

**SOCIAL SUPPORT AND CARDIOVASCULAR DISEASE
RISK REDUCING BEHAVIOURS FOR PEOPLE WITH
SEVERE MENTAL ILLNESSES IN PRIMARY CARE**

Alexandra Burton

Division of Psychiatry, Faculty of Brain Sciences,
University College London

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Primary supervisor: Professor David Osborn

Division of Psychiatry, Faculty of Brain Sciences, University College London

Secondary supervisor: Professor Kate Walters

Department of Primary Care and Population Health, Faculty of Population
Health Sciences, University College London

Declaration

I, Alexandra Burton confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

23rd Dec 2019

Date



Alexandra Burton

Acknowledgements

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To mum and dad, thank you for always telling me to look after myself, reminding me to “work to live”, and for supporting me in whatever I decide to do.

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This thesis is dedicated to my grandma, Mavis, to whom I owe my passion for reading and learning, and who I hope would have been proud to see me finally finish this work.

Abstract

Background

People with severe mental illness (SMI) have an increased risk of cardiovascular disease (CVD). Research in the general population suggests that social support may protect against CVD morbidity and mortality, however little is known about social support and cardiovascular health in people with SMI.

Objectives

For people with SMI:

- Assess the effectiveness of CVD risk-reducing interventions that involve supportive others
- Develop and integrate a social support strategy into a CVD risk-reducing intervention in primary care
- Explore the relationship between social support and cardiovascular health behaviours
- Describe how existing social support was explored within initial appointments in a CVD risk reducing intervention in primary care.

Methods

Systematic review, longitudinal and cross-sectional observational study and qualitative thematic analysis of intervention appointments.

Results

Few studies were identified on effective interventions that used existing support networks to improve cardiovascular health in people with SMI.

Recommendations for involving supportive others in CVD risk reduction were identified from focus groups, workshops and UK clinical guidelines. These included exploring how to involve supportive others, respecting confidentiality and identifying strategies for those without social support.

Higher social support predicted significantly greater appointment attendance in unadjusted but not adjusted analyses and greater medication adherence. There was no association between higher perceived social support and greater physical activity, healthier diet, lower alcohol use or being a non-smoker.

Social support was explored in first appointments, with most participants identifying a supportive other. Reasons to involve others included companionship, positive feedback and health improvements for supportive others and participants. Some participants described family or friends as negative influences on their health.

Conclusions

Perceived social support may be an important facilitator for adherence to CVD medications, but there was limited evidence for an association between perceived social support and other CVD health behaviours in people with SMI. Harnessing positive social relationships within interventions should be considered as a strategy for encouraging uptake of CVD health behaviours in people with SMI. Further work is needed to develop interventions that increase social support and improve health outcomes for people with SMI who have limited social contacts.

Impact statement

Who will benefit from this work?

The findings from this PhD will potentially impact on people with severe mental illnesses (SMI) and their support networks, primary care providers and the academic community.

1. Impact on people with SMI

My work will highlight to providers of services for people with SMI the potential importance of exploring their social networks and available social support to determine how people with SMI can best be supported to improve their cardiovascular health. The potential benefits of involving family and friends to help people with SMI make positive changes to their lifestyle should be highlighted to them in consultations about their health. My work also raises awareness that for some people with SMI, access to supportive family or friends is limited, or family or friends may even have a negative impact on their physical and mental health. Alternative mechanisms of support may be required to help some people with SMI to improve their health and remain healthy.

2. Clinician and health service impact

My research has shown that practice nurses and healthcare assistants can deliver complex behaviour change interventions and were able to explore the social networks of their patients with SMI and how they might help or hinder participation in CVD risk reducing behaviours. The findings could be used to influence training programmes for primary care health professionals to enhance their communication and decision making skills around involving family and friends of people with SMI to help them participate in healthier behaviours and achieve good health. Training could also help to raise awareness of local initiatives to which health providers can refer people with SMI who have limited social support.

3. Academic impact

The findings of this study add to a growing body of literature on the relationship between social support and CVD health outcomes, and the feasibility of incorporating existing social support into interventions to improve health outcomes for people with SMI. The findings are relevant to academics in psychology, primary care, nursing and sociology. I have published the focus group study described in chapter three in a peer reviewed journal (PLOS ONE), presented the findings from chapter four of this thesis at a national conference and I have submitted the work presented in chapter four to a peer reviewed journal for publication. I also aim to influence the design of future health interventions for vulnerable populations by highlighting the potential importance of involving supportive others and addressing social isolation to help improve health outcomes.

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Statement of personal contribution

As the full time programme manager of the Prediction and management of cardiovascular disease (CVD) risk for people with severe mental illnesses (SMI) research programme in primary care (PRIMROSE)¹(Osborn et al., 2019), I was able to incorporate my academic interest in social support and its impact on health outcomes in people with SMI throughout the programme of work, and study part-time for this PhD.

The PRIMROSE programme was a six-year project funded by a National Institute for Health Research Programme Grant for Applied Health Research (NIHR-PGfAR). The programme involved three work packages². I was responsible for managing the delivery of work package two: focus group study and coordinating the development of the intervention, and work package three: randomised controlled trial of the intervention. Professor David Osborn was the chief investigator and the programme ran from May 2011 to August 2017.

My contributions to this thesis were as follows:

- I conceived the idea, designed, and wrote the PhD research proposal with input from my academic supervisors
- I conducted all aspects of the systematic review in chapter two independently from the PRIMROSE programme.
- Data for the development work presented in chapter three were collected from focus groups and workshops delivered for work package two. I recruited all focus group participants, facilitated the focus groups and workshops and led on the data analysis and write up of the published paper. I conducted a secondary analysis of the data focussing on the role of supportive others and the integration of social support independently from the PRIMROSE programme.
- Data for the quantitative study in chapter four was taken from the baseline data collected for work package three of the PRIMROSE programme. I coordinated and

¹ NIHR Programme Grants for Applied Health Research Reference: PGfAR RP-PG-0609-10156

² Details of the three PRIMROSE study work packages are available in Appendix 1

managed all aspects of the study. I further added a measure of social support in to the data collection for the purpose of my thesis and conducted the quantitative analysis independently from the PRIMROSE programme. This analysis of social support was not part of the original funded PRIMROSE protocol and forms additional work exclusively for my PhD.

- Data for the qualitative study in chapter five were collected as part of work package three of the PRIMROSE programme to assess health provider fidelity to delivery of the PRIMROSE intervention. I conducted the qualitative analysis as additional work for my PhD independent of the PRIMROSE programme.
- I wrote all of the thesis content

List of abbreviations

AUDIT	Alcohol Use Disorders Identification Test
AUDIT-C	Alcohol Use Disorders Identification Test-Consumption
BCT	Behaviour change technique
CBT	Cognitive behavioural therapy
CDSR	Cochrane Database of Systematic Reviews
CHD	Coronary heart disease
CI	Confidence interval
CMHT	Community mental health team
COM-B	Capability opportunity motivation – behaviour
CPN	Community psychiatric nurse
CRD	Centre for Reviews and Dissemination
CRN	Clinical research network
CVD	Cardiovascular disease
DINE	Dietary Instrument for Nutrition Education
FG	Focus group
HBA1c	Haemoglobin A1c
HR	Hazard ratio
IPAQ	International Physical Activity Questionnaire
IRR	Incident rate ratio
ISRCTN	International Standard Randomised Controlled Trial Number
MD	Mean difference
MET	Metabolic equivalent of task
MHRN	Mental health research network
MMAS-8	Morisky Medication Adherence Scale
MOS-SSS	Medical Outcomes Study - Social Support Survey
MRC	Medical Research Council
MSPSS	Multidimensional Scale of Perceived Social Support
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
ONS	Office for National Statistics
OR	Odds ratio
PCRN	Primary care research network
PICO	Population, intervention, comparator, outcomes
PIS	Participant information sheet
PRIMROSE	Prediction and management of CVD risk for people with SMI: research programme in primary care
QOLI	Quality of Life Interview
RCT	Randomised controlled trial
SH	Samira Heinkel
SIS	Smoking screening questionnaire
SMART	Specific, measurable, attainable, realistic, time bound
SMD	Standardised mean difference
SMI	Severe mental illness
SSQ	Social Support Questionnaire

