

**Alcohol screening and brief advice in NHS general dental practices: a cluster randomised controlled feasibility trial.**

**Authors**

Antiopi Ntouva <sup>1</sup>

Jessie Porter <sup>1</sup>

Mike J Crawford <sup>2</sup>

Annie Britton <sup>1</sup>

Christine Gratus <sup>1</sup>

Tim Newton <sup>3</sup>

Georgios Tsakos <sup>1</sup>

Anja Heilmann <sup>1</sup>

Hynek Pikhart <sup>1</sup>

Richard G Watt <sup>1\*</sup>

<sup>1</sup> Department of Epidemiology and Public Health, UCL, UK. <sup>2</sup> Department of Medicine, Imperial College London, UK. <sup>3</sup> King's College London Dental Institute, Kings College London, UK.

\* Corresponding author. Department of Epidemiology and Public Health, 1-19 Torrington Place, UCL, London WC1E 6BT, UK. Tel. +44 20 7679 1699; Fax. + 44 20 7813 0280; Email: r.watt@ucl.ac.uk

## Abstract

**Aim:** To assess the feasibility and acceptability of screening for alcohol misuse and delivering brief advice to eligible patients attending NHS general dental practices in London. **Methods:** A two-arm cluster randomised controlled feasibility trial was conducted. Twelve dental practices were recruited and randomised to intervention and control arms. Participants attending for a dental check were recruited into the study and were eligible if they consumed alcohol above recommended levels assessed by the AUDIT-C screening tool. All eligible participants were asked to complete a short baseline socio-demographic questionnaire. Six months after the completion of baseline measures, all participants were contacted via telephone by a researcher masked to their participant's allocation status. The full AUDIT tool was then administered. Alcohol consumption in the last 90 days was also assessed using the Form 90. A process evaluation assessed the acceptability of the intervention and study procedures. **Results:** Over a 7-month period, 229 participants were recruited (95.4% recruitment rate) and at the 6 months follow-up, 176 participants were assessed (76.9% retention rate). At the 6 months follow-up, participants in the intervention arm were significantly more likely to report a longer abstinence period (3.2 vs. 2.3 weeks respectively,  $p=0.04$ ) and non-significant differences in AUDIT (44.9% vs. 59.8% AUDIT positive respectively,  $p=0.053$ ) and AUDIT C difference between baseline and follow-up (-0.67 units vs -0.29 units respectively,  $p=0.058$ ) scores. Results from the process evaluation indicated that the intervention and study procedures were acceptable to dentists both dental professionals and patients. **Conclusions:** This study has demonstrated the feasibility and acceptability of NHS dentists screening for alcohol misuse and providing brief advice.

## Short summary

The results of this study have demonstrated the feasibility and acceptability of NHS dentists screening for alcohol misuse and delivering brief advice to eligible patients attending general dental practices. Recruitment, retention and delivery targets were all met and the process evaluation demonstrated the intervention and study procedures were acceptable.

**Trial registration number**

ISRCTN81193263.

## Introduction

Excessive alcohol consumption is a major risk factor for a range of oral diseases, the most important being oral cancer (Riedel *et al.*, 2003). In 2016 over 3,700 people were diagnosed with oral cavity cancer and over 3,500 people were diagnosed with oropharyngeal cancer in the UK (Conway *et al.*, 2018). Each year there are more than 7,500 new cases of oral cancer in the UK and over 2,300 people die from the condition annually (Cancer Research UK 2012a; Cancer Research UK 2012b). Over the last two decades there has been a steady rise in oropharyngeal cancers in the UK and several other high income countries (Louie *et al.*, 2015; Conway *et al.*, 2018). Alcohol is a major risk factor for both oral cavity and oropharyngeal cancers (Hashibe *et al.*, 2007; Conway *et al.*, 2018). Around 30% (37% in men and 17% in women) of oropharyngeal cancers are linked to alcohol consumption in the UK (Parkin, 2011). A meta-analysis from 49 publications which included 18,000 cases worldwide, showed a direct dose-risk relationship between alcohol consumption and oral cancer, irrespective of smoking (Turati *et al.*, 2013). Other effects of alcohol on oral health include dental trauma and facial injuries due to accidental falls, road traffic accidents or interpersonal violence (Hutchison *et al.*, 1998), dental erosion (Robb and Smith, 1990), haemorrhage during invasive dental treatment (Scully, 2014), tooth staining and halitosis (Rosenberg *et al.*, 2007; Suzuki *et al.*, 2009).

