Benefits of specific products	10.1 Nicotine gum	‘. . . chewing sort of distracts me a bit’ (LW, 24 year old female).
		‘It’s just because I do eat gum, I eat chewing gum anyway. Well I tried the Nicorette gum and it seems to be getting me off that initial craving basically’ (SL, 40 year old male).
		‘. . . I try to use the nicotine gum, which I find is ok. It gives you more or less the mouth action that you miss with cigarettes’ (KG, 76 year old male).
		‘. . . and with the gum it was the initial taste which seemed to satisfy the craving really. Yeh, I suppose I’d say that in a nutshell. It’s the taste you get with the gum’ (GH, 45 year old male).
		‘The gum seems to work, I think it is just having something to do, you know the chewing. As I chew the gum a lot so I think it is just good replacement and it’s easy as well. You can carry it around with you’ (N, 45 year old male).
	10.2 Nicotine patch	‘. . . so it’s much better to put the patch on and no one knows. . . no one knows your using the patch, so it’s much better’ (AM, 45 year old female).

Table 2: Themes Associated With the use of Nicotine Replacement Therapy for Smoking Reduction and Temporary Abstinence (Continued)

Theme	Sub-theme	Example
		‘You can just put them [patches] on and forget about them’ (MM, 70 year old female).
		‘I think the only advantage with the . . . patches, which I only tried for a little bit because of the clash, is because you know, it’s a longer, a much longer effect than lozenges and stuff which is quick . . . the same with the nicotine patches which are slow release’ (BM, 35 year old male)
		‘Um, yeh, and I suppose as the patch is well known, it’s not as dangerous. I um, you know, worry a bit about putting these in me’ (TM, 19 year old female).
	10.3 Nasal spray	‘The nasal spray gives you an instant hit when you’re dying for a cigarette and it actually seems to work for me . . . the thing with the nasal spray is that it gives you an instant hit of nicotine, admittedly a small amount, but it’s enough for an hour, you know. So that kind of works for me’ (KG, 78 year old male).
	10.4 Inhalator	‘. . . and that [inhalator] works brilliantly on that as you get six hours or so into the flight then you end up dying for a cigarette which of course you can’t have . . . it gives you the hand to mouth effect. If you understand what I am saying, you know. You can really con yourself in to thinking that it is a real cigarette. So it works on that score’ (KG, 76 year old male).
11. Disadvantages of specific products	11.1 Nicotine gum	‘Oh yeah, I have heard of the nicotine gum but I don’t like it. I mean if someone said to me, take this and you will stop smoking I would suffer the taste of it’ (JK, 61 year old male).
		‘Well I have heard that the gum, from my neighbour who was chewing the gum, that he got addicted to the gum and he went to a smoking clinic and they told him they were not recommending the gum anymore because you get addicted to it’ (LE, 62 year old female).
		‘Well, I think I tried the gum, but didn’t like it and it’s not something you want to do at my age’ (AM, 45 year old female).
		‘. . . and I’ve tried the gum but that makes my gum very sore’ (LB, 39 year old female).
		‘. . . I think I have developed reflux and I do think that the nicotine gum has contributed to that’ (SS, 44 year old female).
	11.2 Nicotine patch	‘In the past few years I have tried patches which I didn’t really like as they were giving me nightmares and all types of things’ (JR, 49 year old male).
		‘Um, I didn’t like the patch much, and it was more that you put the patch on and forgot you put it on and I didn’t find it did anything. Um, plus it gave me, even putting it in different places, score skin’ (KG, 76 year old male).
		‘I don’t really like the idea of patches to be honest. My little sister used to use them and she used to go off on tangents. I think the nicotine did affect her. She’d get the hump a lot. Plus when she wore a dress she would end up with big patches all over her arm and things like that. Like sticky patches on her arm and things like that. That’s what put me off really’ (DB, 31 year old male).

Table 2: Themes Associated With the use of Nicotine Replacement Therapy for Smoking Reduction and Temporary Abstinence (Continued)

Theme	Sub-theme	Example
		'I ah don't really like the idea of putting patches on the body, I don't know why' (MZ, 59 year old male).
		'I tried the patches and I think they probably work alright but I found them quite strong' (N, 25 year old female).
		'. . . and I found that having nothing to do with my mouth was really hard. I was sticking pens in my mouth all the time and at the time the inhalers weren't around' (SS, 44 year old female).
	11.3 Nicotine inhalator	'I also sometimes use the inhaler, but it can be a bit embarrassing you see. . . I also don't use the inhaler that much, as I said it's too obvious. I would rather smoke a cigarette. It's less embarrassing' (AM, 45 year old female).
		'I don't know, it's really weird. You take a, you have like a pull on it [inhalator] and then you expect there to be smoke and there isn't and basically it's just weird' (N, 25 year old female).
		'Well, I tried them inhalers, and they are a bit embarrassing and don't give you a hit like the gum' (TM, 19 year old female).
	11.4 Nicotine nasal spray	'It's not always acceptable sticking something up your nose . . . when I first tried it [nasal spray] my eyes watered and nose watered but you get quite used to it' (KG, 76 year old male).
	11.5 Nicotine Lozenges	'. . . and they don't last as long as the gum. In sort of 20 minutes they are sort of over and done with' (HR, 41 year old female).
		'I think the only advantage with the . . . patches, which I only tried for a little bit because of the clash, is because you know, it's a lot longer, a much longer effect than the lozenges and stuff which is quick. . . the same with the nicotine patches which are slow release (BM, 35 year old male).
12. Use of Nicotine Replacement Therapy	12.1 Combined use	'Well, I use the patch everyday I think, and the inhalator backs me up' (MD, 30 year old female).
		'. . . Um, I'm putting the patch on in the morning and I'm taking if off about 1 or 2 O'clock and I'm using the gum and then when I get back home I'm putting the patches back on' (RG, 22 year old male).
	12.2 Compliance with dosage	'Um, yeh well, basically you know I did start off um daily, um and realised it was quite expensive, um what I was doing as opposed to, as you change down the level of mg, um so what I just done as opposed to constantly moving down and going down to the less amount ones, I had the strong ones and used the patch every other day sort of thing' (SG, 42 year old male).
		'Well, I tend to use only, I cut it [gum] in half or quarters, each part, each tablet form, so not to get too high. . . I cut them [gum] down into quarters. I may only have one a day' (SS, 44 year old female).
		'I do occasionally chew chewing gum or use the patch, but it's a bit hit and miss really, it depends what I have in my handbag and how I am feeling . . . I sort of put it on [patch] if I remember' (LW, 24 year old female).
	12.3 Correct use	'I put them [patch] on in the morning and then I probably leave them on for a couple of days and then I change them, yeh' (BC, 60 year old male).
		'. . . when I feel I'm sort of getting a craving I just put one [lozenge] in my mouth and just sort of let them gradually dissolve' (LB, 39 year old female).

Table 2: Themes Associated With the use of Nicotine Replacement Therapy for Smoking Reduction and Temporary Abstinence (Continued)

Theme	Sub-theme	Example
		'I do what it says. I chew it [gum] and then stick it in the side of my mouth and then I chew it a bit more and then stick it in the side of my mouth and I just carry on like that really' (HR, 41 year old female).
13. Views of Nicotine Replacement Therapy	13.1 Helpfulness of Nicotine Replacement Therapy	'I used to get the urge to smoke. With the chewing gum it seems to help me out really. When I'm chewing on it I'm not thinking about going out for a fag and things' (DB, 31 year old male), 'I was smoking 25 a day but the nicotine patches which I use every day, um, have helped me cut down a few during the day, you know, at work and things' (CH, 41 year old female). 'I think it does help. . . it just sort of takes the edge off a bit of the craving' (LW, 24 year old female). 'If I cannot smoke for a few hours it calms me down. It does work' (I, 34 year old female). 'This is the first time I have been doing it and it seems to be working. It gives you a bit of willpower as well if that helps' (SL, 40 year old male).
	13.2 Limitations	'. . . it wasn't working for me. In the evening I just felt as though I needed a cigarette as soon as I finished that shift. It was more of a habit thing than anything, um' (HM, 23 year old female). 'Um, yeh, but it doesn't fully stop you craving a cigarette. It only really works when you can't smoke (C, 26 year old female). '. . . yeh, it is useful but I suppose like anything it isn't completely perfect' (SS, 44 year old female) '. . . it takes the sting off, but it's not strong enough' (TM, 19 year old female).
14. Miss-perceptions about Nicotine Replacement Therapy and cigarettes		'Well I have heard that the gum, from my neighbour who was chewing the gum, that he got addicted to the gum and he went to a smoking clinic and they told him they were not recommending the gum anymore because you get addicted to it' (LE, 62 year old female). 'Well I mix and match it with normal gum so I don't get too much, as I don't want to get addicted to it' (NK, 45 year old male). 'Um, I don't really like the idea of patches to be honest. My little sister used to use them and she used to go off on tangents. I think the nicotine did affect her. She'd get the hump a lot' (HM, 23 year old female). 'You tend not to think about it so much when you are smoking as they are to quit' (DB, 31 year old male). 'Those puff fake cigarettes have to be as bad really' (NK, 45 year old male). 'Yeh, I do find it useful, but I do think it has negative side-effects. You know, I do think that liquid nicotine going into your stomach isn't very healthy. It's like chewing tobacco' (SS, 44 year old female). 'I don't know, but it could be that the Nicorette gum and the Nicorette patches have nothing in them, but I'm sure they do have something in them, stop you. But it could be a psychological thing where you go, I don't need to smoke, so yeh' (RG, 22 year old male). 'I always use the excuse that I'm smoking roll-ups and not normal cigarettes as cigarettes have to be worse for you as it's got all the chemicals, but my friends say it's bad for you anyway' (HM, 23 year old female).

Table 3: Themes Associated With Knowledge About Nicotine Replacement Therapy Regulation for Smoking Reduction and Temporary Abstinence

Theme	Sub-theme	Example
15. Advice from healthcare professionals		'. . . yeh, he [GP] advised me to cut down because I want to have children and stuff and he just advised me to cut down for sort of health reasons' (PC, 40 year old male). 'Um, I mean I think she said it's a bad thing to do and I shouldn't do it, and if I do I should try and cut down as much as possible if I can' (JK, 61 year old male). 'But about three years ago I went to a smokers clinic and they told us not to try and cut down before a quit attempt as it would make it worse, and just to smoke normally until the quit date' (RW, 29 year old female). 'Um, yeh, he [GP] just said it might be difficult sometimes.' (CH, 41, year old female).
16. Knowledge of regulations	16.1 Awareness	'Um, not really. I remember being told by the pharmacist that um, gum was good as it would replace some of the actions involved in smoking, but I couldn't tell you which one's specifically for cutting down' (LW, 24 year old female). 'What happened to me before is that I didn't try to cut down, I tried to cut out completely. That was kind of the rule of thumb at the time. That you try and stop altogether. Now I find it easier as I can cut down, I can actually smoke and use the gum and that, and eventually I will get down' (JR, 49 year old male).
	16.2 Interest	'Well, I'd like to know. This is something they never really tell you. They ask if you want to quit and force their choice of product on you and when you say anything suddenly you can't have it anymore' (NK, 45 year old male).
	16.3 Effect on behaviour	'I mean it might do yeh, especially if it's going to help me cut down or help me stop if I decide to [would knowing about the regulations make a difference]' (LW, 24 year old female). 'Can't see it really, the gum seems to work [would knowing about the regulations make a difference]' (JR, 49 year old male).

Table 4: Additional Themes

Theme	Sub-themes	Example
17. Other products	17.1 Medication	'I went to um, um, what do you call it, the NHS stop smoking clinic about six months ago and they put me on a drug called Zyban and it just didn't agree with me so I had to stop, um, but I made every effort to stop smoking' (JK,61 year old male), '. . . and I didn't want to try the actual medication because I think they play around a bit with your brain chemistry and I didn't want that either. You know, like they have got Champix and things, and various other things, which I don't think are that good' (RW, 29 year old female).
	17.2 Electronic cigarette	'Somebody brought me . . . um an electric cigarette and I find it is not bad at all. So if I'm walking around a supermarket or something I get a few looks (JK, 61 year old male), '. . . I have tried one of those electronic cigarettes because it was something you do with your hands. I don't know if that makes a difference or not' (MZ, 59 year old male).
18. Views on smoking and smoking policy	18.1 Smoking ban	'. . . but I think that pubs should have had the choice if they were a smoking venue or a non-smoking venue. Because I work at the Roundhouse sometimes, it's rubbish really, I can see that there are a lot of non-smokers in the audience but they choose to come and if you want to see a band it's still, and you know, pubs have got massive windows, and in the smoking days you couldn't see in, but now if walk past a pub you can just see a lot of drunk people which look really silly and it doesn't really look inviting to go in' (DR, 50 year old female). 'I think that it's my right to smoke in my own home and no one can tell me there. . . I heard they might ban smoking in the home. I think they should leave some pleasure' (AM – 45 year old female).
	18.2 Smoking generally	'Because you know it's a filthy habit isn't it. But yeh, it seems to addict to you like a sort of drug. All I would sort of say to young people, it's a mugs game, you know, and once you start, you know, it's harder' (BC, 60 year old male). '. . . I suppose back then the cigarettes were a lot more reasonable . . . because of the price of cigarettes you know, I think I could be spending the money on other things' (BC, 60 year old male) 'I know it's wrong but I enjoy smoking and that's how we get there in the first place isn't it? How we get addicted in the first place' (MM, 70 year old female).
	18.3 Stop smoking services	'Um, I mean I was referred to one [stop smoking service] by the doctor but I don't really have time to go for all those sessions and it just didn't really appeal to me if I'm honest with you' (LW, 24 year old female)
19. Over-the-counter/ prescription		'. . . but I'm too embarrassed to go to the doctors as they always seem to be a bit angry and go on and on' (C – 26 year old female) 'I'd rather pay for the stuff in Boots. I don't like burdening the NHS' (LB, 39 year old female) 'But they are expensive you know . . . but I am too embarrassed to go to the doctors' (C, 26 year old female)
20. Reasons for smoking	20.1 Health	'Um, cus I just find that I'm ah, as I'm getting older I find that I am developing a kind of cough and my chest is hurting more when I do exercise and I'm on a fit regimen really. So I'm finding that I can't sort of play football and run as well as I used to. That's why, it's about health really' (PC, 40 year old male)

Table 4: Additional Themes (Continued)

Themes	Sub-theme	Example
Reduction	20.2 Significant others	'Just, um, I've got a nephew and nieces now, so I'm trying to cut down so they don't have to see me smoke in front of them . . . around there [his nieces and nephews house] I do have to smoke outside' (PC, 40 year old male). 'Mainly, I'm being badgered terribly by my kids and I know it would make them happy' (JK, 61 year old male).
	20.3 Social	'. . . well social. Smoking is such a pariah these days . . . also my cat has a wheeze and bad chest, and um, there are a million reasons why I cut down . . . and in restaurants it is not nice to have to leave and go and smoke when everyone knows as well. It's just awkward, um, it's much easier if you can wait for a bit' (LE, 62 year old female). 'I'm becoming shamed out of smoking and trying not to have it as a comfort. I think sometimes people would rather you stuck some heroin in your eye than smoking in public. I don't really want to be that group of scruffy people standing outside pubs in the pouring rain and smoking. It's not a good look' (DR, 50 year old female).
	20.4 Financial	'Because of the price of cigarettes you know. I think I could be spending the money on other things and all I'm doing is throwing it down the drain' (BC, 60 year old male).
	20.5 Emotional	'Well obviously it is going to make me happy at the end of the day' (JK, 61 year old male).
	20.6 Personal	'It's also the smell on the clothes. Obviously it smells and gets in your hair and that sort of stuff (BM, 35 year old male). '. . . and it was apparent to myself that I needed to stop smoking because of my singing' (CR, 26 year old male).
	20.7 Quitting	'I feel that the best chance I had of quitting was to do it gradually. I have tried before, you know, stopping dead, but it was too hard for me, so I thought let's just reduce my smoking and see what happens (SG, 42 year old male). 'I think it will help to cut down first rather than trying to stop altogether . . . I would like to stop but I think it would be the right thing to cut down to a lower level and then think about stopping from there' (LW, 24 year old female).
	20.8 Temporary abstinence	'You know I've got to go outside now, I've been banned outside now. You know I have to go outside now in the rain and the cold, it's ridiculous . . . it's only since they brought in all the regulations [that they started cutting down] and things like that, you know, and I think I must be a mug, you know, going outside' (BC, 60 year old male).
21. Quitting behaviour	21.1 Readiness to quit	'I want to get . . . get rid of them completely. Particularly I'm finding I'm physically ok to stop but it's mentally, um, in my head I keep saying I would love a cigarette . . . but I'm still not at the stage . . . head wise I don't actually want one at all. Physically I don't want a cigarette, but my head awww I would like a cigarette' (KG, 76 year old male). 'I have thought about quitting completely but I don't sort of like the idea at the moment. Maybe next year I'll think about it. But at the moment I think I'll just sort of give five ago . . . I just don't seem to get the point of trying to quit at the moment' (LW, 24 year old female) 'I don't really want to quit. I have just stopped drinking and this is the only thing I have now and I don't want to stop it. Giving up drinking was hard and you always have to have, um, some sort of pleasure' (AM, 45 year old female).
	21.2 Past quitting behaviour	'I have tried to give up in the past abysmally' (MZ, 59 year old male). 'What happened to me before is that I didn't try to cut down I tried to cut out completely. That was kind of the rule of thumb at the time that you try and stop altogether' (JR, 49 year old male).

Additional Themes

Theme 17: Other Products

Smokers reported that they had used a number of other medications to help them cut down or to quit smoking, i.e. bupropion (Zyban) and varenicline (Champix). However, use was short lived due to concerns about their side-effects (sub-theme 17.1). Smokers also reported using the electronic cigarette for harm reduction purposes (sub-theme 17.2). Although many noted that they liked the fact it could be used indoors, smokers were unsure whether it was effective because it was not on general sale (see Table 4).

Theme 18: Views on Smoking and Smoking Policy

Smokers appeared hostile towards smoking bans, viewing it as their right to smoke. They were also concerned that smoking may be banned in their own home (sub-theme 18.1). Nonetheless, smokers agreed that smoking was a bad habit and expensive, despite concurrently reporting high levels of enjoyment (sub-theme 18.2). There was also a lack of interest in cessation services, which were viewed as unhelpful (sub-theme 18.3; see Table 4).

Theme 19: Over-the-Counter/Prescriptions

The current sample of smokers rarely reported attaining NRT on prescription, instead opting to purchase it over-the-counter. This appeared to be partially due to the hostility among healthcare professionals about using NRT for harm reduction purposes (see Table 4).

Theme 20: Reasons for Smoking Reduction

Smokers reported a number of reasons for cutting down: to improve health (sub-theme 20.1); pressure from loved ones and concerns about the effect of smoking on significant others (sub-theme 20.2); the social stigma of smoking and inconvenience of having to go outside (sub-theme 20.3); the expense of smoking (sub-theme 20.4); the belief that it may make them happier (20.5); personal reasons including the smell on their clothes (sub-theme 20.6); because they saw it as a step towards smoking cessation (sub-theme 20.7); and due to smoking restrictions which made it harder for them to smoke (sub-theme 20.8; see Table 4).

Theme 21: Quitting Behaviour

Smokers using NRT during attempts at smoking reduction and/or during periods of temporary abstinence reported that they didn't want to quit smoking or wanted to but didn't think they were ready to do so yet (sub-theme 21.1). Smokers also had a general tendency to report either that they had attempted to quit smoking numerous times in the past unsuccessfully or that they had never attempted to stop smoking. This was partially because smoking cessation had been emphasised as the only option and they had not considered cutting down first (sub-theme 21.2; see Table 4).

Synthesis of the Major Themes

In order to provide a framework for future studies the themes above have been grouped in Table 5 into those which may contribute to the lack of reliable reductions in cigarette consumption in national surveys and those which may contribute to the preference reported among smokers for the nicotine patch. For cigarette consumption these fall into three main categories: (1) Methodological issues, which include smokers inaccuracies in recalling their cigarette consumption and the possibility that smokers may not be interpreting smoking reduction in the way that researchers intend the term to be used; possibly due to a reliance on terminology which is unfamiliar to smokers; (2) Psychological/Behavioural issues, which involve the ways in which smokers reduce their consumption; with smokers in the current sample often setting unrealistic goals, using a wide range of methods and aids to attain these, and modifying how they smoke their cigarettes. It was also clear that smokers were under-using and incorrectly using NRT, perhaps due to perceptions about the harmfulness of NRT and unrealistic expectations of what it can achieve; (3) Environmental/social constraints may also account for smokers' difficulty in reducing their cigarette consumption. As brief periods as opposed to longer periods of temporary abstinence appeared to be more common, cigarette consumption may not be noticeably affected. Social circumstance, stress and other emotional factors also appeared to increase smoking rates. The current sample of smokers also reported a lack of support for smoking reduction from healthcare professionals.

Four themes were identified for smokers' preference for the nicotine patch: (1) Its design, with the current sample of smokers reporting that they liked transdermal products as they were discreet, easy to use, had a prolonged effect and were deemed safer than some of the other NRT products; (2) Smokers' mental representation of nicotine cravings may also be pivotal, with their choice of product appearing to be dependent on whether they viewed nicotine dependence as a result of depleted brain nicotine or as a occurring due to smoking-cues; (3) The marketing/history of NRT products, with smokers reporting that their choice of the nicotine patch was based on its long established history, past use for smoking cessation, recommendation, and because it was free of charge and had been heavily advertised. Smokers also appeared to be largely unaware as to which NRT products were licensed for harm reduction purposes and as to the full range of medicinal nicotine products that were available; (4) Disadvantages of other products also appeared to be important, with smokers reporting side effects with non-transdermal products, embarrassment about using them, and that their effect was too short.

Table 5: Summary of the Factors Which may Influence Whether Reductions in Cigarette Consumption Occur and Which may Account for Smokers' Preference for the Nicotine Patch

Issue	**Factors**	**Associated themes**
Reduction in cigarette consumption	Methodological issues	
	• Varying interpretations of 'smoking reduction'	1.2
	• Failure to ensure terminology is used which is consistent with 'smokers language'	1.1
	• Inability of smokers to correctly recall their cigarette consumption	6.1
	Psychological/Behavioural issues	
	• Failure of smokers to establish firm realistic goals	2.1-2.3, 5.3
	• The use of a diverse range of behavioural methods and aids	3.1-3.6, 4.1-4.5
	• The underuse of Nicotine Replacement Therapy	12.2
	○ Due to misperceptions	14
	• The incorrect use of Nicotine Replacement Therapy	12.3
	• Smokers' tendency to adapt or modify how they smoke their cigarettes instead of reducing their cigarette consumption	8.1-8.3
	• Unrealistic expectations about Nicotine Replacement Therapy and consequently an underestimation of the willpower required	5.1-5.2, 13.1-13.2
	Environmental/social constraints	
	• Temporarily abstaining for minimal periods of time	7.1-7.3
	• The influence of social, emotional and physical factors	6.2-6.5
	• Lack of support from healthcare professionals	15
Preference for the nicotine patch	Product design	
	• Discreetness	10.2
	• Ease of use	10.2
	• Its prolonged effect	10.2
	• Belief that it is safer to use than other products	10.2
	Smokers mental representation of nicotine cravings	
	• Depleted brain nicotine versus cravings in response to smoking-cues	3.4, 4.4, 9.1, 10.2
	Marketing/history of Nicotine Replacement Therapy	
	• Long established history	9.3
	• Past use for smoking cessation	9.4
	• Recommended to them	9.2
	• Extensive advertisement	9.3
	• Provided free of charge	9.2
	• Unaware of regulatory guidelines	16
	• Lack of awareness of the other products	9.3
	Disadvantages of non-transdermal products	
	• Side-effects	11.1, 113-11.4
	• Embarrassment associated with their use	11.1, 113-11.4
	• Too short of an effect	11.1, 113-11.4

Discussion

Reductions in Cigarette Consumption

This study, using an interview methodology, identified a variety of reasons why survey-based studies have failed to report sizeable reductions in cigarette consumption among those using NRT during attempts to cut down and for momentary abstinence. As shown in Table 5, these appear to fall into three categories: methodological issues, psychological/behavioural issues, and environmental/social constraints.

Methodological Issues

The previous failure to establish sizable reductions in cigarette consumption may stem from smokers apparent difficultly in accurately recalling how many cigarettes they smoke per day, with reports varying over the course of the interview. Previous studies have noted inaccuracies in smokers' reported cigarette consumption (Perez-Stable et al., 1990), with a tendency for smokers to base answers on broad cognitive heuristics rather than systematically counting consumption. One such heuristic is 'the digit bias', which is the tendency for estimates to cluster around rounded values (Klesges, Debon & Ray, 1995). Consequently, a previous consumption of fourteen cigarettes per day, and a new consumption of eight cigarettes per day, may both be reported as a daily cigarette consumption of ten cigarettes. One means to resolve this would be to use a more objective measure, i.e. biological outcomes or reports from family members.

It may also be the case that smokers are failing to interpret the terms 'smoking reduction' and 'temporary abstinence' in the way intended by researchers. This is nothing new, with previous studies having illustrated differences in how patients and healthcare professionals understand medical terms including 'depression', 'obesity' and 'health' (Ogden et al., 1999; Ogden et al., 2001). There are two resolutions to this issue: surveys need to use repetition, ensure clarity, and check that smokers understand what is required (Ley, 1988), and/or they need to adopt 'smokers speak' (Scott & Weiner, 1984). There is evidence that patients respond better to more familiar lay terms than medical terms. For example, patients responses for the words 'stool', 'urine', 'sexual intercourse' and 'bowel' are judged to be inadequate by researchers, compared to non-technical slang terms to describe sexual and excretory function (Ammerman, Perelli, Adler & Irwin, 1992; Thompson & Pledger, 1993; Blair et al., 1977).

Psychological/Behavioural Issues

Another explanation for the lack of reliable reductions in cigarette consumption may be that smokers are instead attempting to reduce their intake by altering the way they smoke their cigarettes. Such behavioural modifications of smoking were noted by Jarvik over 40 years ago *''There are other ways in which subjects might adjust the amount of nicotine they take in . . . by varying the depth of inhalation and the length of the cigarette they actually smoke''* (Jarvik, 1970; pp. 173). Previous studies have suggested that smokers often compensate for the additional nicotine attained from NRT though the adaptation of cigarette puff frequency (Benowitz et al., 1998; Foulds et al., 1992; Pickworth et al., 1994). Reports of reduced inhalation and attempts to put cigarettes out early have also been noted among those cutting down (Okuyemi et al., 2002; Etter et al., 2002; Johnson et al., 2004). Consequently, although the current findings may not be illustrative of the entire population, combing them with those reported previously, it appears that future survey-based studies need to cover the full range of ways in which smokers might reduce their smoke intake. Failure to consider changes in the ways that cigarettes are smoked could underestimate any effects of NRT. Survey data are needed to assess the prevalence of these different methods and how successful they are at reducing smoke exposure, by relating them to objective measures of smoke intake such as salivary cotinine. One may speculate that because these methods do not involve clear feedback on success, they may have minimal benefit.

There also appeared to be a lack of clear goals set by smokers and a failure to formulate suitable methods in order for them to be achieved; two factors which are pivotal in behaviour change (Borrelli & Mermelstein, 1994; Strecher et al., 1995; Riggs et al., 2001; Riley et al., 2002; Michie et al., 2009). If it is the case that smokers at a population level do fail to set realistic goals, smokers using NRT products for smoking reduction should receive clear instructions and help with goal-setting, and information on the means in which their goals may be achieved; a barrier to this could be healthcare professionals' reluctance to encourage smoking reduction and the use of NRT for such purposes (Warner & Martin, 2003). For example, there is now an extensive body of evidence that more structured approaches, such as increasing the inter-cigarette interval, are the most effective methods of reduction (Riggs et al., 2001; Riley et al., 2002). However, this is based on clinical trials alone, thus the effectiveness of the various strategies used by smokers to reduce their cigarette intake needs to be determined at a population level.

It was also evident that the current sample of smokers often underused NRT products, which is likely to be a limiting factor in whether reductions in cigarette consumption are found (Hatsukami et al., 2007). This may be due to NRT's cost (Hughes et al., 1991), problems with acquisition (Shiffman et al., 1997), and/or beliefs and attitudes towards its use. There is now an extensive literature detailing smokers' lack of knowledge, negative attitudes and misperceptions of NRT, and that attitudes and beliefs about medications predict treatment adherence (Horne & Weinman, 1999; Horne, Weinman & Hankins, 1999). For example, some smokers are concerned about the risk of addiction to nicotine (Bansal et al., 2004; Cummings et al., 2004; Etter & Perneger, 2001), despite empirical evidence for dependence on NRT being rare (Shiffman et al., 2003a; Shiffman et al., 2003b). Smokers also have false beliefs that nicotine is a major cause of tobacco-related health problems (Bansal et al., 2004; Cummings et al., 2004; Etter, Kozlowski & Perneger, 2003). Although nicotine is the chemical chiefly responsible for chronic tobacco use, its health dangers relative to the other compounds in tobacco smoke are small (Benowitz, 1998). Thus in order to improve compliance one may need to counteract these beliefs, in addition to decreasing the cost of NRT relative to the purchase of cigarettes. The latter of which may be more successful, since previous attempts to increase the use of NRT by targeting smokers' perceptions have proved largely ineffective (Willemsen et al., 2006; Mooney et al., 2005).

Many smokers also appeared to be overly optimistic about what NRT could achieve. This resulted in an underestimation of the willpower required on their part. Previous studies have noted that the presence of willpower is seen by only a few smokers as an essential prerequisite to quitting successfully (Kishchuk, Tremblay, Lapierre, Heneman & O'Loughlin, 2004), while a significant number of smokers hold strong expectations about the use of NRT for smoking cessation, such as its ability to completely eliminate all urges to smoke (Bansal et al., 2004; Juliano & Brandon, 2002; Vogt et al., 2008). This appears to be a recurrent theme in the health literature, with many researchers detailing patients' tendency to overestimate the efficacy of treatment they receive (Weeks et al., 1998; Gattellari, Voigt, Butow & Tattersall, 2002). No doubt this may have contributed to the failures reported with smoking reduction in the past, and reports that cutting down is a rather difficult task. Only one previous qualitative study has assessed smokers' experiences during attempts to cut down, similarly reporting that many smokers had failed to reduce their consumption and believed that without NRT reductions in cigarette consumption were unlikely (Richter et al., 2002). It therefore seems necessary to ensure that smokers are aware that willpower will be required in addition to NRT if reductions in cigarette intake are to be realised. However, this will need to occur without decreasing all expectancies regarding the efficacy of NRT, to safe guard against smokers being disinclined towards its use (Bandura, 1977). In line with this, Etter and Perneger (2001) reported that positive attitudes towards NRT were associated with its greater use.

In addition to the use of medicinal nicotine, smokers also appeared to have adopted a number of behavioural coping strategies to help them deal with urges to smoke. These included relaxation using acupuncture, listening to music, exercising and reading books; substituting their cigarettes with normal chewing gum, food or drinks; distraction; avoiding other smokers and smoking paraphernalia; and using periods of enforced temporary abstinence. These behavioural coping strategies have been reported previously amongst smokers attempting to quit smoking and those attempting to cut down, with successful quitters using a greater number of coping techniques and using them more frequently (Shiffman, 1984; Perri, Richards & Schultheis, 1977; Bliss, Garvey & Ward, 1999; Jannone & O’Connell, 2007; Johnson et al., 2004). Consequently, the extent to which smokers use these strategies and the particular coping strategies adopted, i.e. cognitive versus behavioural techniques, may explain the lack of reliable reductions in cigarette consumption. Cognitive coping strategies could include calming self-talk, thinking about the negatives of smoking, and focussing thoughts away from smoking (Folkman & Lazarus, 1980).

One of the most effective of these behavioural strategies appears to be exercise, which helps to relieve urges to smoke and withdrawal symptoms, and is associated with smoking behaviour (Ussher, Taylor & Faulkner, 2008). Because cigarette dependence is at least partially due to the sensory aspects of smoking, methods of substitution may be particularly helpful. Distracting oneself may also decrease the re-bound effect, whereby smokers deliberate attempts to suppress thoughts about smoking, i.e. cognitive avoidance, increases the frequency of their intrusion (Wegner, 1989). This has been shown to be eliminated among smokers using distraction based breathing exercises (Salkovskis & Campbell, 1994;

Salkovskis & Reynolds, 1994). Attempts to reconstruct the environment in order to remove smoking-related cues, i.e. removing ashtrays, tobacco advertising and avoiding other smokers, has also been shown to significantly improve the success rates of attempts to quit (Moore, 2005). Using periods of temporary abstinence could further induce significant reduction in cigarette consumption. However, negative effects may occur if restraint is for too long a period, with a 'what the hell effect' materialising, thus increasing cigarette consumption prior to and following the smoking restrictions (Polivy & Herman, 1985). Population-based studies need to assess the prevalence of these behavioural coping strategies and their success, as well as determine whether cognitive techniques are adopted and if not, why this is the case. This may help to inform future interventions aimed at smokers who are interested in reducing their cigarette consumption and/or temporarily abstaining with pharmacological help.

Environmental/Social Constraints

Failure to report significant declines in cigarette consumption at a population level may also be due to smokers' inability to cope with changes in their emotional state and their social environment. Increased cigarette consumption around other smokers and following stressful events has been reported previously (Scarinci, Silveira, Santos & Beech, 2007). This may also cause day to day fluctuations in cigarette consumption. If this is the case, survey-based studies should consider taking multiple measures over a number of days so that a more reliable measure of cigarette intake can be calculated. One approach that has been suggested for collecting more refined and more accurate self-reports of cigarette consumption is the Time-Line Follow-Back method, which asks subjects to retrospectively report their daily cigarette consumption day-by-day over some period of time (Lewis-Esquerre et al., 2005).

It may also be the case that smokers using NRT for momentary abstinence fail to report reliable reductions in their cigarette consumption because they tend to abstain during ‘short’ rather than ‘moderate’ periods of time, i.e. while in the pub as opposed to at home. It may be hypothesised that longer periods of temporary abstinence would cross more inter-cigarette intervals, thus resulting in reduced cigarette consumption. However, current data, albeit limited, suggests that this is unlikely, with a greater prevalence of NRT use in one’s home, whilst at work and when travelling (Etter, 2003; see Chapter 13). A final explanation is healthcare professionals’ reluctance to advise smoking reduction or the use of NRT for such purposes. Hostility among the tobacco control community regarding the topic of harm reduction has been reported previously (Martin, Warner & Lantz, 2009; Warner & Martin, 2003; Joseph et al., 2004). Moreover, nurses appear to hold misperceptions in the same way as smokers about the dangers of using medicinal nicotine (Borrelli & Novak, 2007). This clearly needs to be addressed, particularly since behavioural support may be the pivotal factor between reporting reliable reductions in randomised controlled trials and failing to do so at a population level, and because English stop smoking services are considering offering harm reduction as a treatment option in the near future (DOH, 2010).

Preference for the Nicotine Patch

This study also found a variety of reasons for why smokers may hold a preference for the nicotine patch. As shown in Table 5, these appear to fall into four categories: product design, smokers’ mental representation of nicotine cravings, the marketing/history of NRT products and the disadvantages of non-transdermal NRT.

Product Design

As hypothesised, the patch was liked as it was easy to use, was invisible, was deemed safer than the other NRT products, and provided a steady availability of nicotine in the blood stream. Previous studies have also reported the belief among smokers that the nicotine patch is safer than other NRT products (Smith, Curbow & Stillman, 2007), while others have noted the importance of product convenience (Hines, 1996). However, this is rather counterintuitive, since one may have assumed that those products which allow the user to respond to urges to smoke would be more suitable. Whereas nicotine gum users find it easy to maintain nicotine levels and can respond to feelings of 'wants' and 'needs' for a cigarette by taking pieces of gum, patch users find it harder to titrate levels of nicotine and do not receive the same sensory satisfaction (Fagerstrom & Hughes, 2002). A suitable compromise may be to use a combination of NRT products, i.e. the use of nicotine patches in addition to nicotine gum; the prior of which will provide a steady release of nicotine, while the latter will provide an instant hit when urges to smoke are felt. A number of smokers in the current study did report the concurrent use of two or more products, with the nicotine patch used as a back-up and one of the other products used to top-up nicotine levels. There is now extensive evidence that using a combination of NRT products is more efficacious in relieving urges to smoke and enabling cessation than monotherapy (Sweeney, Fant, Fagerstrom, McGovern & Henningfield, 2001; Buchanan, 2010).

Smokers' Mental Representation of Nicotine Craving

According to Leventhal's Self-Regulation Model, one's illness cognitions, or mental representations of their illnesses, are comprised of five main components: identity of the condition, its time line, how it can be controlled or cured, its consequences and causes (Leventhal et al., 1997). All of these have been shown to affect choice of medication and adherence levels (Horne & Weinman, 1999). The themes identified in the current study suggest that one of the reasons for smokers' preference for the nicotine patch could well be their mental representation of nicotine dependence, particularly their conceptualisation of its causes. Smokers appeared to be mentally representing nicotine dependence as involving the need to sustain given levels of nicotine in the body, as opposed to a representation based on smoking-cues (West, 2009). However, this assertion is in contrast to previous studies which have examined how the lay public conceptualise why people smoke, and whether this differs from other drug disorders. These studies report a belief among smokers that smoking is more habit based, as opposed to accepting the Disease Concept assigned to other drug use (Cunningham, Sobell, Freedman & Sobell, 1994; Cunningham, Sobell & Sobell, 1996; Eiser, Sutton & Wober, 1977; Weinstein, Slovic & Gibson, 2004; Fabricius, Nagoshi & MacKinnon, 1997; Kozlowski et al., 1989; Cunningham, Sobell & Chow, 1993; Hughes, 2005; Humphreys, Greenbaum, Noke & Finney, 1996). However, these findings may be due to an attributional bias, whereby people have a natural tendency to assign blame to others for their behaviour and negate the idea that bad habits are under biological control (Ross, 1977). Indeed, studies which have instead assessed smokers' views report that only a small minority believe that using aids to quit smoking is a sign of weakness and unnecessary; that if you really want to quit then you will be able to do it by yourself; and occupy the thought that their dependence is more psychological and behavioural, i.e. smoking in order to occupy one's hands (Vogt et al., 2008; Balmford & Borland, 2008). In contrast, the majority appear to believe that cravings for cigarettes will be eliminated by simply increasing nicotine levels with medicinal products (Vogt et al., 2008).

Marketing/History of Nicotine Replacement Therapy

Being provided the nicotine patch free of charge and recommendations by friends, family members, or healthcare professionals, were also noted as important factors governing the decision of which NRT product to use; a finding supported by previous research (Cunningham & Selby, 2008). The preference for the nicotine patch also appeared to stem from its past use for smoking cessation, its reputable history and extensive advertisement, and unawareness of some of the other NRT products. This coincides with the finding that those reporting the past use of NRT tend to hold more favourable attitudes towards NRT (Mooney et al., 2006), and are more likely to report intentions to use it in the future (Levy et al., 2007). The unawareness of certain forms of NRT has also been noted previously (Bansal et al., 2004; Mooney et al., 2006). In contrast, it is perhaps surprising that advertisement was a major reason for choice, with advertisement of NRT traditionally being targeted at smokers who are already primed to stop smoking and not those who are thinking about smoking reduction. It may be the case that smokers fail to take this information on board or choose to ignore it.