TaU	Treatment as usual
TDF	Theoretical domains framework
UCL	University College London
UKCTG	UK clinical trials gateway

Chapter 1: Introduction

1.1 Setting the scene: social support, cardiovascular health and severe mental illness (SMI)

The problem: increased risk of cardiovascular disease (CVD) in people with SMI

People with severe mental illnesses (SMI) such as schizophrenia, psychosis and bipolar disorder are at an increased risk of cardiovascular disease (CVD) and die up to 20 years earlier than the general population from heart disease and stroke (Osborn et al., 2007a). The mortality gap between people with SMI and the general population is still widening with an estimated elevated mortality rate of 1.79 (95% CI 1.67-1.88) in people with bipolar disorder and 2.08 (95% CI 1.98-2.19) in people with schizophrenia (Hayes et al., 2018). A recent analysis by Public Health England confirmed that people with SMI have a higher prevalence of obesity, diabetes, coronary heart disease (CHD), heart failure and stroke than the general population and that younger adults with SMI have the highest health inequality for diabetes, obesity and hypertension (Public Health England, 2018). Efforts to intervene have been unsuccessful in clinical trials of behaviour change interventions to reduce weight, smoking, haemoglobin A1c (HBA1c) and lipids in people with SMI (Druss et al., 2017; Holt et al., 2018; Osborn et al., 2018) and alternative models of prevention may be required.

Factors which may be responsible for health inequalities in people with SMI include increased smoking rates, poor diet and sedentary lifestyles (Brown et al., 1999; Filik et al., 2006; McCreadie, 2002), a high rate of diabetes (Schizophrenia and Diabetes 2003 Expert Consensus Meeting, 2004), side effects of antipsychotic medications which include an increased risk of weight gain, hyperlipidaemia, and hyperglycaemia (Correll et al., 2014; Kahl, Westhoff-Bleck, & Kruger, 2018), diagnostic overshadowing, whereby a patient's physical health complaint is wrongly attributed to their mental illness by health professionals (Lester, Tritter, & Sorohan, 2005; McCabe & Leas, 2008; Nash, 2014) and sub-optimal management by health professionals of CVD risk in this population (Hardy, Hinks, & Gray, 2013; Osborn et al., 2011).

The importance of monitoring and improving the physical health of people with SMI is endorsed by international bodies (World Health Organisation, 2018) and UK National clinical guidelines for people with schizophrenia (National Institute for Health and Care Excellence, 2014e). It is also supported by UK mental health advocacy organisations including Rethink Mental Illness (Disability Rights Commission, 2006; Rethink Mental Illness, 2013; The Royal College of Psychiatrists, 2013; The Schizophrenia Commission, 2012). However, findings from a recent survey with 12,796 users of community mental health services in the UK found that only 30% of responders had received help from mental health services to find support for their physical health needs, a significant decrease from 35% in 2017 (Care Quality Commission, 2018).

The setting: Primary care

Responsibility for monitoring the physical health of people with SMI within the UK is placed with both primary care and secondary mental health care professionals, and national clinical guidelines recommend collaboration and communication of physical health problems between the two services (National Institute for Health and Care Excellence (NICE), 2011e; 2014a; 2014e). It has been estimated however that 31.1% of people with a diagnosis of SMI are seen only in primary care with no access to secondary mental health services, and for those that do have access, 61% have at most two contacts per year with a mental health professional (Reilly et al., 2012). Primary care services may therefore be well placed to monitor and support the physical health of people with SMI both in terms of their wider reach within this population as well as their expertise in long term condition prevention and management. GP practices in England are also financially incentivised to provide physical health checks to people with SMI through the Quality Outcomes Framework (QoF), and while indicators for glucose, lipid and BMI measurements have been retired from the QoF during the lifetime of this thesis, the 2018/19 indicators include screening for smoking, blood pressure and BMI, as well as agreeing a care plan between patients and their family and/or carers as appropriate (NHS England, 2019). The care plan should document the patient's health and social care needs, information on their support networks, whether secondary services are involved in their care, employment status, early warning signs that may indicate relapse and the patient's wishes in the event of a relapse.

While practice nurses and healthcare assistants provide advice and education about physical health conditions, stopping smoking and losing weight; carry out physical health screening across the general population and targeted annual health checks for groups with long term conditions such as asthma, kidney disease and diabetes, there is evidence to suggest that they lack training and confidence in working with people with SMI (Naylor et al., 2016). One small study that offered practice nurses' brief training in SMI and increased risk of CVD, alongside an accompanying manual and website containing information on mental health conditions and links to resources and services, led to an increase in CVD screening and lifestyle advice being provided to SMI patients in primary care (Hardy, Hinks, & Gray, 2013). The training also reduced practice nurse's negative attitudes towards SMI (Hardy, 2012). Other potential difficulties for people with SMI accessing primary care include difficulties getting an appointment and the length of the appointment on offer, with the average GP appointment only lasting 10 minutes and annual health checks appointments lasting between 20-30 minutes (Baird et al., 2016). These contextual difficulties may lead to patient dissatisfaction and disengagement with services (Curtice et al., 2019).

Social support and health outcomes

One factor which may have an influence on cardiovascular health outcomes is the availability of social support and the degree to which an individual perceives to be integrated within a social network. There is a wealth of research indicating that people with low levels of social support have worse health outcomes than those who have positive social relationships including an increased risk of mortality in people with CVD (Barth, Schneider, & von Kanel, 2010; Czajkowski, Arteaga, & Burg, 2011; Holt-Lunstad, Smith, & Layton, 2010; Wheeler et al., 2012), diabetes (Loprinzi & Ford, 2018; Strom & Egede, 2012) and hypertension (Menéndez-Villalva et al., 2014; Yang, Boen, & Mullan Harris, 2015). A large meta-synthesis on the relationship between social support and mortality included 148 studies with 308,849 participants and found a 50% increased chance of survival for people with greater social support (OR=1.50 (95% CI 1.42 to 1.59) in analyses adjusted for sex, age, initial health status, cause of death and follow-up duration (Holt-Lunstad et al., 2010).

It has been theorised that social support may have a direct impact on cardiovascular health through its influence on social norms and behaviours such as cigarette smoking, alcohol use, dietary intake and physical activity, or an indirect or “buffering” effect through reducing stress which in turn influences cognitive, emotional and physiological responses to illness (Cobb, 1976; Cohen & Wills, 1985). Research also suggests that people with SMI have better psychiatric outcomes if they experience more positive social relationships (Cohen et al., 2004; Corrigan & Phelan, 2004; Johnson et al., 1999; Koenders et al., 2015; Norman et al., 2005; San et al., 2013; Tempier et al., 2013), however the relationship between social support and physical and especially cardiovascular health outcomes in the SMI population has received less empirical attention. The NICE clinical guidelines for people with schizophrenia (NICE, 2014e) and bipolar disorder (NICE, 2014a) emphasise the importance of involving carers, family and friends in the psychiatric assessment process but also suggest that supportive others have a key role to play in improving engagement with health services, and “in the long-term successful delivery of effective treatments.” The guidelines advocate that carers should be involved in decision making if the person with SMI agrees, and specify that discussions around alcohol use, smoking and medications should be held with both the person with SMI and carer if appropriate.