Nearly 60% of English adults (29.8 million individuals) were seen by NHS dentists over a 2 year period (NHS England, 2014). Studies in Scotland and the US estimate that 25-31% of patients attending dental practices drink alcohol at harmful levels (Goodall *et al.*, 2006; Miller *et al.*, 2006). The direct and significant links between alcohol and oral health, as well as the relatively high rate of patient attendance, suggests that NHS dental practices may be an ideal setting to identify those who are drinking excessively and for offering brief advice.

Increasingly, dentists are involved in providing preventive support including advice about diet and tobacco use (Yusuf *et al.*, 2015). However, screening for excessive alcohol consumption and providing alcohol-related advice in general dental practice is met with reluctance by the majority of dental

practitioners. The main reasons given by dentists for this is the lack of time, funding and training, as well as their attitudes towards alcohol (McAuley *et al.*, 2011). Practitioners also cite a lack of confidence to raise the issue of alcohol as they feel it will potentially damage their rapport with their patients (Shepherd *et al.*, 2011).

Alcohol brief interventions have been successfully used in a variety of settings including general medical settings (Kaner *et al.*, 2013), sexual health clinics (Crawford *et al.*, 2015) and A&E departments (Crawford *et al.*, 2004) and have been shown to be as effective as longer and more complex interventions (Kaner *et al.*, 2007). The short and structured nature of these interventions, as well as the fact that they are specifically designed for non-specialists, make them an ideal tool that dentists could use to screen patients for harmful alcohol consumption and provide brief advice.

A small number of UK studies in maxillofacial settings have investigated screening and delivering alcohol brief advice using motivational interviewing techniques (Smith *et al.*, 2003; Goodall *et al.*, 2008; Oakey *et al.*, 2008). Additionally, two small audits assessed alcohol screening methods in dental hospital emergency clinics (Roked *et al.*, 2014). In primary dental care settings, a study in 13 dental practices in the United States assessed a 3-5 minute intervention for heavy drinkers delivered by dental hygienists combining motivational interviewing and a computer generated personalised feedback report (Neff *et al.*, 2015). Results from 103 patients showed significant decreases in the number of drinks consumed at 6 months follow-up (43% reduction in the intervention arms versus 21% reduction in controls), equivalent to 4 drinks per week difference. However, the study was underpowered and there were issues with selection bias that limited the generalisability of the findings.

There is very limited UK research concerning screening for alcohol misuse and providing advice in NHS general dental practice. In a small study in Bradford, team members from a single general dental practice were trained to use the AUDIT-C tool and provide brief advice. The dental staff successfully screened 29 patients after the training and reported an increase in their confidence in discussing

alcohol with patients (Csikar *et al.*, 2015). A very small randomised controlled trial conducted in one general dental practice in Wales, assessed the feasibility of screening for alcohol misuse using a modified version of the Single Alcohol Screening Question (M-SASQ) questionnaire. In this study, 46 patients were identified as consuming alcohol above the recommended levels and were randomised into receiving a motivational interviewing intervention or usual care. After 3 months, 22 patients (48%) were followed up; 2 patients from the intervention group and 5 from the control group changed their M-SASQ score from positive to negative (Roked *et al.*, 2015).

Given the paucity of research in NHS general dental practices, the question remains whether it is feasible for NHS dentists to be trained to successfully screen and deliver alcohol brief advice to their patients. The Dental Alcohol Reduction Trial (DART) study aimed to assess the feasibility and acceptability of screening for alcohol misuse and delivering brief advice to patients attending NHS general dental practices in London.