Failure to take note of information may also account for the lack of awareness of regulations concerning which products were licensed for use whilst smoking. Although smokers appear to read package inserts (Bansal et al., 2004), they may not do so carefully. This should be investigated, since a great deal of time and resources go into these inserts and regulators subject them to close scrutiny (MHRA, 2010). If they are not being read fully, it raises a question concerning whether key items of information should be extracted and presented in a different way. It would be worthwhile developing such materials and after appropriate piloting, undertaking a randomised trial to evaluate them. There is evidence to suggest that accurately informing smokers about the use of NRT for harm reduction can increase not only their interest in using NRT for such purposes, but also their motivation to quit (Etter et al., 2003).

Disadvantages of Non-Transdermal Products

Smokers noted a number of disadvantages with the non-transdermal NRT products. These included embarrassment about using them, side-effects, and that their effects were too short lived. Feelings of awkwardness when using certain NRT products, in particular the nicotine inhalator, have been reported previously (Hajek et al., 1999), as have side-effects. For the nasal spray these include, as would be predicted, nasal and throat irritation, coughing, runny eyes and nose, sinusitis, palpitations, and nausea; while for the inhalator, transient mouth and throat irritation (Prochazka, 2000). Consequently, it has been argued that smokers may erroneously attribute nicotine withdrawal symptoms to NRT, believing them to be medication side-effects (Barefoot & Girodo, 1972; Tate et al., 1994). Such misperceptions need to be addressed to ensure uptake, and smokers adequately informed that although side-effects for the nasal spray may be severe to start with, adaption does occur over time.

Other Themes

It is on interest that a number of smokers reported having used bupropion and varenicline during attempts to cut down and during attempts to quit smoking. Bupropion, an antidepressant, has been shown to have similar efficacy to NRT, but in contrast has the disadvantage of a number of unpleasant side-effects (Hughes, Stead & Lancaster, 2004; Jorenby et al., 1999). This is true also of varenicline (Hughes, 2008). Smokers appear to be aware of these side-effects and may thus be deterred from using them (Bansal et al., 2004). This was a theme which emerged in the current analysis. Nonetheless, proposals have been made for these two alternative drug forms to be licensed as aids to harm reduction. Currently there is no evidence regarding varenicline's utility, however, studies have demonstrated some efficacy for bupropion (Evins et al., 2007; Tsoi, Porwal & Webster, 2010). Moreover, it appears that a higher proportion of those cutting down prior to a quit attempt use varenlicine and bupropion than those who stop smoking abruptly (Kotz et al., 2009).

Smokers' hostility towards the smoking ban is perhaps not surprising. Although many smokers support the current ban on smoking in public places and an outright ban, those smokers with a higher cigarette consumption, who enjoy smoking and who are content with being a smoker, tend to be opposed (Fong et al., 2006; Shahab & West, 2010). Nonetheless, the current sample acknowledged that smoking was a ‘dirty’ habit and that perhaps they should not be doing it. This is far from the fashionable image smoking had a few decades ago; a result of strong advertising campaigns by the tobacco industry (Watson, Clarkson, Donovan & Giles-Corti, 2003). Adolescents in the early part of this century even noted that smoking would become less fashionable (Zhang, Wang, Zhao & Vartiainen, 2000). Tobacco control efforts aimed at exposing tobacco industry manipulation, restrictions on tobacco use and sales, and an increased emphasis on the health effects of smoking, are likely to have been instrumental in this change (Ling & Glantz, 2002; Thomson, Siegel, Winickoff, Biener & Rigotti, 2005). Nonetheless, many continue to smoke, with the tobacco industry making cigarettes effectively more addictive, particularly though enhancing the physiological effects of nicotine via the introduction and use of compounds that interact with nicotine but do not directly alter its form or delivery (Wayne & Carpenter, 2009).

The current sample of smokers also reported purchasing their NRT over-the-counter as opposed to collecting a prescription. Previous population-based studies have reported a higher prevalence of over-the-counter purchases of NRT amongst those attempting harm reduction relative to those attempting to quit (Hammond et al., 2008). Smokers were also rather hostile about stop smoking services, perhaps not surprising since these have traditionally focussed on abrupt cessation treatments. However, this may change if the proposals of the DOH to extend stop smoking services to provide advice on smoking reduction is implemented (DOH, 2010). If this does occur, campaigns to encourage those smokers who may be less willing or unable to quit smoking into the services could be necessary.

A number of reasons were noted for attempting smoking reduction with the aid of NRT, including concerns about the effect of smoking on one’s health; the influence of significant others; social factors including embarrassment; financial cost; improved happiness;

personal factors such as smell and effects on their working life; viewing reduction as a step towards smoking cessation; and as a consequence of smoking restrictions. Previous studies have reported that many smokers believe that cutting down one's cigarette consumption will result in improvements to health (Joseph et al., 2008). There also appears to be interest in cutting down prior to quitting (Hughes et al., 2007), while the cost of cigarettes have been associated with abstinence (DeCicca, Kenkel & Mathios, 2008). It is of interest to understand the reasons why smokers attempt to reduce their cigarette consumption with the aid of NRT for a number of reasons: in order to identify ways in which the uptake of harm reduction activities may be increased, particularly among smokers who are unlikely to stop smoking using traditional methods; and to provide some indication as to the misperceptions smokers may hold regarding what smoking reduction can achieve. For example, if it is the case that smokers are cutting down as a means to improve their health, they will need to be made aware that this may only occur if significant declines in intake result (Hughes & Carpenter, 2006).

Limitations

An interview-based study can only describe smokers' reports of their behaviour, but can none the less provide potentially useful insights that can be followed-up using objective measures. Similarly, the study cannot give estimates of the prevalence of the phenomena observed; this would require population-based surveys. Biases and errors may also occur in the interpretation of interview data; however, quality assurance methods were included to check on the accuracy of the interpretations. The study took place in England which has one of the most liberal licensing arrangements for NRT in the world; thus different findings may be obtained in different jurisdictions. Moreover, although our sample was of an adequate size (Marshall, 1996), and saturation was reached – with few new themes emerging from the latter participants – it is possible that different findings may emerge from an alternative subset of smokers. Consequently, survey-based studies should not exclusively focus on those factors identified here, but use them as a spring board for future research.

Conclusion

Smokers appear to be using a variety of means to reduce their cigarette exposure without stopping completely, including ones that do not involve reducing cigarette consumption, i.e. putting their cigarettes out early. This may partially explain why previous studies have failed to report reliable reductions in cigarette consumption amongst those using NRT for harm reduction purposes at a population level. Others reasons include smokers' failure to set realistic goals, inaccuracies in reported cigarette consumption, and the underuse of NRT. The previously reported preference amongst smokers for the nicotine patch may steam from its discreteness, ease of use, prolonged effect, and its long established history. Smokers also appeared to be largely unaware as to which products were and were not licensed for harm reduction purposes.

Chapter 15: Beliefs of Stop Smoking Practitioners and Managers in England on the use of Nicotine Replacement Therapy for Smoking Reduction: A National Survey

‘‘Chekhov once observed that a good writer helps us to feel not just life as it is, but life as it should be. The movement for evidence-based medicine offers something similar – enlightenment coupled with views of a promised land. While the conflict between these two states – as it is, and as it should be – is the vehicle for many successful works of art, its force in scientific revolutions is often more divisive. Thus, while evidence-based medicine has a large groundswell of support within the profession, it also has many detractors who prefer the status quo’’ (Donaldson, 1997; pp. 1)

Introduction

There is a concern that the recent proposal to include smoking reduction as a treatment option in stop smoking services may not be adequately or correctly implemented by healthcare professionals. The argument being, that the historical emphasis on abrupt cessation only approaches over many years, could have led to negative opinions towards tobacco harm reduction strategies. This chapter takes a first step in assessing this, by determining the beliefs about the safety of using NRT during attempts to cut down, and the job and personal characteristics associated with these beliefs, among those working at the heart of stop smoking services, i.e. stop smoking practitioners and stop smoking managers.

Knowledge translation is a relatively new term which the World Health Organisation (2005; pp. 2) defines as: ‘‘*The synthesis, exchange, and application of knowledge by relevant stakeholders to accelerate the benefits of global and local innovation in strengthening health systems and improving people’s health.’’* The term is now being adopted in health-care fields to represent a process of moving what we learned through research, to the actual application of such knowledge in a variety of practice settings and circumstances. This appears to coincide with the growing engagement in the evidence-based practice (EBP) approach, in which practitioners make practice decisions based on the integration of the research evidence with clinical expertise (Straus, Richardson, Glasziou & Haynes, 2005). The Institute of Medicine's report *'Bridging the Gap Between Practice and Research'* (Lamb, Greenlick & McCarty, 1998), calls for such an approach.

Despite a strong endorsement for EBP in health-care fields, the use of research in practice continues to be lacking (Bennett et al., 2003; Meline & Paradiso, 2003; Metcalfe, Lewin, Wisher, Perry, Bannigan & Moffett, 2001; Turner & Whitfield, 1997). Studies in the US and the Netherlands suggest that about 30% to 40% of patients do not receive care according to current scientific evidence (Schuster, McGlynn & Brook, 1998). In the UK just over a decade ago the analyses of many hundreds of controlled trials by the Cochrane Centre on Effective and Organisational Practice, showed that the impact of introducing guidelines on actual practice is limited in most cases, with only small to moderate improvements in care provisions (NHS Centre for Reviews & Dissemination, 1999). This implies that patients may not receive necessary care, or receive care that is not needed or that is even potentially damaging.

The failure to implement evidence-based guidelines appears to be a particular problem for smoking cessation. Smoking cessation guidelines and the NICE Public Health Intervention Guidance (West et al., 2000a; National Institute for Clinical Excellence, 2006), recommend that general practitioners advise all smokers to stop smoking and provide medications and/or refer smokers who are motivated to stop to NHS stop smoking services. NHS stop smoking services were established in the UK in 1999 following the publication of the Government White Paper *'Smoking Kills'* (DOH, 1998; West et al., 2000a), and have been instrumental in reducing smoking rates in the UK (Bauld, Bell, McCullough, Richardson & Greaves, 2010). However, it is estimated that smoking cessation advice is given in only 20-30% of UK primary care consultations with smokers (Coleman & Wilson, 2000), while studies have estimated that less than 10% of GPs refer smokers to stop smoking smokers' clinics (McEwen & West, 2001; Coleman, Wynn, Barrett & Wilson, 2003). There are also wide variations in the reported success amongst NHS stop smoking services (NHS, 2008). This variation will in part be due to smoker characteristics (Bauld, Chesterman, Judge, Pound & Coleman, 2003), but may also result from variations in the delivery of the services, including the availability of operational manuals, and where these exist, whether scientifically based behaviour change techniques are incorporated (West et al., 2010).

There is a concern that the recent proposal to include harm reduction approaches in NHS stop smoking services may similarly be implemented in an ad hoc way. The idea behind this proposal was that not all smokers want or feel able to stop smoking straight away, and therefore a large proportion of smokers are unlikely to engage with the current stop smoking services. Consequently, recommendations have been made to extend these services to provide medicinal nicotine for smoking reduction as a route to quit (DOH, 2010). This new Routes to Quit Model would aim to provide a system to engage more smokers into evidence-based stop smoking support by using a 'hierarchy of evidence': offering abrupt cessation as the first line of treatment, followed by rapid reduction, medication, gradual reduction and self-care. Although a number of pilots are already underway to assess the feasibility of extending the services to include such advice on smoking reduction (Croghan & Chambers, 2011), its large scale acceptance is currently unclear.

It is important to determine the likelihood of this new model being accepted prior to its implementation, as if hostility is high, extensive modifications to the current training of stop smoking practitioners and managers may be needed. Although a number of factors will be important in the application of a harm reduction approach (Michie et al., 2005), healthcare professionals' beliefs have been argued to be pivotal (Bonetti et al., 2003; Graham, 2006);

with individuals' attitudes, beliefs and values being repeatedly incorporated into social cognition models as a way of explaining health and non-health behaviours (Fishbein & Ajzen, 1975; Ajzen, 1985).

Studies to date suggest that members of the tobacco control community hold varying and contradictory views on harm reduction. Many believe that the introduction of a tobacco harm reduction programme alongside traditional tobacco control policies could reduce the rates of smoking cessation, encourage relapse in former smokers, initiation by non-smokers, or have unintended negative side-effects on the health of users (Martin et al., 2009; Warner & Martin, 2003; Joseph et al., 2004). These concerns are more prevalent regarding smokers who may continue to use NRT for extended periods of time (Stratton et al., 2001). Moreover, opposition to health practitioners recommending the use of NRT for harm reduction has been reported to range from 18% to 48%, depending on the product, with more support for nicotine patches relative to nicotine gum and lozenges (Warner & Martin, 2003). A study in the US also found that a majority of the nurses studied believed that nicotine causes cancer and/or increases the likelihood of a heart attack, and one-quarter believed that nicotine gum was as likely or more likely to cause addiction as cigarettes (Borreli & Novak, 2007). Furthermore, many healthcare professionals believe that assisting smokers by directing them to use NRT is inappropriate, unfeasible, and not cost effective (McEwen & West, 2001; McEwen, Akotia & West, 2001; Vogt, Hall & Marteau, 2006).

This is despite evidence to the contrary; nicotine is not a significant risk factor in cardiovascular events, does not cause cancer, and does not cause respiratory diseases (Benowitz, 1998; Smith et al., 1997). A fatal dose of nicotine would require roughly 60mg for an average person, which is far more than the levels obtained by consumers. The abuse potential of NRT products, defined as the ability to facilitate dependence in non-users, has also been shown to be very low. Novice users generally perceive nicotine as moderately unpleasant (Foulds et al., 1997). Moreover, although the use of NRT for harm reduction purposes does not appear to be associated with a reduction in harm, evidence neither points towards an increased risk to smokers, with the use of NRT in this way appearing to increase the propensity of smokers to quit (see Chapters 5-11).

It is unclear whether similar beliefs are prevalent amongst those most directly involved with the smoking population, i.e. stop smoking practitioners and managers, who would be involved in the implementation of a harm reduction approach in stop smoking services. On the basis of previous studies, it is possible that inaccurate beliefs will be more prevalent, since lower levels of awareness and greater hostility towards harm reduction approaches are found amongst those focussing on local rather than national tobacco control issues. For example, twice as many of those working at a state level report concerns about the use of NRT for smoking reduction compared to those working in international departments (Warner & Martin, 2003; Joseph et al., 2004). Although there is evidence that other healthcare professionals working at the frontline of treatment, such as dentists, are more inclined to recommend that smokers cut down as oppose to quit; this possibly reflects their lack of training in the 1980s on smoking cessation (Secker-Walker, Hill, Solomon & Flynn, 1987). Variations in opinions have also been established amongst those working in alternative addictions. For example, Rosenberg, Devine and Rothrock (1996) found that 62% of outpatient treatment facilities favoured moderate drinking as a treatment outcome compared to 43% of mixed inpatient/outpatient agencies, 28% of correctional facilities, and 18% of halfway houses; while Ogborne, Wild, Braum and Newton-Taylor (1998) reported that support for methadone maintenance was higher among outpatient agencies than residential agencies.

In order to aid future policies and their implementation it may also be helpful to determine the factors associated with these beliefs. Personal characteristics including the length of time they have been working in stop smoking services, relationships with others, and feelings of involvement in the team, could be important factors (Babin & Boles, 1996); as may characteristics of the job, how much training is provided, and receipt of post-qualification updates. For example, McEwen and West (2001) reported that nurses highly trained in smoking cessation practices engaged in more activity relating to smoking cessation, had more positive attitudes towards their role, and were more knowledgeable; a finding reported by others (Hepburn, Johnson, Ward & Longfield, 2000; Prochazka, Koziol-McLain, Tomlinson & Lowenstein, 1995). Those who are more involved in tobacco control research are also less likely to report concerns about the use of NRT during attempts at smoking reduction than those working in other areas (Warner & Martin, 2003).

Another question which arises is whether such beliefs are correlated with practice outcomes, including the length of time NRT is recommended for and whether smokers are advised to reduce gradually. Borrelli et al. (2001) reported that nurses' beliefs regarding the importance of counselling and self-efficacy in their ability to deliver relevant interventions were related to the extent of advice they gave about methods of smoking cessation, and whether they recommended the use of NRT for such purposes. Although it is unclear whether this applies to the use of NRT for smoking reduction, indirect evidence has shown that those more aware of the topic of harm reduction are less likely to be against healthcare practitioners recommending the use of NRT as a means to cut down (Warner & Martin, 2003).

Methods

Study Design and Sampling

An email was sent to all 164 stop smoking service managers in England on behalf of the NHS Centre for Smoking Cessation and Training, with a link to the survey website and a request to take part. They were also asked to forward the link to all their staff. Reminders were sent ten and twenty days later, and three days preceding the surveys close. The online survey was open between the 26th of November and the 24th of December 2010. This paper reports on a sub-set of questions which assessed stop smoking managers' and stop smoking practitioners' beliefs about the use of NRT during attempts at smoking reduction.

Ethical Approval

The surveys were classified as 'Service Evaluations' of stop smoking services by the NHS Research Ethics Committee and so were exempt from ethical review.

Measures

The survey collected data on socio-demographic (i.e. gender & age) and professional characteristics. Stop smoking managers were asked: 'Do you have regular arranged meetings with your commissioner?' – (yes; no) and 'Do you think that you have a good relationship with your commissioner?' – (yes; no). They were also asked to: 'Indicate how much you agree with the following statements: a.) I feel I am able to influence the commissioning process; and b.) I feel fully involved in the strategic planning of my service' – (strongly agree; disagree; unsure; agree; strongly agree). They were also asked how long they had been working as a stop smoking manager for, the percentage of their time spent managing the stop smoking services, and the length of time NRT was recommended for in their service (less than 12 months or more than 13 months).

Stop smoking practitioners were asked: 'What is your approach to gradual versus abrupt cessation?' – (I always use the abrupt cessation model, i.e. smokers smoke as they wish until the quit date and stop abruptly at that point; I encourage abrupt cessation but allow smokers to cut down gradually if they do not feel they can manage to stop abruptly; I encourage smokers to cut down gradually before stopping). They were also asked: ‘How many days ‘off the job’ training did you receive when you started working for the NHS Stop smoking service?’ and ‘How often do you attend ‘off the job’ update training?’ – (once a year; twice a year; once every two years). Finally, they were asked to report how long they had been working in NHS stop smoking services for, and whether their main role was the provision of intensive support for highly dependent smokers.

Both managers and practitioners were then asked: ‘Do you think that nicotine replacement products such as patches and gum are harmful to the health if used for a year or more?’ – (no; yes; I don’t know). If they answered yes they were asked: ‘What do you think the harms are?’ – (lung cancer; oral/mouth cancer; other type of cancer; heart attack; high blood pressure; other type of heart disease; emphysema, chronic lung disease, chronic obstructive pulmonary disease; addiction; nicotine overdose; other please write). A further question which asked was: ‘Do you think that nicotine replacement products such as patches and gum are harmful to the health if used while smoking?’ – (no; yes; I don’t know). If they answered yes they were asked: ‘What do you think the harms are?’ – (lung cancer; oral/mouth cancer; other type of cancer; heart attack; high blood pressure; other type of heart disease; emphysema, chronic lung disease, chronic obstructive pulmonary disease; addiction; nicotine overdose; other please write). Finally, they were asked ‘Do you think that using nicotine replacement products such as patch or gum to help with cutting down is likely to promote or hinder quitting?’ – (promote; hinder; no effect; I don’t know). See Appendices I and J for the full list of questions used in the practitioners’ and managers’ surveys.

Analysis

Parametric Assumptions

The assumption of 'normality' required for *t*-test and ANOVA analyses was assessed using the Kolmogorov-Smirnov (K-S) statistic, while 'homogeneity of variance' using Levene's statistic (Levene, 1960). Due to the small number of managers reporting that the long-term use of NRT was harmful to health, and that the use of NRT for smoking reduction may have no effect on abstinence, K-S statistics could not be calculated for managers' age, the number of months they had worked for, or the percentage of their current role which involved the management of stop smoking services. Consequently, non-parametric tests were used. Age was found to be normally distributed among managers reporting that the concurrent use of NRT and cigarettes was harmful and not harmful to health, while the number of months worked for was normally distributed among those reporting that the use of NRT for smoking reduction was harmful.

In contrast, the number of months worked for was substantially non-normal among those reporting that the concurrent use of NRT and cigarettes was not harmful ($D(23)=0.182$, $p<0.05$). The percentage of managers current role spent managing stop smoking services was also established to be non-normal among those reporting that the use of NRT for smoking reduction was not harmful ($D(23)=0.265$), $p<0.001$) and harmful ($D(5)=0.358$, $p<0.05$) to health. Because the large sample size means that the K-S test may be significant even when the distribution only differs slightly from normal, histograms and P-P plots were calculated. These confirmed the non-normality present in the data. Attempts to correct issues with normality were undertaken using square root transformations and log transformations (reverse score transformations were performed first due to the negative skew in the data). These were successful for differences in the number of months worked for among those reporting that the concurrent use of NRT and cigarettes was not harmful to health ($D(23)=0.171$, $p>0.05$ versus

D(23)=0.154, $p>0.05$). Variances amongst those reporting that the concurrent use of NRT and cigarettes was and was not harmful to health were equal in terms of age ($F=0.556$, $p>0.05$) and months worked for ($F=0.008$, $p>0.05$). Consequently, *t*-tests were used for the assessment of differences in age and months worked for among managers reporting varying beliefs about the use of NRT for smoking reduction. For all other analyses non-parametric tests were sought.

There was also substantial violation of normality for the assessment of differences in age, months worked for, and extent of update training, as a function of beliefs about using NRT for harm reduction purposes among stop smoking practitioners. P-P plots confirmed the non-normality present in the data. Although this was corrected for in number of cases using square root and log transformations, issues with normality still be prevailed; with at least one category in each assessment presenting data on age, months worked for and frequency of update training, that was significantly non-normal. There was one exception: log transformation successfully corrected normality issues for data on the number of months worked for among those reporting that the long-term use of NRT was harmful to health (D(69)=0.065, $p>0.05$); square root transformation successfully corrected normality issues for those who reported it was not harmful to health (D(288)=0.050, $p>0.05$); while square root and log transformations were successful for those who reported they didn't know (D(38)=0.128, $p>0.05$ versus D(38)=0.131, $p>0.05$). However, heterogeneity was established among these groups and only eliminated by square root transformation procedures. Consequently, non-parametric tests were used for all analyses on the differences in beliefs among stop smoking practitioners as a function of their characteristics (see Appendix G).

Statistical Analysis

Good practice guidelines for the reporting of survey studies were followed throughout (Kelley, Clark, Brown & Sitzia, 2003). Differences in beliefs about the harmful effects of using NRT during attempts to cut down among managers and practitioners were assessed using Chi-squared analyses. Differences in beliefs about the effects of using NRT for harm reduction as a function of managers and practitioners' personal and job characteristics, were also assessed using Chi-squared analyses, in addition to Mann-Whitney tests, *t*-tests and Kruskal-Wallis tests. Post-hoc analysis for the latter was carried out using multiple Mann-Whitney tests with the Bonferroni correction applied (effects are reported at a 0.017 level of significance). Corresponding effect sizes were also calculated (r=Z score/$\sqrt{\text{total}}$ sample size). To assess significance following the Chi-squared analyses, standardised residuals were compared to the critical values that correspond to an alpha of 0.05 (+/-1.96), an alpha of 0.01 (+/-2.58) or an alpha of 0.001 (+/-3.10). Odds Ratios were then calculated where significance was evident. For all analyses SPPS version 18.0 was used.

Power

Post-hoc power analysis using G*Power (Erdfelder, Faul & Buchner, 1996), revealed that for the assessment of differences in beliefs among managers as a function of age, an effect size of 0.5 could be detected with 50% power using an alpha of 0.001, 78% power using an alpha of 0.01, while 92% power using an alpha of 0.05. For the assessment of differences in beliefs among practitioners as a function of age, an effect size of 0.5 could be detected with 100% power using an alpha of 0.001, 100% power using an alpha of 0.01, while 100% power using an alpha of 0.05.

Results

One hundred and sixty-four stop smoking managers were contacted. Eighty-five (51.8%) completed the online survey; of whom, twenty-seven were excluded because questionnaires were incomplete or there were duplicate entries. For the duplicated entries, the most complete set of answers was retained. This resulted in a final sample of fifty-eight managers. In total 686 responses were recorded for the stop smoking practitioners survey. A response rate could not be calculated because currently it is not known how many stop smoking practitioners work in the NHS. Of these, 202 were excluded either because the respondents reported that they did not see smokers on behalf of an NHS stop smoking service, the files did not contain any data, or there were duplicate entries. This resulted in a final sample of 484 stop smoking practitioners. Table 1 provides details of the stop smoking managers' characteristics, while Table 2 details of the characteristics of stop smoking practitioners.

Table 1: Characteristics Stop Smoking Managers Completing the Survey

SSM (*n*=58)	
Age M(*SD*)	44.5 (9.22)
Gender %(*n*)	
Female	60.3 (35)
Male	39.7 (23)
Percentage of SSM current role which involves running a SSS M(*SD*)	83.4 (22.67)
Length of time having worked as a SSM (months) M(*SD*)	44.5 (3.79)
Regular meetings with their commissioner %(*n*)	75.9 (44)
Good relationship with their commissioner %(*n*)	75.9 (44)
Feels that they are able to influence the commissioning process %(*n*)	
Disagree	20.7 (12)
Agree	56.9 (33)
Unsure	6.9 (4)
Not stated	15.5 (9)
Feels involved in the strategic planning of their service %(*n*)	
Disagree	15.5 (9)
Agree	56.9 (33)
Unsure	12.1 (7)
Not stated	15.5 (9)
Recommended length of NRT use in their SSS %(*n*)	
<12 months	69.0 (40)
>13 months	31.0 (18)

Note: *n*=number; M=mean; *SD*=Standard Deviation; SSS=stop smoking service; SSM=stop smoking managers; NRT=Nicotine Replacement Therapy

Sixty-nine per cent (*n*=375) of the sample reported that they did not think the continued use of NRT for a year or more was harmful to health (68.9% (*n*=40) of stop smoking managers and 69.2% (*n*=335) of stop smoking practitioners). Sixteen per cent (*n*=85) reported that they believed that it was harmful to health (12.0% (*n*=7) of stop smoking managers and 16.1% (*n*=78) of stop smoking practitioners), while 7.9% (*n*=43) that they didn't know (0% (*n*=0) of stop smoking managers and 8.9% (*n*=43) of stop smoking practitioners). No significant difference in responses was found between stop smoking managers and stop smoking practitioners (χ^2=5.33 (*df* 2), *p*=0.070); nor did beliefs differ as a function of the managers' characteristics, the characteristics of their job, relationship with their commissioner or the length of time NRT was recommended for in their stop smoking services (see Table 3).

Table 2: Characteristics of Stop Smoking Practitioners Completing the Survey

SSP (*n*=484)	
Age M(*SD*)	44.0 (10.80)
Gender %(*n*)	
Female	78.3 (379)
Male	21.7 (105)
Percentage of SSP main role which involves support for highly dependent smokers %(*n*)	59.7 (289)
Length of time having worked as a SSP M(*SD*)	59.9 (49.94)
Approach to cessation %(*n*)	
Encourage abrupt	39.3 (190)
Encourage abrupt but allow gradual	49.2 (238)
Encourage gradual	3.9 (19)
Not stated	7.6 (37)
Number of days training received M(*SD*)	4.1 (10.28)
Frequency of with update to training %(*n*)	
Once a year	32.2 (156)
Twice a year	18.6 (90)
Less than once every two years	27.9 (135)
Not stated	21.3 (103)

Note: *n*=number; M=mean; *SD*=Standard Deviation; SSP=stop smoking practitioners; NRT=Nicotine Replacement Therapy

In contrast, Table 4 shows that beliefs differed as a function of the length of time stop smoking practitioners had been working for. Those who reported that they did not believe the long-term use of NRT was harmful to health had worked for a longer period of time than those who reported that they believed it was harmful to health (*U*=8885.500; *r*=-0.15), and those who reported that they didn't know (*U*=4020.500; *r*=-0.21). Beliefs also differed as a function of the number of training days that they had received; those who reported that the long-term use of NRT was safe had undertaken fewer trainings days than those reporting that it was harmful to health (*U*=9246.000; *r*=-0.15).

Table 3: Differences in Beliefs about the Harmful Effects of the Long-term use of Nicotine Replacement Therapy as a Function of the Personal and Job Characteristics of Stop Smoking Managers

Personal/job characteristic	**Not harmful (*n*=40)**	**Harmful (*n*=7)**	
Percentage of SSM current role which involves running a SSS M(*SD*)	82.2 (23.66)	88.3 (22.18)	*U*=111.000, *p*=0.640
Length of time having worked as a SSM (months) M(*SD*)	48.3 (38.23)	27.1 (32.00)	*U*=83.5000, *p*=0.193
Age M(*SD*)	45.2 (9.44)	43.3 (8.78)	*U*=84.5000, *p*=0.517
Gender %(*n*)			
Male	77.7 (9)	22.2 (9)	χ^2=0.65 (*df* 1), *p*=0.421
Female	88.2 (30)	11.8 (4)	
Regular meetings with their commissioner %(*n*)			
Yes	89.5 (34)	10.5 (4)	χ^2=2.99 (*df* 1), *p*=0.084
No	66.7 (6)	33.3 (3)	
Good relationship with their commissioner %(*n*)			
Yes	86.8 (7)	12.2 (2)	χ^2=0.47 (*df* 1), *p*=0.492
No	77.8 (33)	22.2 (5)	
Feels that they are able to influence the commissioning process %(*n*)			
Disagree	81.8 (9)	18.2 (2)	χ^2=4.75 (*df* 3), *p*=0.093
Agree	90.6 (29)	9.4 (3)	
Unsure	50.0 (2)	50.0 (2)	
Feels involved in the strategic planning of their service %(*n*)			
Disagree	77.8 (7)	22.2 (2)	χ^2=2.76 (*df* 3), *p*=0.252
Agree	90.6 (29)	9.4 (3)	
Unsure	66.7 (4)	33.3 (2)	
Recommended length of NRT use in their SSS % (*n*)			
<12 months	75.0 (30)	25.0 (7)	χ^2=2.22 (*df* 1), *p*=0.136
>13 months	100 (10)	0 (0)	

Note: *n*=number; M=mean; *SD*=Standard Deviation; SSS=stop smoking service; SSM=stop smoking managers; NRT=Nicotine Replacement Therapy
Significant difference among groups (* p<0.05, ** p<0.01, *** p<0.001)
Percentages given are within 'Personal/job characteristic'

Overall 57.0% (n=309) of the sample reported that they did not think the concurrent use of NRT and cigarettes was harmful to health (63.8% (n=37) of stop smoking managers and 56.2% (n=272) of stop smoking practitioners). Thirty per cent (n=160) reported that they believed that it was harmful to health (15.5% (n=9) of stop smoking managers and 31.1% (n=151) of stop smoking practitioners), while 4.1% (n=22) that they didn't know (0% (n=0) of stop smoking managers and 4.5% (n=22) of stop smoking practitioners). Stop smoking managers were less likely to report that the concurrent use of NRT and cigarettes was harmful to health than stop smoking practitioners (χ^2=7.39 (df 2), p=0.025).

4: Differences in Beliefs about the Harmful Effects of the Long-term use of Nicotine Replacement Therapy as a Function of the Personal and Job Characteristics of Stop Smoking Practitioners

Personal/job characteristic	**Not harmful (*n*=335)**	**Harmful (*n*=78)**	**Don't know (*n*=43)**	
Age M(*SD*)	44.0 (10.65)	43.5 (9.97)	45.0 (11.76)	χ^2=0.511, (df 2), p=0.775
Gender %(*n*)				
Male	74.3 (52)	12.9 (9)	12.9 (9)	χ^2=1.90, (df, 2), p=0.386
Female	73.0 (262)	18.1 (65)	8.9 (32)	
Length of time having worked as a SSP (months) M(*SD*)	64.1 (48.99)	48.4 (44.2)	36.6 (32.96)	χ^2=20.613 (df 2) p=0.001***
Percentage of SSP main role which involves support for highly dependent smokers %(*n*)				
Yes	76.4 (214)	15.0 (42)	8.6 (24)	χ^2=3.7 (df 2), p=0.154
No	67.7 (90)	21.8 (29)	10.5 (14)	
Approach to cessation %(*n*)				
Abrupt	77.3 (140)	12.7 (23)	9.9 (18)	χ^2=7.67 (df 4), p=0.104
Abrupt but allow gradual	72.5 (166)	19.7 (45)	7.9 (18)	
Gradual	52.9 (9)	29.4 (5)	17.6 (3)	
Number of days training received M(*SD*)	4.1 (5.01)	5.4 (22.8)	2.7 (1.67)	χ^2=11.797 (df 2), p=0.003**
Frequency of update training %(*n*)				
Once a year	77.0 (144)	18.2 (27)	4.7 (7)	χ^2=1.578 (df 2), p=0.454
Twice a year	72.4 (63)	19.5 (17)	8.0 (7)	
< once every two years	74.6 (97)	16.9 (22)	8.5 (11)	

Note: *n*=number; M=mean; *SD*=Standard Deviation; SSP=stop smoking practitioners; NRT=Nicotine Replacement Therapy

Significant difference between groups (* p<0.05, ** p<0.01, *** p<0.001)

Percentages given are within 'Personal/job characteristic'

Table 5: Differences in Beliefs About the use of Nicotine Replacement Therapy for Smoking Reduction as a Function of the Personal and job Characteristics of Stop Smoking Managers

Personal/job characteristic	**Not harmful (*n*=37)**	**Harmful (*n*=9)**	
Percentage of SSM current role which involves running a SSS M(*SD*)	82.7 (23.7)	85.6 (20.9)	*U*=126.0000, *p*=0.679
Length of time having worked as a SSM (months) M(*SD*)	47.4 (37.76)	34.8 (38.15)	*t*=0.915 (*df* 40), *p*=0.366
Age M(*SD*)	45.4 (9.58)	42.43 (7.70)	*t*=0.774 (*df* 38), *p*=0.444
Gender %(*n*)			
Male	77.8 (7)	22.2 (2)	χ^2=0.30 (*df* 1), *p*=0.587
Female	85.3 (29)	14.7 (5)	
Regular meetings with their commissioner %(*n*)			
Yes	81.6 (31)	18.4 (7)	χ^2=0.18 (*df* 1), *p*=0.670
No	75.0 (6)	25.0 (2)	
Good relationship with their commissioner %(*n*)			
Yes	78.9 (30)	21.1 (8)	χ^2=0.31 (*df* 1), *p*=0.579
No	87.5 (7)	12.5 (1)	
Feels that they are able to influence the commissioning process %(*n*)			
Disagree	90.9 (10)	9.1 (1)	χ^2=1.02 (*df* 1), *p*=0.600
Agree	77.4 (24)	22.6 (7)	
Unsure	75.0 (3)	25.0 (1)	
Feels involved in the strategic planning of their service %(*n*)			
Disagree	100 (9)	0 (0)	χ^2=5.72 (*df* 1), *p*=0.057
Agree	80.6 (25)	19.4 (6)	
Unsure	50.0 (3)	50.0 (3)	
Recommended length of NRT use in their SSS % (*n*)			
<12 months	77.8 (28)	22.2 (8)	χ^2=0.74 (*df* 1), *p*=0.390
>13 months	90.0 (9)	10.0 (1)	

Note: *n*=number; M=mean; *SD*=Standard Deviation; SSS=stop smoking service; SSM=stop smoking managers; NRT=Nicotine Replacement Therapy
Significant difference between groups (* *p*<0.05, ** *p*<0.01, *** *p*<0.001)
Percentages given are within 'Personal/job characteristic'

Although beliefs about the harmful effects of concurrently using NRT and cigarettes were not related to the job and personal characteristics of the stop smoking managers (see Table 5), beliefs were related to the number of months stop smoking practitioners had been working in their role for, and the frequency of update training they received. Stop smoking practitioners who reported that the use of NRT for smoking reduction was not harmful to health had worked for a longer time than those who reported that they didn't know whether it was harmful to health (*U*=15597.500; *r*=-0.11). Those who reported that they didn't know whether the use of NRT for smoking reduction was harmful to health reported less frequent update training than those who reported it was not harmful (*U*=901.500; *r*=-0.16) or was harmful (*U*=508.500; *r*=-0.20). Female respondents were also less likely to report that they didn't know whether or not the concurrent use of NRT and cigarettes was harmful to health than male respondents [Odds Ratio 0.38; Confidence Interval 0.15-0.99, $p<0.05$; (see Table 6)]

Table 6: Differences in Beliefs About the use of Nicotine Replacement Therapy for Smoking Reduction as a Function of the Personal and job Characteristics of Stop Smoking Practitioners

Personal/job characteristic	**Not harmful (*n*=272)**	**Harmful (*n*=151)**	**Don't know (*n*=22)**	
Age M(*SD*)	44.3 (10.80)	43.1 (10.26)	43.6 (12.67)	χ^2=1.504 (*df* 2), *p*=0.421
Gender %(*n*)				
Male	50.7 (36)	39.4 (28)	9.9 (7)	χ^2=6.30 (*df* 2), *p*=0.043*
Female	63.2 (220)	32.8 (114)	4.0 (14)	
Length of time having worked as a SSP (months) M(*SD*)	62.0 (49.97)	52.6 (43.45)	42.9 (36.22)	χ^2=6.368 (*df* 2), *p*=0.041*
Percentage of SSP main role which involves support for highly dependent smokers %(*n*)				χ^2=4.24 (*df* 2), *p*=0.120
Yes	64.3 (175)	32.4 (88)	3.3 (9)	
No	55.7 (73)	37.4 (49)	6.9 (9)	
Approach to cessation %(*n*)				
Abrupt	60.1 (104)	36.4 (63)	3.5 (6)	χ^2=2.88(*df* 4), *p*=0.578
Abrupt but allow gradual	63.7 (144)	31.4 (71)	4.9 (11)	
Gradual	55.6 (10)	44.4 (8)	0 (0)	
Number of days training received M(*SD*)	4.3 (12.82)	3.8 (5.35)	5.5 (7.26)	χ^2=1.262 (*df* 2), *p*=0.532
Frequency of update training %(*n*)				
Once a year	59.6 (87)	39.0 (57)	1.4 (2)	χ^2=6.181 (*df* 2), *p*=0.045*
Twice a year	70.2 (59)	27.4 (23)	2.4 (2)	
< once every two years	58.1 (75)	34.9 (45)	7.0 (9)	

Note: *n*=number; M=mean; *SD*=Standard Deviation; SSP=stop smoking practitioners; NRT=Nicotine Replacement Therapy
Significant difference between groups (* $p<0.05$, ** $p<0.01$, *** $p<0.001$)
Percentages given are within 'Personal/job characteristic'

Table 7 shows that those stop smoking managers and stop smoking practitioners who reported that they believed that the long-term use of NRT was harmful to health were more likely to report that this was because it could cause addiction (83%), mouth/oral cancer (33%) and high blood pressure (18%). In contrast, those who reported that that they believed that the concurrent use of NRT and cigarettes was harmful to health were most likely to report that this was because it could cause addiction (44%), nicotine overdose (73%) and high blood pressure (26%). Reports did not differ among stop smoking managers and stop smoking practitioners ($p>0.05$). A number of other complications were also reported. For the long-term use of NRT these included oral/dental problems ($n=3$), increased psychological dependence ($n=3$), mental health issues ($n=2$), increased salt intake from lozenges ($n=1$), stimulant effects of NRT ($n=1$) and problems during pregnancy ($n=1$). For the use of NRT as an aid to smoking reduction these included palpitations ($n=3$), does not break the habit ($n=1$), sickness ($n=2$), damage to the foetus during pregnancy ($n=4$), increased side-effects ($n=1$), increased smoking if NRT is stopped ($n=1$), less effective ($n=1$), lowers the likelihood of quitting ($n=3$) and mental health problems ($n=1$).