In this chapter, I will explore the literature on the relationship between social support and cardiovascular health outcomes in people with SMI. I begin by defining what social support is, how it is measured and consider the characteristics and predictors of social support for people with SMI. Theoretical frameworks which attempt to understand the mechanisms of how social support may influence health are then described. I then consider evidence on the relationship between social support and health outcomes in people with SMI, as well as how social support has been used within interventions to improve health outcomes for this population. A review of what national health guidelines specific to SMI and CVD risk related conditions and behaviours say about involving supportive others is presented to determine how social support might be incorporated into interventions aimed at reducing cardiovascular risk in people with SMI at a national level. The chapter concludes with a summary of the identified evidence and

how this evidence has been used to inform the research questions and subsequent work described in this thesis.

1.2 Defining and measuring social support

A recent conceptual review on social isolation identified a number of terms that have been used in the literature to describe the presence or lack of social connections in populations with mental health problems (Wang et al., 2017). The review concluded that there are seven related but distinct concepts used to describe social connectedness including loneliness, social isolation, social capital, alienation, social network, confiding relationships and social support. Social support is perhaps the most widely studied and universally defined conceptual term used to describe social connectedness. It refers to the perceived and actual receipt of care and help from others and is defined as three distinct functions; i) being integrated within a supportive social network, ii) perceived support which is the subjective perception that support will be available if and when required and iii) received support which is the actual receipt of care, advice or assistance from others. (Taylor, 2011; Uchino, 2009) Social support has been further categorised into four common functions or types (Uchino, 2004):

- Emotional support (e.g. empathy, trust, affection)
- Companionship (e.g. shared interests to engage in social activities together)
- Material support (e.g. financial and practical help)
- Informational support (e.g. the provision of advice or guidance)

Research suggests that social network size, received and perceived social support have different associations with health, with perceived support more strongly linked to better mental health than received support or network size (Uchino, 2009). An individual may experience low perceived social support despite having access to a large number of social ties, however the presence of individuals within a person's social network is needed for any feeling of being supported or not to exist (Berkman et al, 2000; Thoits, 2011).

Social support can be either informal (provided by friends, family and/or a spouse/partner) or formal (provided by support workers, health professionals, peer groups, community groups) (Taylor, 2011). NICE guidelines for people with schizophrenia and bipolar disorder define the carer role to include “relatives, friends, non-professional advocates and significant others who play a supporting role for the person using mental health services” (National Institute for Health and Care Excellence, 2011e, 2014a, 2014e).

Several instruments exist that measure the concept of social support ranging from basic binary variables such as marital or living status; measures of structural support which assess unidimensional constructs such as the composition of social ties and relationships e.g. the number of people that a person has in their social network, through to functional support measures that assess more complex and multi-dimensional aspects of the specific types of received or perceived social support that the social network provides, often using validated questionnaires. In some cases these different categories of social support are combined and measured within a single questionnaire.

Barrera (1986), argued that social support measurement tools should acknowledge the distinct concepts of social support and seek to measure, for example, the number of contacts or members within social networks, instances of received support and perceptions of support separately, rather than these constructs being combined into a single measure. A systematic review of social support measures for people with type 2 diabetes (Al-Dwaikat & Hall, 2017) found that social support was predominantly assessed by one of three self-report measures in this population; the Medical Outcomes Study – Social Support Survey (MOS-SSS) (Sherbourne & Stewart, 1991), the Multidimensional Scale of Perceived Social Support (MSPSS) and the Social Support Questionnaire (SSQ6) (Sarason et al., 1983). All three questionnaires were assessed as user friendly, brief to administer and reported to have good psychometric properties (assessed as valid and reliable in a range of populations). They do however measure different constructs of social support; perceived availability of different types of support (MOS-SSS), adequacy of perceived social support in term of the resources it provides (MSPSS), and the number of people in the support network and satisfaction with support

(SSQ6). The authors concluded that it is important to establish the construct of social support that is of interest to the study before determining which tool to use. It also makes it difficult to compare results across studies that assess different constructs of social support.

A meta-synthesis on the relationship between social support and mortality included 148 studies (308,849 participants) and found that more complex validated measures of social integration (OR=1.91; 95% CI 1.63 to 2.23) and perceived social support (OR=1.35; 95% CI 1.22 to 1.49) were significantly associated with an increased chance of survival from CVD and cancer, however measures of received support (OR=1.22; 95% CI 0.91 to 1.63) and binary measures of living status (e.g. living alone or with others) were not significantly associated with an increased chance of survival (OR= 1.19; 95% CI 0.99 to 1.44) (Holt-Lunstad et al., 2010). Barth et al (2010) found that functional measures of perceived social support significantly predicted mortality in people with pre-existing coronary heart disease (CHD) (HR of 1.59 (95% CI, 1.21–2.08) but structural measures did not (HR of 1.12 (95% CI, 0.98–1.29) (Barth et al., 2010).

It has been theorised that received support may be weakly associated with health outcomes because it is typically evaluated with reference to stressful or difficult situations or scenarios in which specific help is required within a specified time period, whereas perceived social support represents a generalisation of experiences of being supported by social network members over time (Thoits, 2011).

These findings highlight the importance of identifying the appropriate construct of social support to be measured within research studies and suggest that it is the feeling of being supported rather than the receipt of support or the number of people in your social network that might be particularly important for health outcomes.

1.3 Characteristics of social support for people with SMI

A number of studies assessing the characteristics of social support in people with SMI are described in more detail below and have suggested that people with SMI identify a small number of social contacts and include formal support from support workers or

health professionals as a key part of their social networks. The majority of this research assesses the size and composition of the social network with few studies assessing the structural or functional aspects of social support in SMI populations.

1.3.1 Existing reviews of the literature

A narrative synthesis of evidence on the social network size of people with psychosis included 23 studies conducted between 1978 and 2015 with 1184 participants (n =18 to 578 participants) (Palumbo et al., 2015). The review found on average, that people with psychosis had 11.7 (weighted mean and median) people within their social network (range 4.6 - 44.9) incorporating 43% family members and 27% friends. The average number of friends was reported as 3.6 (range 1 - 4.7). The review also found that networks consisted of a range of people from family, spouses, friends, co-workers, neighbours, other people with SMI, and health professionals including mental health, general medical and social workers. Only two of the studies included in the review were from the UK and the large range between studies of the number of people reported in a person's social network suggests that different assessment tools and definitions were used to measure social network size, making comparisons between studies difficult.

A narrative synthesis of studies conducted between 1963 and 1996 on social network size and psychiatric hospital use in people with SMI identified 25 studies (number of participants and countries not reported) and found an average of 13 people (range 3.1 to 16) within the social network. A large proportion of the network consisted of family members (Albert et al., 1998).

In both of these reviews, the conceptualisation of social network size and the assessment tools used to measure the number of contacts that participants had in their social networks varied across the included studies, making it difficult to draw comparisons between studies. Studies specified different frequencies of contact and asked about different types of relationships, with some focusing only on informal networks of friends and families and excluding relationships with professionals, and others specifying that all relationships could be included. The average number of people

within the social network of people with SMI may have therefore been underestimated by some of the studies.