## **Methodology**

### **Trial design**

This was a two-arm, cluster randomised controlled feasibility trial. Ethical approval was granted from Camden and Islington Research Ethics Committee (Reference: 13/LO/0292). An overview of the study design is presented here and a detailed description of the study protocol has been published elsewhere (Ntouva *et al.*, 2015).

The study comprised two phases. In the developmental phase, focus groups with dental patients and dental professionals were conducted to explore their general views on alcohol and oral health, and to inform the development of the intervention. In the feasibility phase, dental practices (clusters) were recruited and their staff trained to deliver the intervention, recruit study participants and collect data, and finally the study procedures were evaluated. A cluster design was chosen

We initially sent invitation letters to 293 NHS dental practices across North London. Fifteen practices expressed interest and were then visited by members of the study team to assess their suitability for the study. Twelve practices who were considered suitable for the study were then randomised. The intervention arm was offered a tailor made, comprehensive training programme on alcohol brief advice and oral health. The programme included an overview of the impact of alcohol and oral health but focused mainly on practical aspects of raising the issue of alcohol with dental patients, screening for alcohol misuse and providing brief advice as appropriate, through a combination of practical exercises and role plays. Details of the training programme and its evaluation have been published elsewhere (Ntouva *et al.*, 2016). All participating practices in both arms were offered training on study recruitment methods, data collection and storage, and consent.

## **Participants**

Participants were recruited by dental staff in each dental practice and assessed for eligibility, after obtaining verbal consent. Participants were deemed eligible for the study if they were registered at the participating dental practice, were aged 18 or over, spoke sufficient English to understand the participant information sheet and the brief advice, and scored 5 or above on the AUDIT-C questionnaire (Bush *et al.*, 1998). Participants answered a self-complete paper version of the AUDIT-C questionnaire whilst waiting for their dental appointment. The AUDIT-C questionnaire consists of three questions: 1. How often do you have a drink containing alcohol? 2. How many units of alcohol do you drink on a typical day when you are drinking? 3. How often have you had 6 or more units if female, or 8 or more units if male, on a single occasion in the last year? A score of 5 or above indicated at-risk drinkers. Participants who had underlying medical conditions, were taking part in other dental research or were being treated for alcohol problems were excluded from the study. Eligible participants in both arms were then invited to provide written consent to formally participate. Data

were collected from general dental practices in Islington, Camden, Haringey, Brent, Enfield, and Redbridge across north London.

### **Baseline and follow-up measures**

At baseline, all eligible and consenting participants also completed a short demographic questionnaire and the EuroQol (EQ-5D-5L) questionnaire to measure health related quality of life (Herdman *et al.*, 2011). After 6 months, all participants were contacted by researchers for a follow-up telephone interview. During this interview, the full AUDIT questionnaire (Saunders *et al.*, 1993) was administered along with the EQ-5D-5L and a patient satisfaction questionnaire on dental services received. Alcohol consumption in the past 90 days was also assessed at follow-up using the Form 90 (Tonigan *et al.*, 1997).

### **Interventions**

Eligible participants in the intervention arm were offered brief advice delivered by the dentist during their appointment using a tailored version of the brief advice tool used in the Screening and Intervention Programme for Sensible drinking (SIPS) study (Kaner *et al.*, 2009). The tool included information about the effects of alcohol on oral health and the benefits of reducing alcohol intake to both oral and general health. It also included a graph showing the proportion of people in the UK who drank above, and below, the recommended levels, as well as some practical advice on ways of reducing alcohol intake. The advice was then followed by giving the participant the Change for Life “Don’t let drink sneak up on you” leaflet and - if the participant’s AUDIT-C score was 10 or above - contact details of local alcohol support services.

During their dental appointment, eligible participants in the control arm were given by the dentist a mouth cancer prevention leaflet produced by Cancer Research UK. For ethical reasons it was deemed appropriate to give control participants some form of general health promotion advice and in keeping with other trials of brief advice.