Table 7: Percentage of Stop Smoking Practitioners and Managers Reporting Various Harmful Effects of Using Nicotine Replacement Therapy for a Year or more and While Attempting Smoking Reduction

The use of NRT for a year or more[a]			
	Overall (n=85)	Managers (n=7)	Practitioners (n=78)
Lung cancer %(n)	2 (2)	0 (0)	3 (2)
Oral/ mouth cancer %(n)	33 (28)	57 (4)	31 (24)
Other type of cancer %(n)	2 (2)	0 (0)	3 (2)
Heart attack %(n)	5 (4)	0 (0)	5 (4)
High blood pressure %(n)	18 (15)	0 (0)	19 (15)
Other type of heart disease %(n)	5 (4)	0 (0)	5 (4)
Emphysema, chronic lung disease, COPD %(n)	2 (2)	0 (0)	3 (2)
Addiction %(n)	83 (71)	86 (6)	83 (65)
Nicotine overdose %(n)	11 (9)	14 (1)	10 (8)
Use of NRT for smoking reduction[b]			
	Overall (n=160)	Managers (n=9)	Practitioners (n=151)
Lung cancer %(n)	5 (8)	0 (0)	5 (8)
Oral/ mouth cancer %(n)	8 (13)	0 (0)	9 (13)
Other type of cancer %(n)	3 (4)	0 (0)	3 (4)
Heart attack %(n)	10 (16)	0 (0)	11 (16)
High blood pressure %(n)	26 (41)	11 (1)	27 (40)
Other type of heart disease %(n)	7 (9)	0 (0)	6 (9)
Emphysema, chronic lung disease, COPD %(n)	3 (5)	0 (0)	3 (5)
Addiction %(n)	44 (71)	44 (4)	44 (67)
Nicotine overdose %(n)	73 (117)	77 (7)	73 (110)

Note: n=number; NRT=Nicotine Replacement Therapy; COPD=chronic obstructive pulmonary disease
[a] Beliefs among those reporting that the long term use of NRT was harmful
[b] Beliefs among those reporting that the use of NRT for smoking reduction was harmful

Table 8: Differences in Beliefs About Whether the use of Nicotine Replacement Therapy for Smoking Reduction Undermines or Promotes Cessation as a Function of the Personal and job Characteristics of Stop Smoking Managers

Personal/job characteristic	**Promote (*n*=29)**	**Hinder (*n*=11)**	**No effect (*n*=6)**	
Percentage of SSM current role which involves running a SSS M(*SD*)	87.22 (18.47)	86.40 (21.27)	68.00 (30.13)	χ^2=2.62 (*df* 2) *p*=0.270
Length of time having worked as a SSM (months) M(*SD*)	51.6 (40.69)	38.2 (30.93)	32.0 (31.14)	χ^2=1.93 (*df* 2), *p*=0.523
Age M(*SD*)	44.2 (9.87)	44.7 (7.99)	47.6 (11.52)	χ^2=2.62 (*df* 2), *p*=0.270
Gender %(*n*)				χ^2=2.83 (*df* 2), *p*=0.283
Male	62.5 (20)	21.9 (7)	15.6 (5)	
Female	60 (6)	40 (4)	0 (0)	
Regular meetings with their commissioner %(*n*)				χ^2=6.04 (*df* 2), *p*=0.049*
Yes	71.1 (27)	18.4 (7)	10.5 (4)	
No	25.0 (2)	50.0 (4)	25.0 (2)	
Good relationship with their commissioner %(*n*)				χ^2=8.46 (*df* 2), *p*=0.015*
Yes	73.0 (27)	18.9 (7)	8.1 (3)	
No	22.2 (2)	44.4 (4)	33.3 (3)	
Feels that they are able to influence the commissioning process %(*n*)				χ^2=7.78 (*df* 4), *p*=0.100
Disagree	39.0 (3)	40.0 (4)	30.0 (3)	
Agree	75.0 (24)	18.8 (6)	6.3 (2)	
Unsure	50.0 (2)	25.0 (1)	25.0 (1)	
Feels involved in the strategic planning of their service %(*n*)				χ^2=9.80 (*df* 4), *p*=0.044*
Disagree	25.0 (2)	37.5 (3)	37.5 (3)	
Agree	75.8 (25)	18.2 (6)	6.1 (2)	
Unsure	64.0 (2)	40.0 (2)	20.0 (1)	
Recommended length of NRT use in their SSS % (*n*)				χ^2=2.71 (*df* 2) *p*=0.873
<12 months	61.1 (22)	25.0 (9)	13.9 (5)	
>13 months	70.0 (7)	20.0 (2)	10.0 (1)	

Note: *n*=number; M=mean; *SD*=Standard Deviation; SSS=stop smoking service; SSM=stop smoking managers; NRT=Nicotine Replacement Therapy
Significant difference between groups (* *p*<0.05, ** *p*<0.01, *** *p*<0.001)
Percentages given are within 'Personal/job characteristic'

Overall 57.0% (*n*=309) of the sample reported that the use of NRT for smoking reduction would promote cessation (50.0% (*n*=29) of stop smoking managers and 57.9% (*n*=280) of stop smoking practitioners). Seventeen per cent (*n*=93) reported that they believed it would hinder cessation (19.0% (*n*=11) of stop smoking managers and 16.9% (*n*=82) of stop smoking practitioners), while 7.4% (*n*=40) that it would have no effect (6.9% (*n*=4) of stop smoking managers and 7.4% (*n*=36) of stop smoking practitioners). Eight per cent (*n*=42) reported that they didn't know (3.4% (n=2) of stop smoking managers and 8.3% (n=40) of stop smoking practitioners). No significant difference in responses was found between stop smoking managers and stop smoking practitioners (χ^2=1.70 (*df* 3), p=0.637).

Table 8 shows that beliefs about whether the use of NRT for smoking reduction hindered or promoted cessation differed as a function of stop smoking managers' relationship with their commissioner, whether they felt involved in the strategic planning of their service, and if they had regular meetings with their commissioner. Those reporting that they had a good relationship with their commission were almost ten times as likely to report that they believed the use of NRT for smoking reduction would promote cessation (Odds Ratio (*OR*) 9.45; Confidence Interval (CI) 2.67-53.35; p<0.001). Mangers who reported regular meetings with their commission were also around seven times as likely to report that the use of NRT for smoking reduction may increase the propensity of smokers to quit (*OR* 7.36; CI 1.28-42.25; p<0.01), and were substantially less likely to report that it would hinder attempts to quit than those reporting that they did not have regular meetings (*OR* 0.23; CI 0.05-1.00; p<0.05). Finally, those who felt involved in the strategic planning of their service were more likely to report that the concurrent use of NRT and cigarettes could increase smokers' motivation to quit (*OR* 9.38; CI 1.57-56.01; p<0.001), and were less likely to report that it would have no effect on smokers' motivation to quit (*OR* 0.17; CI 0.02-1.00; p<0.05); relative to those reporting that they did not feel involved in the strategic planning of their service.

Whether stop smoking practitioners recommended abrupt or gradual cessation to clients also appeared to differ as a function of their beliefs about the effect of the use of NRT for smoking reduction on attempts to quit smoking. This appeared to reflect the fact that those who only advised abrupt cessation were less likely to believe that the use of NRT for smoking reduction would promote smoking cessation (Odds Ratio (*OR*) 0.47; Confidence Interval (CI) 0.31-0.72; p<0.05), and were more likely to report that they didn't know whether it would promote or undermine attempts to quit smoking (*OR* 2.70; CI 1.34-5.46; $p<0.05$), relative to those offering abrupt cessation but allowing gradual reduction (Table 9).

Table 9: Differences in Beliefs About Whether the use of Nicotine Replacement Therapy for Smoking Reduction Undermines or Promotes Cessation as a Function of the Personal and Job Characteristics of Stop Smoking Practitioners

Personal/job characteristic	**Promote (*n*=280)**	**Hinder (*n*=82)**	**No effect (*n*=36)**	**Don't know (*n*=40)**	
Age M(*SD*)	44.4 (10.30)	43.8 (12.03)	42.3 (10.90)	42.0 (10.52)	χ^2=2.272 (*df* 3), *p*=0.518
Gender %(*n*)					
Male	63.6 (222)	17.1 (60)	9.3 (27)	10.1 (35)	χ^2=6.36 (*df* 3), *p*=0.095
Female	64.3 (37)	19.2 (18)	7.1 (9)	9.4 (4)	
Length of time having worked as a SSP (months) M(*SD*)	57.1 (46.31)	64.1 (57.36)	43.3 (39.93)	55.4 (40.88)	χ^2=3.88 (*df* 3), *p*=0.275
Percentage of SSP main role which involves support for highly dependent smokers %(*n*)					χ^2=0.78 (*df* 3), *p*=0.855
Yes	54.4 (171)	26.5 (51)	13.2 (19)	5.9 (25)	
No	64.5 (82)	17.4 (22)	7.8 (12)	10.2 (13)	
Approach to cessation %(*n*)					
Abrupt	53.8 (93)	23.7 (41)	8.1 (14)	14.5 (25)	χ^2=18.45 (*df* 6), *p*=0.005*
Abrupt but allow gradual	71.0 (157)	14.9 (33)	7.7 (17)	6.3 (14)	
Gradual	77.8 (14)	11.1 (2)	11.1 (2)	0 (0)	
Number of days training received M(*SD*)	4.2 (12.65)	3.8 (4.28)	4.8 (7.14)	3.5 (2.34)	χ^2=1.404 (*df* 3), *p*=0.705
Frequency of update training %(*n*)					
Once a year	61.7 (87)	23.4 (33)	7.8 (11)	7.1 (10)	χ^2=1.693 (*df* 3), *p*=0.639
Twice a year	72.6 (61)	15.5 (13)	6.0 (5)	6.0 (5)	
< once every two years	61.6 (77)	19.8 (25)	7.9 (10)	11.1 (14)	

Note: *n*=number; M=mean; *SD*=Standard Deviation; SSP=stop smoking practitioners; NRT=Nicotine Replacement Therapy
Significant difference between groups (* $p<0.05$, ** $p<0.01$, *** $p<0.001$)
Percentages given are within 'Personal/job characteristic'

Discussion

Sixteen per cent and 30% of stop smoking practitioners and stop smoking managers respectively, believed that the long-term use of NRT and the concurrent use of NRT and cigarettes were harmful to health. Seventeen per cent of the sample also reported that the use of NRT for smoking reduction may hinder attempts at smoking cessation. Reports about the harmful effects of NRT used whilst concurrently smoking were slightly more common among stop smoking practitioners. The most frequently reported potential harms of the long-term use of NRT and the concurrent use of NRT and cigarettes were addiction, overdose and mouth cancer. Reports differed as a function of stop smoking managers' relationship with their commissioner, feelings of involvement in the strategic planning of their service, and whether they had regular meetings with their commissioner; while reports among stop smoking practitioners differed as a function of the length of time they had been working as practitioners for, gender, amount of training received and frequency of update training. Stop smoking practitioners who believed that the use of NRT for smoking reduction may hinder cessation were less also likely to advise reduction as a treatment option.

In line with previous research a significant number of stop smoking practitioners and stop smoking managers were concerned about the effect of using NRT for a year or more, the implications of using NRT concurrently with smoking, and believed that the use of NRT for harm reduction may undermine cessation (Martin et al., 2004; Warner & Martin, 2003). Moreover, the significant amount of 'don't know' answers is suggestive that the topic of NRT use for smoking reduction is not well understood. This is despite research reporting that NRT use concurrently with cigarettes does not appear to be a risk factor for cardiovascular disease, respiratory disease, cancer or mortality (Moore et al., 2009; Benowitz, 1998; Fagerström & Hughes, 2002). Addiction and overdose are also unlikely, with previous clinical trials and studies on those spontaneously reducing their cigarette consumption with NRT failing to find any increase in biological measures of nicotine intake, i.e. cotinine (see Chapters 6 & 12; Fagerstrom & Hughes, 2002). There is also an extensive and growing body of evidence that the use of NRT for harm reduction may actually increase the propensity of smokers to quit (see Chapters 5-11). These concerns likely arise from the earlier downfall of the 'light' cigarette; marketed as an alternative to cessation, leading medical textbooks advised physicians to encourage smokers to switch to lower tar cigarettes for over a decade

(Holbrook, 1983). These were later implicated in the development of a new form of lung cancer, a result of vigorous compensatory pulling on the cigarette (National Cancer Institute, 2001).

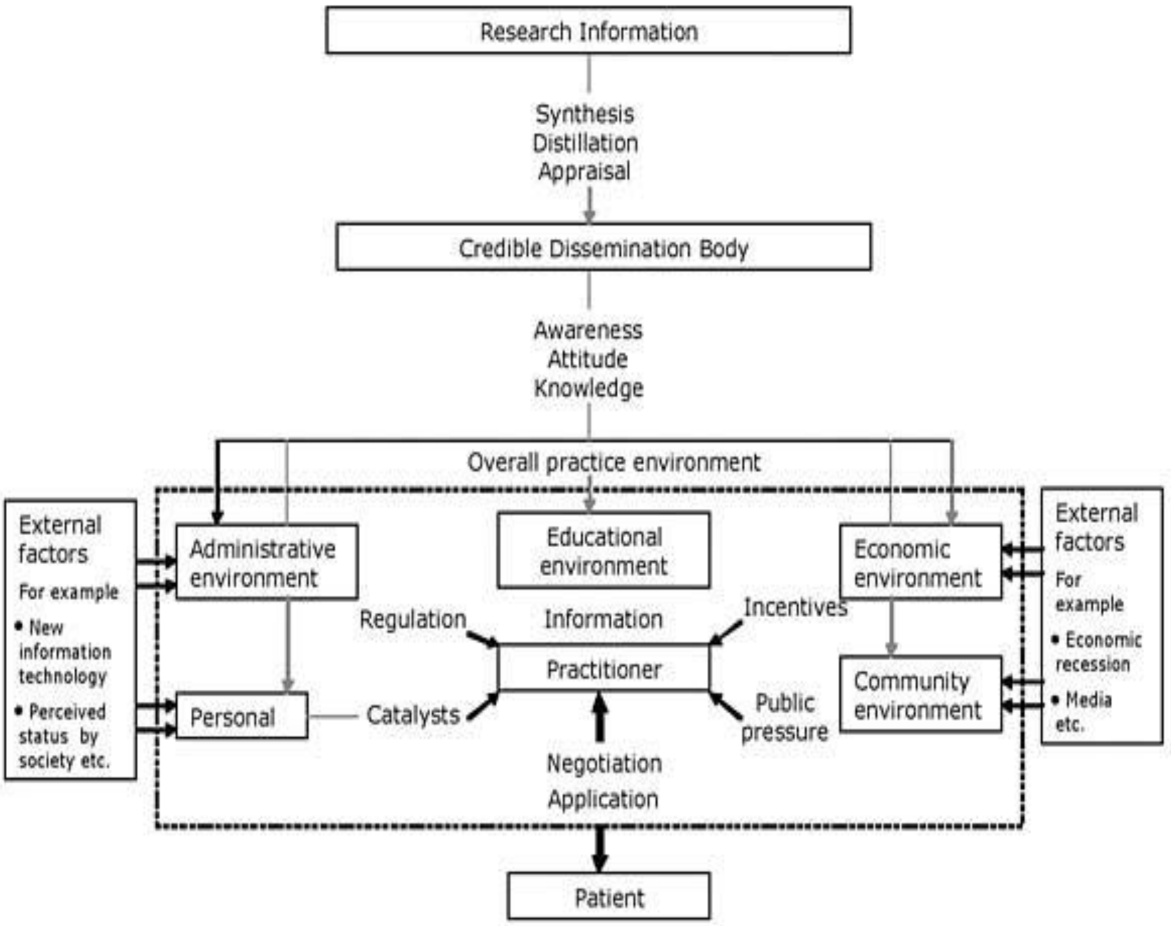


Figure 1: Coordinated Implementation Model (Lomas, 1993)

These misperceptions need to be addressed if stop smoking managers and stop smoking practitioners are to be adequately engaged in extending treatment to involve the use of NRT for harm reduction. If smokers who are unwilling or unable to quit are informed that alternative treatment options to abrupt cessation have adverse health implications, they may be inclined to continue with their current smoking patterns. The present findings demonstrate that concerns about the use of NRT for smoking reduction undermining smoking cessation among practitioners could be associated with discouragement against gradual smoking reduction. Previous studies have also reported that many of those working in tobacco control are hesitant about recommending NRT for harm reduction, and that healthcare professionals often feel that their role is not to deal with smokers who may be interested in using NRT in this way (Warner & Martin, 2003; Nagel, Schofield & Reman, 1999).

It is perhaps surprising that beliefs about the harmful effects of using NRT in the longer term and for smoking reduction did not influence the method of cessation that was recommended, i.e. abrupt or gradual. This is likely to reflect the fact that a lack of knowledge and miss-perceptions about harm reduction are not the only factors which may influence the implementation of a harm reduction approach in smoking cessation clinics. This could also explain why a significant number of those who despite believing that the use of NRT for smoking reduction could increase smokers' propensity to quit, failed to recommend gradual reduction approaches. Numerous models have been developed to capture schematically the competing factors of influence on the implementation process (Lomas, 1993; Canadian Institutes of Health Research, 2005; Jacobson, Butterill & Goering, 2003; Logan & Graham, 1998). For example, the key components of the Coordinated Implementation Model by Lomas (1993) are shown in Figure 1.

Possibly the most comprehensive and theoretically driven model comes from Michie et al. (2005). They developed a framework identifying the main factors influencing the implementation of evidence-based guidelines. Although more designed to assess why guidelines are not being implemented and for intervention development accordingly, it can be reliably adapted to assess the possibility of the acceptance of evidence-based practice. In phase one of development Michie et al. identified theories and theoretical constructs which fell into three groups: motivational, action and organisational. In total 128 constructs drawing on thirty-three psychological theories were identified. These were then synthesised into theoretical domains in phase two. In total twelve domains were identified: (1) knowledge, (2) skills, (3) social/professional role and identity, (4) beliefs about capabilities, (5) beliefs about consequences, (6) motivation and goals, (7) memory, attention and decision processes, (8) environmental context and resources, (9) social influences, (10) emotion regulation, (11) behavioural regulation, and (12) nature of the behaviour. Consequently, these 12 factors need to be assessed before strong conclusions can be drawn about the likelihood of a harm reduction approach being implemented in stop smoking services.

The question that naturally arises is how to counteract these misperceptions. The current findings point towards the possibility of increasing the amount of on job training received by practitioners, and ensuring that managers have a good relationship with their commissioner and feel that they are fully involved in the strategic planning of their service. This will ensure that practitioners and managers are adequately informed and kept up to date with the harm reduction literature and recommendations. There is some support for this; nurses trained in smoking cessation engage in more activity related to smoking cessation, hold more positive attitudes, and are more knowledgeable about cessation treatment (McEwen & West, 2001; Borrelli et al., 2001). Focus groups aimed at establishing knowledge about tobacco harm reduction have also shown an increase in positive opinions pre- and post-discussion (Joseph et al., 2004), while good relationships with colleagues and involvement in the organisational process appear to be related to job performance generally (Babin & Boles, 1996). Moreover, because it appears that managers hold fewer negative beliefs about the use of NRT for smoking reduction than practitioners, improving the relaying of information between different levels of the stop smoking services may help to modify belief systems.

However, as a consequence of the historical bombardment of managers and practitioners with the idea that only abrupt cessation options should be offered to clients, this is unlikely to be a straightforward process. According to the Health Belief Model, these core ingrained views will only change if a multi-dimensional approach is taken, which emphasises the benefits of harm reduction over its potential costs, provides cues to action in the form of educational documents, and ensures that healthcare professionals are aware that there are many smokers whom without this approach may never quit smoking (Rosenstock, 1974). Support for this comes from Arkes, Boehm and Xu (1991) who demonstrated that repeating a statement in multiple formats caused it to be judged truer, compared to non-repeated control statements, presumably because familiarity is used as one basis for judging validity.

However, according to the Elaboration-Likelihood Model and Chaiken's Heuristic-Systematic Model, even if information overload is achieved, attitudinal change is not definitive (Petty & Cacioppo, 1986; Chaiken, Liberman & Eagly, 1989); only when individuals process a message carefully and are motivated to do so, will enduring stable belief changes occur, with argument strength being the only determining factor (known as systematic processing). Motivation can be increased by improving the personal relevance of the topic. For example, practitioners with experience of smoking themselves may benefit from a self-referent processing strategy, whereby they are encouraged to remember their own experiences with smoking cessation or those of significant others (Burnkrant & Unnava, 1989). Ensuring that practitioners and managers are actively involved in the learning process and future developments, is also likely to be fundamental.

In contrast, when individuals are unable or unmotivated to process information carefully, temporary or unstable changes result (known as heuristic processing). In this instance, a focus more on readily accessible information will be necessary, which may include the authority or attractiveness of the speaker. Consequently, messages will need to comprehensible and credible (Ratneshwar & Chaiken, 1991). Positively framed messages also appear to be more persuasive (describing benefits gained from use of NRT for smoking reduction), than negatively framed ones (describing benefits lost by using NRT for smoking reduction; Maheswaran & Meyers-Levy, 1990), as are messages delivered by in-group than out-group sources (Wilder, 1990). Other limiting factors include the characteristics of the practitioners and managers, which are non-amendable, and emotional context. For example, Meyers-Levy and Sternthal (1991) have made the provocative suggestion that women, compared to men, have a lower threshold for elaborating on message cues; thus cues may be better recalled and exert more influence on judgments for women than men. Confidence in one's own ability also appears to be important, with McGuire (1968) showing that low self-esteem individuals have difficulty with message reception due to anxiety and a lack of attention. Accordingly, practitioners and managers must be reassured that they are capable at implementing new guidelines and approaches.

Finally, humans have a general drive towards consistency, whereby we seek congruence between attitudes and behaviours. If a lack of consistency occurs then discomfort may result, leading to an individual attempting to ease the tension by adjusting beliefs or behaviours in order to once again achieve balance (O'Keefe, 1990; Festinger, 1957). Therefore, simply enforcing practitioners to provide advice on the use of NRT for smoking reduction may concurrently result in adaptations to their belief systems, which may have an outward spiral effect on other clinically related behaviours. Even if enforcement is not used, a shift in their belief systems may occur through a desire to comply, i.e. with individual's changing their behaviour in the hope of gaining rewards or avoiding punishment from other practitioners or their management. This will result in cognitive dissonance, with the only way to resolve it being attitudinal change (Asch, 1956).

This study has a number of limitations which require consideration. First, because the response rate was relatively low among stop smoking managers it is possible that the sample attained is not representative of stop smoking managers generally. The same may also apply to stop smoking practitioners. Nevertheless, a significant degree of misunderstanding was evident and it is unlikely that this is overestimated by the present sample. Secondly, no objective data were available on respondents' clinical practice. It will be important in future to examine how far beliefs and attitudes, such as those measured in this study, translate into the treatment offered by practitioners and clinical outcomes. Thirdly, because the survey was designed to collect data on a wide range of topics and not just knowledge about the use of NRT for harm reduction, a number of important questions could not be answered. For instance, it would be useful to determine whether beliefs differ among rural areas and cities, and as a function of whether or not managers and practitioners are provided with information on tobacco harm reduction during training. Fourthly, although the survey questions were piloted among researchers working in the area of tobacco control, there is a concern that they may not have been interpreted as intended by respondents. However, it is difficult to envisage how differences in interpretation may have affected the findings reported. Finally, the current study was based on English stop smoking services. It is quite likely that the findings may not apply to other countries that perhaps have less liberal regulatory systems regarding the use of NRT during attempts to cut down. This would be a useful area for future research.

Conclusion

A significant minority of managers and practitioners believe that the use of NRT for harm reduction purposes could be harmful to health and may undermine smoking cessation. Educational programmes are required to increase awareness and to ensure that managers and practitioners provide accurate information and capitalise on the medical encounter with smokers, many of which may be unable or unwilling to quit smoking. Improving relationships with colleagues and ensuring that managers feel involved in the strategic planning of their service, may go some way in accomplishing this goal.

Chapter 16: General Discussion

Summary of the Findings

The specific objectives of this thesis were:

1. To review the current literature on harm reduction; in particular, previous clinical trials and survey-based studies which have assessed the use of NRT for smoking reduction and/or temporary abstinence.

2. To determine the prevalence of NRT use for harm reduction purposes.

3. To determine the effectiveness of the use of NRT for smoking reduction and/or temporary abstinence at a population level, by assessing the association with:-

    a. Cigarette consumption

    b. Nicotine intake

    c. Attempts to quit smoking

    d. Smoking cessation

4. To identify those who may be the most interested in using NRT for smoking reduction and/or temporary abstinence, by assessing the association with:-

    a. Age

    b. Gender

    c. Social-grade

    d. Nicotine dependence

5. To determine smokers' beliefs, views, and understanding of the use of NRT for smoking reduction and/or temporary abstinence, and the ways in which smokers use NRT for such purposes.

6. To determine whether healthcare professionals are likely to encourage smokers to use NRT for smoking reduction and/or during periods of temporary abstinence.

To achieve objective 1, a meta-analysis and systematic review of previous survey-based studies and randomised controlled trials was conducted. It was established that the use of NRT as part of a smoking reduction programme can result in significant declines in cigarette consumption, and to a lesser extent, reductions in toxin intake. More importantly, those using NRT to cut down in clinical trials appear to have greater odds of reporting an attempt to quit smoking and abstinence at follow-up than control groups (see Chapter 5). These findings were largely supported by the survey-based studies, which found that the use of NRT at a population level for harm reduction purposes does not at least appear to undermine cessation and may promote attempts to stop smoking. However, based on the findings from these studies, it is unlikely that the spontaneous use of NRT for harm reduction purposes induces large reductions in cigarette consumption.

To achieve objectives 2 to 4, population-based data from a sample of English smokers were used. It was established that few smokers were currently using NRT in England during attempts to cut down and/or when they are unable to smoke. Of interest, is that although prevalence did not appear to have changed substantially since 2007, NRT use for harm reduction purposes was related to a number of demographic and smoking characteristics. Women of a younger age and higher nicotine dependency were more likely to report the use of NRT during attempts at smoking reduction and/or during periods of temporary abstinence (see Chapters 7-9, 11 & 13).

Although NRT was deemed only moderately helpful (see Chapter 13), its use for harm reduction purposes was established to be positively associated with attempts to quit smoking and smoking status (see Chapters 7, 10 & 13); with a higher odds of an attempt to quit smoking amongst those using NRT both during attempts to cut down and when they were unable to smoke (see Chapter 8). The current findings suggest that the association between the use of NRT for harm reduction and attempts to stop smoking may occur by escalating smokers' motivation to stop smoking and by reducing their enjoyment of smoking, but not via any change in self-efficacy levels (see Chapter 11). Interestingly, the association between the use of NRT for harm reduction purposes and smoking abstinence occurred regardless of whether smokers were asked if they were cutting down or if they were cutting down without an intention to quit smoking (see Chapter 9). Consequently, question format does not appear to be a major reason for previous survey study variation, which may be dependent more so on design issues and differences in methods of recruitment. Of further interest, is that the use of NRT during periods of temporary abstinence in the office and at home was associated with the greatest odds of an attempt to quit smoking, relative to the use in a pub, restaurant or whilst travelling; the odds of a quit attempt were also greater amongst those using NRT in multiple situations requiring momentary abstinence as opposed to only one situation (see Chapter 13).

In contrast, it appeared that the use of NRT for smoking reduction and/or during periods of temporary abstinence may not result in reliable reductions in cigarette consumption, at least not to the extent of the previous clinical trials (see Chapters 7 & 10). Despite the concern that this apparent failure to reduce cigarette consumption whilst using NRT could result in an increased nicotine intake, stability in cotinine pre- and post-NRT use for smoking reduction and/or during periods of temporary abstinence was established (see Chapter 12). Of further interest, is that smokers were found to hold a preference for the nicotine patch, which in addition to the nicotine inhalator, was deemed to be the most helpful product during periods of temporary abstinence (see Chapter 7 and 13). Although there did not appear to be large differences in the superiority of the various NRT products, the gum was associated with a slightly lower cigarette consumption, but also concurrently with reduced odds of reporting an attempt to quit smoking (see Chapter 7).

To achieve objective 5, an interview methodology was used. Not only were varying interpretations of the term 'smoking reduction' found among smokers, but many were unaware of which products were licensed for harm reduction purposes. Smokers also appeared to hold misperceptions about the effect of NRT on their health and about what it could achieve; resulting in the underestimation of the willpower required on their part. Smokers were found to use varying methods to reduce their cigarette consumption, and often set unrealistic and ill-defined goals (see Chapter 14). Moreover, reports of modified cigarette smoking were noted, i.e. reducing puff frequency or inhalation rate. The findings also suggest that smokers choice of NRT product may depend on its history; past use for smoking cessation; smokers' mental representation of nicotine addiction; discreteness; ease of use; beliefs about safety; unawareness of other NRT products; and the side-effects of other products (see Chapter 14).

Finally, to achieve objective 6, data from a sample of stop smoking practitioners and managers were used. It was established that many stop smoking practitioners and managers hold the misperception that use of NRT for harm reduction may be harmful to health and undermine smokers' motivation to quit. Of concern, is that these beliefs were related to whether or not gradual reduction was recommended as a treatment option in clinic (see Chapter 15). The establishment of an association between stop smoking practitioners' and managers' beliefs with job and personal characteristics, demonstrated a number of ways in which these beliefs may be counteracted. These included the possibility of increasing the frequency of update training, fully involving managers in the strategic planning of their service, and forging strong relationships among colleagues.

Implications and Future Considerations

There appeared to be a significant minority of smokers who were using NRT during attempts at smoking reduction and/or for periods of temporary abstinence. However, many more were opting to cut down or to temporarily abstain without pharmacological help. Consequently, ways in which to increase the uptake of NRT need to be considered. These could include correcting the historical belief among smokers that NRT is a cessation only medication; adapting smokers' misperceptions about the safety and efficacy of NRT treatments (Etter & Perneger, 2001; Bansal et al., 2004; Cummings et al., 2004; Johnson et al., 1992; Hajek et al., 1999; Siahpush et al., 2006a); decreasing the cost of concurrently purchasing NRT and cigarettes (Curry et al., 1998); and encouraging healthcare professionals to offer NRT for harm reduction purposes to smokers who are unable or unwilling to stop smoking (Martin et al., 2004; Warner & Martin, 2003).

Of further concern, is that there appears to be some overlap in the demographic of those attempting harm reduction and those attempting smoking cessation, with both tending to be smokers of a lower nicotine dependency (Hyland et al., 2006; Zhou et al., 2009; Hymowitz et al., 1997; Jaen et al., 1993; Der & Graham, 1999; Dale et al., 2001). This suggests that current harm reduction strategies may not be targeting the sub-set of smokers of interest, i.e. those who have become discontented with traditional abrupt cessation approaches. However, this may be due to the cross-sectional nature of the data used in the current thesis, with the possibility that those attempting smoking reduction were a priori more nicotine dependent, but that this faded as a consequence of reductions in cigarette consumption; thus firmer more conclusive data are required to ensure that public health benefits are being realised. Moreover, unlike previous surveys on smoking cessation, no association between smoking reduction and social-grade was established (for example:- Kotz & West, 2009); and although younger female smokers appeared to be more likely to attempt to cut down, consistent relationships have not been reported between these demographic variables and attempts to stop smoking (Hagimoto et al., 2010; Rose, Chassin, Presson & Sherman, 1996; Whitson, Heflin & Burchett, 2006; Hyland et al., 2004; Hymowitz et al., 1997; Dale et al., 2001; Hyland et al., 2006; West et al., 2001a; Zhu, Sun, Billings, Choi & Malarcher, 1999; Abdullah, Lam, Chan & Hedley, 2006).

It is of particular interest that smokers demonstrated a preference for the nicotine patch, which until recently was not licensed for harm reduction purposes (MHRA, 2010). This is counterintuitive, since one may have assumed that smokers would choose a product that better allowed them to deal with urges to smoke and which provided sensory and behavioural relief (Fagerstrom & Hughes, 2002). However, this does not appear to be of huge concern, with the use of NRT being positively associated with motivation to quit smoking regardless of the product used, and since smokers appear to find transdermal products the most helpful during momentary abstinence (see Chapters 7 & 13). Nonetheless, the use of the nicotine gum for smoking reduction and/or during periods of temporary abstinence was related to the lowest cigarette consumption, which may be hypothesised due to its speed of delivery and behavioural aspects associated with its use. Of course, this could reflect the fact that those with a higher dependency are more likely to opt to use the nicotine patch, and is perhaps of little importance when combined with the finding that the nicotine patch was superior with regards to attempts to stop smoking.

A cause for concern is that despite smokers reporting the inhalator to be more helpful than the other non-transdermal products, few appeared to opt for its use either as a means to cut down or during periods of momentary abstinence. Future studies need to determine why this is the case and potentially incorporate the findings into new product design. Better advertisement and awareness of the various medicinal nicotine products may also be beneficial. Moreover, the current findings point towards the possibility that smokers interested in the use of NRT for harm reduction hold a mental representation of dependence as involving depleted brain nicotine concentrations, and consequently choose a product which provides a steady prolonged release of nicotine (see Chapter 14). It may be of use to educate smokers that nicotine dependence is caused not only by biological factors, but also the social environment in which we live and psychological process.

The current thesis also sheds light on the need for a better conceptualisation of the use of NRT for harm reduction purposes. Prior research has often failed to recognise that the use of NRT during attempts at smoking reduction and the use of NRT for periods of temporary abstinence are not mutually exclusive behaviours (see Chapter 7); that smokers may not only attempt to cut down the number of cigarettes they smoke but also adapt their smoking style (see Chapter 14); and that temporary abstinence is multifaceted, involving both enforced and voluntary periods of momentary restraint (see Chapter 13). Thus it may be better to conceive of attempts to reduce harm with the aid of NRT as occurring via four methods: the use of NRT during short periods of voluntary abstinence; the use of NRT during short periods of enforced abstinence; the use of NRT to reduce cigarette consumption; and/or the use of NRT to reduce smoke intake from cigarettes. Thus attempts to reduce the harm from smoking with NRT may or may not involve periods of abstinence and may or may not involve reductions in cigarette consumption (see Table 1). Each of these should be considered in future studies.

Table 1: Methods of Reducing Harm With the aid of Nicotine Replacement Therapy Whilst Continuing to Smoke

Category	Example
Short periods of voluntary abstinence	Smokers may wish to reduce their risk by not smoking at home or for some part of the day and use NRT to help them with this
Short periods of enforced abstinence	Smokers may be unable to smoke due to public restrictions and so use NRT to cope with withdrawal during these periods
Reductions in cigarette consumption	Smokers may intersperse NRT and cigarettes in order to reduce their cigarette consumption
Reductions in smoke intake from cigarettes	Smokers may use NRT to reduce the need for nicotine so that cigarettes are smoked less intensively

Note: NRT=Nicotine Replacement Therapy

Although the findings from the current thesis do not prove that the use of NRT for harm reduction purposes results in an increased likelihood of cessation among smokers who are unwilling or unable to quit, they do provide real-world evidence in support of the findings from the clinical trials (i.e. Carpenter et al., 2004; Batra et al., 2005; Haustein et al., 2003; Wennike et al., 2003; Bolliger et al., 2000; Rennard et al., 2002; Etter et al., 2004; Kralikova et al., 2002; Wood-Baker, 2001; Carpenter et al., 2003; Joseph et al., 2008; Tonnesen et al., 2005; Chan et al., 2011). Thus it could be concluded that the use of NRT for smoking reduction and/or during periods of temporary abstinence at a population level may increases the propensity of smokers to attempt to stop smoking, and that it is highly unlikely that the use of NRT in these ways has any negative impact on cessation (Stratton et al., 2001).

The current thesis also indicates those situations in which the use of NRT for smoking reduction and/or temporary abstinence may be optimal, including the use of NRT both as a means to cut down one's cigarette intake and to tide one over during periods when they are unable to smoke (see Chapter 8). This could be for a number of reasons: those using NRT for both purposes may simply be a priori more motivated to change behaviour, or the combined use of NRT in these ways may consequent in higher nicotine intake (Hatsukami et al., 2007). Moreover, it appears advantageous to encourage smokers who are using NRT for temporary abstinence to do so in multiple situations and in those which are voluntary, i.e. in one's own residence. Of course, due to the cross-sectional nature of these studies, it is equally likely that those who use NRT for multiple purposes are more motivated to mitigate the harmful effects of smoking. Prospective survey designs are required to resolve this issue.

Moreover, there are a number of unanswered questions and concerns which need to be addressed before firmer conclusions can be drawn regarding the association between the use of NRT for harm reduction purposes and smoking cessation. One being, that although the use of NRT for smoking reduction and/or during periods of momentary abstinence may move smokers towards a quit attempt, it could still have detrimental effects on the process of relapse prevention. This materialises out of the finding of a negative association between the use of NRT for smoking reduction and/or temporary abstinence and self-efficacy (see Chapter 11), which is a factor implicated in the maintenance of abstinence (Marlatt & Gordon, 1985; Marlatt, Baer & Quigley, 1995). The only evidence for this to date comes from a longitudinal clinical trial, which reported that despite initial superiorities of active NRT for smoking cessation relative to placebo and no-treatment controls, that rates were similar among groups at five years follow-up (Etter et al., 2007). Longitudinal population-based studies are necessary to address this further; of course, this may be hindered by cost and time, particularly as answers are required in the more immediate future. Perhaps the only way this can be addressed in a timely manner is with retrospective data collection, despite the pitfalls of this method.

Questions also remain as to whether the success of the use of NRT for smoking reduction and/or during periods of temporary abstinence is dependent on smoker characteristics. This is a necessary area of research if one is considering rolling out a harm reduction programme, with a potential need for tailoring to those who may find the process of smoking reduction and/or temporary abstinence more difficult. Of particularly importance is the determination of the utility of the use of NRT for harm reduction purposes among those suffering from psychiatric disorders and chronic conditions, who often find it harder to quit smoking, and as such, may benefit the most from a harm reduction approach (Lemmonds et al., 2004; Moeller-Saxone, 2008). A better understanding of the factors which mediate between the use of NRT for harm reduction and quit attempts is also necessary. Chapter 11 found evidence of only partial mediation for three of the four variables assessed: enjoyment of smoking, intention to stop smoking and motivation to quit. Moreover, the data were cross-sectional in nature, meaning that the associations could have been for a number of reasons. It is important to understand the mechanisms involved in NRT's ability to increase smokers' propensity to quit, not only to allow for the refinement of current theories, but also to ensure that interventions are adequately informed as to which variables and factors they should be targeting. For example, if the reduced enjoyment of cigarettes is a major factor, identifying was to induce larger reductions in the pleasure of smoking could further increase the propensity of smokers to quit. One means to so may be the development of more effective medicinal nicotine products (Hatsukami et al., 2007).

Prior to such research, methodological issues also require consideration. Although it does not appear that changing the format of the question assessing smoking reduction impacts on the associations reported with attempts to quit smoking; those responding to a question simply asking if they were cutting down were slightly more likely have quit smoking in the previous year than those who were cutting down without an intention to stop smoking (see Chapter 9). Thus future surveys should ensure that they are recruiting smokers they intend to and that participants are interpreting questions as designed by investigators; this will prevent spurious associations from occurring. This may include the adoption of questions with familiar words which appear to be answered more accurately (Blair et al., 1977). For example, there is evidence that ‘smoking reduction’ is more proverbial among smokers compared to ‘cutting down’ (Richter et al., 2002); thus researchers should perhaps consider adopting the former.