1.3.2 Descriptive studies – who is in the social networks of people with SMI?

Bengtsson-Tops & Hansson (2001) explored the relationships of 120 outpatients with SMI and found that nearly a quarter had no close relationships and a third had nobody they could turn to for emotional support. The majority of participants did however identify supportive others in their networks and of those who did, 52% had access to relatives within their immediate family (sibling, parents, partner, or children); 24% received support from friends and 16% stated that professionals were their main source of emotional support

In 1396 outpatients with schizophrenia, 65.7% reported having a close friend, while 55.1% had seen a friend in the last week (Giacco et al., 2012). The authors were only interested in contacts with friends and did not measure overall social network size or contact with others such as family or professionals. In another study with 184 people with SMI in the community, most participants identified family, friends and work colleagues in their social network, with fewer people having a partner or children (Muller et al., 2007). Participants were not asked about formal contacts with health professionals and perceived their partner or friends as offering the most support. Those without a friend reported lower perceived social support than those with friends. A UK study asked 150 people with SMI to report both informal and formal contacts and found that their networks mainly consisted of friends (32.7% of contacts in the participant's network), followed by family (29.1%), neighbours, work colleagues and acquaintances (19.6%) and health professionals (18.6%) (Pinfold et al., 2015).

Tsai, Desai, & Rosenheck (2011) studied 531 male outpatients with SMI and found a relationship between the amount of informal and formal support that participants reported that they received. Participants with more people in their informal networks, and who felt more supported by family or friends, also reported more health professionals in their networks and felt more supported by them as well. The authors suggested that the availability of one may enhance the likelihood of being supported by

the other. Two smaller studies with people with SMI (N<30) however found that an absence of informal support may increase the likelihood of people accessing support from health professionals (Crotty et al., 2015; Meeks & Murrell, 1994). In one of these studies, a broad range of existing relationships were reported with informal networks consisting of family members, friends, spouses or partners, neighbours and pets, while formal networks included paid professionals; from health workers, pharmacists and nurses to taxi drivers and cleaners (Crotty et al., 2015).

Pinfold et al (2015) identified three distinct network types in 150 community living people with SMI: diverse and active, family and stable, and formal and sparse. Just over a third of participants had diverse and active networks containing high frequency contact with a wide range of loose knit relationships (e.g. friends and colleagues), while just under a third reported close ties with family, neighbours and informal carers with very few other relationships reported. The remaining participants (31.3%) reported few family, friends or wider contacts and mainly described the presence of health professionals in their networks.

Only one descriptive study was identified that assessed perceptions of social support in SMI populations rather than social network size or composition (Munikanan et al., 2017). The authors conducted a cross sectional study with 160 Malaysians with schizophrenia in the community and found that 72% of the sample had low perceived social support (as measured by a validated scale; the Multidimensional Scale of Perceived Social Support (MSPSS)), with perceived support from a partner being the lowest, followed by friends and family. More descriptive research is therefore needed to understand the level of perceived social support experienced by people with SMI.

1.3.3 Comparisons of social networks between SMI and non-SMI populations

Seven studies were identified that compared the social networks of SMI with non SMI populations (Cohen & Sokolovsky, 1978; Erickson et al., 1989; Macdonald, Hayes, & Baglioni, 2000; Meeks & Murrell, 1994; Neeleman & Power, 1994; Semple et al., 1997; Tolsdorf, 1976). These studies found that participants with SMI had smaller social networks, reported having fewer friends, were less likely to perceive their relationships

as reciprocal with more emphasis on receiving help from others than being a provider of help to others, and were more likely to include mental health professionals in their social networks. Findings on family contacts were mixed with one study reporting that people with SMI had more family members in their networks than controls (Tolsdorf, 1976), and another finding less family contacts in people with SMI than controls with mild depression or anxiety (Meeks & Murrell, 1994). Limitations of these studies included small sample sizes and two studies limited the number of people that participants could report as present in their social networks, therefore the social network size may have been underestimated (Meeks & Murrell, 1994; Macdonald et al., 2000). Only one study controlled for participant demographics by matching the SMI group with healthy controls on age, sex, employment, education and marital status. This study found no difference between the groups in perceived social support, number of family members and number of acquaintances (Macdonald et al., 2000). Differences were found however in the size of the network. Those with psychosis had smaller networks, fewer friends and more health professionals in their networks, as well as fewer people to turn to in a crisis. The sample size was small (N=52) and therefore the results should be interpreted with caution.

The studies reviewed above suggest that people with SMI may have a small number of social contacts within their social network and lower perceived social support than other populations, however in many cases, social contacts are present and include a diverse range of individuals, from friends and family to work colleagues and neighbours. Some studies may even be underestimating the size of social networks for people with SMI by restricting the number of contacts and the types of relationships that could be reported. Family members generally seemed to play a more prominent role than friends, and health professionals were also identified as a key part of the social network. It would seem realistic to try and harness the specific types of social support that individuals with SMI have, to try and improve health outcomes in this population. It may also be easier for people with SMI to identify specific individuals to support them if the pool from which to choose from is smaller, if relationships are less likely to be reciprocal (i.e. the relationship is a function of the supportive other providing support but not receiving it back from the person with SMI) and if they are more likely to be family orientated.

1.4 Predictors of social support in people with SMI

A small number of studies were identified that assessed the potential predictors of social support in SMI populations. Potential predictors included age, employment, income, education, ethnicity and severity of psychiatric symptoms.

Two studies reported that younger adults had larger networks than older adults (Macdonald et al., 2000; Thorup et al., 2006) and that men had smaller networks than women (Muller et al., 2007; Thorup et al., 2006). One study found that males were more likely than females to receive help from significant others to take their psychiatric medication (McCann & Lu, 2009), while another found that being unemployed and having a low income were associated with having less diverse social networks (Muller et al., 2007). A study assessing the relationship between social support and physical activity and diet in people with SMI found that older adults reported more frequent family contact than younger adults, and those who had completed high school reported less contact with friends than those who had not (Aschbrenner et al., 2013). The measure of social support used in this study was specific to perceived social support for diet and exercise behaviours rather than a generic measure of support (Sallis et al., 1987). This study also found that people from non-white backgrounds were more likely to feel encouraged by family to pursue a healthy diet than white people, and females were more likely to receive encouragement from friends for healthy eating than males.

The severity of psychiatric symptoms may play a part in the level of social support available to people with SMI. A cross sectional study found that in 536 males with schizophrenia, those who had a greater severity of psychiatric symptoms were less socially integrated and reported less informal support than those with less severe symptoms (Tsai et al., 2011). They were also less likely to rely on formal mental health professional support. People with few negative symptoms and low hostility were significantly more likely to report having a close friend than people with moderate negative symptoms (Giacco et al., 2012) and smaller social networks have been found in people with higher levels of negative symptoms (Bengtsson-Tops & Hansson, 2001; Palumbo et al., 2015; Thorup et al., 2006). Pinfold et al (2015) reported that those with

a diagnosis of schizophrenia or psychosis had significantly fewer family and stable networks than those with bipolar disorder.

1.5 Theoretical considerations: social support and health outcomes

A number of theoretical models exist which seek to explain why social support may be beneficial to health, and a lack of support detrimental to health. Durkheim's seminal work in 1897 explored the relationship between changing patterns of suicide and social integration from a sociological perspective (Berkman et al., 2000). Durkheim observed that suicide rates were relatively stable across time within countries, localities and social groups and that suicide rates could be explained by the social cohesiveness of the group (Durkheim, 1951). He hypothesised that during times of economic or political crises, societies or social groups would become less cohesive, and suicide rates would increase. This work paved the way for further exploration of the link between social support and health outcomes from psychological, anthropological and epidemiological perspectives.