## **Outcomes**

The trial feasibility outcomes assessed were:

- Recruitment rate (number of participants assessed for eligibility, excluded and randomised) measured at the end of the recruitment period. (Target 85% to be recruited within specified recruitment period)
- Retention rate (number of participants followed up, withdrew or were lost to follow-up) measured at the end of the 6-month follow-up. (Target 75% of outcome to be completed at follow-up)
- Eligibility rate (number of participants deemed eligible to take part after screening with the AUDIT-C questionnaire)
- Delivery rate (number of participants allocated to intervention arm received advice) (Target 60% of participants to receive intervention)

The proposed primary outcome for the study was the score on the full AUDIT tool, assessed at the 6-month follow-up by telephone interview. Scores of 8 and above indicated participants as “AUDIT positive” as defined in the SIPS trial (Kaner *et al.*, 2009). Rates of data completeness of the AUDIT questionnaire (% participants who answered all 10 questions) were also assessed at the end of the study. Secondary outcomes included mean weekly units of alcohol consumed in the previous 90 days as measured by Form 90 (Tonigan *et al.*, 1997) average drinks per day and health related quality of life using EQ-5D-5L (Herdman *et al.*, 2011).

## **Sample size**

As this was a feasibility trial, a formal sample size calculation was not performed (Lancaster *et al.*, 2004). Based on pragmatic considerations, a convenience sample of 12 clusters, recruiting around 20 eligible participants per practice was estimated to be required at baseline, totalling 240 eligible participants. Assuming a 30% drop out rate at 6 months, this would give 168 patients at follow-up.

### **Randomisation, allocation concealment and blinding**

Once dental practices were recruited, they were randomly allocated into control and intervention in a ratio of 1 to 1 using simple randomisation performed by a member of the study team not involved in data collection (GT). A cluster design was chosen as the dental practice teams were all trained in the study procedures so individual randomisation would not have been possible and there would have been a high risk of contamination between trial arms. Participants in the control group were not aware the study was related to alcohol, as the screening tool was masked in a lifestyle questionnaire and the baseline data collection did not include any additional alcohol consumption measures. The researchers collecting follow-up data were blind to the participants' allocation status.

### **Statistical methods**

The analyses of this feasibility trial were mainly descriptive as per the study protocol. For both arms, the number of practices approached, randomly assigned to control/intervention, and the recruitment, eligibility and retention rates were reported. Baseline and 6 month follow-up outcome measures were also summarised. Rates of data completeness for the primary and secondary outcomes were calculated. The outcome measures as well as the independent variables were assessed for normality using a histogram as well as the Shapiro Wilk test. Means with 95% CI and medians with interquartile ranges were reported. For normally distributed variables, differences between the control and intervention groups were reported using a t-test with a level of significance at 5%. For non-normally distributed variables, differences between the groups were determined by Mann-Whitney test with a level of significance at 5%. Intention to treat analyses at follow-up were performed with the observations from baseline carried forward for participants who were lost to follow-up. Analyses were performed using STATA v12.

### **Process evaluation**

In line with MRC guidance a process evaluation was conducted to assess the acceptability and feasibility of the study procedures and intervention design (Moore *et al.*, 2015). After the 6 months follow-up data had been collected, individual face-to-face interviews were conducted with dental staff (n=12) from the intervention and control practices and telephone interviews were conducted with a purposive sample of patients (n=7) who had received the intervention as well as patients from the control group (n=7). In addition, the fidelity of the intervention was assessed by a modified checklist form (Crawford *et al.*, 2015) completed by dentists for each participant who received the brief advice.

## Results

Fifteen dental practices from across North London were approached and agreed to participate in the study, and 12 practices were randomly allocated to the control and intervention arms of the trial. Over a 7-month period, 567 dental patients were screened across 10 dental practices for eligibility (2 dental practices did not manage to screen any patients for the study) (Figure 1). Out of these patients, 259 participants were deemed eligible to take part in the trial (eligibility rate 45.7%) and 229 of them consented to take part (recruitment rate 95.4%). No participants were excluded due to any medical condition, involvement in other studies or receiving treatment for alcohol related problems. Of those randomised to the intervention arm (n=119), all received the brief intervention. Six months after entry to the study, 176 participants were followed up (retention rate 76.9%).