In contrast, the findings from the current thesis point towards the possibility that the spontaneous use of NRT for harm reduction purposes does not result in reliable reductions in cigarette consumption, as least not to the extent of the previous clinical trials (i.e. Carpenter et al., 2004; Batra et al., 2005; Haustein et al., 2003; Wennike et al., 2003; Bolliger et al., 2000; Rennard et al., 2002; Etter et al., 2004; Kralikova et al., 2002; Wood-Baker, 2001; Carpenter et al., 2003; Joseph et al., 2008; Tonnesen et al., 2005; Chan et al., 2011). Accordingly, it may be hypothesised that the use of NRT for smoking reduction and/or during periods of temporary abstinence is unlikely to reduce disease risk in the short-term at a population level. Smokers need to be made fully aware of this, being informed that health benefits may only be reaped if they quit smoking. Previous research has reported that many smokers opting to cut down do so without this in mind (Joseph et al., 2008). However, it may be that smokers are modifying instead how they smoke their cigarettes, with stable cotinine levels pre- and post-NRT use for smoking reduction and/or temporary abstinence (see Chapter 13). Although significant declines in cotinine would be assumed to be necessary for reductions in toxin intake to occur, stable NRT levels have been associated with concurrent reductions in carbon monoxide intake (Fagerstrom & Hughes, 2002). Further research is necessary to determine whether or not the use of NRT at a population level is associated with improved clinical outcomes. An issue with conducting studies such as these is that associations between biological markers and disease risk are relatively unclear, while assessing disease outcomes would take many years (Hurt et al., 2000).

However, although there is evidence that smokers have a tendency to reduce their puff frequency and to put their cigarettes out early (Okuyemi et al., 2002; see Chapter 12), it remains possible that the permanence of cotinine pre- and post- NRT use is due instead to the underuse of NRT. Previous studies have reported poor compliance with NRT at a population level (Shiffman et al., 2003a; Shiffman et al., 2003b), while in Chapter 10 there was evidence that smokers terminated NRT use after a relatively short period of time. If this is the case, it may be worth encouraging smokers to use NRT for longer periods of time and to increase their usage, particularly because higher doses of NRT are associated with greater reductions in cigarette consumption (Hatsukami et al., 2007). However, prior to this, there is a need to assess the extent and length of NRT use for harm reduction purposes at a population level, and the associations between these and cigarette consumption. It would also be of interest for surveys to measure the numerous ways in which smokers may reduce the amount of toxins they consume from cigarettes and the effectiveness of these approaches. Nonetheless, what can be taken from these findings is that it appears unlikely that the use of NRT for harm reduction purposes causes any increased harm to continuing smokers (see Chapter 12). Moreover, the possibility remains that the use of NRT for harm reduction purposes may have beneficial effects on mental health even if it does not do so for physical health. Improvements in quality of life have been established following participation in smoking reduction programmes (Wennike et al., 2003; Wood-Baker, 2001; Rennard et al., 2006; Bolliger et al., 2000; Haustein et al., 2003; Joseph et al., 2008). This clearly needs to be addressed further using a population-based sample.

Apart from the underuse of NRT and possible modifications to smoking behaviour explaining the lack of reliable reductions in cigarette consumption, one particular methodological factor may also be held to account: inaccuracies of recalled cigarette consumption among smokers (see Chapter 14). Previous studies have noted that smokers often fail to accurately recall cigarette consumption (Perez-Stable et al., 1990), with a tendency to base answers on broad cognitive heuristics rather than systematically counting intake (Klesges et al., 1995). Thus consideration needs to be given to using newer more reliable methods, such as including a record of consumption over the past few days. The current findings also shed light on a number of other ways in which one may induce sizeable reductions in cigarette consumption: encouraging smokers to set realistic goals and determining the best methods in which to achieve these goals; two factors which are pivotal in behaviour change (Borrelli & Mermelstein, 1994; Strecher et al., 1995; Riggs et al., 2001; Riley et al., 2002; Michie et al., 2009). The first step in achieving this will be to assess the prevalence of goal setting and the various methods used to accomplish these goals at a population level, while determining the behavioural components associated with success in the previous clinical trials, using meta-regression techniques (Michie et al., 2009).

It also appears possible from the findings in Chapter 15 that there may be some reluctance towards offering NRT for smoking reduction as a route to quit in stop smoking services, with practitioners and managers possessing negative beliefs about the use of NRT in this way, and evidence that these beliefs may impact on the advice given to smokers. Possible ways to counteract such misperceptions can be taken from the associations which were established between these beliefs and practitioners' and managers' personal and job characteristics. These include offering better guidance and educational training, improving and increasing the frequency of updates, establishing relationships among colleagues, and providing greater involvement in the strategic planning of stop smoking services. Of course, beliefs are not the only factors which may influence the implementation of a harm reduction approach in practice; memory and abilities to offer such treatment, in addition to other factors, will also need to be addressed (Michie et al., 2005). Future studies should aim to assess these factors and their associations with clinical practice prior to the implementation of harm reduction approaches in stop smoking services (DOH, 2010). This will enable policy makers to identify the areas in which interventions may be needed, and thus ensure the application of evidence-based practice.

Finally, we need to keep in mind the possible population effects of such a strategy. Even if it is the case and the use of NRT for smoking reduction and/or during periods of temporary abstinence increases smokers propensity to quit, the promotion of the use of NRT in these ways could still have unintended consequences in populations other than smokers not trying to stop smoking. For example, it could undermine resolve among smokers about to quit, or send a message to teenagers that small amounts of smoking are safe. Obviously this is hard to determine. Moreover, ethical considerations are required in relation to this. Even if promoting harm reduction strategies leads to greater total public health harm, objecting to the presentation of information on harm reduction to smokers so that they are unable to make an informed choice to reduce health risk, would represent a violation of their human rights (Kozlowski, 2002).

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Appendix A

Logistic Regression

Multicollinearity

Table 1A: Multicollinearity statistics for the association between the use of NRT for smoking reduction and the use of NRT for temporary abstinence

Model	Collinearity Statistics	
	Tolerance	VIF
Time to first cigarette	.964	1.038
Gender	.992	1.008
Social-Grade	.958	1.044
Age	.999	1.001
Smoking reduction with NRT	.999	1.001

Table 2A: Multicollinearity statistics for the association between attempts at smoking reduction and the use of NRT for temporary abstinence

Model	Collinearity Statistics	
	Tolerance	VIF
Time to first cigarette	.956	1.046
Gender	.991	1.009
Social-Grade	.958	1.044
Age	.997	1.003
Smoking reduction	.989	1.012

Table 3A: Multicollinearity statistics for the association between socio-demographic characteristics and attempts at smoking reduction

Model	Collinearity Statistics	
	Tolerance	VIF
Age	.998	1.002
Social-Grade	.958	1.043
Time to first cigarette	.964	1.038
Gender	.993	1.007

Table 4A: Multicollinearity statistics for the association between socio-demographic characteristics and the use of NRT for smoking reduction

Model	Collinearity Statistics	
	Tolerance	VIF
Age	.998	1.002
Social-Grade	.959	1.043
Time to first cigarette	.967	1.034
Gender	.990	1.010

Table 5A: Multicollinearity statistics for the association between socio-demographic characteristics the use of NRT for temporary abstinence

Model	Collinearity Statistics	
	Tolerance	VIF
Age	.998	1.002
Social-Grade	.958	1.043
Time to first cigarette	.964	1.038
Gender	.993	1.007

Table 6A: Multicollinearity statistics for the association between smoking reduction and attempts to quit smoking in the previous 12 months

Model	Collinearity Statistics	
	Tolerance	VIF
Time to first cigarette	.956	1.046
Gender	.992	1.009
Social-Grade	.958	1.044
Age	.997	1.003
Smoking reduction	.989	1.012

Table 7A: Multicollinearity statistics for the association between the use of NRT for smoking reduction and attempts to quit smoking in the previous 12 months

Model	Collinearity Statistics	
	Tolerance	VIF
Time to first cigarette	.963	1.039
Gender	.990	1.010
Social-Grade	.959	1.043
Age	.998	1.002
Smoking reduction with NRT	.994	1.006

Table 8A: Multicollinearity statistics for the association between the use of NRT for temporary abstinence and attempts to quit smoking in the previous 12 months

Model	Collinearity Statistics	
	Tolerance	VIF
Time to first cigarette	.960	1.041
Gender	.992	1.008
Social-Grade	.958	1.044
Age	.999	1.001
Temporary abstinence with NRT	.996	1.004

Table 9A: Multicollinearity statistics for the association between the use of the nicotine gum for smoking reduction and attempts to quit smoking in the previous 12 months

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.998	1.002
Social-Grade	.990	1.010
Age	.957	1.045
Time to first cigarette	.998	1.002
Gum	.965	1.036

Table 10A: Multicollinearity statistics for the association between the use of the nicotine patch for smoking reduction and attempts to quit smoking in the previous 12 months

	Collinearity Statistics	
Model	Tolerance	VIF
Gender	.991	1.009
Social-Grade	.956	1.046
Age	.997	1.003
Time to first cigarette	.961	1.040
Patch	.996	1.004

Table 11A: Multicollinearity statistics for the association between the use of the nicotine lozenges for smoking reduction and attempts to quit smoking in the previous 12 months

	Collinearity Statistics	
Model	Tolerance	VIF
Gender	.991	1.009
Social-Grade	.958	1.044
Age	.996	1.004
Time to first cigarette	.965	1.036
Lozenges	.996	1.004

Table 12A: Multicollinearity statistics for the association between the use of the nicotine inhalator for smoking reduction and attempts to quit smoking in the previous 12 months

	Collinearity Statistics	
Model	Tolerance	VIF
Gender	.990	1.010
Social-Grade	.957	1.045
Age	.998	1.002
Time to first cigarette	.964	1.038
Inhalator	.997	1.003

Table 13A: Multicollinearity statistics for the association between the use of the nicotine nasal spray for smoking reduction and attempts to quit smoking in the previous 12 months

	Collinearity Statistics	
Model	Tolerance	VIF
Gender	.991	1.010
Social-Grade	.956	1.046
Age	.999	1.001
Time to first cigarette	.964	1.037
Nasal Spray	1.000	1.000

Table 14A: Multicollinearity statistics for the association between the use of combined NRT for smoking reduction and attempts to quit smoking in the previous 12 months

	Collinearity Statistics	
Model	Tolerance	VIF
Gender	.990	1.010
Social-Grade	.957	1.045
Age	.999	1.001
Time to first cigarette	.962	1.039
Combined NRT	.997	1.003

Table 15A: Multicollinearity statistics for the association between the use of the nicotine patch for temporary abstinence and attempts to quit smoking in the previous 12 months

	Collinearity Statistics	
Model	Tolerance	VIF
Gender	.992	1.008
Social-Grade	.957	1.045
Age	.999	1.001
Time to first cigarette	.961	1.041
Patch	.997	1.003

Table 16A: Multicollinearity statistics for the association between the use of the nicotine gum for temporary abstinence and attempts to quit smoking in the previous 12 months

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.992	1.008
Social-Grade	.958	1.044
Age	.997	1.003
Time to first cigarette	.964	1.038
Gum	.998	1.002

Table 17A: Multicollinearity statistics for the association between the use of the nicotine inhalator for temporary abstinence and attempts to quit smoking in the previous 12 months

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.992	1.008
Social-Grade	.958	1.044
Age	.999	1.001
Time to first cigarette	.962	1.039
Inhalator	.998	1.002

Table 18A: Multicollinearity statistics for the association between the use of the nicotine lozenges for temporary abstinence and attempts to quit smoking in the previous 12 months

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.958	1.044
Age	.998	1.002
Time to first cigarette	.964	1.038
Lozenges	.999	1.001

Table 19A: Multicollinearity statistics for the association between the use of the nicotine nasal spray for temporary abstinence and attempts to quit smoking in the previous 12 months

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.957	1.044
Age	.999	1.001
Time to first cigarette	.963	1.038
Nasal spray	1.000	1.000

Table 20A: Multicollinearity statistics for the association between the use of combined NRT for temporary abstinence and attempts to quit smoking in the previous 12 months

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.958	1.044
Age	.999	1.001
Time to first cigarette	.961	1.040
Combined NRT	.998	1.002

Linearity of the Logit

Table 21A: Linearity of the logit statistics for the association between age and attempts at smoking reduction

	B	S.E.	Wald	Df	Sig.	Exp(B)
Age by Log(Age)	-.001	.000	35.117	1	.000	.999
Constant	.352	.031	126.071	1	.000	1.422

Table 22A: Linearity of the logit statistics for the association between age and the use of NRT for smoking reduction

	B	S.E.	Wald	Df	Sig.	Exp(B)
Age by Log(Age)	.001	.000	12.576	1	.000	1.001
Constant	-1.260	.050	644.257	1	.000	.284

Table 23A: Linearity of the logit statistics for the association between age and the use of NRT for temporary abstinence

	B	S.E.	Wald	Df	Sig.	Exp(B)
Age by Log(Age)	.000	.000	.152	1	.697	1.000
Constant	-1.897	.046	1668.581	1	.000	.150

Linear Regression

Multicollinearity

Table 24A: Multicollinearity statistics for the association between attempts at smoking reduction and cigarette consumption

	Collinearity Statistics	
Model	Tolerance	VIF
Time to first cigarette	.956	1.046
Gender	.992	1.009
Social-Grade	.958	1.044
Age	.997	1.003
Smoking reduction	.989	1.011

Table 25A: Multicollinearity statistics for the association between the use of NRT for smoking reduction and cigarette consumption

	Collinearity Statistics	
Model	Tolerance	VIF
Time to first cigarette	.963	1.039
Gender	.990	1.010
Social-Grade	.959	1.043
Age	.998	1.002
Smoking reduction with NRT	.994	1.006

Table 26A: Multicollinearity statistics for the association between the use of NRT for temporary abstinence and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Time to first cigarette	.961	1.041
Gender	.992	1.008
Social-Grade	.958	1.044
Age	.999	1.001
Temporary abstinence with NRT	.996	1.004

Table 27A: Multicollinearity statistics for the association between the use of the nicotine gum for smoking reduction and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.998	1.002
Social-Grade	.990	1.010
Age	.957	1.045
Time to first cigarette	.998	1.002
Gum	.965	1.036

Table 28A: Multicollinearity statistics for the association between the use of the nicotine patch for smoking reduction and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.991	1.009
Social-Grade	.956	1.046
Age	.997	1.003
Time to first cigarette	.961	1.040
Patch	.996	1.004

Table 29A: Multicollinearity statistics for the association between the use of the nicotine lozenges for smoking reduction and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.991	1.009
Social-Grade	.958	1.044
Age	.996	1.004
Time to first cigarette	.965	1.036
Lozenges	.996	1.004

Table 30A: Multicollinearity statistics for the association between the use of the nicotine inhalator for smoking reduction and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.990	1.010
Social-Grade	.957	1.045
Age	.998	1.002
Time to first cigarette	.964	1.038
Inhalator	.997	1.003

Table 31A: Multicollinearity statistics for the association between the use of the nicotine nasal spray for smoking reduction and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.991	1.010
Social-Grade	.956	1.046
Age	.999	1.001
Time to first cigarette	.964	1.037
Nasal Spray	1.000	1.000

Table 32A: Multicollinearity statistics for the association between the use of combined NRT for smoking reduction and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.990	1.010
Social-Grade	.957	1.045
Age	.999	1.001
Time to first cigarette	.962	1.039
Combined NRT	.997	1.003

Table 33A: Multicollinearity statistics for the association between the use of the nicotine patch for temporary abstinence and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.992	1.008
Social-Grade	.957	1.045
Age	.999	1.001
Time to first cigarette	.961	1.041
Patch	.997	1.003

Table 34A: Multicollinearity statistics for the association between the use of the nicotine gum for temporary abstinence and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.992	1.008
Social-Grade	.958	1.044
Age	.997	1.003
Time to first cigarette	.964	1.038
Gum	.998	1.002

Table 35A: Multicollinearity statistics for the association between the use of the nicotine inhalator for temporary abstinence and cigarette consumption

Model	Collinearity Statistics Tolerance	VIF
Gender	.992	1.008
Social-Grade	.958	1.044
Age	.999	1.001
Time to first cigarette	.962	1.039
Inhalator	.998	1.002

Table 36A: Multicollinearity statistics for the association between the use of the nicotine lozenges for temporary abstinence and cigarette consumption

Model	Collinearity Statistics Tolerance	VIF
Gender	.993	1.007
Social-Grade	.958	1.044
Age	.998	1.002
Time to first cigarette	.964	1.038
Lozenges	.999	1.001

Table 37A: Multicollinearity statistics for the association between the use of the nicotine nasal spray for temporary abstinence and cigarette consumption

Model	Collinearity Statistics Tolerance	VIF
Gender	.993	1.007
Social-Grade	.957	1.044
Age	.999	1.001
Time to first cigarette	.963	1.038
Nasal spray	1.000	1.000

Table 38A: Multicollinearity statistics for the association between the use of combined NRT for temporary abstinence and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.958	1.044
Age	.999	1.001
Time to first cigarette	.961	1.040
Combined NRT	.998	1.002

Independent Errors

Table 39A: Independent errors statistics for the association between attempts at smoking reduction and cigarette consumption

	Durbin-Watson
Adjusted	1.940

Table 40A: Independent errors statistics for the association between the use of NRT for smoking reduction and cigarette consumption

	Durbin-Watson
Adjusted	1.938

Table 41A: Independent errors statistics for the association between the use of NRT for temporary abstinence and cigarette consumption

	Durbin-Watson
Adjusted	1.941

Table 42A: Independent errors statistics for the association between the use of the nicotine gum for smoking reduction and cigarette consumption

	Durbin-Watson
Adjusted	1.949

Table 43A: Independent errors statistics for the association between the use of the nicotine patch for smoking reduction and cigarette consumption

	Durbin-Watson
Adjusted	1.975

Table 44A: Independent errors statistics for the association between the use of the nicotine lozenges for smoking reduction and cigarette consumption

	Durbin-Watson
Adjusted	1.959

Table 45A: Independent errors statistics for the association between the use of the nicotine inhalator for smoking reduction and cigarette consumption

	Durbin-Watson
Adjusted	1.958

Table 46A: Independent errors statistics for the association between the use of the nicotine nasal spray for smoking reduction and cigarette consumption

	Durbin-Watson
Adjusted	1.950

Table 47A: Independent errors statistics for the association between the use of combined NRT for smoking reduction and cigarette consumption

	Durbin-Watson
Adjusted	1.942

Table 48A: Independent errors statistics for the association between the use of the nicotine patch for temporary abstinence and cigarette consumption

	Durbin-Watson
Adjusted	1.963

Table 49A: Independent errors statistics for the association between the use of the nicotine gum for temporary abstinence and cigarette consumption

	Durbin-Watson
Adjusted	1.957

Table 50A: Independent errors statistics for the association between the use of the nicotine inhalator for temporary abstinence and cigarette consumption

	Durbin-Watson
Adjusted	1.960

Table 51A: Independent errors statistics for the association between the use of the nicotine lozenges for temporary abstinence and cigarette consumption

	Durbin-Watson
Adjusted	1.964

Table 52A: Independent errors statistics for the association between the use of the nicotine nasal spray for temporary abstinence and cigarette consumption

	Durbin-Watson
Adjusted	1.959

Table 53A: Independent errors statistics for the association between the use of combined NRT for temporary abstinence and cigarette consumption

	Durbin-Watson
Adjusted	1.965

Normality

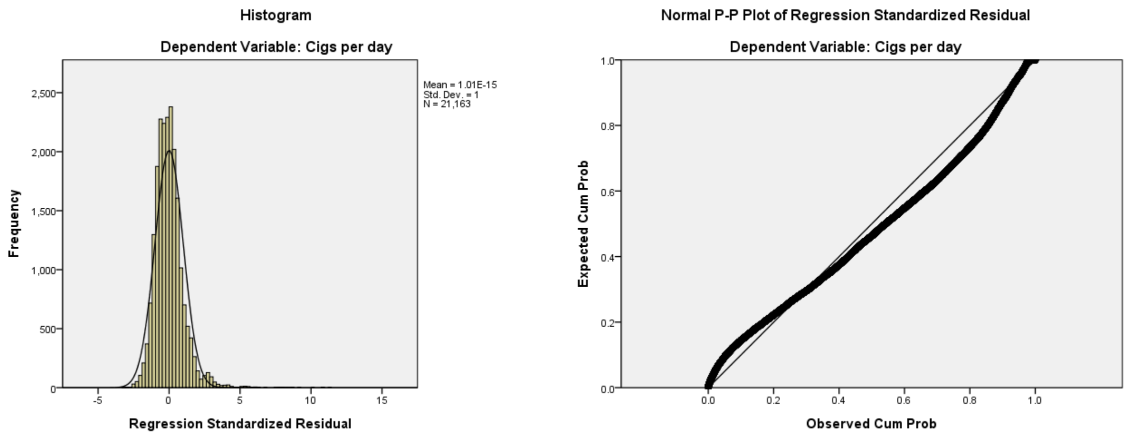


Figure 1A: Histogram and normal probability plot for the association between attempts at smoking reduction and cigarette consumption

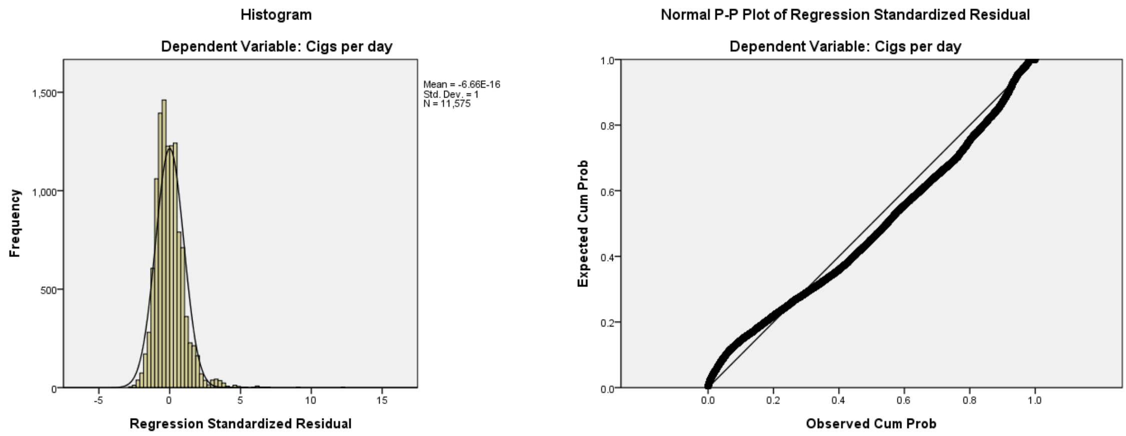


Figure 2A: Histogram and normal probability plot for the association between the use of NRT for smoking reduction and cigarette consumption

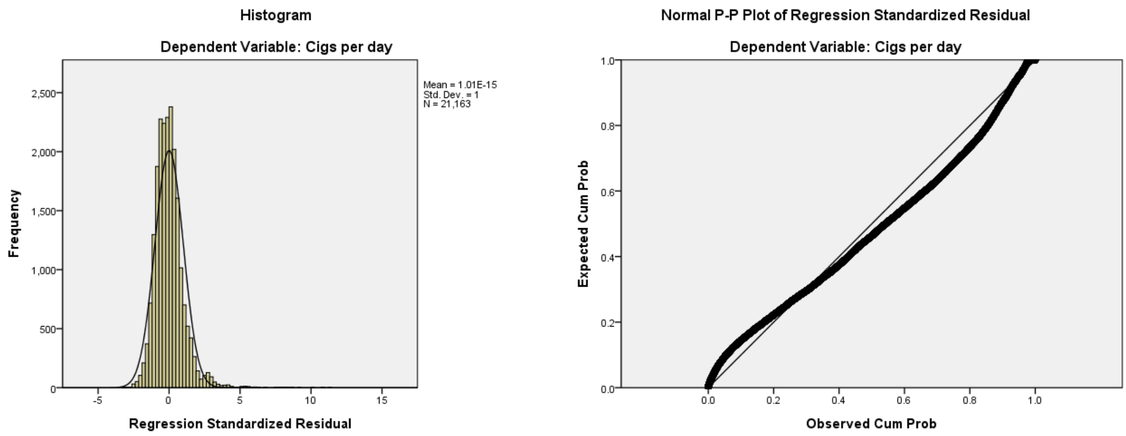


Figure 3A: Histogram and normal probability plot for the association between the use of NRT for temporary abstinence and cigarette consumption

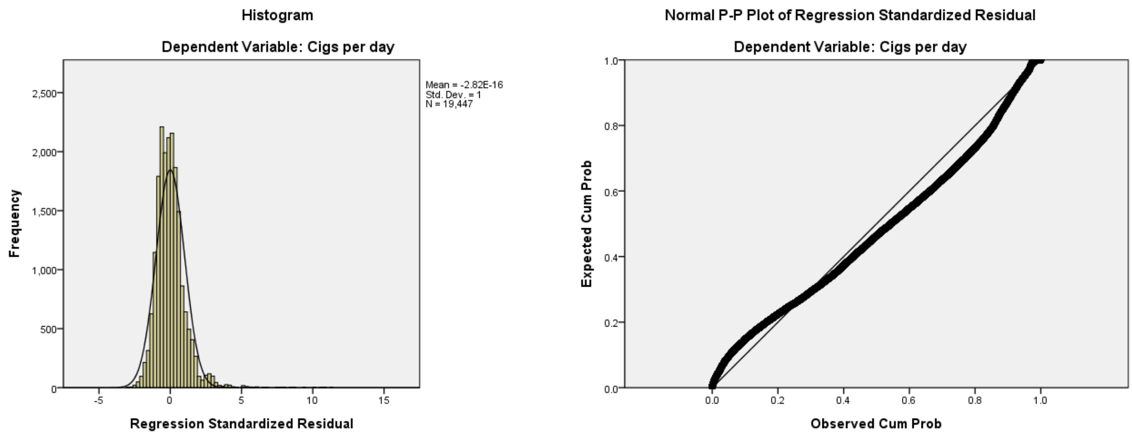


Figure 4A: Histogram and normal probability plot for the association between the use of the nicotine gum for smoking reduction and cigarette consumption

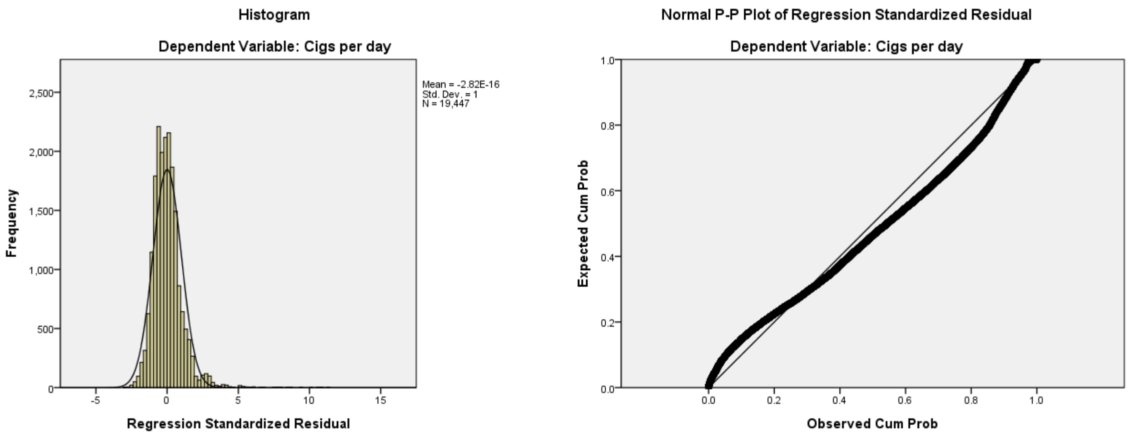


Figure 5A: Histogram and normal probability plot for the association between the use of the nicotine patch for smoking reduction and cigarette consumption

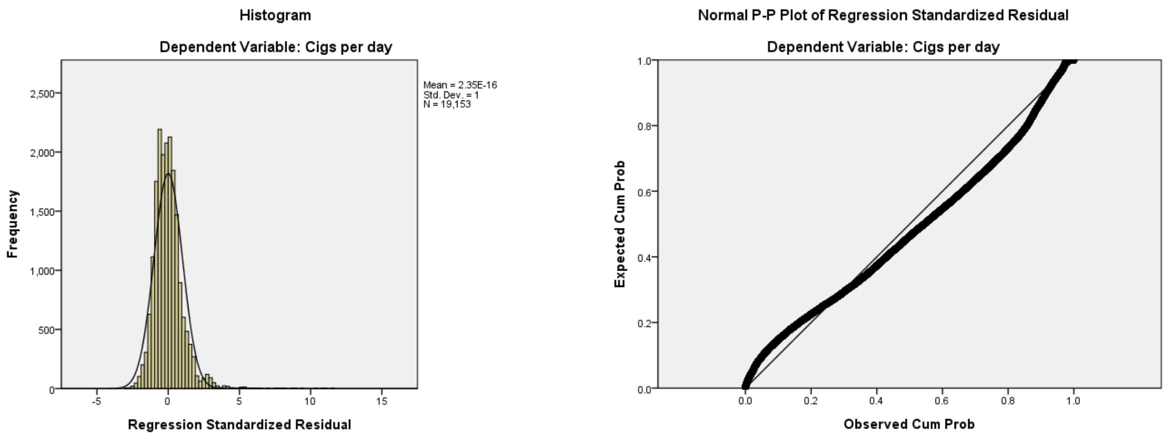


Figure 6A: Histogram and normal probability plot for the association between the use of the nicotine inhalator for smoking reduction and cigarette consumption

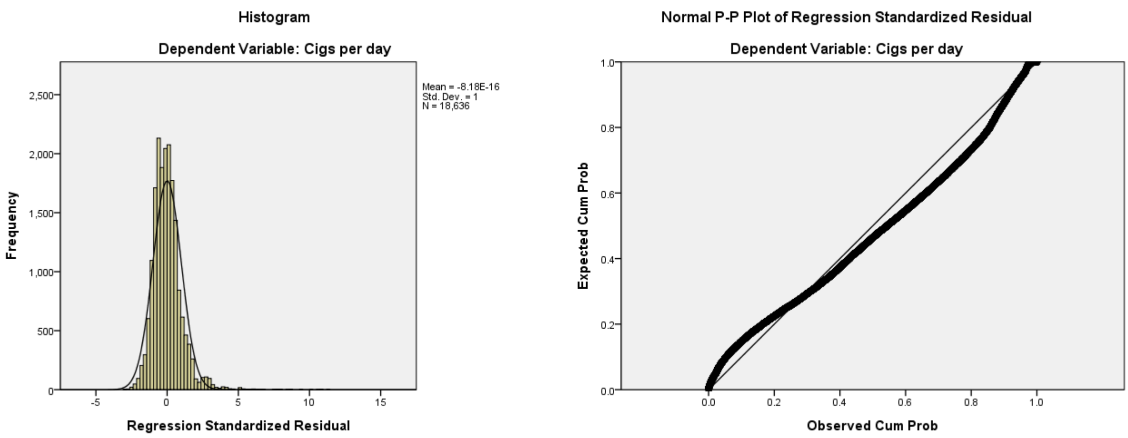


Figure 7A: Histogram and normal probability plot for the association between the use of the nicotine nasal spray for smoking reduction and cigarette consumption

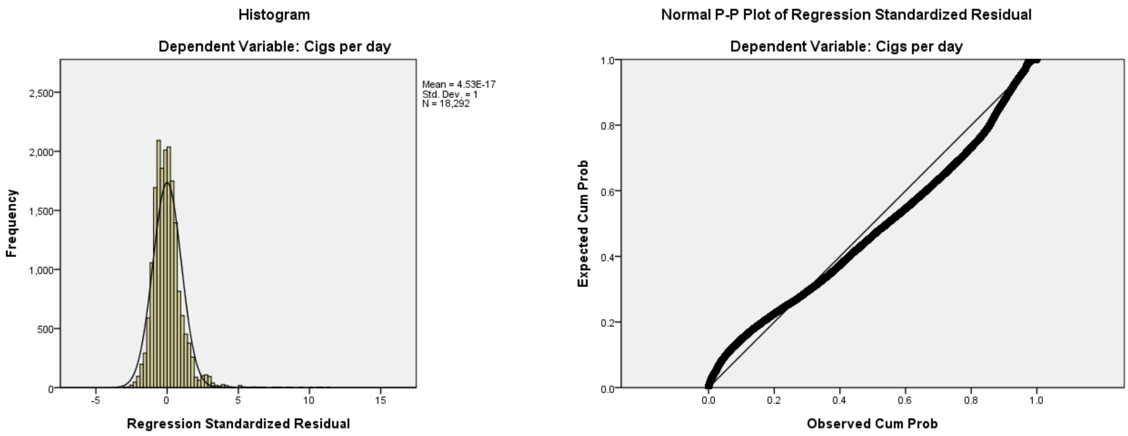


Figure 8A: Histogram and normal probability plot for the association between the use of the nicotine lozenges for smoking reduction and cigarette consumption

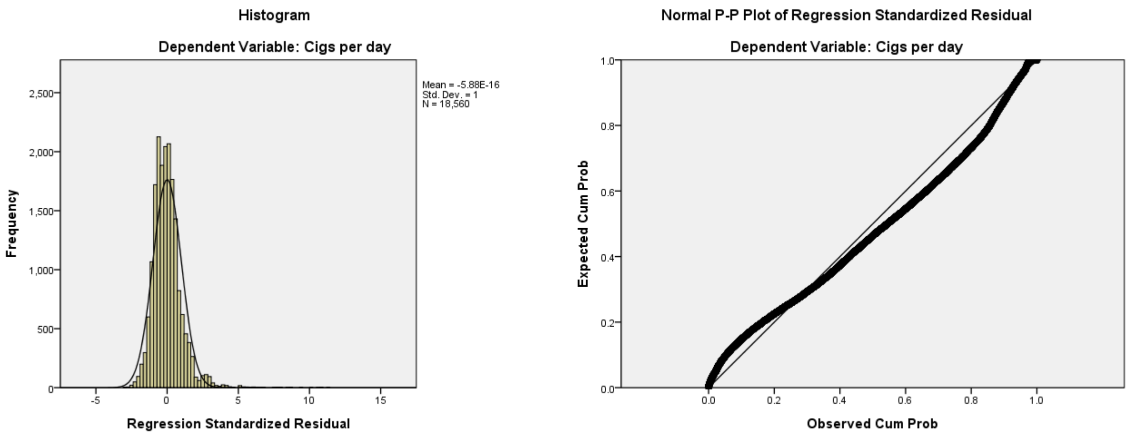


Figure 9A: Histogram and normal probability plot for the association between the use of combined NRT for smoking reduction and cigarette consumption

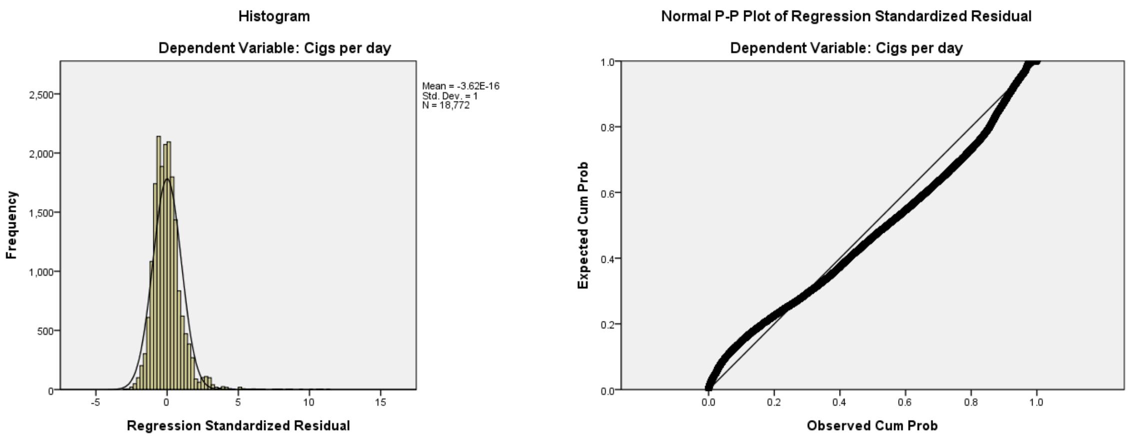


Figure 10A: Histogram and normal probability plot for the association between the use of the nicotine patch for temporary abstinence and cigarette consumption

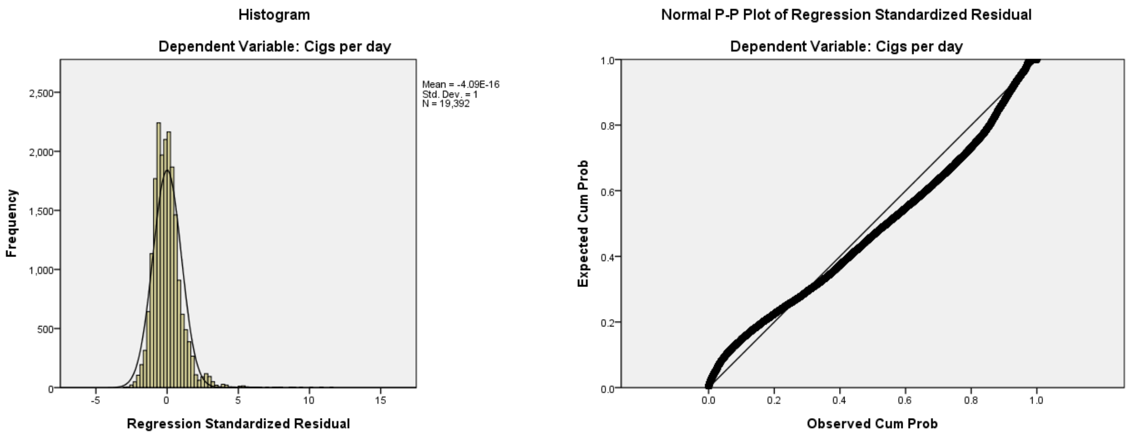


Figure 11A: Histogram and normal probability plot for the association between the use of the nicotine gum for temporary abstinence and cigarette consumption

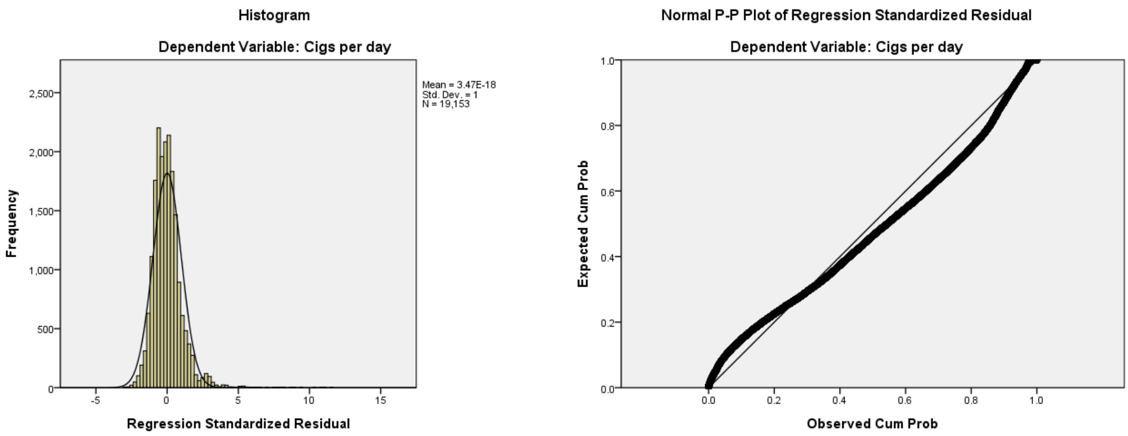


Figure 12A: Histogram and normal probability plot for the association between the use of the nicotine inhalator for temporary abstinence and cigarette consumption