Two key models of how social relationships may have an impact on health have been proposed; the stress-buffering hypothesis and the main effects model (Cohen, Gottlieb, & Underwood, 2000). The stress-buffering hypothesis suggests that the presence of support from others is a protective factor against poor physical and mental health outcomes because it decreases the negative impact of stressful life events on health (Cobb, 1976; Cohen & Wills, 1985). There is little empirical evidence to support this hypothesis within the SMI population however, and a small study with 32 people with schizophrenia found that perceived social support was not associated with stress induced cortisol response (Tas et al., 2018). The main effects model hypothesises that social support has a direct impact on health and wellbeing because those who have greater social support may be more likely to participate in normative health behaviours such as exercise or healthy eating (Lewis & Rook, 1999). Those with greater perceived social support may also benefit from increased informational and practical support such as information on health services, provision of informal care or support with accessing care. A critique of this model however is that social support may also promote participation in negative social health behaviours such as smoking or alcohol use (Burg

& Seeman, 1994). Studies assessing the direct association between social support and CVD risk reducing behaviours in people with SMI are described in section 1.7.2.

More recently proposed theoretical models have recognised the influence of both behavioural and socio-psychological processes on physiological responses to illness which in turn lead to morbidity and mortality (Thoits, 2011; Uchino, 2006). Berkman et al (2000) proposed a multilevel theoretical framework to describe how different levels of social influence ultimately impact on health outcomes. They proposed that structural conditions such as culture, politics, socioeconomic factors and periods of social change shape the nature and size of social networks which in turn provide opportunities for psychosocial mechanisms such as social influence, social engagement and social support. These psychosocial mechanisms then influence health outcomes through their impact on the enactment of health behaviours such as smoking, diet, exercise, alcohol use, adherence to treatments and help-seeking behaviours as well as their impact on psychological and physiological responses to illness. Uchino (2006) proposed that social support (both structural and functional) exerts an independent influence on normative health behaviours and psychological coping which both then influence physiological responses to illness and ultimately morbidity and mortality.

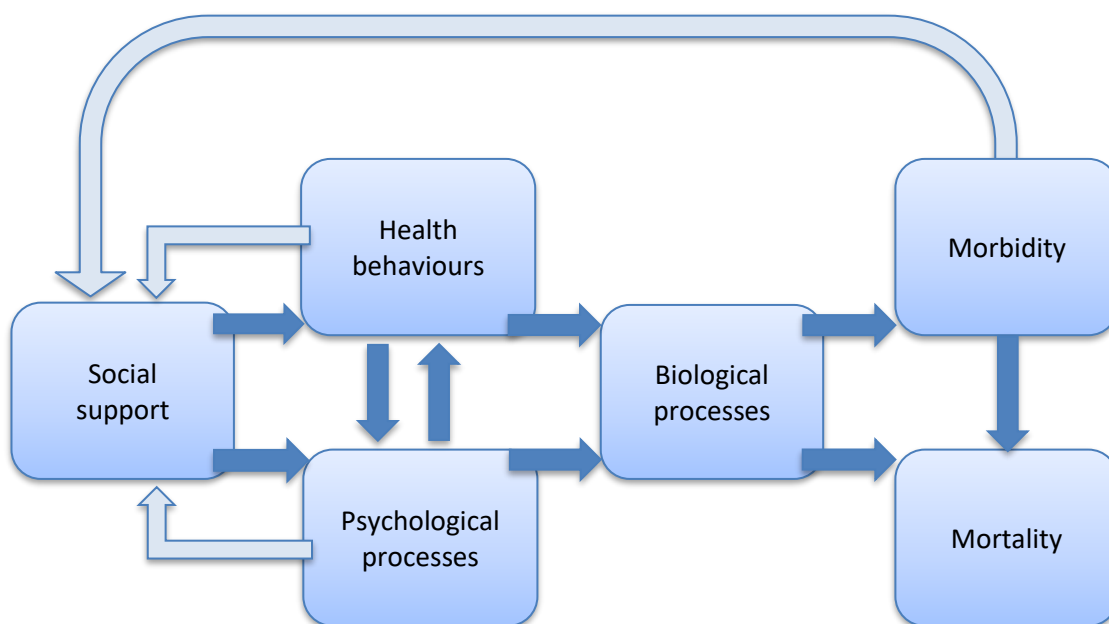
Thoits (2011) proposed seven psychosocial mechanisms through which the presence of social ties has an impact on physiological responses and ultimately mental and physical health morbidity and mortality: social comparison, social control, having purpose and meaning, self-esteem, sense of control, companionship and perceived social support. Table 1.1 lists these mechanisms with descriptions of how they might influence health behaviours.

Table 1.1. Psychosocial mechanisms through which social ties may influence health outcomes (Thoits, 2011)

Mechanism	How might it influence health?
Social comparison	Participation in normative health behaviours occur as a result of comparisons with similar others in the social network or group. Risky or unhealthy behaviours may also be modelled by the social network
Social control	Members of the social network explicitly attempt to influence, encourage or monitor participation in healthy behaviours
Purpose and meaning	Individuals avoid participation in unhealthy behaviours due to role obligations and their responsibilities to others in their social networks
Self-esteem	Feelings of self-worth in relation to how individuals think they are perceived by others impact positively on mental health which in turn leads to better overall health
Sense of control	The successful accomplishment of role performances or tasks leads to a sense of mastery and ability to cope with major stressors which in turn leads to better health
Companionship	Connections to others gives opportunity for participation in joint social activities which may include healthy lifestyle activities, which in turn impacts positively on mental health
Perceived social support	The availability of social ties leads to perceptions of feeling supported which in turn impacts on health outcomes

It is therefore hypothesised that the presence of social ties lead to perceptions and experiences of social support. Social support then influences participation in normative health behaviours and positive psychological coping which in turn influences physiological response and ultimately health morbidity and mortality. Uchino (2006) also recognised that health behaviours, psychological process and morbidity may have an impact on social support. Figure 1.1 depicts Uchino’s model of potential pathways that link social support to health outcomes.

Figure 1.1: Potential pathways linking social support to physical health*



*Reproduced from Uchino (Uchino, 2006)

1.6 Social support, psychiatric outcomes and adherence to psychiatric treatments

Most of the research assessing the relationship between social support and morbidity in SMI populations has focused on psychiatric outcomes including relapse, symptom severity, psychiatric hospital admission, engagement with mental health services and adherence to psychiatric medications. This evidence is described below.

Relapse, symptom severity and hospital admissions

A systematic review on perceived social support and psychiatric outcomes identified four longitudinal studies published between 1999 and 2015 with people diagnosed with bipolar disorder (Wang et al., 2018). The review found that greater perceived social support reduced the risk of symptom recurrence at one year (OR = 0.92, 95% CI 0.85–0.99) (Cohen et al., 2004) and lower perceived social support predicted greater depression (beta – 0.14 to – 0.25, coefficient – 1.33) (Daniels, 2000; Johnson et al., 1999; Koenders et al., 2015) and greater impaired functioning (beta – 0.14 to – 0.67) (Daniels,

2000; Koenders et al., 2015) at both three and six-month follow up. Two of these studies found no relationship between perceived social support and manic symptoms at follow up (Johnson et al., 1999; Koenders et al., 2015) Sample sizes ranged from 59 to 173 people with SMI and studies were conducted in USA and Dutch community and inpatient populations. Studies were rated as being of at least “acceptable” quality and used validated questionnaires to assess perceived social support. Three of the reported studies adjusted for baseline outcome measures (Daniels, 2000; Johnson et al., 1999; Koenders et al., 2015).