Figure 1 here

The baseline characteristics of the study participants are shown in Table 1. There were no major differences between the control and intervention arms in terms of participants' age, sex, qualifications, marital status, smoking status, and fruit and vegetable consumption.

Table 1 here

Table 2 shows the baseline outcomes for the participants. Overall there were no major differences in the AUDIT-C score and its individual components apart from the number of units consumed. A higher proportion of participants in the control arm consumed 1-2 units per week (17.4% vs 8.4%) and a higher proportion of participants in the intervention arm consumed 5-6 units (37% vs 26.6%).

Table 2 here

At 6 months follow-up there was a significant difference in the numbers of weeks of abstinence in the past 90 days between controls and intervention arms, with the intervention arm reporting an extra week of abstinence compared to the control arm (3.2 versus 2.3 weeks respectively,  $p=0.04$ ) (Table 3). There were non-significant differences in AUDIT status, with the intervention arm having fewer participants classified as AUDIT positive, compared to the control arm (44.9% versus 59.8% respectively,  $p=0.053$ ). A non-significant difference was also observed in the AUDIT-C scores between baseline and follow-up periods between the 2 groups (-0.67 units versus -0.29 units respectively,  $p=0.058$ ). There were no other statistically significant differences between the 2 groups at follow-up.

Table 3 here

#### *Process evaluation*

The interviews with the dentists and reception staff uncovered some important insights into the acceptability of the study procedures and delivery of the intervention. Dentists reported that the initial face-to-face meetings with University College London staff were very important in successfully engaging with the study. Sending out letters and emails were seen as less useful ways of encouraging busy NHS practices to become involved in a research study. A range of reasons were given for why dentists agreed to take part in the study including interest in research, value of staff training and professional development, particularly for newly qualified dentists in the training practices, and the opportunity to engage in something different. Dentists and receptionists really appreciated the support and assistance that the research staff provided in terms of explaining all the study procedures,

particularly the screening and consenting processes. Evaluation of the training programme has been reported elsewhere (Ntouva *et al.*, 2016)

Across the 10 participating dental practices different procedures were adopted in terms of recruiting participants into the study. In some practices the dental staff only approached patients that they knew well, whereas in others, all patients attending the surgery were asked to participate. The screening tool was praised as being very helpful and easy to use – the visual format and incorporation of smoking and diet questions were particularly welcomed. Overall, the dental staff found delivering the intervention straightforward and clear, although a range of challenges were identified. A small minority of staff reported a degree of anxiety in raising the topic of alcohol, especially with new patients. Delivering the intervention took some time and this was a concern in some busy NHS practices. However in the training practices where the newly qualified dentists were working, this was not seen as a problem. Finally, some of the staff were concerned with the amount of paperwork involved in the study.

The interviews with the patients who had received the intervention indicated that all (n=7, 100%) felt comfortable with the way the dentist introduced the issue of alcohol. They all thought that the advice given to them was helpful and 6 out of 7 (86%) felt that the advice was tailored to their individual needs. All thought that it was appropriate for the dentist to give advice on alcohol and 3 (43%) reported that the advice made a difference to the way they were drinking.

Data from the fidelity assessment forms showed that 111 participants completed all the components of the brief advice intervention in the recommended manner (93%). The mean duration of the intervention was estimated to be 9.3 minutes (median: 10 minutes). In terms of data completeness, between 97-100% of each of the questionnaire items in the baseline and follow-up measures were fully completed.