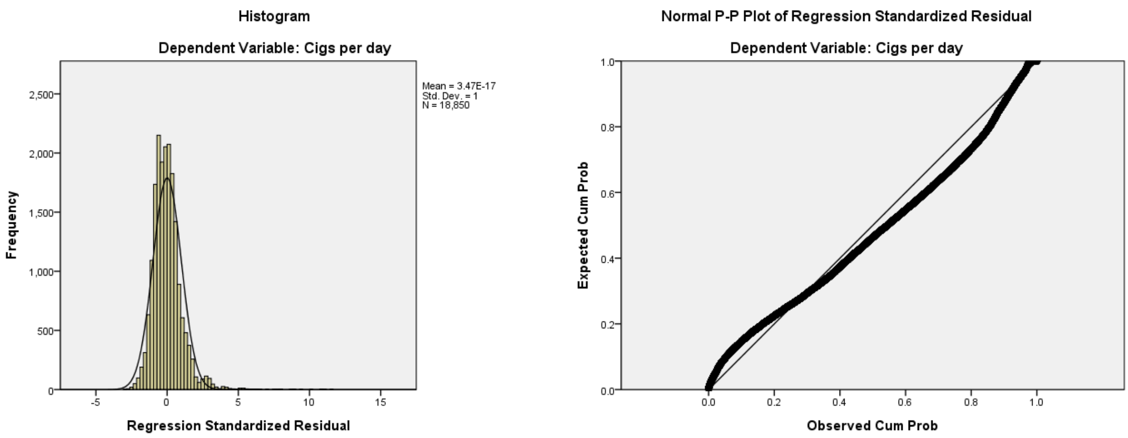


Figure 13A: Histogram and normal probability plot for the association between the use of the nicotine nasal spray for temporary abstinence and cigarette consumption

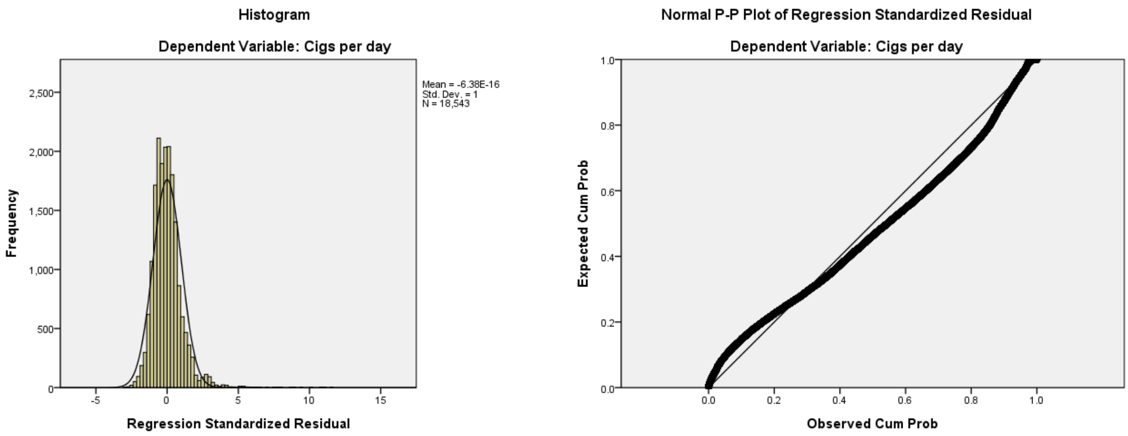


Figure 14A: Histogram and normal probability plot for the association between the use of the nicotine lozenges for temporary abstinence and cigarette consumption

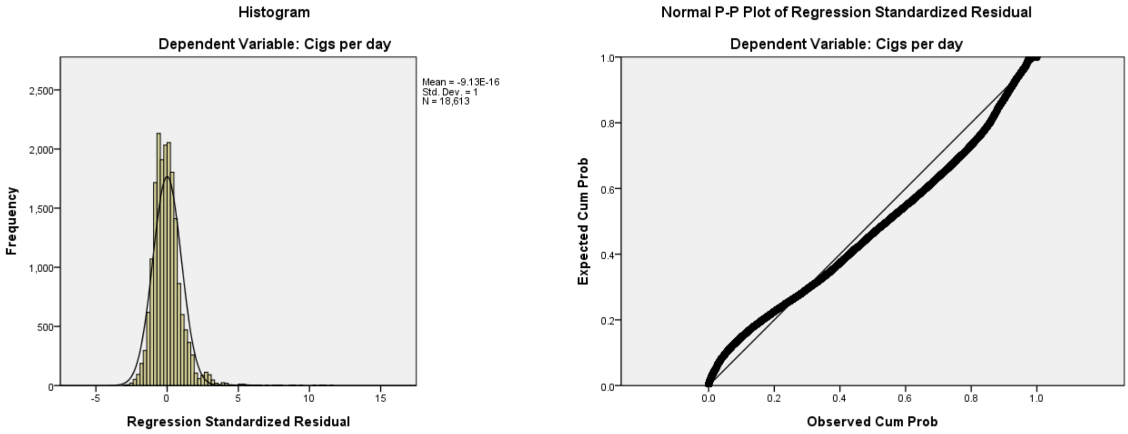


Figure 15A: Histogram and normal probability plot for the association between the use of combined NRT for temporary abstinence and cigarette consumption

Homoscedasticity and Linearity

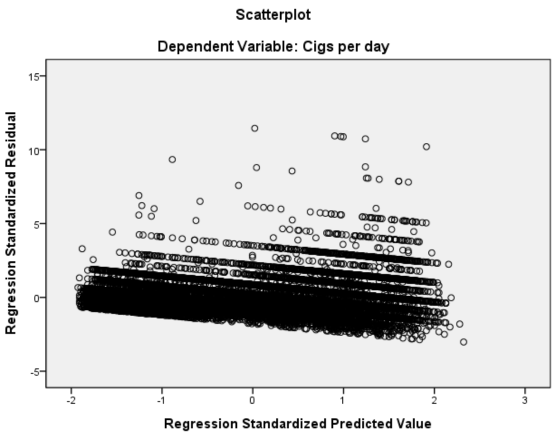


Figure 16A: Graph of standardised residuals against predicted values for the association between attempts at smoking reduction and cigarette consumption

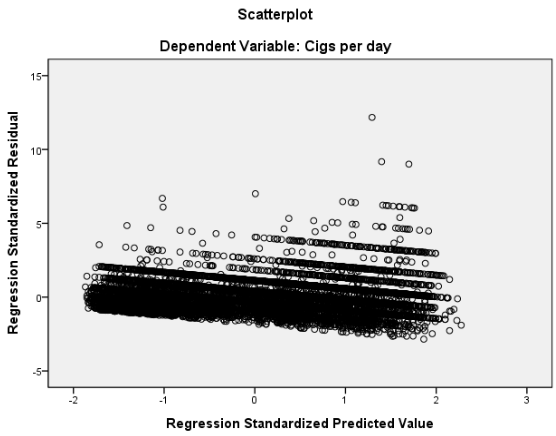


Figure 17A: Graph of standardised residuals against predicted values for the association between the use of NRT for smoking reduction and cigarette consumption

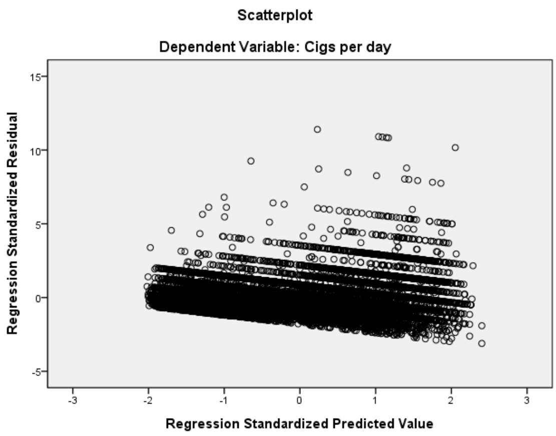


Figure 18A: Graph of standardised residuals against predicted values for the association between the use of NRT for temporary abstinence and cigarette consumption

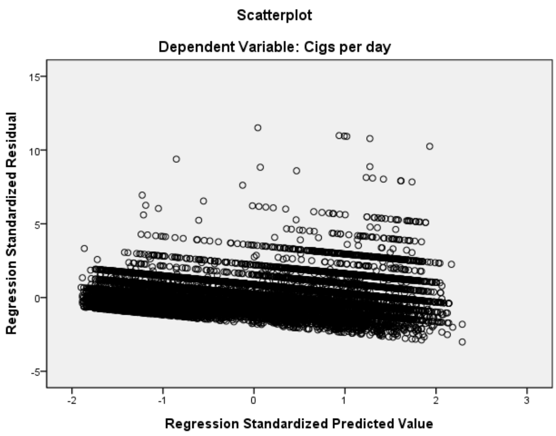


Figure 19A: Graph of standardised residuals against predicted values for the association between the use of the nicotine gum for smoking reduction and cigarette consumption

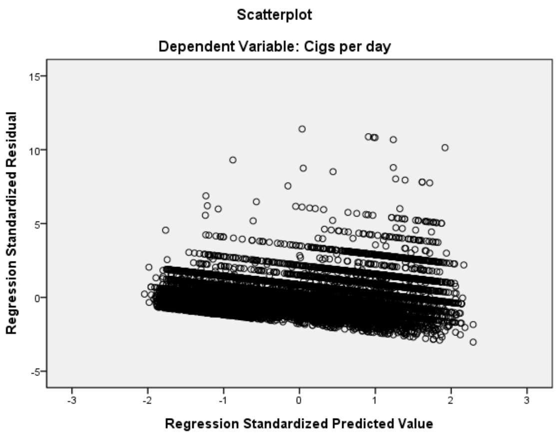


Figure 20A: Graph of standardised residuals against predicted values for the association between the use of the nicotine patch for smoking reduction and cigarette consumption

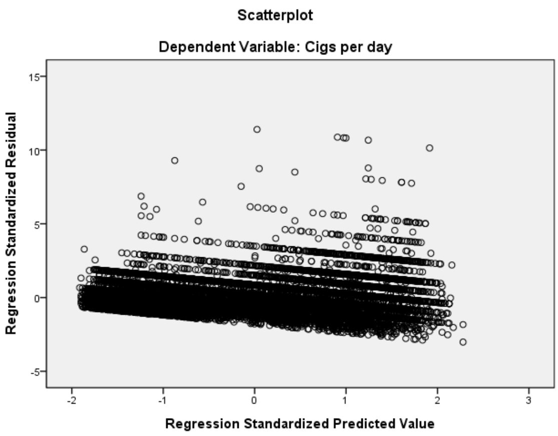


Figure 21A: Graph of standardised residuals against predicted values for the association between the use of the nicotine inhalator for smoking reduction and cigarette consumption

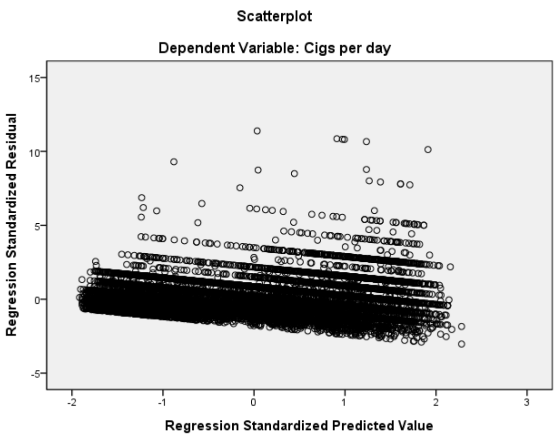


Figure 22A: Graph of standardised residuals against predicted values for the association between the use of the nicotine lozenges for smoking reduction and cigarette consumption

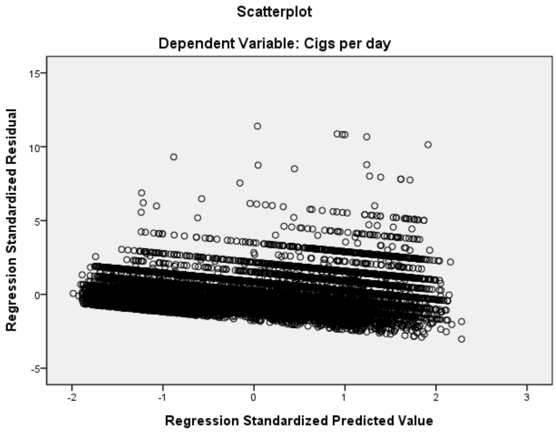


Figure 23A: Graph of standardised residuals against predicted values for the association between the use of the nicotine nasal spray for smoking reduction and cigarette consumption

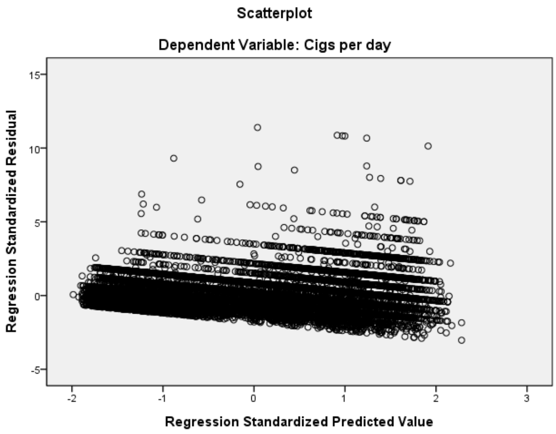


Figure 24A: Graph of standardised residuals against predicted values for the association between the use of combined NRT for smoking reduction and cigarette consumption

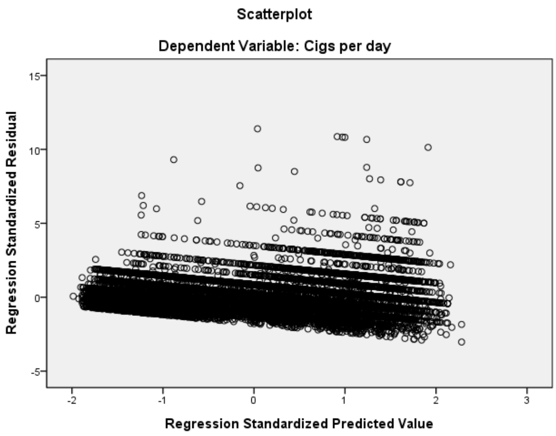


Figure 25A: Graph of standardised residuals against predicted values for the association between the use of the nicotine patch for temporary abstinence and cigarette consumption

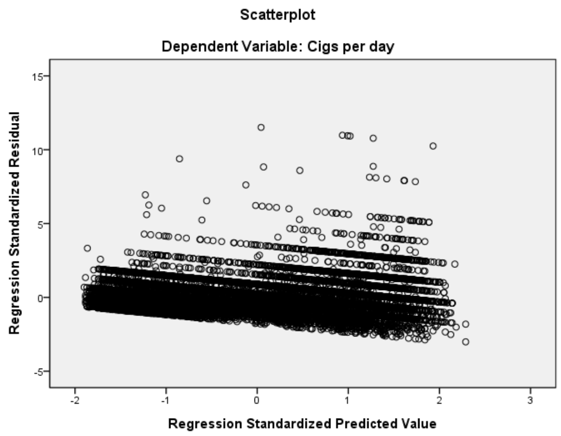


Figure 26A: Graph of standardised residuals against predicted values for the association between the use of the nicotine gum for temporary abstinence and cigarette consumption

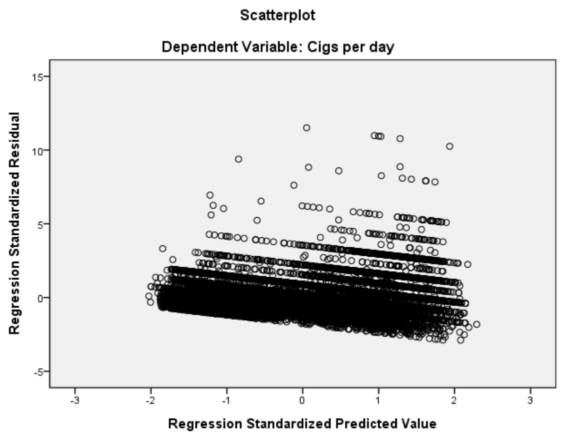


Figure 27A: Graph of standardised residuals against predicted values for the association between the use of the nicotine inhalator for temporary abstinence and cigarette consumption

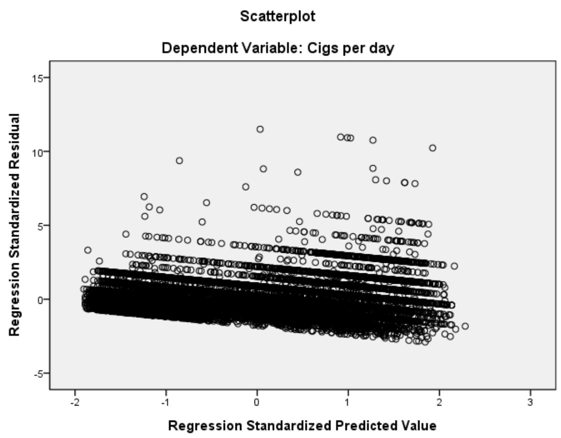


Figure 28A: Graph of standardised residuals against predicted values for the association between the use of the nicotine nasal spray for temporary abstinence and cigarette consumption

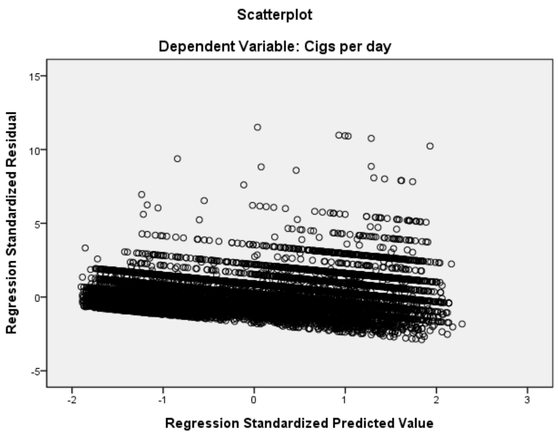


Figure 29A: Graph of standardised residuals against predicted values for the association between the use of the nicotine lozenges for temporary abstinence and cigarette consumption

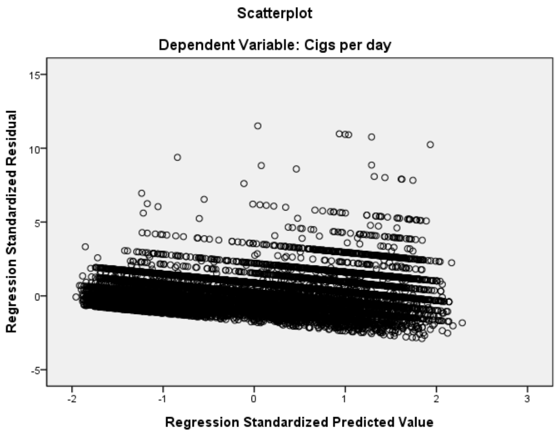


Figure 30A: Graph of standardised residuals against predicted values for the association between the use of combined NRT for temporary abstinence and cigarette consumption

ANOVA

Normality

Table 54A: Kolmogorov-Smirnov statistics for the assessment of differences in cigarette consumption among those using various NRT products for smoking reduction

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Cigarettes per day	Gum	.181	669	.000
	Lozenges	.151	277	.000
	Inhalator	.167	349	.000
	Spray	.176	22	.074
	Patch	.172	1099	.000
	Combined	.147	475	.000
Sqrt(Cigarettes per day)	Gum	.123	669	.000
	Lozenges	.116	277	.000
	Inhalator	.125	349	.000
	Spray	.122	22	.200*
	Patch	.138	1099	.000
	Combined	.113	475	.000
Log(Cigarettes per day)	Gum	.196	669	.000
	Lozenges	.189	277	.000
	Inhalator	.190	349	.000
	Spray	.199	22	.023
	Patch	.193	1099	.000
	Combined	.189	475	.000

Table 55A: Kolmogorov-Smirnov statistics for the assessment of differences in cigarette consumption among those using various NRT products for temporary abstinence

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Cigarettes per day	Gum	.163	724	.000
	Lozenges	.149	184	.000
	Inhalator	.150	420	.000
	Spray	.157	113	.000
	Patch	.165	963	.000
	Combined	.149	327	.000
Sqrt(Cigarettes per day)	Gum	.126	724	.000
	Lozenges	.151	184	.000
	Inhalator	.116	420	.000
	Spray	.157	113	.000
	Patch	.132	963	.000
	Combined	.120	327	.000
Log(Cigarettes per day)	Gum	.205	724	.000
	Lozenges	.238	184	.000
	Inhalator	.173	420	.000
	Spray	.204	113	.000
	Patch	.176	963	.000
	Combined	.185	327	.000

Homogeneity of Variance

Table 56A: Levene's statistics for the assessment of differences in cigarette consumption among those using various NRT products for smoking reduction

	Levene Statistic	df1	df2	Sig.
Cigarettes per day	1.550	5	2892	.171
Sqrt(Cigarettes per day)	.679	5	2892	.639
Log(Cigarettes per day)	3.813	5	2885	.002

Table 57A: Levene's statistics for the assessment of differences in cigarette consumption among those using various NRT products for temporary abstinence

	Levene Statistic	df1	df2	Sig.
Cigarettes per day	3.912	6	2732	.001
Sqrt(Cigarettes per day)	1.567	6	2732	.153
Log(Cigarettes per day)	2.818	6	2724	.010

Appendix B

Logistic Regression

Multicollinearity

Table 1B: Multicollinearity statistics for the association between socio-demographic characteristics and the use of NRT for smoking reduction

Model	Collinearity Statistics	
	Tolerance	VIF
Age	.998	1.002
Social-Grade	.957	1.045
Time to first cigarette	.964	1.037
Gender	.991	1.009

Table 2B: Multicollinearity statistics for the association between socio-demographic characteristics and the use of NRT for temporary abstinence

Model	Collinearity Statistics	
	Tolerance	VIF
Age	.998	1.002
Social-Grade	.957	1.045
Time to first cigarette	.962	1.040
Gender	.993	1.007

Table 3B: Multicollinearity statistics for the association between socio-demographic characteristics and the use of NRT for both temporary abstinence and smoking reduction

Model	Collinearity Statistics	
	Tolerance	VIF
Age	.998	1.002
Social-Grade	.958	1.044
Time to first cigarette	.963	1.038
Gender	.992	1.008

Table 4B: Multicollinearity statistics for the association between the use of NRT for both smoking reduction and temporary abstinence and attempts to quit smoking in the previous 12 months

	Collinearity Statistics	
Model	Tolerance	VIF
Gender	.991	1.009
Social-Grade	.957	1.045
Age	.998	1.002
Time to first cigarette	.965	1.036
Smoking reduction and temporary abstinence with NRT	.999	1.001

Table 5B: Multicollinearity statistics for the association between the use of NRT for temporary abstinence and attempts to quit smoking in the previous 12 months

	Collinearity Statistics	
Model	Tolerance	VIF
Gender	.992	1.008
Social-Grade	.957	1.045
Age	.998	1.002
Time to first cigarette	.956	1.046
Temporary abstinence with NRT	.993	1.007

Table 6B: Multicollinearity statistics for the association between the use of NRT for smoking reduction and attempts to quit smoking in the previous 12 months

	Collinearity Statistics	
Model	Tolerance	VIF
Gender	.990	1.010
Social-Grade	.957	1.045
Age	.997	1.003
Time to first cigarette	.962	1.039
Smoking reduction with NRT	.995	1.005

Linearity of the Logit

Table 7B: Linearity of the logit statistics for the association between age and the use of NRT for both temporary abstinence and smoking reduction

	B	S.E.	Wald	Df	Sig.	Exp(B)
Age by Log(Age)	.000	.000	.549	1	.459	1.000
Constant	-2.440	.060	1640.29	1	.000	.087

Table 8B: Linearity of the logit statistics for the association between age and the use of NRT for smoking reduction

	B	S.E.	Wald	Df	Sig.	Exp(B)
Age by Log(Age)	.001	.000	12.069	1	.001	1.001
Constant	-2.066	.069	906.396	1	.000	.127

Table 9B: Linearity of the logit statistics for the association between age and the use of NRT for temporary abstinence

	B	S.E.	Wald	Df	Sig.	Exp(B)
Age by Log(Age)	.000	.000	.048	1	.827	1.000
Constant	-2.694	.068	1550.030	1	.000	.068

Linear Regression

Multicollinearity

Table 10B: Multicollinearity statistics for the association between the use of NRT for both smoking reduction and temporary abstinence and cigarette consumption

	Collinearity Statistics	
Model	Tolerance	VIF
Smoking reduction and temporary abstinence with NRT	.999	1.001
Gender	.992	1.008
Social-Grade	.958	1.044
Age	.999	1.001
Time to first cigarette	.963	1.038

Table 11B: Multicollinearity statistics for the association between the use of NRT for temporary abstinence and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Temporary abstinence with NRT	.993	1.007
Gender	.992	1.008
Social-Grade	.957	1.045
Age	.999	1.001
Time to first cigarette	.956	1.046

Table 12B: Multicollinearity statistics for the association between the use of NRT for smoking reduction and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Smoking reduction with NRT	.995	1.005
Gender	.990	1.010
Social-Grade	.957	1.045
Age	.997	1.003
Time to first cigarette	.962	1.039

Independent Errors

Table 13B: Independent errors statistics for the association between the use of NRT for both smoking reduction and temporary abstinence and cigarette consumption

	Durbin-Watson
Adjusted	1.964

Table 14B: Independent errors statistics for the association between the use of NRT for temporary abstinence and cigarette consumption

	Durbin-Watson
Adjusted	1.961

Table 15B: Independent errors statistics for the association between the use of NRT for smoking reduction and cigarette consumption

	Durbin-Watson
Adjusted	1.963

Normality

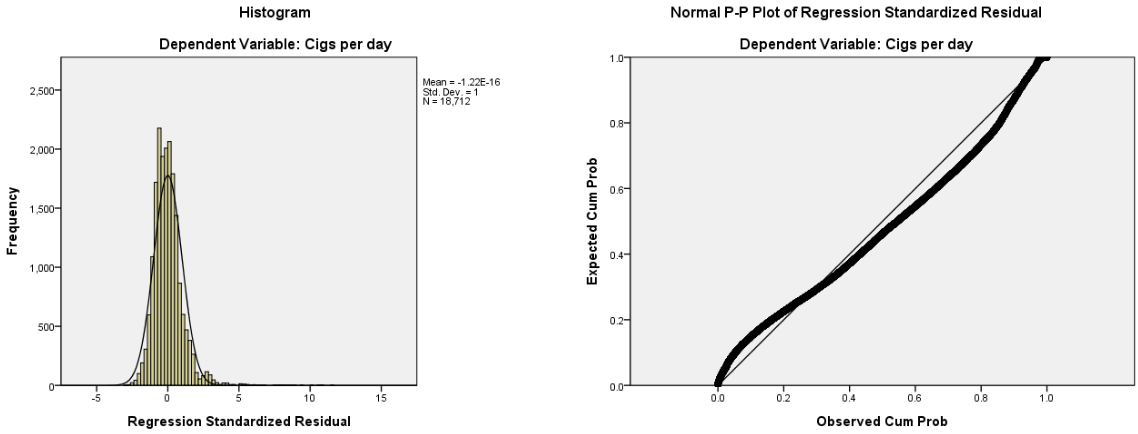


Figure 1B: Histogram and normal probability plot for the association between the use of NRT for both smoking reduction and temporary abstinence and cigarette consumption

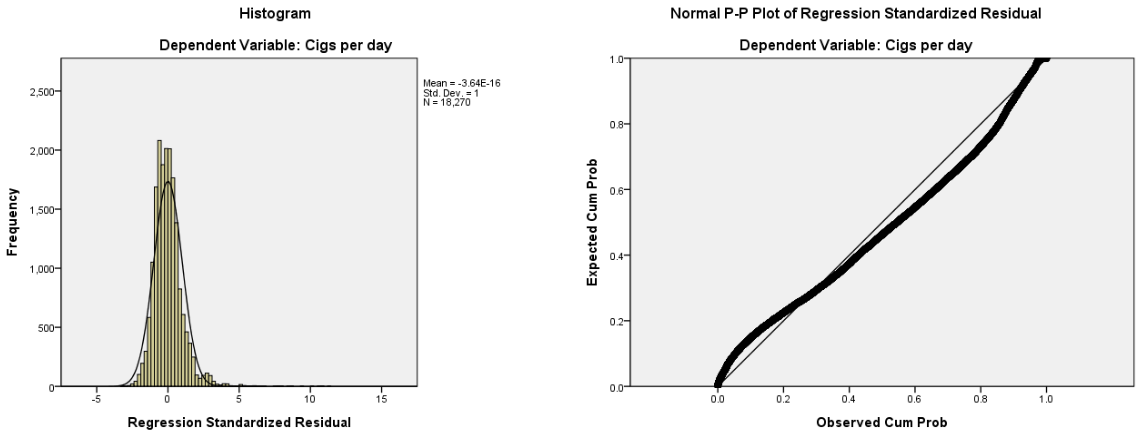


Figure 2B: Histogram and normal probability plot for the association between the use of NRT for temporary abstinence and cigarette consumption

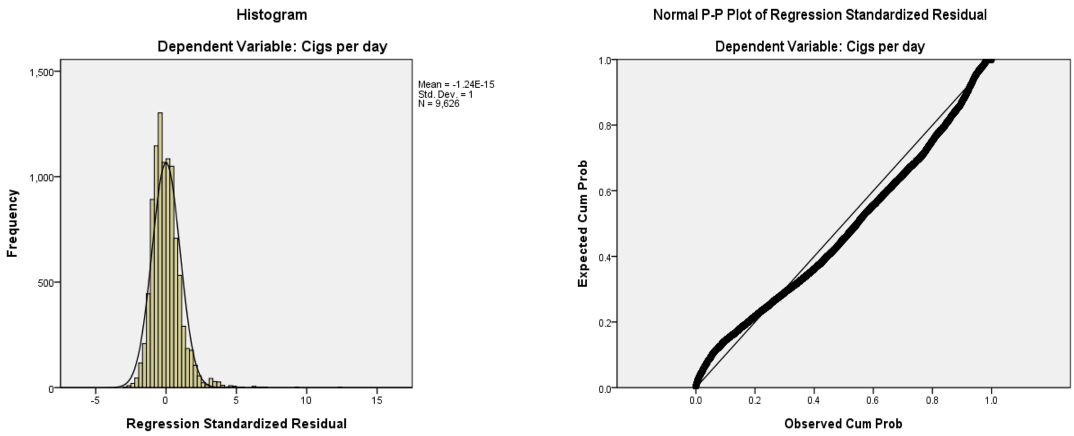


Figure 3B: Histogram and normal probability plot for the association between the use of NRT for smoking reduction and cigarette consumption

Homoscedasticity and Linearity

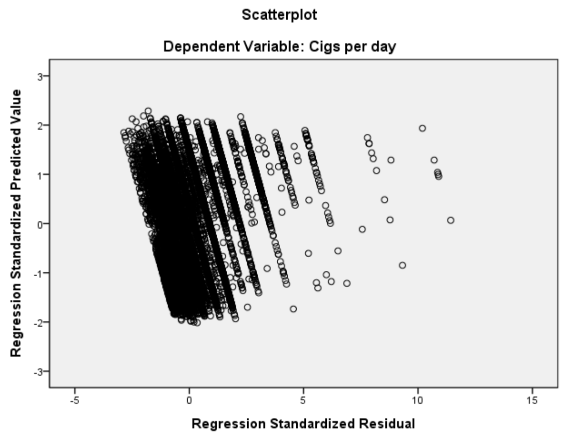


Figure 4B: Graph of standardised residuals against predicted values for the association between the use of NRT for both smoking reduction and temporary abstinence and cigarette consumption

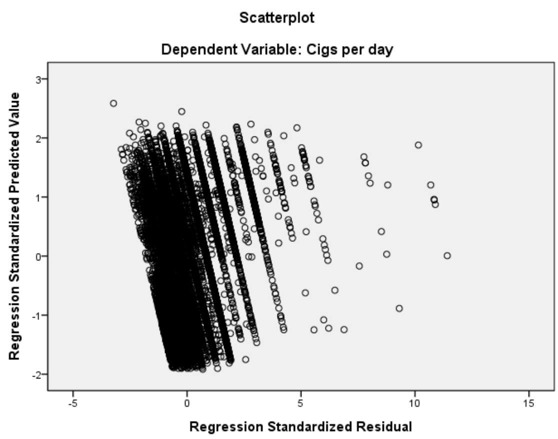


Figure 5B: Graph of standardised residuals against predicted values for the association between the use of NRT for temporary abstinence and cigarette consumption

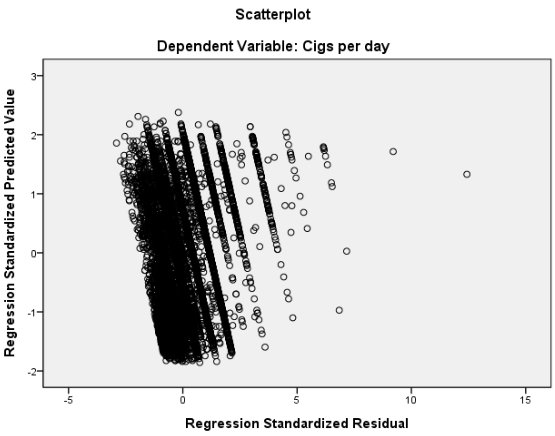


Figure 6B: Graph of standardised residuals against predicted values for the association between the use of NRT for smoking reduction and cigarette consumption

ANOVA

Normality

Table 16B: Kolmogorov-Smirnov statistics for the assessment of differences in cigarette consumption among those using NRT for temporary abstinence, those using NRT for smoking reduction, and those using NRT for both purposes

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Cigarettes per day	NRT for both	.174	1586	.000
	NRT for smoking reduction	.162	1305	.000
	NRT for temporary abstinence	.187	1145	.000
Sqrt(Cigarettes per day)	NRT for both	.124	1586	.000
	NRT for smoking reduction	.122	1305	.000
	NRT for temporary abstinence	.148	1145	.000
Log(Cigarettes per day)	NRT for both	.200	1586	.000
	NRT for smoking reduction	.187	1305	.000
	NRT for temporary abstinence	.173	1145	.000

Homogeneity of Variance

Table 17B: Levene's statistics for assessment of differences in cigarette consumption among those using NRT for temporary abstinence, those using NRT for smoking reduction, and those using NRT for both purposes

	Levene Statistic	df1	df2	Sig.
Cigarettes per day	4.283	2	4033	.014
Sqrt(Cigarettes per day)	.624	2	4044	.536
Log(Cigarettes per day)	2.455	2	4033	.086

Appendix C

Independent Samples *t*-test

Normality

Table 1C: Kolmogorov-Smirnov statistics for the assessment of differences in age and cigarette consumption among those responding between November 2007-June 2009 (Group1) and those responding between July 2009-March 2011 (Group2)

		Kolmogorov-Smirnov[a]		
		Statistic	df	Sig.
Age	Group1	.063	13211	.000
	Group2	.075	9282	.000
Sqrt(Age)	Group1	.056	13211	.000
	Group2	.062	9282	.000
Log(Age)	Group1	.052	13211	.000
	Group2	.059	9282	.000
Cigarettes per day	Group1	.144	13211	.000
	Group2	.145	9282	.000
Sqrt(Cigarettes per day)	Group1	.115	13211	.000
	Group2	.109	9282	.000
Log(Cigarettes per day)	Group1	.202	13211	.000
	Group2	.195	9282	.000

Table 2C: Kolmogorov-Smirnov statistics for the assessment of differences in cigarette consumption among those reporting smoking reduction between November 2007-June 2009 (SR1) and those reporting smoking reduction between July 2009-March 2011 (SR2)

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Cigarettes per day	SR1	.167	7474	.000
	SR2	.166	4878	.000
Sqrt(Cigarettes per day)	SR1	.123	7474	.000
	SR2	.117	4878	.000
Log(Cigarettes per day)	SR1	.200	7474	.000
	SR2	.194	4878	.000

Table 3C: Kolmogorov-Smirnov statistics for the assessment of differences in cigarette consumption among those reporting using NRT for smoking reduction between November 2007-June 2009 (SRNRT1) and those reporting using NRT for smoking reduction between July 2009-Februrary 2011 (SRNRT2)

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Cigarettes per day	SRNRT1	.167	1859	.000
	SRNRT2	.172	1204	.000
Sqrt(Cigarettes per day)	SRNRT1	.126	1859	.000
	SRNRT2	.128	1204	.000
Log(Cigarettes per day)	SRNRT1	.194	1859	.000
	SRNRT2	.204	1204	.000

Homogeneity of Variance

Table 4C: Levene's statistics for the assessment of differences in age and cigarette consumption among those responding between November 2007-June 2009 (Group1) and those responding between July 2009-Februrary 2011 (Group2)

	Levene's Test for Equality of Variances	
	F	Sig.
Age	5.996	.014
Sqrt(Age)	5.202	.023
Log(Age)	3.936	.047
Cigarettes per day	1.385	.239
Sqrt(Cigarettes per day)	8.287	.004
Log(Cigarettes per day)	8.703	.003

Table 5C: Levene's statistics for the assessment of differences in cigarette consumption among those reporting smoking reduction between November 2007-June 2009 (SR1) and those reporting smoking reduction between July 2009-Februrary 2011 (SR2)

	Levene's Test for Equality of Variances	
	F	Sig.
Cigarettes per day	.770	.380
Sqrt(Cigarettes per day)	.216	.642
Log(Cigarettes per day)	2.870	.090

Table 6C: Levene's statistics for the assessment of differences in cigarette consumption among those reporting using NRT for smoking reduction between November 2007-June 2009 (SRNRT1) and those using NRT for smoking reduction between July 2009-Februrary 2011 (SRNRT2)

	Levene's Test for Equality of Variances	
	F	Sig.
Cigarettes per day	4.742	.030
Sqrt(Cigarettes per day)	.812	.367
Log(Cigarettes per day)	.001	.977

Logistic Regression

Multicollinearity

Table 7C: Multicollinearity statistics for the association between socio-demographic characteristics and attempts at smoking reduction (Group1)

	Collinearity Statistics	
Model	Tolerance	VIF
Age	.997	1.003
Social-Grade	.957	1.045
Time to first cigarette	.963	1.038
Gender	.992	1.008

Table 8C: Multicollinearity statistics for the association between socio-demographic characteristics and attempts at smoking reduction (Group2)

	Collinearity Statistics	
Model	Tolerance	VIF
Age	.999	1.001
Social-Grade	.961	1.040
Time to first cigarette	.966	1.035
Gender	.993	1.007

Table 9C: Multicollinearity statistics for the association between socio-demographic characteristics and the use of NRT for smoking reduction (Group1)

Model	Collinearity Statistics	
	Tolerance	VIF
Age	.998	1.002
Social-Grade	.956	1.047
Time to first cigarette	.964	1.038
Gender	.990	1.010

Table 10C: Multicollinearity statistics for the association between socio-demographic characteristics and the use of NRT for smoking reduction (Group2)

Model	Collinearity Statistics	
	Tolerance	VIF
Age	.998	1.002
Social-Grade	.965	1.037
Time to first cigarette	.973	1.027
Gender	.990	1.010

Table 11C: Multicollinearity statistics for the association between attempts at smoking reduction and attempts to quit smoking in the previous 12 months (Group1)

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.991	1.009
Age	.996	1.004
Social-Grade	.957	1.045
Time to first cigarette	.954	1.048
Smoking reduction	.988	1.012

Table 12C: Multicollinearity statistics for the association between attempts at smoking reduction and attempts to quit smoking in the previous 12 months (Group2)