A recent meta-analysis on the association between social network size and psychiatric symptoms in 1,929 people with schizophrenia identified 16 studies conducted between 1970 and 2016 across the USA, UK, Australia and Europe (Degnan et al., 2018). The review found evidence that a smaller social network size was associated with more severe psychiatric symptoms, ($g = -0.53$, 95% CI = - 0.875 to - 0.184, $p = 0.003$) and more negative symptoms ($g = -0.75$, 95% CI = - 0.997 to - 0.512, $p = 0.000$). There was no association between social network size and positive symptoms or social functioning ($g = 0.36$, 95% CI = - 0.078 to 0.801, $p = 0.107$). Only half of the included studies adjusted for confounding and the majority of studies were cross sectional therefore while associations were identified, causal inferences could not be made.

A study with 123 outpatients with first episode psychosis in the UK found that perceived social support was associated with longer time spent in remission over 18-month follow ($z = 2.60$, coefficient = 0.01, $p < 0.01$) (Tempier et al., 2013). Conversely, a moderate amount of contact with family was associated with a shorter time spent in remission than those reporting a low amount of contact ($z = -2.10$, coefficient = -0.28, $p = 0.02$). This suggests that perceived support may protect against relapse, however structural support may be detrimental. The study adjusted for age and gender in the analysis and a validated measure of social support was used, however social support was only measured at six-month follow-up and not at baseline therefore causation cannot be inferred.

A prospective study with 113 outpatients with bipolar disorder in Canada found that perceived social support predicted a greater reduction in positive symptoms (coefficient= -0.30, $p=0.002$) and fewer psychiatric hospitalisations (coefficient= -0.23, $p=0.018$), but not negative symptoms at three-year follow up (Norman et al., 2005). Although perceived social support was measured using a validated questionnaire, a limitation of the study was that perceived social support was rated by the clinician rather than the patient.

Engagement with mental health services

A systematic review on predictors of engagement with mental health services by people with first episode psychosis and SMI identified the involvement of family as potentially important (Doyle et al., 2014). The authors conducted a narrative synthesis and found that a lack of family involvement predicted greater disengagement with services in three studies (HR 1.75-4.8; 95% CI 1.22-11.2), greater engagement in one study (HR=0.46; 95% CI 0.21-1.00) and no association was found in two studies. These studies did not include validated measures and simply assessed whether the participant was living with a family member or not. One of the studies that found no association included only 41 participants and was possibly underpowered, however studies that did detect an association were fairly large ($n=157$ to 786) and adjusted the analysis for confounders.

A limited number of studies have assessed the relationship between perceived social support and attendance at psychiatric appointments. One small study with 34 people with SMI found an association between perceived social support (measured using the Social Support Index) and participation in a nurse led support group ($r = 0.54$, $p < 0.01$) (Perese, Getty, & Wooldridge, 2003), while another small study with 48 participants with SMI found no association between perceived social support (measured by the perceived social support scale-friends and perceived social support scale-family) and attendance at community mental health service appointments (Primm et al., 2000).

Adherence to psychiatric medications

International clinical expert consensus guidelines on adherence to antipsychotic and antidepressant medications in SMI highlight that a lack of social support to help with medication taking as well as negative or ambivalent attitudes from caregivers towards medications are contributing factors to adherence problems (Bellack et al., 2009).

Studies assessing the relationship between social support and adherence to antipsychotic medications offered mixed findings. A systematic review on factors related to antipsychotic medication adherence in people with schizophrenia identified five studies that assessed the impact of social support (Tham et al., 2016). The studies were conducted in Korea, Thailand, Australia and the USA. Two small studies identified a positive association between instrumental social support and adherence (Ramirez-Garcia et al (2006): n=30, cross sectional design, OR=4.8: 95% CI 1.1-21.7, p<0.05; Glick et al (2011): n=50, longitudinal design over 18-months, effect size not reported). Glick et al (2011) did not control for confounding in the analysis and the measure used to assess instrumental support was not described, while Ramirez-Garcia et al (2006) only controlled for duration of mental illness and did not use a validated measure of social support. The sample consisted of recently admitted inpatients; arguably these participants may have had more dependent relationships with supportive others at this time, and although adherence was measured in the nine-months following discharge from hospital, they may have also had increased supervision of their medication taking to avoid relapse and readmission.

Three of the included studies (n=51, n=81 and n=225) found no association between perceived social support and psychiatric medication adherence (Rungruangsiripan et al., 2011; Yang et al., 2012; McCann & Lu, 2009). The smaller studies may have been underpowered to detect an association and only one study adjusted the analysis for potential confounding variables (Yang et al., 2012). In one of these studies, the authors developed their own measure comprising of questions specific to support for medication taking (McCann & Lu, 2009). This was not a validated or global measure of social support and measurement bias may therefore have been present. The other two

studies used a validated measure of perceived social support; the Medical Outcomes Study- Social Support Survey (MOS-SSS) (Rungruangsiripan et al., 2011), the MSPSS (Yang et al., 2012) and four of the five studies recruited participants from outpatient or community mental health settings (Glick et al., 2011; McCann & Lu, 2009; Rungruangsiripan et al., 2011; Yang et al., 2012).

Three additional cross sectional studies were identified, all of which found a relationship between perceived social support and adherence to psychiatric medications in SMI populations (Magura, Rosenblum, & Fong, 2011; Seo & Min, 2005; Tham et al., 2018). A study with 131 participants recruited from community mental health services with a diagnosis of SMI and comorbid substance misuse in the USA found that lower perceived support with managing mental health problems and substance misuse was associated with lower adherence to psychiatric medications (effect size not reported) (Magura et al., 2011), while another study with 208 participants in Korea with schizophrenia found that higher perceived social support was associated with greater adherence to antipsychotic medications ($r=0.48$, $p<0.05$) (Seo & Min, 2005). Research with 92 inpatients with schizophrenia in Singapore found that those with poor social support from significant others were less likely to adhere to their medication than those with good social support (OR=0.95: 95% CI 0.91-0.99, $p<0.05$) (Tham et al., 2018). All of these studies controlled for confounders and used validated measures of perceived social support, however reverse causation cannot be ruled out as greater adherence to psychiatric medication may result in better mental health and subsequently a greater ability to participate in positive social relationships and interactions.

One prospective study with 152 participants with first-episode psychosis accessing community services found that the influence of social support on adherence to antipsychotic medications while significant in the short term, did not have a lasting impact over time (Rabinovitch et al., 2013). Again this study controlled for confounders and used a validated measure of perceived social support.

1.7 Social support and cardiovascular health outcomes

1.7.1 Social support and cardiovascular morbidity and mortality

While there is an established body of epidemiological evidence supporting the relationship between greater social support and reduced mortality and morbidity in populations with CVD (Barth et al., 2010; Holt-Lunstad et al., 2010; House, Landis, & Umberson, 1988; Orth-Gomér et al., 1998; Wheeler et al., 2012), only one study involving people with schizophrenia (Christensen et al., 1999) was included in a meta-analysis of social relationships and CVD mortality risk (Holt-Lunstad et al., 2010). While the authors found that a higher number of social contacts was significantly related to survival rates among people with schizophrenia, the study had many limitations. Firstly the data were extracted from medical records between 1934 and 1944 and may no longer be representative of the population today. Also the authors did not describe the system they used to categorise social support making it difficult to establish which aspects of social support they were measuring. No other studies have been conducted into the link between social support and mortality in people with SMI and no studies were identified assessing the link between social support and cardiovascular morbidity in people with SMI.