## Discussion

Hazardous alcohol consumption remains a significant public health problem in the UK with major health, social and economic consequences for society (Room *et al.*, 2005). Despite the strong evidence base for alcohol brief interventions delivered in primary medical care settings (Kaner *et al.*, 2007), NHS dental services are an under-utilised and novel setting for providing alcohol brief advice, as most NHS dentists do not currently provide this form of preventive care due to a lack of training, limited materials and lack of confidence in providing alcohol advice (Shepherd *et al.*, 2010). The aim of this study was to assess the feasibility and acceptability of screening for alcohol misuse and delivering brief advice to eligible patients attending NHS general dental practices in North London.

The study results have demonstrated the feasibility and general acceptability of NHS dentists providing brief alcohol advice to eligible patients in primary dental care settings. Indeed the feasibility targets set for the study were all met. The study team successfully engaged with NHS dental practices and recruited, and then randomised 12 practices. Ten of the practices actively participated in all elements of the trial although 2 practices were not able to recruit participants due to organisational changes in these practices. Over a 7-month period 229 participants were recruited (95.4% recruitment rate) and at the 6 months follow-up, 176 participants were assessed (76.9% retention rate). All participants randomised to the intervention arm received brief advice and the fidelity assessment demonstrated that the vast majority (93%) received all elements of the intervention as outlined in the study protocol.

Encouraging results were obtained from the evaluation of the effect of the intervention on the alcohol consumption of the participants who had received the brief advice with a significant increase in number of weeks abstinent, but non-significant differences in AUDIT status, at follow-up. The study was not fully powered to detect significant changes in alcohol consumption but the results demonstrated a positive trend in all alcohol measures assessed.

Findings from the process evaluation also highlighted the acceptability of the intervention to both dental staff and patients. Useful insights were obtained on the most effective ways of engaging and recruiting dental practices into the study – personal contact with senior members of the study team were seen as being especially important. Data from the process evaluation also highlighted the importance of providing on-going support to the practices to ensure study procedures were followed and of the value of providing tailored training to the practice staff.

A very limited number of studies have evaluated alcohol brief advice interventions in NHS dental practices so it is difficult to directly compare our findings with other comparable studies. Our findings are however, in line with the encouraging results of trials conducted in maxillofacial secondary care settings in Wales (Smith *et al.*, 2003; Goodall *et al.*, 2008; Oakey *et al.*, 2008) and the US and UK small scale trials undertaken in general dental practices (Neff *et al.*, 2015; Roked *et al.*, 2015).

It is important to acknowledge the limitations of this study. The study was only undertaken in North London and therefore the generalisability of the findings need to be viewed with a degree of caution. Although all the recruitment and retention targets were met, the sample size is relatively modest and the participants recruited into the study may not have been fully representative of the practice patient population. The strengths of the study include the comprehensive and detailed assessment of the feasibility of the intervention and study procedures was undertaken. This included useful process evaluation data on the acceptability of the intervention to both dental professionals and the patients. The study also successfully engaged with a diverse mix of NHS dental practices including large group practices and smaller practices where only a couple of dentists were working. Some training dental practices where newly qualified dentists were employed and supported by their senior colleagues were also included in the study.

In recognition of the underutilised potential of dental professionals in providing alcohol advice to the general adult population, Health Education England have recently produced an online alcohol brief advice training resource for NHS dentists (Health Education England, 2015). It is important to note

however that there is currently no evidence from randomised controlled trials of the effectiveness of brief alcohol advice delivered by NHS dentists working in primary dental care settings. The findings from this feasibility study can however be used to design a future trial to assess the effectiveness of such an intervention. Based upon the results of this study, it is estimated that a future definitive multicentre cluster trial would require a sample size of approximately 620 participants recruited across 26 dental practices.

In conclusion, this study has demonstrated the feasibility and acceptability of NHS dentists screening and providing alcohol brief advice in general dental practice settings. The study also demonstrated the feasibility of the study procedures and provides valuable insights to inform the design and conduct of a future definitive trial to assess the effectiveness and cost effectiveness of NHS dentists providing alcohol brief advice to eligible patients.



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**Conflict of interest statement**

All authors declare there is no conflict of interest in relation to this study.

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