Model	Collinearity Statistics	
	Toleran ce	VIF
Gender	.992	1.008
Age	.998	1.002
Social-Grade	.961	1.040
Time to first cigarette	.959	1.042
Smoking reduction	.991	1.009

Table 13C: Multicollinearity statistics for the association between the use of NRT for smoking reduction and attempts to quit smoking in the previous 12 months (Group1)

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.990	1.010
Age	.996	1.004
Social-Grade	.954	1.048
Time to first cigarette	.959	1.043
Smoking reduction with NRT	.992	1.008

Table 14C: Multicollinearity statistics for the association between the use of NRT for smoking reduction and attempts to quit smoking in the previous 12 months (Group2)

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.989	1.011
Age	.997	1.003
Social-Grade	.965	1.036
Time to first cigarette	.970	1.031
Smoking reduction with NRT	.995	1.005

Linearity of the Logit

Table 15C: Linearity of the logit statistics for the association between age and attempts at smoking reduction (Group1)

	B	S.E.	Wald	Df	Sig.	Exp(B)
Age by (Age)Log	-.001	.000	32.478	1	.000	.999
Constant	.465	.040	135.410	1	.000	1.592

Table 16C: Linearity of the logit statistics for the association between age and attempts at smoking reduction (Group2)

	B	S.E.	Wald	Df	Sig.	Exp(B)
Age by (Age)Log	-.001	.000	8.452	1	.004	.999
Constant	.221	.047	22.295	1	.000	1.248

Table 17C: Linearity of the logit statistics for the association between age and the use of NRT for reduction (Group1)

	B	S.E.	Wald	Df	Sig.	Exp(B)
Age by Log(Age)	.001	.000	10.814	1	.001	1.001
Constant	-1.289	.062	434.701	1	.000	.276

Table 18C: Linearity of the logit statistics for the association between age and the use of NRT for reduction (Group2)

	B	S.E.	Wald	Df	Sig.	Exp(B)
Age by Log(Age)	.001	.000	2.955	1	.086	1.001
Constant	-1.236	.076	262.095	1	.000	.290

Linear Regression

Multicollinearity

Table 19C: Multicollinearity statistics for the association between attempts at smoking reduction and cigarette consumption (Group1)

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.991	1.009
Age	.996	1.004
Social-Grade	.957	1.045
Time to first cigarette	.955	1.047
Smoking reduction	.988	1.012

Table 20C: Multicollinearity statistics for the association between attempts at smoking reduction and cigarette consumption (Group2)

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.992	1.008
Age	.998	1.002
Social-Grade	.961	1.040
Time to first cigarette	.959	1.042
Smoking reduction	.991	1.009

Table 21C: Multicollinearity statistics for the association between the use of NRT for smoking reduction and cigarette consumption (Group1)

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.990	1.010
Age	.996	1.004
Social-Grade	.954	1.048
Time to first cigarette	.959	1.043
Smoking reduction with NRT	.992	1.008

Table 22C: Multicollinearity statistics for the association between the use of NRT for smoking reduction and cigarette consumption (Group2)

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.989	1.011
Age	.997	1.003
Social-Grade	.965	1.037
Time to first cigarette	.970	1.031
Smoking reduction with NRT	.995	1.005

Independent Errors

Table 23C: Independent errors statistics for the association between attempts at smoking reduction and cigarette consumption (Group1)

	Durbin-Watson
Adjusted	1.977

Table 24C: Independent errors statistics for the association between attempts at smoking reduction and cigarette consumption (Group2)

	Durbin-Watson
Adjusted	1.943

Table 25C: Independent errors statistics for the association between the use of NRT for smoking reduction and cigarette consumption (Group1)

	Durbin-Watson
Adjusted	1.971

Table 26C: Independent errors statistics for the association between the use of NRT for smoking reduction and cigarette consumption (Group2)

	Durbin-Watson
Adjusted	1.950

Normality

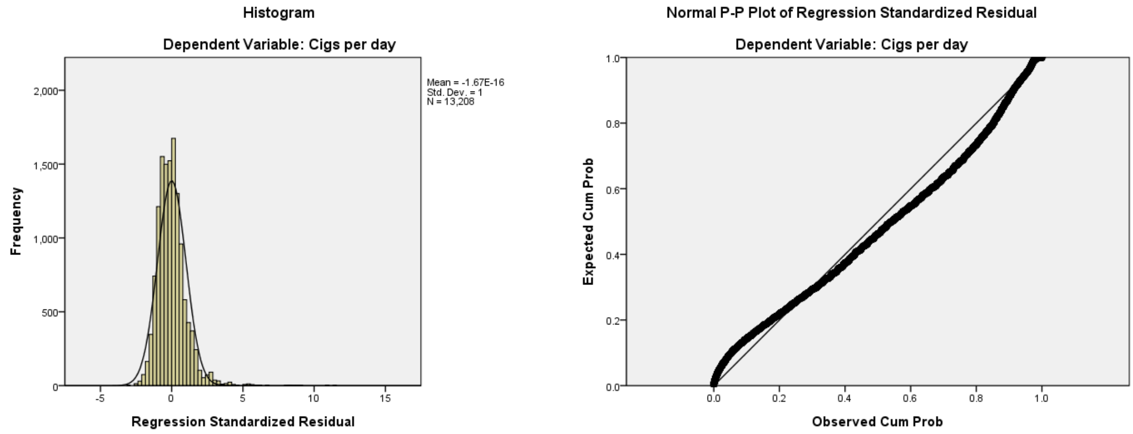


Figure 1C: Histogram and normal probability plot for the association between attempts at smoking reduction and cigarette consumption (Group1)

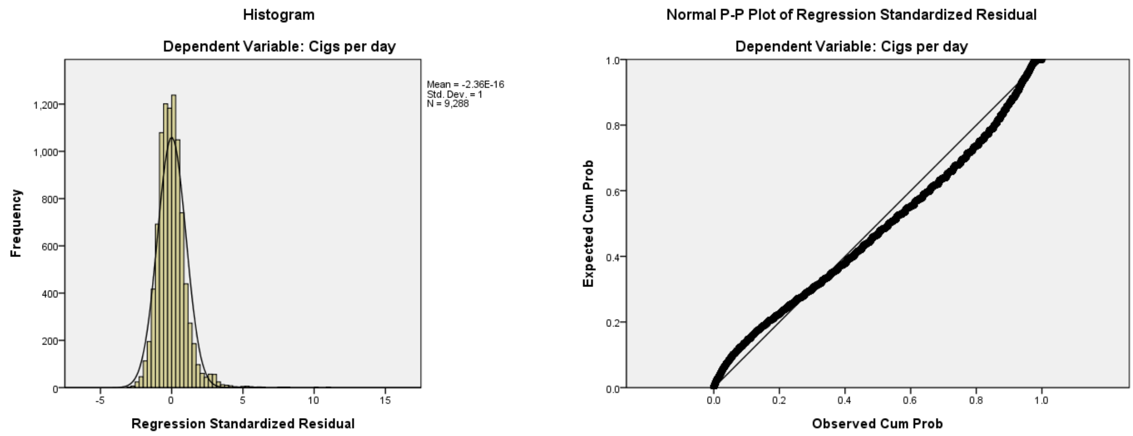


Figure 2C: Histogram and normal probability plot for the association between attempts at smoking reduction and cigarette consumption (Group2)

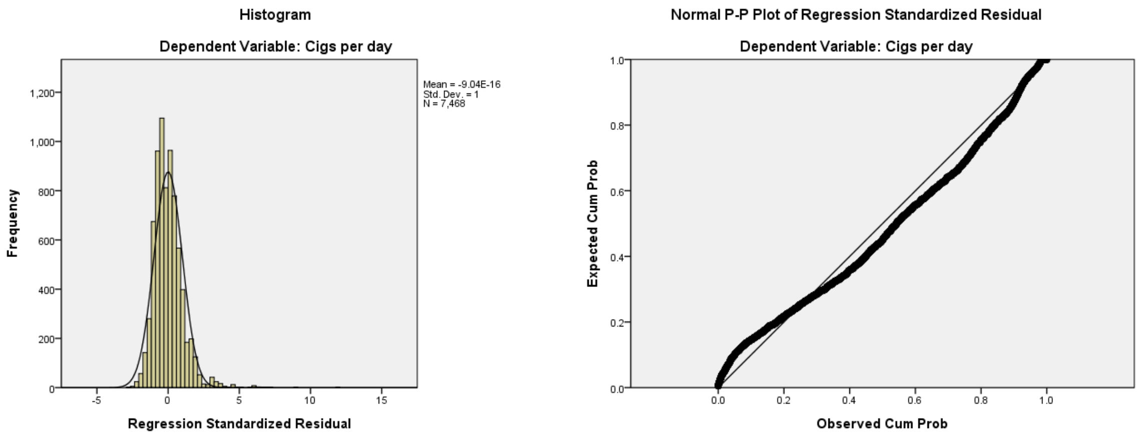


Figure 3C: Histogram and normal probability plot for the association between the use of NRT for smoking reduction and cigarette consumption (Group1)

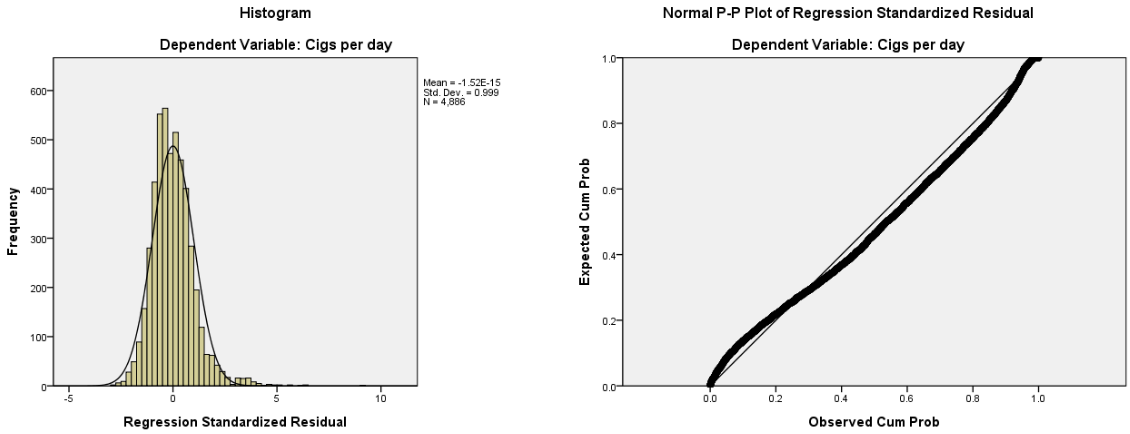


Figure 4C: Histogram and normal probability plot for the association between the use of NRT for smoking reduction and cigarette consumption (Group2)

Homoscedasticity and Linearity

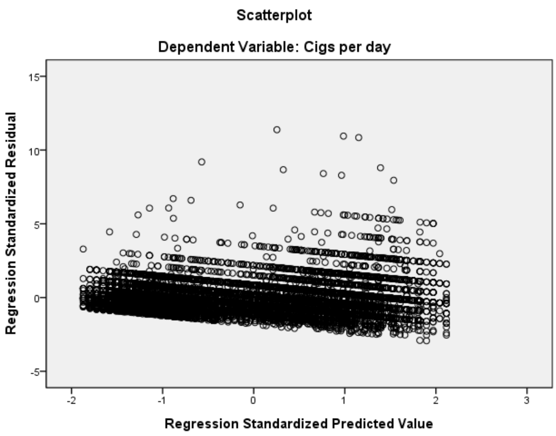


Figure 5C: Graph of standardised residuals against predicted values for the association between attempts at smoking reduction and cigarette consumption (Group1)

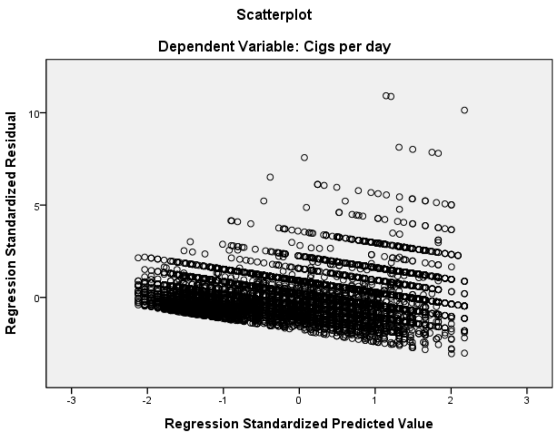


Figure 6C: Graph of standardised residuals against predicted values for the association between attempts at smoking reduction and cigarette consumption (Group2)

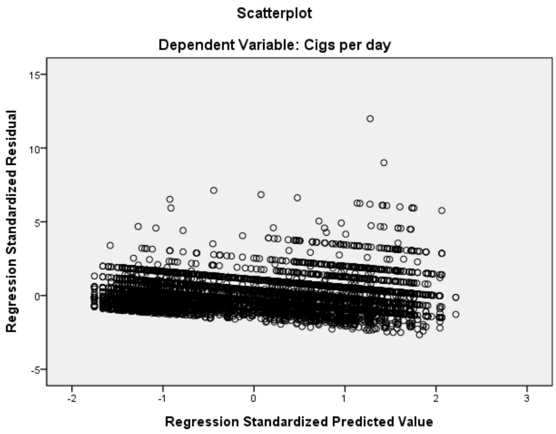


Figure 7C: Graph of standardised residuals against predicted values for the association between the use of NRT for smoking reduction and cigarette consumption (Group1)

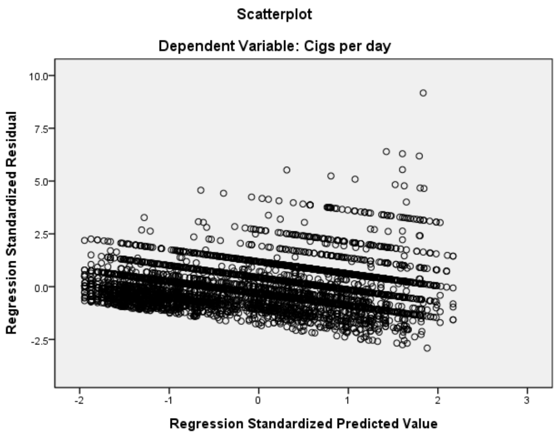


Figure 8C: Graph of standardised residuals against predicted values for the association between the use of NRT for smoking reduction and cigarette consumption (Group2)

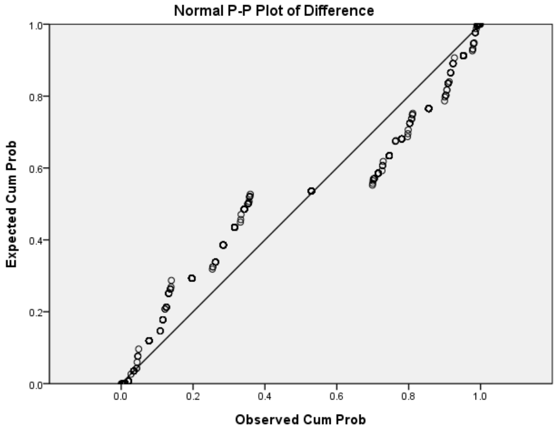
Appendix D

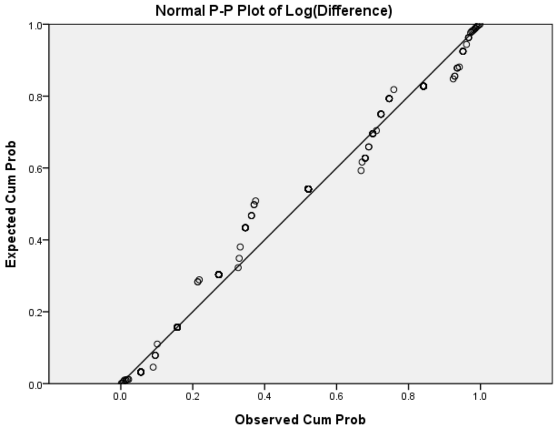
Independent and Paired Samples t-test

Normality

Table 1D: Kolmogorov-Smirnov statistics for the assessment of differences among responders and non-responders in the number of cigarettes smoked per day and age

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Age	Responders	.041	3586	.000
	Non-responders	.074	13424	.000
Sqrt(Age)	Responders	.043	3586	.000
	Non-responders	.064	13424	.000
Log(Age)	Responders	.066	3586	.000
	Non-responders	.056	13424	.000
Cigarettes per day	Responders	.154	3586	.000
	Non-responders	.148	13424	.000
Sqrt(Cigarettes per day)	Responders	.122	3586	.000
	Non-responders	.114	13424	.000
Log(Cigarettes per day)	Responders	.199	3586	.000
	Non-responders	.201	13424	.000





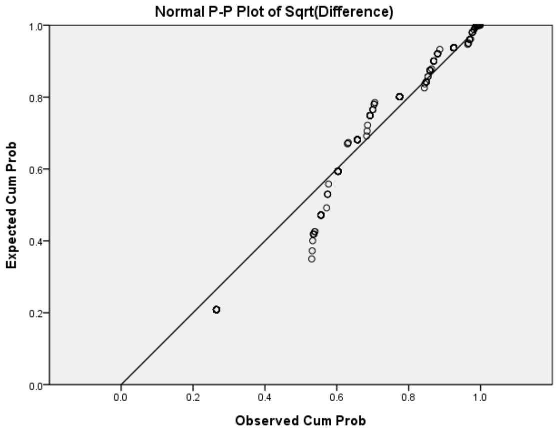


Figure 1D: P-P plots of the differences in cigarette consumption when smokers were and were not attempting smoking reduction

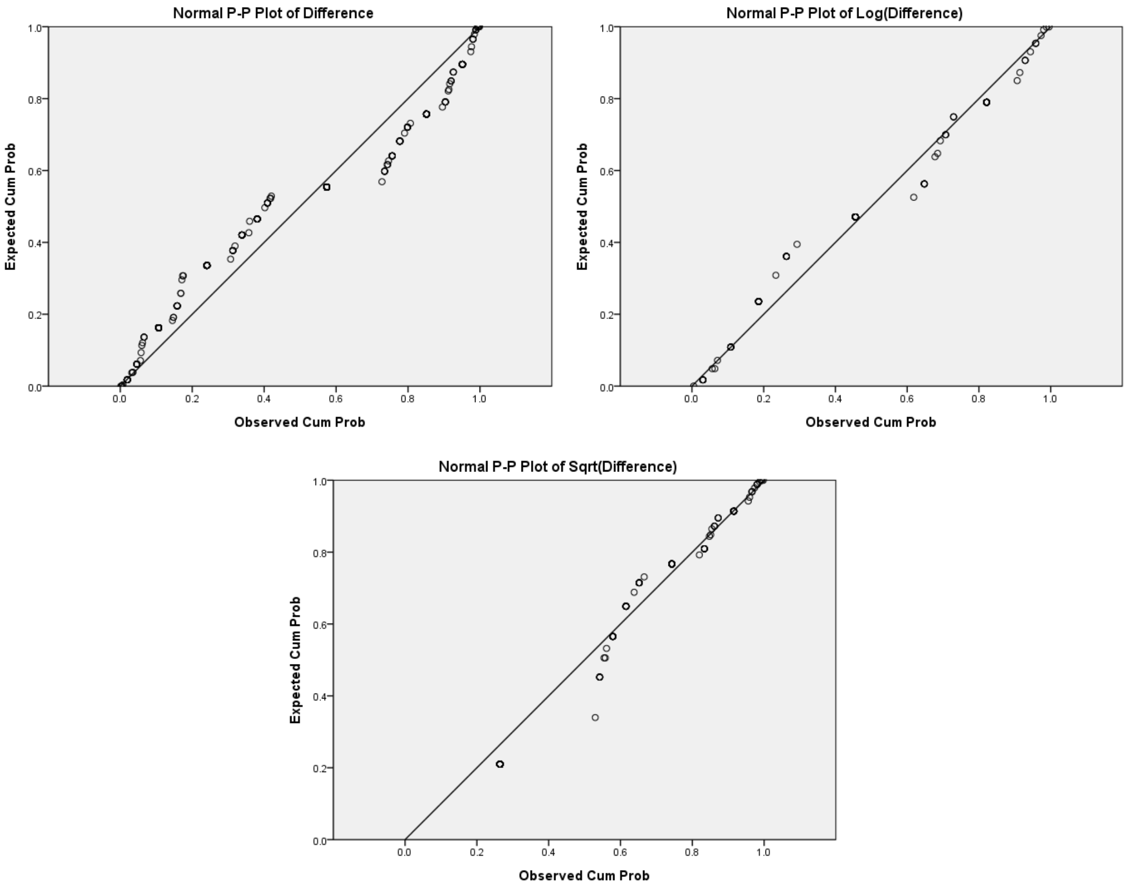


Figure 2D: P-P plots of the differences in cigarette consumption when smokers were and were not using NRT for smoking reduction

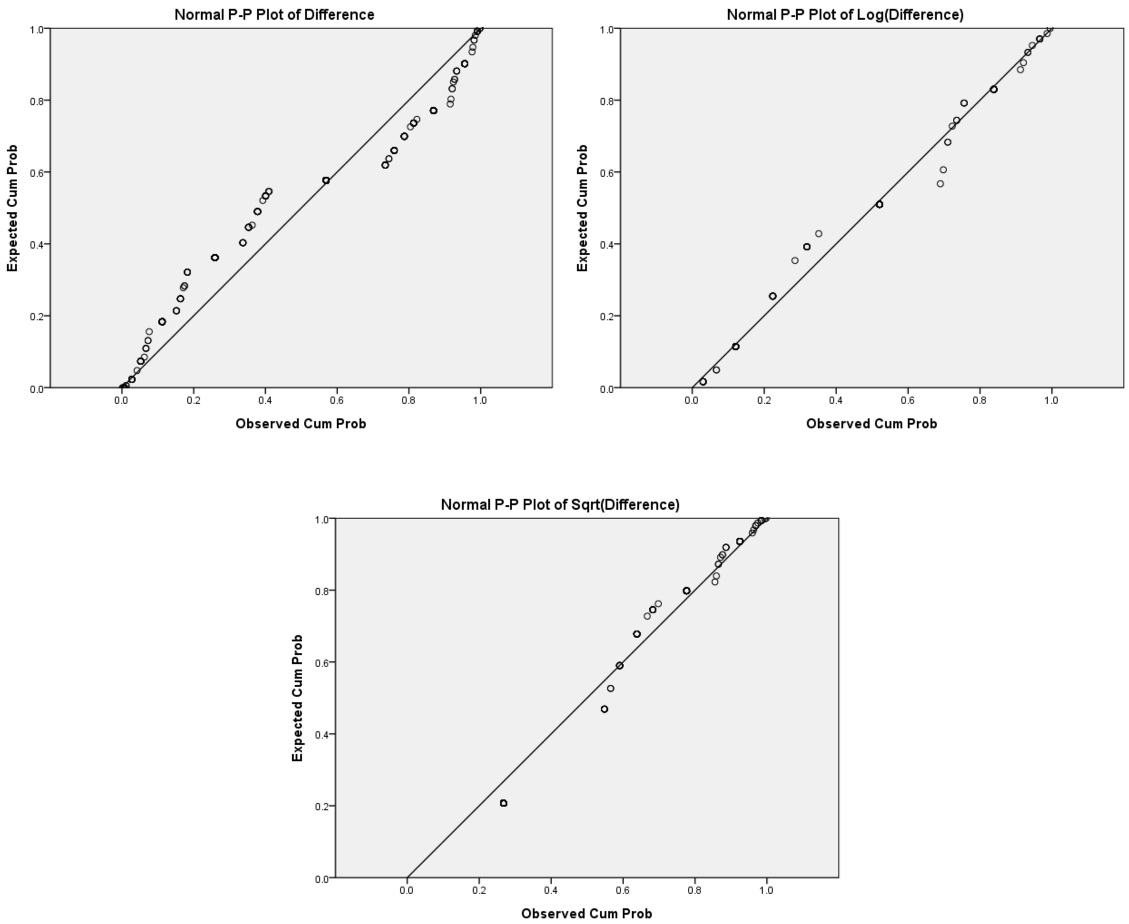


Figure 3D: P-P plots of the differences in cigarette consumption when smokers were and were not using NRT for temporary abstinence

Homogeneity of Variance

Table 2D: Levene's statistics for the assessment of differences among responders and non-responders in the number of cigarettes smoked per day and age

	Levene's Test for Equality of Variances	
	F	Sig.
Age	21.714	.000
Sqrt(Age)	83.005	.000
Log(Age)	191.195	.000
Cigarettes per day	.539	.464
Sqrt(Cigarettes per day)	.172	.678
Log(Cigarettes per day)	3.429	.064

Logistic regression

Multicollinearity

Table 3D: Multicollinearity statistics for the association between the use of NRT for smoking reduction and attempts to quit smoking/smoking status

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.972	1.029
Social-Grade	.964	1.038
Age	.973	1.027
Time to first cigarette	.964	1.037
Smoking reduction with NRT	.992	1.008

Table 4D: Multicollinearity statistics for the association between attempts at smoking reduction and attempts to quit smoking/smoking status

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.981	1.020
Social-Grade	.962	1.039
Age	.985	1.015
Time to first cigarette	.950	1.052
Smoking reduction	.981	1.020

Table 5D: Multicollinearity statistics for the association between the use of NRT for temporary abstinence and attempts to quit smoking/smoking status

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.981	1.019
Social-Grade	.964	1.037
Age	.987	1.013
Time to first cigarette	.961	1.041
Temporary abstinence with NRT	.995	1.005

Table 6D: Multicollinearity statistics for the association between the use of NRT for smoking reduction and the use of NRT for smoking reduction at follow-up

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.972	1.029
Social-Grade	.964	1.038
Age	.973	1.027
Time to first cigarette	.964	1.037
Smoking reduction with NRT	.992	1.008

Table 7D: Multicollinearity statistics for the association between attempts at smoking reduction and attempts at smoking reduction at follow-up

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.981	1.020
Social-Grade	.962	1.039
Age	.985	1.015
Time to first cigarette	.950	1.052
Smoking reduction	.981	1.020

Table 8D: Multicollinearity statistics for the association between the use of NRT for temporary abstinence and the use of NRT for temporary abstinence at follow-up

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.981	1.019
Social-Grade	.964	1.037
Age	.987	1.013
Time to first cigarette	.961	1.041
Temporary abstinence with NRT	.995	1.005

Repeated Measures ANOVA

Normality

Table 9D: Kolmogorov-Smirnov statistics for the assessment of differences in cigarette consumption between baseline and follow-up as a function of smokers stopping and starting attempts at smoking reduction

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Cigarettes per day baseline	Smoking reduction at baseline only	.153	407	.000
	Smoking reduction at follow-up only	.186	673	.000
Cigarettes per day follow-up	Smoking reduction at baseline only	.190	407	.000
	Smoking reduction at follow-up only	.210	673	.000
Sqrt(Cigarettes per day baseline)	Smoking reduction at baseline only	.139	407	.000
	Smoking reduction at follow-up only	.142	673	.000
Sqrt(Cigarettes per day follow-up)	Smoking reduction at baseline only	.144	407	.000
	Smoking reduction at follow-up only	.155	673	.000
Log(Cigarettes per day baseline)	Smoking reduction at baseline only	.189	407	.000
	Smoking reduction at follow-up only	.162	673	.000
Log(Cigarettes per day follow-up)	Smoking reduction at baseline only	.163	407	.000
	Smoking reduction at follow-up only	.165	673	.000

Table 10D: Kolmogorov-Smirnov statistics for the assessment of differences in cigarette consumption between baseline and follow-up as a function of smokers stopping and starting the use of NRT for smoking reduction

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Cigarettes per day baseline	NRT baseline only	.142	288	.000
	NRT follow-up only	.223	175	.000
Cigarettes per day follow-up	NRT baseline only	.193	288	.000
	NRT follow-up only	.260	175	.000
Sqrt(Cigarettes per day baseline)	NRT baseline only	.141	288	.000
	NRT follow-up only	.161	175	.000
Sqrt(Cigarettes per day follow-up)	NRT baseline only	.152	288	.000
	NRT follow-up only	.190	175	.000
Log(Cigarettes per day baseline)	NRT baseline only	.210	288	.000
	NRT follow-up only	.144	175	.000
Log(Cigarettes per day follow-up)	NRT baseline only	.162	288	.000
	NRT follow-up only	.166	175	.000

Table 11D: Kolmogorov-Smirnov statistics for the assessment of differences in cigarette consumption between baseline and follow-up as a function of smokers stopping and starting the use of NRT for temporary abstinence

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Cigarettes per day baseline	NRT baseline only	.189	285	.000
	NRT follow-up only	.212	129	.000
Cigarettes per day follow-up	NRT baseline only	.261	285	.000
	NRT follow-up only	.197	129	.000
Sqrt(Cigarettes per day baseline)	NRT baseline only	.142	285	.000
	NRT follow-up only	.147	129	.000
Sqrt(Cigarettes per day follow-up)	NRT baseline only	.203	285	.000
	NRT follow-up only	.138	129	.000
Log(Cigarettes per day baseline)	NRT baseline only	.147	285	.000
	NRT follow-up only	.142	129	.000
Log(Cigarettes per day follow-up)	NRT baseline only	.155	285	.000
	NRT follow-up only	.144	129	.000

Homogeneity of Variance

Table 12D: Levene's statistics for the assessment of differences in cigarette consumption among those starting and stopping smoking reduction

	F	df1	df2	Sig.
Cigarettes per day baseline	.031	1	1048	.860
Cigarettes per day follow-up	1.907	1	1048	.168

	F	df1	df2	Sig.
Sqrt(Cigarettes per day baseline)	.234	1	1048	.629
Sqrt(Cigarettes per day follow-up)	1.500	1	1048	.221

	F	df1	df2	Sig.
Log(Cigarettes per day baseline)	.107	1	974	.744
Log(Cigarettes per day follow-up)	.005	1	974	.944

Table 13D: Levene's statistics for the assessment of differences in cigarette consumption among those starting and stopping the use of NRT for smoking reduction

	F	df1	df2	Sig.
Cigarettes per day baseline	.001	1	383	.982
Cigarettes per day follow-up	1.406	1	383	.236

	F	df1	df2	Sig.
Sqrt(Cigarettes per day baseline)	.129	1	383	.720
Sqrt(Cigarettes per day follow-up)	3.988	1	383	.047

	F	df1	df2	Sig.
Log(Cigarettes per day baseline)	.723	1	357	.396
Log(Cigarettes per day follow-up)	4.642	1	357	.032

Table 14D: Levene's statistics for the assessment of differences in cigarette consumption among those starting and stopping the use of NRT for temporary abstinence

	F	df1	df2	Sig.
Cigarettes per day baseline	.541	1	437	.462
Cigarettes per day follow-up	4.061	1	437	.044

	F	df1	df2	Sig.
Sqrt(Cigarettes per day baseline)	2.577	1	437	.109
Sqrt(Cigarettes per day follow-up)	4.190	1	437	.041

	F	df1	df2	Sig.
Log(Cigarettes per day baseline)	.869	1	411	.352
Log(Cigarettes per day follow-up)	4.379	1	411	.037

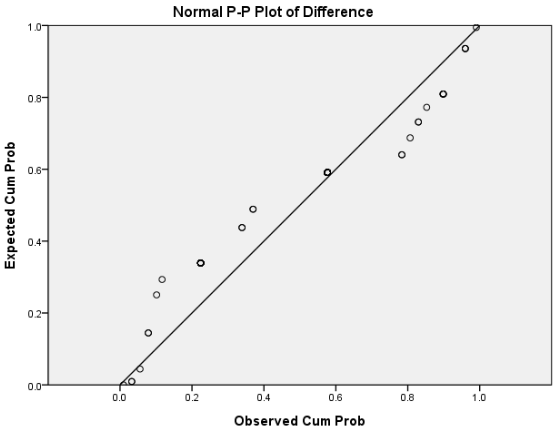
Appendix E

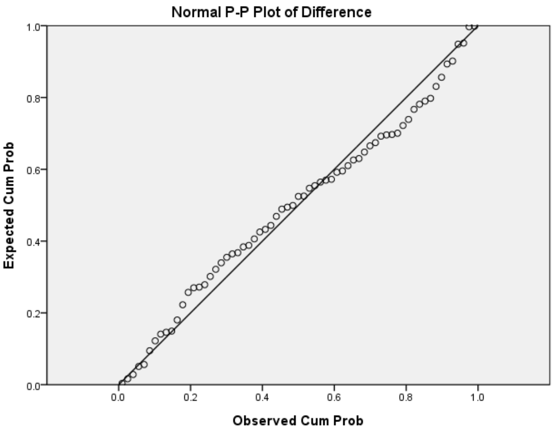
Independent and Paired Samples t-test

Normality

Table 1E: Kolmogorov-Smirnov statistics for the assessment of differences in age and cigarette consumption among responders and non-responders

		Kolmogorov-Smirnov[a]		
		Statistic	df	Sig.
Age	Non-responders	.065	15214	.000
	Responders	.050	604	.001
Sqrt(Age)	Non-responders	.058	15214	.000
	Responders	.058	604	.000
Log(Age)	Non-responders	.053	15214	.000
	Responders	.081	604	.000
Cigarettes per day	Non-responders	.145	15214	.000
	Responders	.182	604	.000
Sqrt(Cigarettes per day)	Non-responders	.113	15214	.000
	Responders	.144	604	.000
Log(Cigarettes per day)	Non-responders	.201	15214	.000
	Responders	.197	604	.000





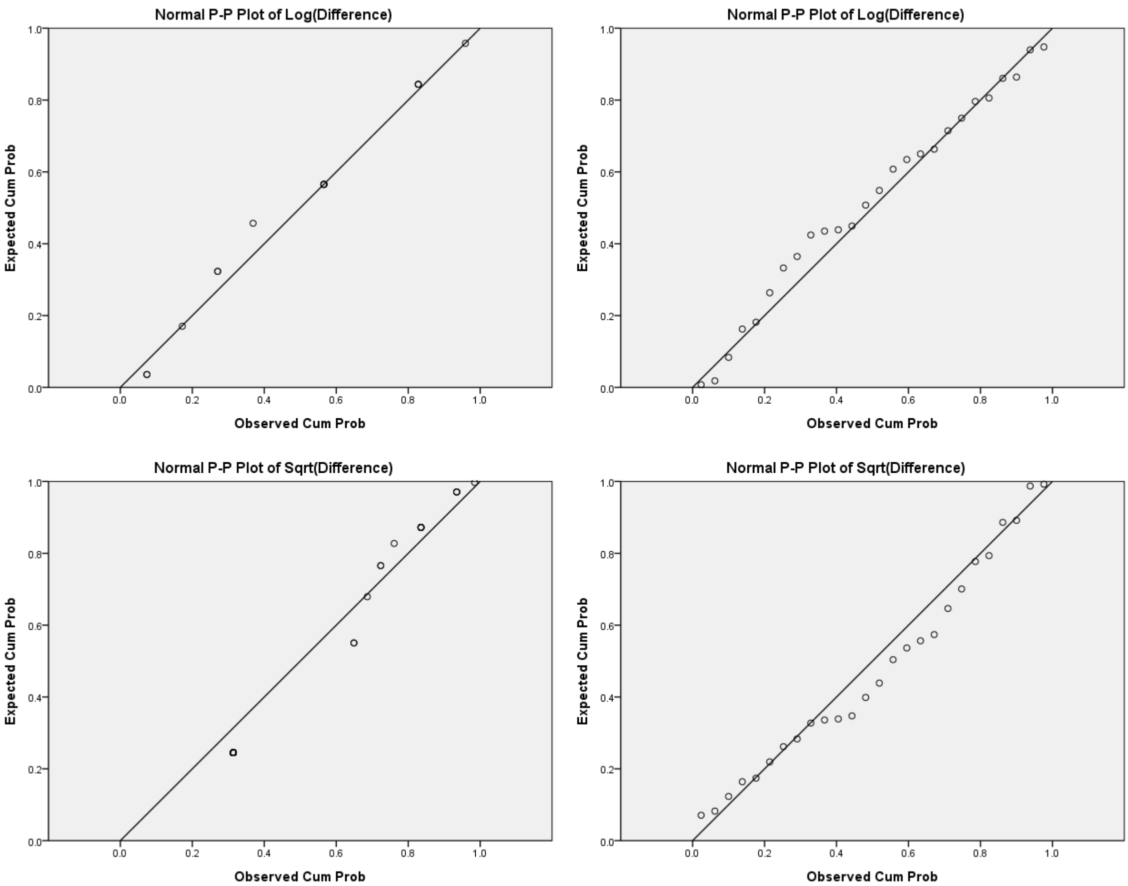
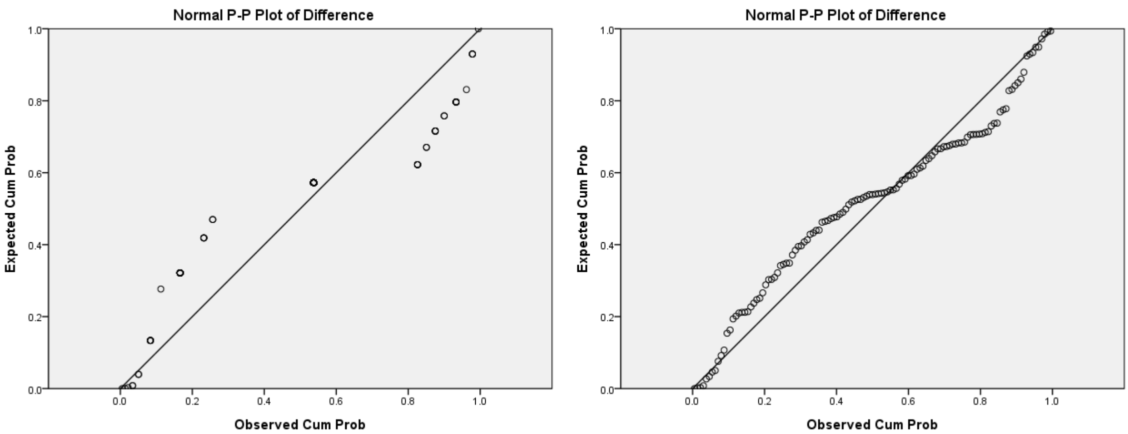


Figure 1E: P-P plots of the differences in cigarette consumption and cotinine when smokers were and were not attempting smoking reduction