1.7.2 Social support and cardiovascular health behaviours

In the general population, perceived social support has been linked to participation in physical activity (Croezen et al., 2012; (OR=1.23; 95% CI: 1.08-1.41); Murray et al., 2013 (qualitative study)), greater consumption of fruit and vegetables (Croezen et al., 2012; (OR=1.36; 95% CI: 1.20-1.53)), attendance at preventative health screening appointments (Hoebel et al., 2014 (Odds not reported); Petrova, Garcia-Retamero, & Catena, 2015 (OR=1.02; 95% CI: 1.01-1.02)) and adherence to CVD preventative medications (Gu et al., 2017 (beta=0.08; 95% CI: 0.03-0.13); Magrin et al., 2015 (d=0.18; 95% CI 0.05-0.31:)). Low support has been associated with increased smoking reduced smoking (Croezen et al., 2012 (OR=1.39; 95% CI 1.20-1.61)). The evidence for social support and participation in cardiovascular health behaviours in people with SMI is considered below.

Social support and physical activity

While a systematic review of qualitative studies identified the importance of social support for participation in physical activity, the review excluded studies that involved people with SMI (Murray et al., 2013). There are however a number of qualitative studies exploring the link between social support and physical activity in people with SMI which have highlighted that having a training partner is a motivating factor to participation in physical activity (Bassilios, Judd, & Pattison, 2014; Firth et al., 2016; Fogarty & Happell, 2005; Pereira et al., 2019) and that a lack of social support is a barrier to participating in physical activity (Muralidharan et al., 2016; Bassilios et al., 2014; Klingaman et al., 2014; Yarborough et al., 2016). A systematic review of facilitators and barriers to physical activity in people with SMI found that 50% of 5,646 respondents identified a lack of social support as a barrier to exercise (Firth et al., 2016). Pinfold et al (2015) found that those with more friends, family and wider contacts engaged in more physical activities than those with formal (comprising mainly of health professionals) and sparse networks. Those with smaller family networks and lower perceived social support were more likely to engage in unstructured activities such as watching television than physical activities.

Two large surveys conducted in the USA with 5,388 veterans with schizophrenia and 9,044 older adults with schizophrenia and bipolar disorder, found that people with SMI were more likely than those without SMI to cite a lack of social support as a barrier to physical activity (19% and 20% of respondents with SMI compared to 6% and 7% of respondents without SMI) (Muralidharan et al., 2016; Klingaman et al., 2014).

Only two cross sectional studies were identified that quantified the relationship between social support and self-reported levels of physical activity in people with SMI. Social support and physical activity were assessed in 200 outpatients with schizophrenia, schizoaffective disorder, major depression and bipolar disorder in the USA (Daumit et al., 2005). Those with no social contact in the previous month were three times more likely to be physically inactive than those with a social contact in the last month (OR = 3.11; 95% CI: 1.24–8.39), however a validated measure of social support was not used. The second study found no relationship between perceived emotional support assessed

using a validated scale (The Social Support Scale), and self-reported diet, smoking or physical activity (Leas & McCabe, 2007). The primary hypothesis of this study however, was to investigate whether components of a particular theory (Protection Motivation Theory) could be used to explain health risk behaviours in 83 people with schizophrenia and 70 people with depression recruited through psychiatric rehabilitation services in Australia. Social support was added as a secondary predictor and did not form part of the original theoretical model that was being tested, therefore the study may have been underpowered to assess this relationship.

One prospective study conducted in Canada, found that perceived social support, measured using a validated measure (MSPSS) did not significantly predict participation in moderate to vigorous physical activity assessed using seven-day accelerometry among 101 adults with schizophrenia or schizoaffective disorder at four-week follow up (OR= 0.74; 95% CI: 0.47-1.16) (Arbour-Nicitopoulos et al., 2017).

Social support and smoking

Two qualitative studies investigating motivations for quitting smoking identified the social network as both a barrier and a facilitator (Aschbrenner et al., 2017a; Heffner et al., 2018). Barriers included socialising with smokers and people who did not want to quit, being encouraged to smoke by others and stressful and unhelpful interactions with members of the social network. Facilitators included quitting alongside network members, and positive feedback, advice and guidance as well as verbalised concerns about the health impacts of smoking from network members. Aschbrenner et al (2017b) also assessed smokers' preferences for support from family and friends to quit smoking. Themes included a desire for financial assistance to purchase smoking cessation medications, encouragement to reduce and stop smoking and for supportive others to not smoke around them or offer them cigarettes.

Two cross-sectional studies assessed whether social support was a predictor of smoking behaviour in people with SMI. The first study was conducted in the USA with 174 people with SMI and substance use disorders recruited through community mental health services, and found that more social contact with non-substance using friends was

associated with more self-reported attempts to quit smoking, but not self-reported smoking abstinence or the number of cigarettes smoked (Ferron et al., 2011). Social support was measured using two questions which asked about contact with non-substance abusing friends from a subscale of a validated quality of life interview (QOLI). This study specifically measured social support associated with smoking, such as the number of smokers in a person's social network, or perceptions that their family or friends would support them to quit, rather than using global measures of social support.

The second study was conducted in South Korea with 208 people with schizophrenia recruited through community mental health services. The study found no association between satisfaction with social relationships as measured using a validated scale (Sarason's social support questionnaire) and self-reported daily cigarette use (Seo & Min, 2005). This finding may again have been because the relationships that were being assessed were with other smokers and drinkers. Socialising with smokers and with people who do not want to give up smoking has been identified as a barrier to quitting smoking in people with SMI (Aschbrenner et al., 2017a).

Two longitudinal studies were identified that assessed the relationship between baseline social support and smoking at follow up. One USA study with 124 smokers with an SMI diagnosis accessing community mental health services reported mixed findings at two-month follow-up (Aschbrenner et al., 2015). Social support was measured using non-validated assessment tools; participants were asked to indicate the number of smokers and non-smokers in their network and were asked questions on smoking behaviours among people in their social networks. Stop smoking medication use was collected via self-report and corroborated through clinician report and medical records. In this study, if participants perceived that their family and friends would use medication to stop smoking, they were more likely to adhere to pharmacological support for smoking cessation independently of age, gender and ethnicity. A lack of perceived approval to use smoking cessation medication from smokers in the participant's network however, significantly increased the likelihood of medication use. This may have been because participants who were motivated to quit no longer identified with the social norms of smokers in their networks.

A second smaller study with 58 young adult smokers with SMI conducted in the USA found that baseline perceived social support measured using a validated questionnaire (MSPSS), was not associated with self-reported quit attempts at three-month follow-up. (Brunette et al., 2019). This study may have been underpowered to detect a difference.

Social support and diet

Only one cross sectional study was identified and found no relationship between perceived emotional support and self-reported diet in 153 people with schizophrenia and depression (Leas & McCabe, 2007). This study is described in the “Social support and physical activity” section above.