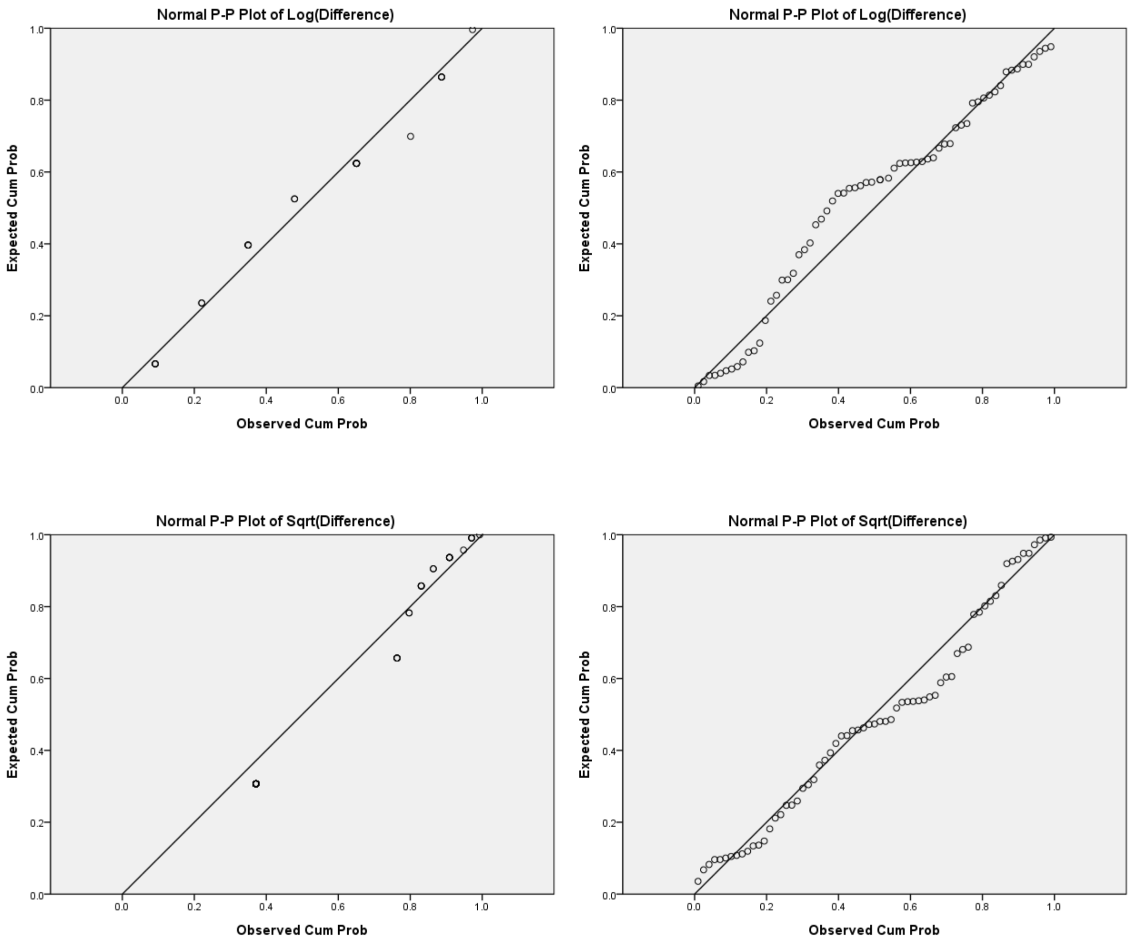


Figure 2E: P-P plots of the differences in cigarette consumption and cotinine when smokers were and were not using NRT for smoking reduction and/or temporary abstinence

Homogeneity of Variance

Table 2E: Levene's statistics for the assessment of differences in age and cigarette consumption among responders and non-responders

	Levene's Test for Equality of Variances	
	F	Sig.
Age	6.625	.010
Sqrt(Age)	17.887	.000
Log(Age)	36.413	.000
Cigarettes per day	.143	.705
Sqrt(Cigarettes per day)	.871	.351
Log(Cigarettes per day)	2.596	.107

Repeated Measures ANOVA

Normality

Table 3E: Kolmogorov-Smirnov statistics for the assessment of differences in cigarette consumption and cotinine between baseline and follow-up as a function of smokers stopping and starting attempts at smoking reduction

		Kolmogorov-Smirnov[a]		
		Statistic	df	Sig.
Cigarettes per day baseline	Smoking reduction at baseline only	.181	57	.000
	Smoking reduction at follow-up only	.256	49	.000
Cigarettes per day follow-up	Smoking reduction at baseline only	.211	57	.000
	Smoking reduction at follow-up only	.263	49	.000
Sqrt(Cigarettes per day baseline)	Smoking reduction at baseline only	.195	57	.000
	Smoking reduction at follow-up only	.170	49	.001
Sqrt(Cigarettes per day follow-up)	Smoking reduction at baseline only	.206	57	.000
	Smoking reduction at follow-up only	.265	49	.000
Log(Cigarettes per day baseline)	Smoking reduction at baseline only	.182	57	.000
	Smoking reduction at follow-up only	.195	49	.000
Log(Cigarettes per day follow-up)	Smoking reduction at baseline only	.181	57	.000
	Smoking reduction at follow-up only	.216	49	.000
Cotinine baseline	Smoking reduction at baseline only	.074	57	.200*
	Smoking reduction at follow-up only	.104	49	.200*
Cotinine follow-up	Smoking reduction at baseline only	.077	57	.200*
	Smoking reduction at follow-up only	.101	49	.200*
Sqrt(Cotinine baseline)	Smoking reduction at baseline only	.205	57	.000
	Smoking reduction at follow-up only	.138	49	.021
Sqrt(Cotinine follow-up)	Smoking reduction at baseline only	.216	57	.000
	Smoking reduction at follow-up only	.141	49	.016
Log(Cotinine baseline)	Smoking reduction at baseline only	.097	57	.200*
	Smoking reduction at follow-up only	.045	49	.200*
Log(Cotinine follow-up)	Smoking reduction at baseline only	.102	57	.200*
	Smoking reduction at follow-up only	.055	49	.200*

Table 4E: Kolmogorov-Smirnov statistics for the assessment of differences in cigarette consumption and cotinine between baseline and follow-up as a function of smokers stopping and starting the use of NRT for smoking reduction and/or temporary abstinence

		Kolmogorov-Smirnov[a]		
		Statistic	df	Sig.
Cigarettes per day baseline	NRT use at Baseline only	.209	29	.002
	NRT use at Follow-up only	.274	29	.000
Cigarettes per day follow-up	NRT use at Baseline only	.172	29	.027
	NRT use at Follow-up only	.150	29	.096
Sqrt(Cigarettes per day baseline)	NRT use at Baseline only	.235	29	.000
	NRT use at Follow-up only	.224	29	.001
Sqrt(Cigarettes per day follow-up)	NRT use at Baseline only	.186	29	.012
	NRT use at Follow-up only	.140	29	.156
Log(Cigarettes per day baseline)	NRT use at Baseline only	.251	29	.000
	NRT use at Follow-up only	.197	29	.005
Log(Cigarettes per day follow-up)	NRT use at Baseline only	.230	29	.000
	NRT use at Follow-up only	.144	29	.131
Cotinine baseline	NRT use at Baseline only	.100	29	.200*
	NRT use at Follow-up only	.170	29	.032
Cotinine follow-up	NRT use at Baseline only	.112	29	.200*
	NRT use at Follow-up only	.165	29	.043
Sqrt(Cotinine baseline)	NRT use at Baseline only	.150	29	.094
	NRT use at Follow-up only	.130	29	.200*
Sqrt(Cotinine follow-up)	NRT use at Baseline only	.135	29	.188
	NRT use at Follow-up only	.118	29	.200*
Log(Cotinine baseline)	NRT use at Baseline only	.228	29	.001
	NRT use at Follow-up only	.087	29	.200*
Log(Cotinine follow-up)	NRT use at Baseline only	.177	29	.021
	NRT use at Follow-up only	.078	29	.200*

Homogeneity of Variance

Table 5E: Levene's statistics for the difference in cigarette consumption among those starting and stopping attempts at smoking reduction

	F	df1	df2	Sig.
Cigarettes per day baseline	3.486	1	119	.064
Cigarettes per day follow-up	.096	1	119	.757
Cotinine baseline	.186	1	119	.667
Cotinine follow-up	.002	1	119	.967

	F	df1	df2	Sig.
Sqrt(Cigarettes per day baseline)	1.061	1	119	.305
Sqrt(Cigarettes per day follow-up)	1.627	1	119	.205
Sqrt(Cotinine baseline)	.022	1	119	.882
Sqrt(Cotinine follow-up)	.276	1	119	.600

	F	df1	df2	Sig.
Log(Cigarettes per day baseline)	1.317	1	104	.254
Log(Cigarettes per day follow-up)	.119	1	104	.731
Log(Cotinine baseline)	.664	1	104	.417
Log(Cotinine follow-up)	.401	1	104	.528

Table 6E: Levene's statistics for the difference in cigarette consumption among those starting and stopping the use of NRT for smoking reduction and/or temporary abstinence

	F	df1	df2	Sig.
Cigarettes per day baseline	.013	1	63	.909
Cigarettes per day follow-up	.013	1	63	.911
Cotinine baseline	1.183	1	63	.281
Cotinine follow-up	.489	1	63	.487

	F	df1	df2	Sig.
Sqrt(Cigarettes per day baseline)	.551	1	63	.461
Sqrt(Cigarettes per day follow-up)	.143	1	63	.706
Sqrt(Cotinine baseline)	.596	1	63	.443
Sqrt(Cotinine follow-up)	.198	1	63	.658

	F	df1	df2	Sig.
Log(Cigarettes per day baseline)	.232	1	56	.632
Log(Cigarettes per day follow-up)	.330	1	56	.568
Log(Cotinine baseline)	.293	1	56	.591
Log(Cotinine follow-up)	1.843	1	56	.180

Appendix F

Logistic Regression

Multicollinearity

Table 1F: Multicollinearity statistics for the association between the use of NRT whilst in the office and attempts to quit smoking in the previous 12 months

	Collinearity Statistics	
Model	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.956	1.046
Age	.999	1.001
Time to first cigarette	.965	1.036
Office	.994	1.006

Table 2F: Multicollinearity statistics for the association between the use of NRT while at home and attempts to quit smoking in the previous 12 months

	Collinearity Statistics	
Model	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.959	1.042
Age	.999	1.001
Time to first cigarette	.964	1.038
Home	.996	1.004

Table 3F: Multicollinearity statistics for the association between the use of NRT while in the pub and attempts to quit smoking in the previous 12 months

	Collinearity Statistics	
Model	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.961	1.041
Age	.999	1.001
Time to first cigarette	.964	1.038
Pub	.998	1.002

Table 4F: Multicollinearity statistics for the association between the use of NRT while in a restaurant and attempts to quit smoking in the previous 12 months

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.960	1.042
Age	.999	1.001
Time to first cigarette	.965	1.037
Restaurant	.999	1.001

Table 5F: Multicollinearity statistics for the association between the use of NRT whilst travelling and attempts to quit smoking in the previous 12 months

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.992	1.008
Social-Grade	.956	1.046
Age	.999	1.001
Time to first cigarette	.963	1.039
Travel	.993	1.007

Table 6F: Multicollinearity statistics for the association between the use of NRT in 'other' situations and attempts to quit smoking in the previous 12 months Association between the

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.960	1.041
Age	.999	1.001
Time to first cigarette	.965	1.037
Other	.999	1.001

Table 7F: Multicollinearity statistics for the association between reports of the helpfulness of NRT and attempts to quit smoking in the previous 12 months

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.990	1.010
Social-Grade	.900	1.111
Actual age (raw data)	.996	1.004
Time to first cigarette	.935	1.070
Helpful	.973	1.028

Linear Regression

Multicollinearity

Table 8F: Multicollinearity statistics for the association between the use of NRT whilst in the office and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.956	1.046
Age	.999	1.001
Time to first cigarette	.965	1.036
Office	.994	1.006

Table 9F: Multicollinearity statistics for the association between the use of NRT while at home and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.959	1.042
Age	.999	1.001
Time to first cigarette	.964	1.038
Home	.996	1.004

Table 10F: Multicollinearity statistics for the association between the use of NRT while in the pub and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.961	1.041
Age	.999	1.001
Time to first cigarette	.964	1.038
Pub	.998	1.002

Table 11F: Multicollinearity statistics for the association between the use of NRT while in a restaurant and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.960	1.042
Age	.999	1.001
Time to first cigarette	.965	1.037
Restaurant	.999	1.001

Table 12F: Multicollinearity statistics for the association between the use of NRT whilst travelling and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.992	1.008
Social-Grade	.956	1.046
Age	.999	1.001
Time to first cigarette	.963	1.039
Travel	.993	1.007

Table 13F: Multicollinearity statistics for the association between the use of NRT in 'other' situations and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.993	1.007
Social-Grade	.960	1.041
Age	.999	1.001
Time to first cigarette	.965	1.037
Other	.999	1.001

Table 14F: Multicollinearity statistics for the association between reports of the helpfulness of NRT and cigarette consumption

Model	Collinearity Statistics	
	Tolerance	VIF
Gender	.990	1.010
Social-Grade	.900	1.111
Actual age (raw data)	.996	1.004
Time to first cigarette	.935	1.070
Helpfulness	.973	1.028

Independent Errors

Table 15F: Independent error statistics for the association between the use of NRT whilst in the office and cigarette consumption

	Durbin-Watson
Adjusted	1.963

Table 16F: Independent error statistics for the association between the use of NRT while at home and cigarette consumption

	Durbin-Watson
Adjusted	1.964

Table 17F: Independent error statistics for the association between the use of NRT while in the pub and cigarette consumption

	Durbin-Watson
Adjusted	1.963

Table 18F: Independent error statistics for the association between the use of NRT while in a restaurant and cigarette consumption

	Durbin-Watson
Adjusted	1.963

Table 19F: Independent error statistics for the association between the use of NRT whilst travelling and cigarette consumption

	Durbin-Watson
Adjusted	1.964

Table 20F: Independent error statistics for the association between the use of NRT while in 'other' situations and cigarette consumption

	Durbin-Watson
Adjusted	1.964

Table 21F: Independent error statistics for the association between reports of the helpfulness of NRT and cigarette consumption

	Durbin-Watson
Adjusted	2.124

Normality

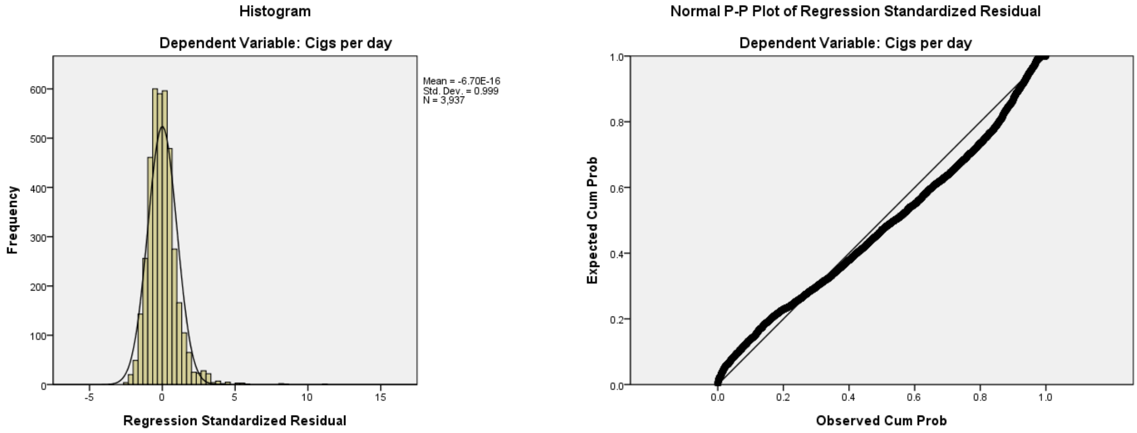


Figure 1F: Histogram and normal probability plot for the association between the use of NRT whilst in the office and cigarette consumption

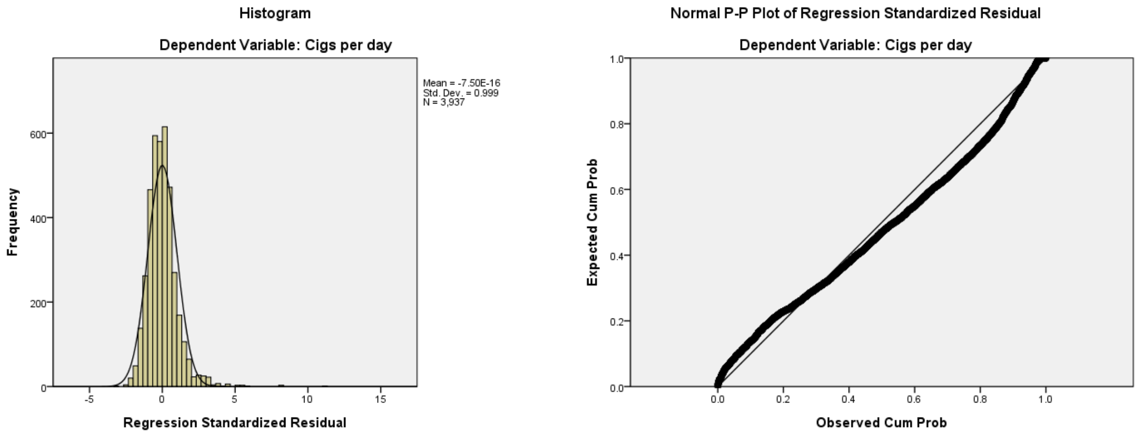


Figure 2F: Histogram and normal probability plot for the association between the use of NRT while at home and cigarette consumption

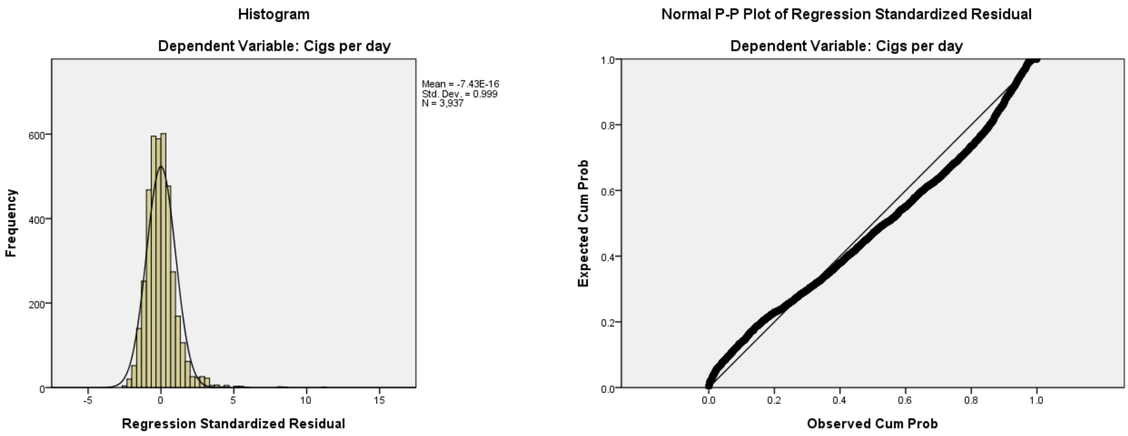


Figure 3F: Histogram and normal probability plot for the association between the use of NRT while in the pub and cigarette consumption

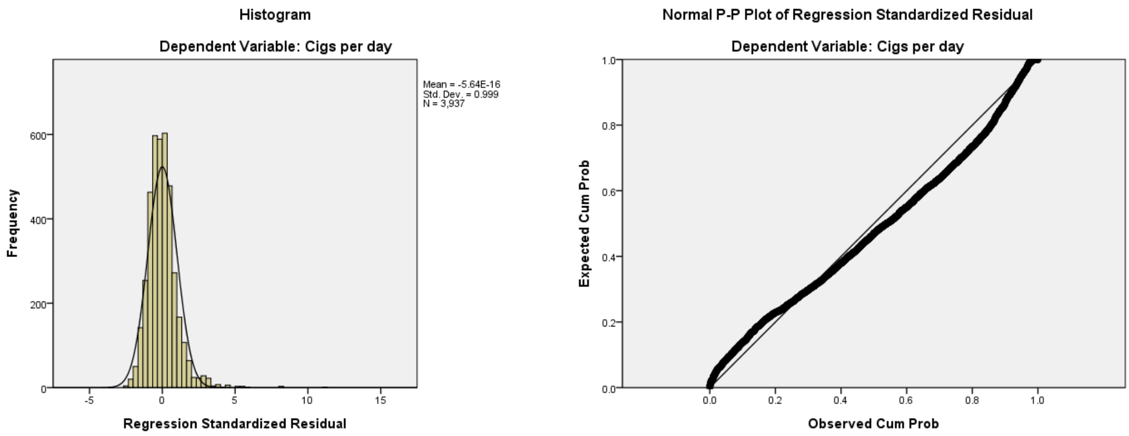


Figure 4F: Histogram and normal probability plot for the association between the use of NRT while in a restaurant and cigarette consumption

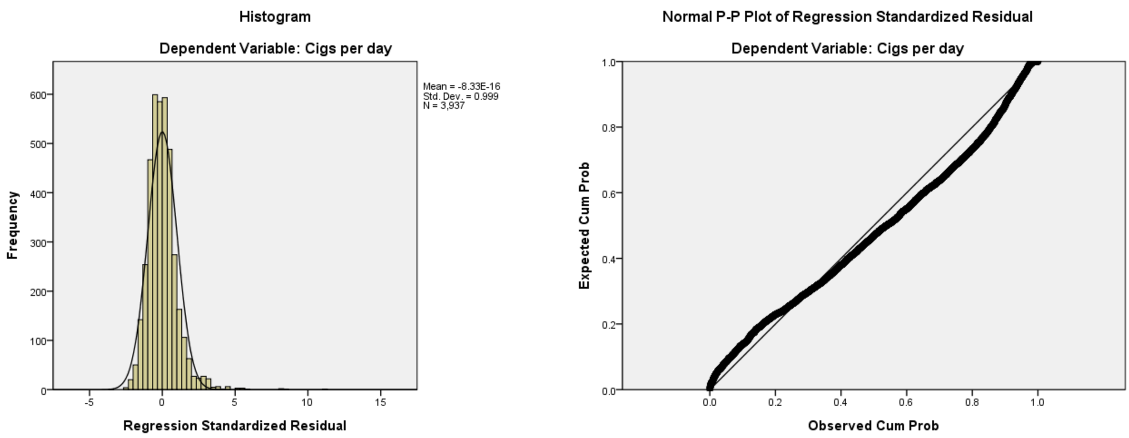


Figure 5F: Histogram and normal probability plot for the association between the use of NRT whilst travelling and cigarette consumption

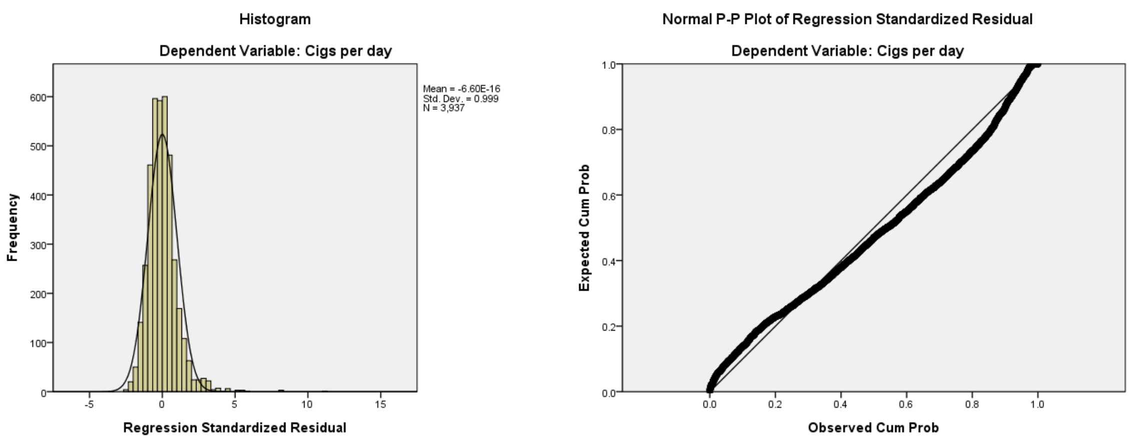


Figure 6F: Histogram and normal probability plot for the association between the use of NRT in 'other' situations and cigarette consumption

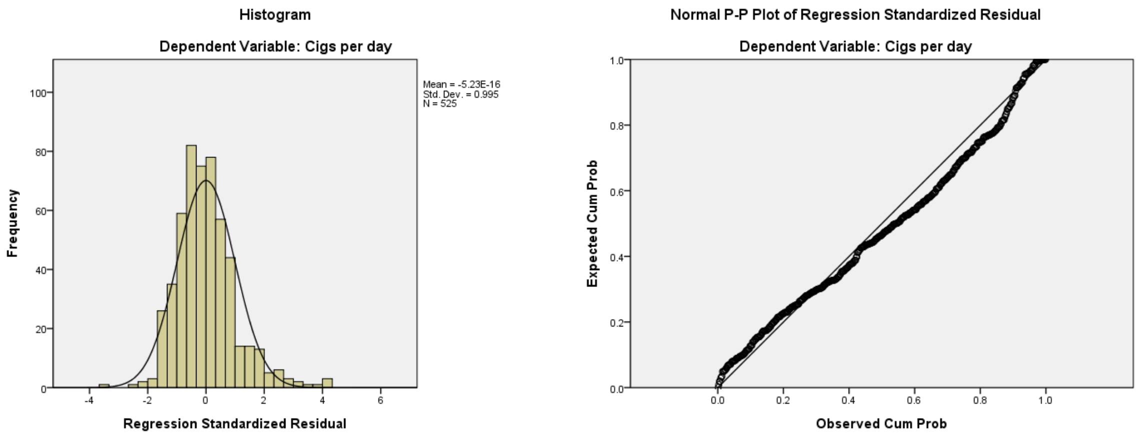


Figure 7F: Histogram and normal probability plot for the association between reports of the helpfulness of NRT and cigarette consumption

Homoscedasticity and Linearity

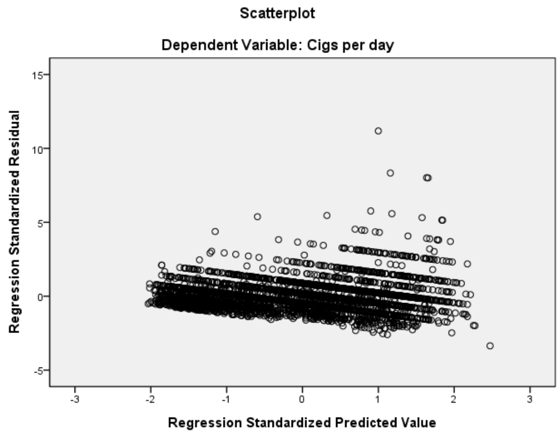


Figure 8F: Graph of standardised residuals against predicted values for the association between use of NRT whilst in the office and cigarette consumption

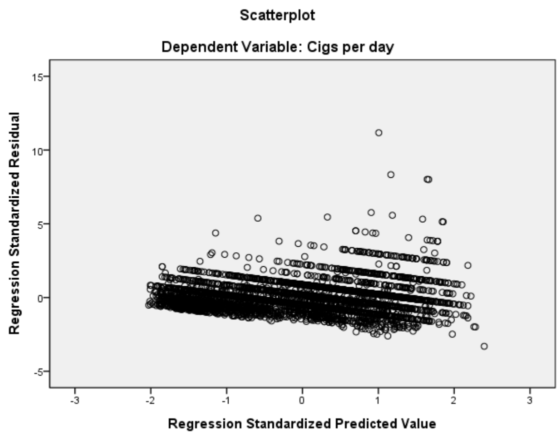


Figure 9F: Graph of standardised residuals against predicted values for the association between use of NRT while at home and cigarette consumption

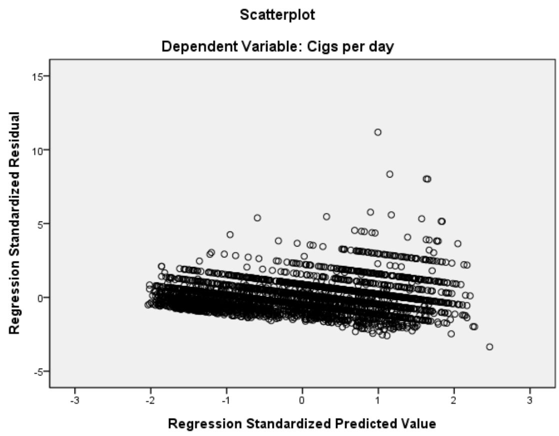


Figure 10F: Graph of standardised residuals against predicted values for the association between use of NRT while in the pub and cigarette consumption

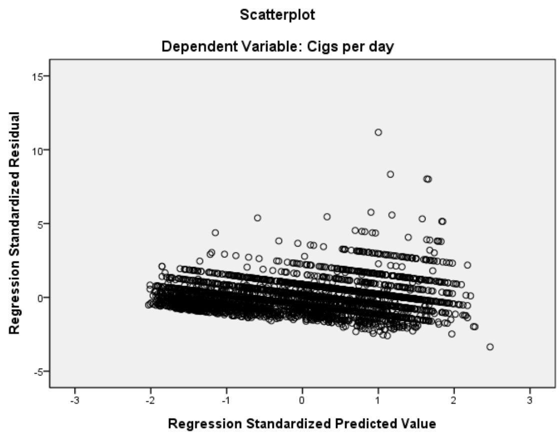


Figure 11F: Graph of standardised residuals against predicted values for the association between use of NRT while in a restaurant and cigarette consumption

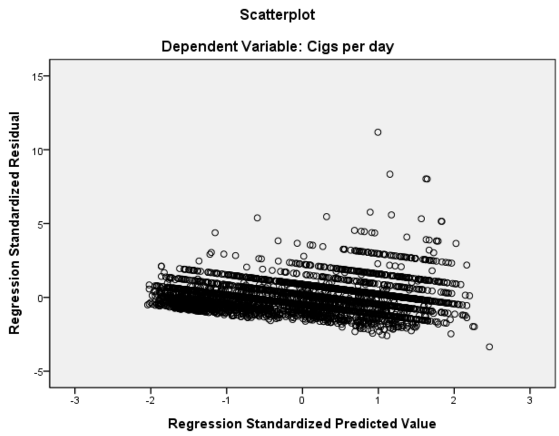


Figure 12F: Graph of standardised residuals against predicted values for the association between use of NRT whilst travelling and cigarette consumption

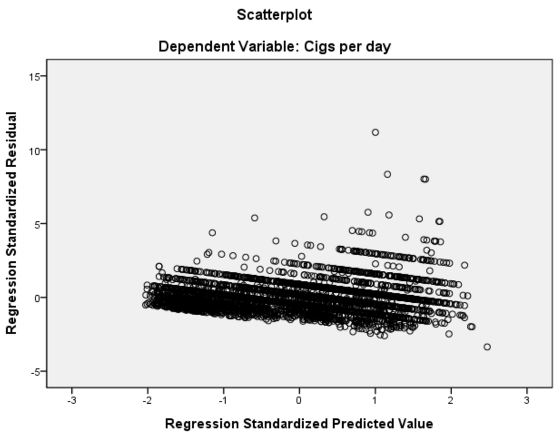


Figure 13F: Graph of standardised residuals against predicted values for the association between use of NRT in 'other' situations and cigarette consumption

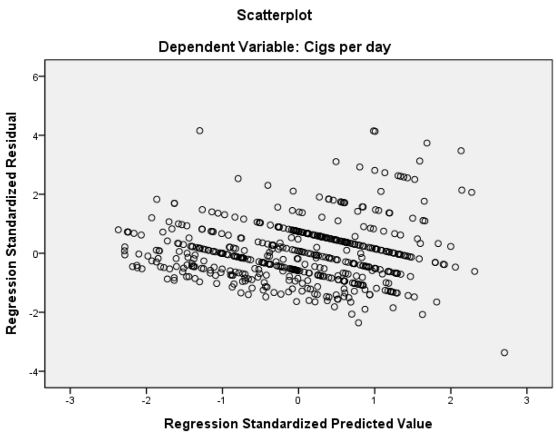


Figure 14F: Graph of standardised residuals against predicted values for the association between reports of the helpfulness of NRT and cigarette consumption

ANOVA

Normality

Table 22F: Kolmogorov-Smirnov statistic for the assessment of differences in age among those using NRT in various situations requiring temporary abstinence

		Kolmogorov-Smirnov[a]		
		Statistic	df	Sig.
Age	Office	.116	30	.200*
	Home	.083	159	.009
	Pub	.078	35	.200*
	Restaurant	.109	13	.200*
	Travelling	.049	108	.200*
	Other	.109	35	.200*
Sqrt(Age)	Office	.127	30	.200*
	Home	.046	159	.200*
	Pub	.101	35	.200*
	Restaurant	.116	13	.200*
	Travelling	.072	108	.200*
	Other	.133	35	.122
Log(Age)	Office	.136	30	.164
	Home	.073	159	.038
	Pub	.139	35	.085
	Restaurant	.131	13	.200*
	Travelling	.104	108	.006
	Other	.176	35	.008

Table 23F: Kolmogorov-Smirnov statistic for the assessment of differences in cigarette consumption among those using NRT in various situations requiring temporary abstinence

		Kolmogorov-Smirnov[a]		
		Statistic	df	Sig.
Cigarettes per day	Office	.193	30	.006
	Home	.183	159	.000
	Pub	.156	35	.030
	Restaurant	.183	13	.200*
	Travelling	.167	108	.000
	Other	.154	35	.035
Sqrt(Cigarettes per day)	Office	.125	30	.200*
	Home	.145	159	.000
	Pub	.129	35	.148
	Restaurant	.164	13	.200*
	Travelling	.159	108	.000
	Other	.098	35	.200*
Log(Cigarettes per day)	Office	.146	30	.103
	Home	.217	159	.000
	Pub	.164	35	.018
	Restaurant	.159	13	.200*
	Travelling	.172	108	.000
	Other	.178	35	.007

Homogeneity of Variance

Table 24F: Levene's statistics for the assessment of differences in age and cigarette consumption among those using NRT in various situations requiring temporary abstinence

	Levene Statistic	df1	df2	Sig.
Age	2.260	5	375	.048
Sqrt(Age)	1.612	5	375	.156
Log(Age)	1.264	5	375	.279
Cigarettes per day	.616	5	374	.688
Sqrt(Cigarettes per day)	.678	5	374	.640
Log(Cigarettes per day)	1.337	5	374	.248

Independent t-test

Normality

Table 25F: Kolmogorov-Smirnov statistic for the assessment of differences in age and cigarette consumption among those using NRT in single or multiple situations requiring temporary abstinence

		Kolmogorov-Smirnov[a]		
		Statistic	df	Sig.
Age	Singular use	.049	380	.027
	Multiple use	.102	129	.002
Sqrt(Age)	Singular use	.058	380	.004
	Multiple use	.094	129	.007
Log(Age)	Singular use	.070	380	.000
	Multiple use	.080	129	.039
Cigarettes per day	Singular use	.160	380	.000
	Multiple use	.135	129	.000
Sqrt(Cigarettes per day)	Singular use	.131	380	.000
	Multiple use	.114	129	.000
Log(Cigarettes per day)	Singular use	.184	380	.000
	Multiple use	.200	129	.000

Homogeneity of Variance

Table 26F: Kolmogorov-Smirnov statistic for the assessment of differences in age and cigarette consumption among those using NRT in single or multiple situations requiring temporary abstinence

	Levene's Test for Equality of Variances	
	F	Sig.
Age	.000	.982
Sqrt(Age)	.100	.752
Log(Age)	.304	.582
Cigarettes per day	.713	.399
Sqrt(Cigarettes per day)	3.860	.050
Log(Cigarettes per day)	9.032	.003

Appendix G

Independent Samples t-test

Normality

Table 1G: Kolmogorov-Smirnov statistics for the assessment of differences in beliefs about the harmful effects of the long-term use of NRT among managers as a function of age, the number of months worked for and the percentage of current role which involves working as a stop smoking manager

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Age	Not harmful	.133	24	.200*
	Harmful	.257	4	.
Sqrt(Age)	Not harmful	.156	24	.135
	Harmful	.260	4	.
Log(Age)	Not harmful	.179	24	.045
	Harmful	.262	4	.
Months worked for	Not harmful	.169	24	.074
	Harmful	.237	4	.
Sqrt(Months worked for)	Not harmful	.155	24	.138
	Harmful	.218	4	.
Log(Months worked for)	Not harmful	.167	24	.081
	Harmful	.224	4	.
Percentage of current role	Not harmful	.275	24	.000
	Harmful	.408	4	.
Sqrt(Percentage of current role)	Not harmful	.161	15	.200*
	Harmful	.278	3	.
Log(Percentage of current role)	Not harmful	.122	15	.200*
	Harmful	.331	3	.

Table 2G: Kolmogorov-Smirnov statistics for the assessment of differences in beliefs about the harmful effects of using NRT for smoking reduction among managers as a function of age, the number of months worked for and the percentage of current role which involves working as a stop smoking manager

		Kolmogorov-Smirnov[a]		
		Statistic	df	Sig.
Age	Not harmful	.109	23	.200*
	Harmful	.211	5	.200*
Sqrt(Age)	Not harmful	.131	23	.200*
	Harmful	.225	5	.200*
Log(Age)	Not harmful	.155	23	.161
	Harmful	.239	5	.200*
Months worked for	Not harmful	.182	23	.047
	Harmful	.239	5	.200*
Sqrt(Months worked for)	Not harmful	.171	23	.081
	Harmful	.249	5	.200*
Log(Months worked for)	Not harmful	.154	23	.167
	Harmful	.259	5	.200*
Percentage of current role	Not harmful	.265	23	.000
	Harmful	.358	5	.035
Sqrt(Percentage of current role)	Not harmful	.134	14	.200*
	Harmful	.264	3	.
Log(Percentage of current role)	Not harmful	.169	14	.200*
	Harmful	.259	3	.

Homogeneity of Variance

Table 3G: Levene's statistics for the assessment of differences in beliefs about the harmful effects of the long-term use of NRT among managers as a function of age, the number of months worked for and the percentage of current role which involves working as a stop smoking manager

	Levene's Test for Equality of Variances	
	F	Sig.
Age	.144	.706
Sqrt(Age)	.188	.667
Log(Age)	.269	.607
Months worked for	1.183	.283
Sqrt(Months worked for)	.012	.915
Log(Months worked for)	.000	.995
Percentage of current role	.173	.679
Sqrt(Percentage of current role)	.375	.544
Log(Percentage of current role)	5.627	.028

Table 4G: Levene's statistics for the assessment of differences in beliefs about the harmful effects of using NRT for smoking reduction among managers as a function of age, the number of months worked for and the percentage of current role which involves working as a stop smoking manager

	Levene's Test for Equality of Variances	
	F	Sig.
Age	.556	.461
Sqrt(Age)	.429	.516
Log(Age)	.407	.527
Months worked for	.008	.930
Sqrt(Months worked for)	.034	.854
Log(Months worked for)	.590	.449
Percentage of current role	.007	.931
Sqrt(Percentage of current role)	.078	.781
Log(Percentage of current role)	1.441	.244

ANOVA

Normality

Table 5G: Kolmogorov-Smirnov statistics for the assessment of differences in beliefs about whether the use of NRT for smoking reduction undermines or promotes cessation among managers as a function of age, the number of months worked for and the percentage of current role which involves working as a stop smoking manager

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Age	Promote	.147	18	.200*
	Hinder	.206	6	.200*
	No effect	.257	4	.
Sqrt(Age)	Promote	.147	18	.200*
	Hinder	.225	6	.200*
	No effect	.279	4	.
Log(Age)	Promote	.146	18	.200*
	Hinder	.243	6	.200*
	No effect	.300	4	.
Months worked for	Promote	.219	18	.022
	Hinder	.270	6	.197
	No effect	.252	4	.
Sqrt(Months worked for)	Promote	.211	18	.033
	Hinder	.255	6	.200*
	No effect	.264	4	.
Log(Months worked for)	Promote	.199	18	.057
	Hinder	.235	6	.200*
	No effect	.270	4	.
Percentage of current role	Promote	.349	18	.000
	Hinder	.374	6	.009
	No effect	.340	4	.
Sqrt(Percentage of current role)	Promote	.168	12	.107
	Hinder	.230	5	.200*
	No effect	.255	4	.
Log(Percentage of current role)	Promote	.186	12	.200
	Hinder	.287	5	.200
	No effect	.240	4	.

Table 6G: Kolmogorov-Smirnov statistics for the assessment of differences in beliefs about the harmful effects of the long-term use of NRT among practitioners as a function of age, the number of months worked for and number of training days received

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Age	Not harmful	.103	288	.000
	Harmful	.094	69	.200*
	Don't know	.092	38	.200*
Sqrt(Age)	Not harmful	.068	310	.002
	Harmful	.063	73	.200*
	Don't know	.088	40	.200*
Log(Age)	Not harmful	.066	310	.002
	Harmful	.096	73	.089
	Don't know	.100	40	.200*
Months in role	Not harmful	.112	288	.000
	Harmful	.181	69	.000
	Don't know	.157	38	.019
Sqrt(Months in role)	Not harmful	.050	288	.073
	Harmful	.129	69	.006
	Don't know	.128	38	.119
Log(Months in role)	Not harmful	.108	288	.000
	Harmful	.065	69	.200*
	Don't know	.131	38	.097
Number of training days	Not harmful	.309	288	.000
	Harmful	.453	69	.000
	Don't know	.261	38	.000
Sqrt (Number of training days)	Not harmful	.252	288	.000
	Harmful	.303	69	.000
	Don't know	.249	38	.000
Log(Number of training days)	Not harmful	.208	288	.000
	Harmful	.250	69	.000
	Don't know	.223	38	.000

Table 7G: Kolmogorov-Smirnov statistics for the assessment of differences in beliefs about the harmful effects of using NRT for smoking reduction among practitioners as a function of age, the number of months worked for and number of training days received

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Age	Not harmful	.104	237	.000
	Harmful	.088	128	.016
	Don't know	.108	19	.200*
Sqrt(Age)	Not harmful	.071	251	.004
	Harmful	.061	140	.200
	Don't know	.133	21	.200
Log(Age)	Not harmful	.066	251	.011
	Harmful	.065	140	.200
	Don't know	.194	21	.038
Months in role	Not harmful	.129	237	.000
	Harmful	.145	128	.000
	Don't know	.147	19	.200*
Sqrt(Months in role)	Not harmful	.074	237	.003
	Harmful	.078	128	.056
	Don't know	.151	19	.200*
Log(Months in role)	Not harmful	.101	237	.000
	Harmful	.096	128	.006
	Don't know	.166	19	.182
Number of training days	Not harmful	.397	237	.000
	Harmful	.311	128	.000
	Don't know	.318	19	.000
Sqrt (Number of training days)	Not harmful	.267	237	.000
	Harmful	.250	128	.000
	Don't know	.254	19	.002
Log(Number of training days)	Not harmful	.206	237	.000
	Harmful	.200	128	.000
	Don't know	.213	19	.024

Table 8G: Kolmogorov-Smirnov statistics for the assessment of differences in beliefs about whether the use of NRT for smoking reduction undermines or promotes cessation among practitioners as a function of age, the number of months worked for and number of training days received

		Kolmogorov-Smirnov[a]		
		Statistic	Df	Sig.
Age	Promote	.083	240	.000
	Hinder	.102	72	.059
	No effect	.078	30	.200*
	Don't know	.171	36	.009
Sqrt(Age)	Hinder	.060	255	.029
	No effect	.087	77	.200*
	Don't know	.073	35	.200*
	Don't know	.138	38	.065
Log(Age)	Promote	.063	255	.016
	Hinder	.106	77	.032
	No effect	.108	35	.200*
	Don't know	.130	38	.107
Months in role	Promote	.133	240	.000
	Hinder	.145	72	.001
	No effect	.107	30	.200*
	Don't know	.169	36	.011
Sqrt(Months in role)	Promote	.075	240	.002
	Hinder	.094	72	.192
	No effect	.066	30	.200*
	Don't know	.092	36	.200*
Log(Months in role)	Promote	.100	240	.000
	Hinder	.106	72	.045
	No effect	.171	30	.025
	Don't know	.128	36	.141
Number of training days	Promote	.399	240	.000
	Hinder	.261	72	.000
	No effect	.386	30	.000
	Don't know	.269	36	.000
Sqrt(Number of training days)	Promote	.266	240	.000
	Hinder	.231	72	.000
	No effect	.324	30	.000
	Don't know	.238	36	.000
Log(Number of training days)	Promote	.201	240	.000
	Hinder	.188	72	.000
	No effect	.284	30	.000
	Don't know	.191	36	.002

Homogeneity of Variance

Table 5G: Kolmogorov-Smirnov statistics for the assessment of differences in beliefs about whether the use of NRT for smoking reduction undermines or promotes cessation among managers as a function of age, the number of months worked for and the percentage of current role which involves working as a stop smoking manager

	Levene Statistic	df1	df2	Sig.
Age	.853	2	36	.435
Sqrt(Age)	.755	2	36	.477
Log(Age)	.677	2	36	.515
Months worked for	1.239	2	38	.301
Sqrt(Months worked for)	.317	2	38	.730
Log(Months worked for)	1.848	2	28	.176
Percentage of current role	1.790	2	39	.180
Sqrt(Percentage of current role)	.017	2	39	.983
Log(Percentage of current role)	10.374	2	18	.001

Table 10G: Levene's statistics for the assessment of differences in beliefs about the harmful effects of the long-term use of NRT among practitioners as a function of age, the number of months worked for and number of training days received

	Levene Statistic	df1	df2	Sig.
Age	.708	2	421	.493
Sqrt(Age)	1.347	2	421	.261
Log(Age)	.741	2	420	.477
Months in role	4.051	2	422	.018
Sqrt(Months in role)	2.027	2	422	.133
Log(Months in role)	3.435	2	420	.033
Number of training days	3.287	2	424	.038
Sqrt(Number of training days)	.930	2	424	.395
Log(Number of training days)	.337	2	411	.714

Table 11G: Levene's statistics for the assessment of differences in beliefs about the harmful effects of using NRT for smoking reduction among practitioners as a function of age, the number of months worked for and number of training days received

	Levene Statistic	df1	df2	Sig.
Age	.646	2	410	.525
Sqrt(Age)	1.051	2	409	.164
Log(Age)	1.815	2	410	.350
Months in role	.548	2	412	.579
Sqrt(Months in role)	.249	2	412	.779
Log(Months in role)	5.464	2	410	.005
Number of training days	.357	2	414	.700
Sqrt(Number of training days)	.769	2	414	.464
Log(Number of training days)	1.510	2	401	.222

Table 12G: Levene's statistics for the assessment of differences in beliefs about whether the use of NRT for smoking reduction undermines or promotes cessation among practitioners as a function of age, the number of months worked for and number of training days received

	Levene Statistic	df1	df2	Sig.
Age	2.171	3	401	.091
Sqrt(Age)	1.891	3	401	.130
Log(Age)	1.904	3	401	.128
Months in role	2.583	3	403	.053
Sqrt(Months in role)	1.296	3	403	.275
Log(Months in role)	.181	3	401	.909
Number of training days	.376	3	407	.770
Sqrt(Number of training days)	.513	3	407	.674
Log(Number of training days)	.377	3	395	.770

Appendix H

Those indicating that they are using NRT to cut down

Important notes: if participants are reluctant to provide information use the following prompts (or similar) 'That's interesting, can you tell me more about that?' 'Can you give me an example of ….?'

- Hello, my name is [-------], and I'm calling from University College London. You recently contacted me to say you would be interested in taking part in a study looking at how Nicotine Replacement Therapy products are used for cutting down.
- It will involve a telephone interview which will last about 30 minutes and will be recorded but your name and any other identifying details removed, so what you say will not be connected to you. You have the right to withdraw at any time. Your contact details will only be used to post your voucher to you. Do you have any questions? Would you still like to take part?

Response:

Yes (go to 2)

No – thank them and terminate the call

2. Good. Are you available now?

Response:

No – Record call back information and terminate call

Yes (go to 3)

3. Thank-you. Could I just take a few details first?

    1. Gender
    2. Age/DOB
    3. Ethnicity
    4. Marital status
    5. Contact details
    6. How long smoked for?

4. Firstly could you tell me about your current smoking behaviour?

- Things to cover:
    - How many cigarettes do you smoke now?
    - Have you made any changes to the way you smoke?
    - *If they are still cutting down determine how many they reduced by*

- *If they are not cutting down determine why they are no longer cutting down e.g., have they quit smoking or resumed at a lower or previous level?*

Cutting down

5. You indicated that you are/were cutting down, what do/did you mean by this?

- Things to cover:
  - *What does the term cutting down mean to them? E.g., does it mean just reducing by 1-2 cigarettes or substantially reducing their intake?*
  - *Are they cutting down with an aim to quit or simply reduce?*
  - *What is their ultimate goal? Do they aim to reduce by 50%*
  - *Does cutting down mean smoking less cigarettes or half a cigarette at a time??*
- History of quitting: Do they intend to quit soon? Have they made a quit attempt in the past month etc?

d. Can you tell me a bit more about how you cut down? What strategies did you use?

- Things to cover:
  - *Determine whether they cut down in a structured or unstructured manner e.g., cut down by 1 cigarette per day*
  - *Did they leave out specific cigarettes e.g., the first one of the day?*
  - *Determine whether they use any other medication*
  - *Determine if they use any behavioural strategies e.g., exercise, increasing food consumption*
  - *Determine whether these behaviours were useful*
  - *Where did they find out about them?*

d. What led you to decide to cut down the number of cigarettes you smoke?

- Things to cover:
  - *Determine why they decided to cut down e.g., to save money, advised to or to improve health*
  - *Determine whether they think there are any benefits in reducing cigarette intake*

d. Is this the first time that you have tried to cut down? If not: Can you tell me about when you cut down before?

- Things to cover:
  - *Determine whether they are a chronic 'cutter' or an acute 'cutter'.*
  - *Is this the first time or is there a long history of trying to reduce?*
  - *Why have they cut down before? Why did it fail?*
  - *How long have they been cutting down for?*

Use of NRT

9. Which nicotine replacement products have/are you used/using? How did/do you use them to cut down?

- Things to cover:
  - *Determine which NRT products they used*
  - *Determine how they used them e.g., one piece of gum for every cigarette*
  - *Determine why they chose a specific product over other products e.g., side-effects, more effective, cost etc*
  - *Determine whether they use multiple products and how they use these*

10. Could you explain why you chose to use ------(NRT product) T to help you cut down and whether it was effective?

- Things to cover:
  - *Determine whether personal choice or advised to do so*
  - *Do they think it helped them to cut down and would they use it again?*
  - *How was it effective what did it do?*

11. Before using (----) to cut down on your smoking, had you used this or any other nicotine replacement products before?

- Things to cover:
  - *Have they used it previously for a quit attempts?*
  - *Did they use similar products?*
  - *Did it help?*

12. Only some of the nicotine replacement products are recommended for use in cutting down smoking. Do you know which ones these are?

- Things to cover:
  - Did/would this affect your choice?
  - *Determine how they found out about the regulations e.g., told by health care professional or read on packet etc.*
  - *Did knowledge of the regulations affect their use of NRT?*
  - *If they were aware of the regulations would this make a difference?*

Smoking cessation clinics

14. Have you ever visited a smoking cessation clinic? If yes: Did anyone speak to you about cutting down?

- Things to cover:
  - *Determine whether they have ever been recommended to cut down at a cessation clinic*
  - *Determine if they have heard about it from any other health professional of the media*
  - *Find out what they were told*
  - *Did this affect what they did?*

15. Thank-you for your time. Is there anything else you would like to add?

Those indicating that they are using NRT for temporary abstinence

Hello, my name is [-------], and I'm calling from University College London. You recently contacted me to say you would be interested in taking part in a study looking at the use of Nicotine Replacement Therapy products during times when you are not able to smoke .

It will involve a telephone interview which will last about 30 minutes and will be recorded but your name and any other identifying information removed so that what you say will not be connected to you. You have the right to withdraw at any time. Your contact details will only be used to post you your voucher. Do you have any questions? Would you still like to take part?

Response:

Yes (go to 2)

No – thank them and terminate the call

2. Good. Are you available now?

Response:

No – Record call back information and terminate call

Yes (go to 3)

3. Thank-you. Could I just take a few details first?

1. Gender
2. Age/DOB
3. Ethnicity
4. Marital status
5. Contact details if they would like to receive a brief over view of the results (money?)
6. How long smoked for?

4. Could you tell me a bit about your current smoking behaviour?

- Things to cover:
    - How many cigarettes do you smoke per day?
    - Have you made any changes to the way you smoke?
    - *Have they cut down or quit smoking etc?*
- History of quitting: Do they intend to quit soon? Have they made a quit attempt in the past month etc?

Temporary abstinence

5. Under what circumstances are you unable to smoke?

- Things to cover:
  - *Determine when they must temporarily abstain*
  - *Is it forced or out of choice?*
  - *If out of choice why do they do it? E.g., to reduce intake or protect others from passive smoking?*

NRT products

d. Could you tell me about which NRT products you used and how you used them during periods when you were unable to smoke?

- Things to cover:
  - *Determine which NRT products they used*
  - *Determine how they used them*
  - *Determine why they chose a specific product over other products e.g., side-effects, more effective, cost etc*
  - *Determine whether they use multiple products and how they use these*

d. How did you come to use NRT during times when you are not able to smoke?

- Things to cover:
  - *Determine whether personal choice or advised to do so*
  - *Do they think it helped them to temporarily abstain and would they use it again*
  - How effective was it?

d. Before using ---- during periods where you were unable to smoke, had you used this or any other nicotine replacement product before?

- Things to cover:
  - *Have they used it previously for a quit attempts?*
  - *Did they use similar products?*
  - *Have they used it previously for cutting down or temporary abstinence?*
  - *Did it help?*

9. Only some of the nicotine replacement products are recommended for use during times when you are unable to smoke. Do you know which ones these are?

- Things to cover:
  - *Did/would this affect your choice?*
  - *Determine how they found out about the regulations e.g., told by health care professional or read on packet etc.*
  - *Did knowledge of the regulations affect their use of NRT?*
  - *If they were aware of the regulations would this make a difference?*

10. Apart from using NRT what else did you do to help you during the periods where you are unable to smoke?

- Things to cover:
    - Was this helpful?
    - *Determine whether they use any other medication*
    - *Determine if they use any behavioural strategies e.g., exercise, increasing food consumption*
    - *Determine whether these behaviours were/are useful*
    - *Where did they find out about them?*

Smoking cessation clinics

11. Have you ever visited a smoking cessation clinic? If yes: Did anyone speak to you about coping with the periods of time when you are not able to smoke?

- Things to cover:
    - *Determine whether they have ever been recommended to use NRT for temporary abstinence at a cessation clinic*
    - *Determine if they have heard about it from any other health professional of the media*
    - *Find out what they will told*
    - *Did this affect what they did?*

12. Thank-you for your time. Is there anything else you would like to add?

Appendix I

NHS

Centre for Smoking Cessation and Training

NCSCT Annual Survey of Smoking Cessation Practitioners: 2010

The NHS Centre for Smoking Cessation and Training (NCSCT) has been commissioned by the Department of Health to provide training and resources for those that deliver, manage and commission Stop Smoking Services. This is the second annual survey of smoking cessation practitioners conducted by the NCSCT, which gives you the chance to give us an up to date view of the issues, barriers and systems that are important in your area and will help us to plan the delivery of NCSCT services over the coming years for maximum benefit.

The survey should take no more than 15 minutes to complete. Questionnaire responses and any other information given during the course of the research will be anonymous. All information will be used for research purposes only. Please note that confidentiality will be maintained and it will not be possible to identify you from any report about this study.

For more information on the work of the NCSCT see: www.ncsct.co.uk

Contact details:

Note: This information will not be passed onto anyone but will ensure that we have your correct details and will allow us to contact you in the future about resources and training that may be relevant to your needs.

Do you see smokers on behalf of an NHS Stop Smoking Service? Or are you about to? [radio button] [If no, do not continue]	Yes	No

Name:			
Job title:			
Name of Stop Smoking Service:			
Employing organisation:			
Email address:			
Telephone number:			
Postal address:			
Are you registered with the NCSCT? [radio button]		Yes	No

Some questions about the services you provide:

Please indicate whether you offer the following treatment models: [radio button]		
One-to-one appointments	Yes	No
One-to-one drop-in sessions	Yes	No
Closed group programmes	Yes	No
Rolling group programmes	Yes	No
Telephone advice/counselling	Yes	No
Self-help materials	Yes	No
Peer led sessions	Yes	No
Home visits	Yes	No
Other:	Yes	No
Other: please give details		
Please indicate in which settings your services run: [radio button]		
Central base exclusive to SSS	Yes	No
Primary care settings	Yes	No

Secondary health care settings (e.g. hospitals)	Yes	No
Commercially rented venues	Yes	No
Voluntary sector/Local Authority premises	Yes	No
Pharmacies	Yes	No
Work places	Yes	No
Other:	Yes	No
Other: please give details		

Do you routinely ask clients about cannabis use? [radio button]			Yes	No
Do you routinely ask clients about their mental health? [radio button]			Yes	No
How often in your role as a stop smoking practitioner are you asked about weight? [radio button]				
Never	Rarely	Sometimes	Very often	Always
If you are asked about weight, what dietary advice do you give quitting smokers for preventing weight gain? (pick one)				
None, they should stop smoking first and not worry about putting on weight				
Some, they should try and choose healthy foods when they get hungry				
Lots, I help them to set individual goals for changing their eating habits, reducing their calories to control their weight as well as giving up smoking				
What is your approach to gradual versus abrupt cessation? (please select one answer) [radio button]				
I always use the abrupt cessation model i.e. smokers smoke they wish until the quit date and stop abruptly at that point				
I encourage abrupt cessation but allow smokers to cut down gradually if they do not feel they can manage to stop abruptly				
I encourage smokers to cut down gradually before stopping				
How many smokers set a quit date with you in the past 12 months? (please select one answer) [radio button]				
Don’t know				
1-10				

11-25	
26-50	
51-100	
101-150	
151-200	
201-250	
251-300	
301-350	
351-400	
<400	
What percentage of these were CO-verified 4-week quitters? (please select one answer) [radio button]	
Don’t know	
0-10%	
11-20%	
21-30%	
31-40%	
41-50%	
51-60%	
>60%	

Please indicate how much you agree with the following statements: [radio button]	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
Group treatment for smoking cessation is more effective than one-to-one					
It is difficult to recruit enough clients at one time to run successful groups					
Running groups requires additional skills to					

delivering one to one interventions					
Carbon Monoxide testing is an important part of the assessment process					
Carbon Monoxide validation is an important marker of data quality					
All stop smoking advisers should be trained in CO monitoring and provided with the necessary equipment to carry it out					

Are you provided with a carbon monoxide (CO) monitor for use with clients? [radio button]	Yes	No
Do you **regularly** monitor client's carbon monoxide (CO) levels to validate their self-reported abstinence? [radio button]	Yes	No
Do you ever recommend a particular medication to clients? [radio button]	Yes	No

If **Yes**, which medication do you most frequently recommend that clients use? (**Please select one only**) [radio button]	
Varenicline (Champix)	
Bupropion (Zyban)	
Nicotine patch (16 hour)	
Nicotine patch (24 hour)	
Nicotine gum	
Nicotine lozenge	
Nicotine microtab	
Nicotine nasal spray	
Nicotine inhalator	
Combination NRT	

Are you provided with a carbon monoxide (CO) monitor for use with clients? [radio button]	Yes	No
Do you **regularly** monitor client's carbon monoxide (CO) levels to validate their self-reported abstinence?	Yes	No

[radio button]		

We are conducting research into the views of those working in tobacco control on the use of NRT for smoking reduction and would appreciate if you could answer the following questions.

Do you think that nicotine replacement products such as patches and gum are harmful to the health if used for a year or more? (please select one answer): [radio button]			
No	Yes, somewhat harmful	Yes, very harmful	I don't know
If you answered 'yes', what do you think the harms are? (please select all that apply): [radio button]			
Lung cancer			
Oral/ mouth cancer			
Other type of cancer			
Heart attack			
High blood pressure			
Other type of heart disease			
Emphysema, chronic lung disease, COPD			
Addiction			
Nicotine overdose			
Other (please write in box):			
Do you think that nicotine replacement products such as patches and gum are harmful to the health if used while smoking? (please select one answer): [radio button]			
No	Yes, somewhat harmful	Yes, very harmful	I don't know
If you answered 'yes', what do you think the harms are? (please select all that apply): [radio button]			
Lung cancer			
Oral/ mouth cancer			
Other type of cancer			
Heart attack			
High blood pressure			
Other type of heart disease			

Emphysema, chronic lung disease, COPD	
Addiction	
Nicotine overdose	
Other (please write in box):	

Do you think that using nicotine replacement products such as patch or gum to help with cutting down is likely to promote or hinder quitting?			
Promote	Hinder	No effect	Don't know

There is currently some research interest in the smoking histories of stop smoking practitioners; therefore we would be extremely grateful if you could answer the following questions:

Do your clients ask you about your smoking status/ history? [radio button]				
Never	Rarely	Sometimes	Very often	Always

Do you disclose your smoking status/ history if clients ask about it? [radio button]		
No, I do not disclose it	Yes, I disclose it immediately	Yes, but I wait until treatment is complete

If a client asks about your smoking status it reduces my confidence in advising them? [radio button]				
Strongly disagree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Ex-smokers make better stop-smoking practitioners? [radio button]				
Strongly disagree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Do your clients ever question your ability as an practitioner based on your smoking status? [radio button]				
Never	Rarely	Sometimes	Very often	Always

What kind of personal experience of smoking, if any, do you draw on in a consultation? [radio button]			
Your own as a smoker	Others as smokers	Both your own and others as smokers	Neither your own or others
What is your own smoking status? [radio button]			
Current smoker	Former smoker	Never smoked	Would prefer not to answer

Some questions about training, personal development and supervision:

How many days 'off the job' training did you receive when you started working for the NHS Stop Smoking Service? (Please write number in box)	…………………….. days	
Who provided the training for you? (Please write name of training organisation in box)		
Did this training course include an assessment that you had to pass? [radio button]	Yes	No
Was there any 'qualification' attached to attending this course? [radio button]	None	
	Attendance Certificate	
	Certificate	
	Diploma	
	National Vocational Qualification (NVQ)	
	Other (Please give details)	
If **Yes** which organisation issued it? (Please write in box)		
For how many days after your training did you observe an experienced practitioner before seeing clients of your own? (Please write number in box; if 'none' enter '0')	…………………….. days	

How often do you attend 'off the job' update training? [radio button]	
Twice a year	
Once a year	
Once every two years	
Other (please list):	
How do you normally update your knowledge and skills? (select as many as apply) [radio button]	
Attendance at UK National Smoking Cessation Conference (UKNSCC)	
In-house update event	
Event arranged by regional tobacco policy team	

Event arranged by pharmaceutical company		
Study leave for external courses (e.g. post graduate diplomas)		
Web-based learning		
Reading relevant literature		
Peer observation and review		
Other (please list):		
How often do you receive clinical supervision? (Please write number in box; if you do not receive regular clinical supervision write ‘0’ in box)	I receive clinical supervision every……. Months	
Does your post have a Knowledge & Skills Framework (KSF) post outline? [radio button]	Yes	No
Do you regularly take part in a Knowledge & Skills Framework (KSF) review process? [radio button]	Yes	No
Do you have a Personal Development Plan (PDP)? [radio button]	Yes	No
Do you maintain a portfolio to evidence your personal development/ KSF? [radio button]	Yes	No
Have you ever been observed in practice and received feedback? [radio button]		
Have you ever attended the UK National Smoking Cessation Conference (UKNSCC)? [radio button]	Yes	No
Are you a member of the Association for Treatment of Tobacco Use and Dependence (ATTUD)? [radio button]	Yes	No
Are you a member of the British Association of Stop Smoking Practitioners (BASSP)? [radio button]	Yes	No
Are you a member of GlobaLink? [radio button]	Yes	No

Some questions about working in the field of smoking cessation:

Please indicate how much you agree with the following statements: [radio button]	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree

I gain a lot of job satisfaction in my current role					
I feel valued in my current role by other health professionals/ the NHS					
I feel valued in my current role by society					
There is good opportunity for career progression within smoking cessation and tobacco control					
There is good opportunity for career progression out from smoking cessation and tobacco control to other areas of related work (e.g. public health)					
I have good knowledge and skills about tobacco control (e.g. smokefree environments)					
I have good knowledge and skills about smoking cessation					
Service level treatment protocols are important to my delivery of smoking cessation interventions					
I intend to continue working within smoking cessation?					
Smoking cessation practitioners need a body that they can be registered with to demonstrate their competence and ongoing commitment to professional development					
Smoking cessation practitioners need a professional organisation to represent their interests					
I feel that I have job security in the long term					

Some questions about the NCSCT

Are you aware of the NCSCT online Stage 1 training programme? [radio button]	Yes	No
If yes, have you started the training programme? [radio button]	Yes	No
If no, please state why not (please write in box)		
If yes, have you found it useful? [radio button]	Yes	No

Please give reasons for why you did/ did not find them useful (please write in box)	

Some questions about you:

Are you: [radio button]	Male	Female	No answer
How old are you? (please write age in box)			……Years
How long have you been working in NHS stop smoking services? (please write in box)			…...Years. …..Months
Are you a stop smoking practitioner whose main role is the provision of intensive support for highly dependent smokers? [radio button]		Yes	No
If **Yes**, are you employed on: [radio button]			Band 7 advisor
			Band 6 advisor
			Band 5 advisor
			Band 4 advisor
			Other (please list):
Does your role involve providing structured support programmes for other lifestyle issues (e.g. weight management , alcohol…)?		Yes	No
If yes, please state which			
Are you a stop smoking practitioner who delivers structured support to smokers, but where this is not the main role of your job		Yes	No
If **Yes**, are you a: [radio button]			
Practice nurse			
Community pharmacist			

Pharmacy assistant		
Health visitor		
Hospital nurse		
GP		
Other (please list):		
Do you **lead** on providing a service to**:** [radio button]	Yes	No
Pregnant smokers		
Young smokers		
Smokers with mental health problems		
Prisoners		
Smokers from routine and manual groups		
Smokers from black and minority ethnic groups		
Smokers in the workplace		
Smokers in hospital		
Other (please list):		
Is there anything that you would like to give us feedback on, or additional information you would like to provide, about your role as a practitioner?		
If you wish to be contacted by the NCSCT to learn more about what we do and the services we offer, please click here.		
How would you prefer to be contacted? (Please choose one)		
Telephone		
Email		
Mail		
Other (please write in box):		

Thank you for completing this survey. The results of the survey will be used to develop resources and training and will be posted on the NHS Centre for Smoking Cessation and Training (NCSCT) website (www.ncsct.co.uk).

Appendix J

NHS
Centre for Smoking Cessation and Training

NCSCT Annual Survey of Managers of Stop Smoking Services: 2010

The NHS Centre for Smoking Cessation and Training (NCSCT) has been commissioned by the Department of Health to provide training and resources for those that deliver, manage and commission Stop Smoking Services. This is the second annual survey of smoking cessation managers conducted by the NCSCT, which gives you the chance to give us an up to date view of the issues, barriers and systems that are important in your area and will help us to plan the delivery of NCSCT services over the coming years for maximum benefit.

The survey should take no more than 15 minutes to complete. Questionnaire responses and any other information given during the course of the research will be anonymous. All information will be used for research purposes only. Please note that confidentiality will be maintained and it will not be possible to identify you from any report about this study.

For more information on the work of the NCSCT see: www.ncsct.co.uk

Contact details:

Note: This information will not be passed onto anyone but will ensure that we have your correct details and will allow us to contact you in the future about resources and training that may be relevant to your needs.

Name:	
Job title:	

Name of Stop Smoking Service:			
Employing organisation:			
Does your service provide stop smoking services to any other PCTs? (please list)			
Email address:			
Telephone number:			
Postal address:			
Are you registered with the NCSCT? [radio button]		Yes	No

Some questions about your service:

Please indicate whether your service offers the following treatment models: [radio button]		
One-to-one appointments	Yes	No
One-to-one drop-in sessions	Yes	No
Closed group programmes	Yes	No
Rolling group programmes	Yes	No
Telephone advice/counselling	Yes	No
Home visits	Yes	No
Self-help materials	Yes	No
Peer led sessions	Yes	No
Other:	Yes	No
Other: (please write in box)		
Does the commissioner of the stop smoking service specify the type of treatment models to be offered? [radio button]	Yes	No

Please indicate in which settings your services run: [radio button]		
Central base exclusive to SSS	Yes	No
Primary care settings	Yes	No
Secondary health care settings (e.g. hospitals)	Yes	No
Commercially rented venues	Yes	No
Voluntary sector/Local Authority premises	Yes	No
Pharmacies	Yes	No
Work places	Yes	No
Other:	Yes	No
Other: (please write in box)		
Does the commissioner of the stop smoking service specify the settings in which the service should run?	Yes	No

How many Whole Time Equivalent (WTE) stop smoking practitioners do you currently employ where providing stop smoking services is the main part of their job? (please write in box)				
Is the stop smoking service you manage responsible for the support/ performance management of other practitioners who incorporate smoking cessation as part of their wider role (e.g. health visitors, practice nurses…)? [radio button]			Yes	No
How many of these other practitioners who incorporate smoking cessation as part of their wider role do you support/ performance manage? (please write in box)				
What proportion of other practitioners who incorporate smoking cessation as part of their wider role do you estimate are ‘active’ (ie have seen over 5 clients in the last 6 months and returned monitoring forms) (please write in box)				%
Is the smoking service responsible for performance monitoring other service providers? [radio button]			Yes	No
Please indicate the breakdown of practitioners who incorporate smoking cessation as part of their	a) Health visitors	%	b) Pharmacists	%

wider role by their profession:	c) Practice nurses	%	d) Midwives	%
	e) Psychologists	%	f) Other *please state role and %*	%
How many other WTE other staff do you employ? (please write in box)		Number	Job title (please write in box)	
	a) Administrators			
	b) Special project staff			
	c) Smoking cessation trainers			
	d) Other			

Do you have a dedicated member of staff who leads on providing a service to: [radio button]	Yes	No
Pregnant smokers		
Young smokers		
Smokers with mental health problems		
Prisoners		
Smokers from routine and manual groups		
Smokers from black and minority ethnic groups		
Smokers in the workplace		
Smokers in hospital		
Other (please list):		

Do you regularly conduct client satisfaction surveys **AND** use the results to configure your service? [radio button]	Yes	No
Do you feedback the results of client satisfaction surveys to the	Yes	No

commissioner of stop smoking services? [radio button]		

Is the NHS Stop Smoking Service that you manage responsible for commissioning serviced from: [radio button]		
GPs?	Yes	No
Pharmacists?	Yes	No
Dentists?	Yes	No
Other?	Yes	No
If other please give details (please write in box):		
Is the NHS Stop Smoking Service that you manage responsible for performance monitoring other service providers who may be commissioned by another organisation? [radio button]	Yes	No
If yes, with whom? (please write in box):		

Does your service have specific targets within the service specification around (please select all that apply):		
Achieving 4 week quit rates targets		
Carbon monoxide (CO) validation rates (minimum of 85%)		
Throughput of smokers from Routine and Manual groups (minimum of 50%)		
Reducing local smoking prevalence		
Reducing or contributing to reducing health inequalities		
Reducing prevalence of smoking during pregnancy		
Working with locally identified target groups, e.g. pregnancy, BME, R&M, etc		
Other (please write in box)		
Do you have regular arranged meetings with your commissioner? [radio button]	Yes	No
Do you think that you have a good relationship with your commissioner? [radio button]	Yes	No
What total annual budget is allocated to your service? (please write in box)	£	

Some questions about the training your staff receives?

How many days theoretical training do your stop smoking practitioners receive when they join your team? (Please write number in box)	…………………….. days
Who provides this training for your staff? (Please write name of organisation in box)	
Do your stop smoking practitioners observe an experienced practitioner before seeing clients on their own? (Please indicate the number of days in box)	…………………….. days

Do staff who lead on providing a service to the following have specialist training relating to their field of work?: [radio button]	Yes	No	N/A	Name of training provider
Pregnant smokers				
Young smokers				
Smokers with mental health problems				
Prisoners				
Smokers from routine and manual groups				
Smokers from black and minority ethnic groups				
Smokers in the workplace				
Smokers in hospital				
Other (please list):				

How often do your **stop smoking practitioners** attend update training? [radio button]	
Twice a year	
Once a year	
Once every two years	
Other (please list):	

<table>
<tr><td colspan="3">Is the stop smoking service responsible for providing training to other practitioners who incorporate smoking cessation as part of their wider role?</td><td>Yes</td><td>No</td></tr>
<tr><td colspan="5">How often do your other practitioners who incorporate smoking cessation as part of their wider role attend update training? [radio button]</td></tr>
<tr><td colspan="4">Twice a year</td><td></td></tr>
<tr><td colspan="4">Once a year</td><td></td></tr>
<tr><td colspan="4">Once every two years</td><td></td></tr>
<tr><td colspan="4">Other (please list):</td><td></td></tr>
<tr><td>Is the requirement to attend update training included within the service level agreement of other providers? [radio button]</td><td>Yes</td><td colspan="2">No</td><td>Don’t know</td></tr>
<tr><td>How is your update training usually organised? (tick as many as apply)</td><td colspan="2">Stop smoking practitioners</td><td colspan="2">Other practitioners</td></tr>
<tr><td>Attendance at UK National Smoking Cessation Conference (UKNSCC)</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td>In-house update event</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td>Event arranged by regional tobacco policy team</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td>Event arranged by regional pharmaceutical company</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td>Study leave for external courses (e.g. post graduate diplomas)</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td>Web-based learning</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td>Other (please list):</td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="3">Do all smoking service practitioners employed by an NHS organisation have a Knowledge & Skills Framework (KSF) outline? [radio button]</td><td>Yes</td><td>No</td></tr>
<tr><td colspan="3">Are staff encouraged to participate in Professional Development Programme (PDP)? [radio button]</td><td>Yes</td><td>No</td></tr>
<tr><td colspan="3">Are practitioners observed in practice as part of the PDP process? [radio button]</td><td>Yes</td><td>No</td></tr>
<tr><td colspan="3">Do you feel users of the stop smoking services would benefit from stop smoking practitioners who are also expertly trained in weight gain prevention?</td><td>Yes</td><td>No</td></tr>
<tr><td colspan="3">If ‘no’, please say why? (please write in box)</td><td colspan="2"></td></tr>
<tr><td colspan="3">What annual budget is allocated for training at your service? (please write in box)</td><td colspan="2"></td></tr>
</table>

Some questions about prescribing at your stop smoking service:

What medications are available through your service as a 1st and 2nd line of treatment: [radio button]	***1st line***		***2nd line***	
NRT	Yes	No	Yes	No
Bupropion (Zyban)	Yes	No	Yes	No
Varenicline (Champix)	Yes	No	Yes	No
Other	Yes	No	Yes	No
please give details:				
What are the criteria for eligibilty to second line treatments? (please write in box)				

How are these medications prescribed? (please select all that apply): [radio button]			
	NRT	Bupropion (Zyban)	Varenicline (Champix)
Patient Group Directive (PGD)			
Nurse prescriber			
Patient's GP			
Voucher scheme			
Please state restrictions for voucher scheme: (please write in box)			
Other			
Please give details:			

If your smoking cessation service supplies stop smoking medication via a PGD, which groups of health professionals are permitted to supply medication (please select all that apply): [radio button]	
Smoking cessation advisors	
Practice nurses	

Pharmacists	
Other (please write in box)	

We are conducting research into the views of those working in tobacco control on the use of NRT for smoking reduction and would appreciate if you could answer the following questions.

Do you think that nicotine replacement products such as patches and gum are harmful to the health if used for a year or more? [radio button]			
No	Yes, somewhat harmful	Yes, very harmful	I don't know

If you answered 'yes', what do you think the harms are? (please select all that apply): [radio button]	
Lung cancer	
Oral/ mouth cancer	
Other type of cancer	
Heart attack	
High blood pressure	
Other type of heart disease	
Emphysema, chronic lung disease, COPD	
Addiction	
Nicotine overdose	
Other (please write in box):	

Do you think that nicotine replacement products such as patches and gum are harmful to the health if used while smoking? (please select one answer): [radio button]			
No	Yes, somewhat harmful	Yes, very harmful	I don't know

If you answered 'yes', what do you think the harms are? (please select all that apply): [radio button]	
Lung cancer	
Oral/ mouth cancer	
Other type of cancer	
Heart attack	
High blood pressure	

Other type of heart disease	
Emphysema, chronic lung disease, COPD	
Addiction	
Nicotine overdose	
Other (please write in box):	

Do you think that using nicotine replacement products such as patch or gum to help with cutting down is likely to promote or hinder quitting? (please select one answer): [radio button]			
Promote	Hinder	No effect	Don't know

Some questions about what you think might help with the managing of stop smoking services:

Please indicate how much you agree with the following statements: [radio button]	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
I gain a lot of job satisfaction from managing my service					
I feel I am able to influence the commissioning process					
I feel fully involved in the strategic planning of my service					

Some questions about data monitoring:

In the last year, has the service participated in any other local monitoring or research beyond that required by DH? [radio button]	Yes	No
If yes, please give details (please write in box):		
Do you seek the views of clients about the service using a questionnaire? [radio button]	Yes	No
If yes, is this the DH recommended client satisfaction tool (found at the back of the SSS Monitoring Guidance)? (please write in box):	Yes	No
If no, please give details:		

Some questions about marketing:

Do you have a trained marketing person supporting your service? [radio button]		Yes	No
If yes, please indicate where they are based: [radio	In LSSS	Yes	No

button]			
	In PCT	Yes	No
	In the regional government office	Yes	No
	In SHA	Yes	No
	Other	Yes	No
	Please give details:		
Do you have a LSSS marketing/promotional budget io010/11? [radio button]		Yes	No
If so, how much is this? (please write in box):			

What has been, in your opinion, the most effective promotional/marketing activity you or your LSSS/ PCT has organised in the last year? (please write in box):		
Do you have any concrete evaluation or evidence to back up your opinion? [radio button]	Yes	No
If yes, what is this? (please write in box):		
Do you have a LSSS marketing plan? [radio button]	Yes	No
What is the key objective of your marketing plan/activity? (please write in box):		
Do you use NHS Smokefree branding? [radio button]	Yes	No
If Yes, do you make use of it in: [radio button]		
Leaflets	Yes	No
Posters	Yes	No
Press ads	Yes	No
Standard letters	Yes	No
Standard forms	Yes	No
Website	Yes	No

Display stands	Yes	No
Other	Yes	No
Please give details:		
Do you routinely ask people how they heard about the service, as well as who referred them? [radio button]	Yes	No

Which days of the week and which hours is your LSSS telephone answered by staff (not answer machine)? (please write in box)		
Who potentially answers the calls? [radio button]		
LSSS Admin	Yes	No
LSSS Advisor/Manager	Yes	No
Wider Public Health team	Yes	No
Other	Yes	No
please state who:		
Does the LSSS log, monitor and analyse the number and time of calls taken per week/month? [radio button]	Yes	No
If so, how many calls are taken on average per week? (please write in box)		
What % of calls taken convert into appointments? (please write in box)	%	

Some questions about the NCSCT

Do you recall seeing the email sent by the NCSCT regarding Stage 1 online training? [radio button]	Yes	No
If yes, have you passed it on to your staff? [radio button]	Yes	No
If no, please state why? (please write in box)		
Have you seen our online resources? [radio button]	Yes	No
If yes, have you found them useful? [radio button]	Yes	No
Please give reasons for why you did/ did not find them useful (please write in box)		

Some questions about you:

Are you: [radio button]		Male	Female	No answer
How old are you? (please write age in box)			……Years	
How long have you been managing stop smoking services? (please write in box)			…...Years.…..Months	
What pay grade are you currently on? (please write in box)				
Can you estimate what percentage of your current role involves the managing of your stop smoking service? (please write in box)			%	
What **other services**, if any, do you also have responsibility to manage? (please write in box and estimate the proportion of your time spent on this)			%	
			%	
Who are you accountable to? (please state job title in box)				
Is there anything that you would like to give us feedback on, or additional information you would like to provide, about your management role?				

Thank you for completing this survey. The results of the survey will be used to develop resources and training and will be posted on the NHS Centre for Smoking Cessation and Training (NCSCT) website (www.ncsct.co.uk).

Appendix K