Social support and alcohol use

A number of studies have assessed the relationship between social support and overall substance misuse, however very few studies have measured alcohol use as a separate outcome to illicit drug use. A UK study with 111 participants with SMI found no difference in harmful alcohol use as assessed by clinicians between those who had regular contact with a carer and those who did not (Schofield et al., 2001). A validated measure of social support was not used in this study. A Korean study with 208 outpatients with schizophrenia found no relationship between self-reported daily alcohol intake and perceived social support measured using a validated questionnaire (Sarason’s social support questionnaire) (Seo & Min, 2005).

Social support and adherence to CVD risk reducing treatments and services

It has been suggested that the impact of social support on health outcomes may be mediated by adherence to treatment and medications. A qualitative study conducted in the USA with 20 participants identified barriers to self-management of SMI and diabetes and found that a lack of support from friends and family impacted on the participant’s ability to self-manage their illnesses, however the majority of the quotations used to highlight this issue focused on the person’s mental illness rather than their diabetes (Blixen et al., 2016). The USA study with 124 smokers with SMI described in the previous

section “Social support and smoking” found that as the number of people that the participants smoked with increased, so did their likelihood of accessing smoking cessation group therapy (Aschbrenner et al., 2015). This seems counterintuitive, as having more people to smoke with suggests that smoking is a social activity and quitting smoking may result in loss of these contacts. The group element of the therapy may however have been more attractive to people who wanted to quit but who valued the social aspect of smoking with others. A motivating factor may have been that the smoking network would be replaced with social contacts who wanted to quit smoking as a group.

A secondary analysis of data collected in a clinical trial in the USA with 200 people with depression, schizophrenia or bipolar disorder and a diagnosis of diabetes assessed predictors of attendance at primary, specialty and psychiatric outpatient clinic appointments and found that perceived social support measured using a validated measure (MSPSS) was not a significant predictor (Gunzler et al., 2017). No other qualitative or observational studies were identified assessing the relationship between social support and adherence to CVD risk reducing treatments and services in people with SMI.

1.7.3 Social support and interventions for improving health

In the same way that there is a more substantial body of evidence assessing the relationship between informal social support and psychiatric outcomes than physical health outcomes in the SMI population, the effectiveness of psychological interventions that involve the family to manage and reduce psychiatric symptoms and relapse for people with SMI has been demonstrated in the literature (Lyman et al., 2014; Mueser et al., 2013). Despite this evidence, the 2018 Care Quality Commission community mental health service patient survey found that only 53% of respondents who wanted their family or someone close to them to be involved in their mental health care had experienced their supportive other being involved as much as they would have liked (Care Quality Commission, 2018).

A conceptual review of psychological therapies found ten distinct therapy types, all of which included the patient's social relationships as a component, either with peers, professionals, family or friends, with some therapies focusing on more than one social relationship (Priebe et al., 2014). The authors found that most therapies utilise a 'unidirectional' relationship, with the patient receiving help from one or more individuals. Some therapies did however utilise mutual support between the patient and one or more individuals, however these tended to be peer support interventions rather than harnessing existing support. Three of the identified therapies included engagement in recreational and social activities as a component, with the aim to build confidence and encourage positive relationships with others.

Despite the evidence for involving family and friends in interventions to improve mental health outcomes in people with SMI, research involving family and friends in physical health promotion for this population is absent from the literature and it has been acknowledged that interventions for people with SMI often fail to address social support and social networks (Perese & Wolf, 2005).

There is mixed evidence to support the involvement of supportive others in interventions for reducing cardiovascular risk in the general population. An intervention in primary care to reduce heavy drinking included discussions with family and friends about the impact of, and identifying "triggers and risky situations" for alcohol use (Mavandadi et al., 2015). Participants reporting high support at baseline and randomized to the intervention had significantly fewer days of heavy drinking than those with low support in the intervention arm. Conversely, those reporting low support and randomized to treatment as usual experienced fewer days of heavy drinking than those with low support in the intervention group. Those in the treatment as usual arm with high perceived social support may have had heavy drinkers in their social networks, or this may have been a chance finding. The authors did not assess what was delivered in the intervention nor report on whether the health specialists had discussions with family and friends.

A systematic review of nine interventional studies that involved families and friends of people with type 2 diabetes found lower HBA1c in intervention groups versus controls at three-month follow up (MD= -0.25; 95% CI -0.40 to -0.11) (Spencer-Bonilla et al., 2017). Similarly a systematic review of interventions to improve diet and increase physical activity in adults at risk of diabetes found that therapy involving family members resulted in greater weight loss than the same therapy not involving family members (WMD= -2.96; 95% CI: -5.31 to -0.60) (Greaves et al., 2011). However only 127 participants were included in the meta-analysis and mental health populations were excluded. It is therefore unclear whether social support would be an effective strategy for CVD related behaviour change in this group. People with diabetes who used their existing support networks in a physical activity and diet intervention lost more weight compared to participants who took part in the physical activity and diet intervention without involving their existing support networks ($F(3,204)=3.867$ $p=0.01$) (Hankonen et al., 2015). The authors did not report on how social support was integrated in to the intervention or how it was used.

Two recent studies have assessed the feasibility of involving supportive others in healthy lifestyle interventions for people with SMI. One small study of a diet and exercise intervention involving seven dyads of people with SMI and a self-identified supportive other found high satisfaction with the intervention and a 100% programme completion rate (Aschbrenner et al., 2016). Four participants involved a friend, while one participant involved their parents, one involved their children and one involved a sibling. Participants reported feeling more encouraged and supported by their intervention partner, while supportive others reported making changes to their own behaviours including exercising more and eating a healthier diet. Both participants and their supportive others reported that being involved in the programme had improved the quality of their relationships.

A follow up feasibility study with 18 dyads found that a third of those participating in the diet and exercise programme lost weight, with five participants achieving clinically significant weight loss (Aschbrenner et al., 2017c). Again friends were the most frequently chosen partner followed by parents, significant others, spouses and adult

children. Increased support from family and friends to participate in exercise but not healthy eating were reported.

Overall the existing evidence of CVD risk reducing interventions that utilise supportive others from the participant's social network suggest that social support has the potential to play an important role in promoting and maintaining behaviour change in SMI populations. The integration of existing social support into individual health interventions may increase the success of behaviour change maintenance (World Health Organisation, 2008), however evaluating the effectiveness of social support embedded within interventions can be problematic as studies often do not clearly define how social support was utilised (Verheijden, 2005).

1.8 Social support in clinical guidelines

I conducted a review of NICE guidelines for a range of conditions including schizophrenia, bipolar disorder, weight management, smoking cessation, CVD prevention, medication adherence, behaviour change, diabetes prevention and management and alcohol use to determine whether social support was identified as a strategy for engagement with health services and healthy lifestyle behaviours (NICE, 2007; 2009; 2010; 2011a; 2011b; 2011c; 2011d; 2011e; 2012; 2013a; 2013b; 2014a; 2014b; 2014c; 2014d; 2014e; 2014f; 2015a; 2015b). The majority of guidelines emphasised that families, carers and in some instances friends should be given the opportunity to be involved in decisions about treatment and care.

Within the mental health guidelines, the identification and involvement of families, carers and friends was a key theme throughout, particularly for i) the assessment period, during which social networks and relationships should be identified that are supportive or that may be detrimental to the person with SMI and their mental health, ii) when treatment decisions are required or iii) if there is a change in circumstance such as if a mental health crisis arises (NICE 2011d; 2011e; 2014a; 2014e).

Expert consensus guidelines in the USA on adherence to antipsychotic and antidepressant medications in SMI suggest incorporating questions about social support

into clinical interviews aimed at assessing adherence levels such as whether family members encourage and prompt medication taking, and how family members feel about the medications (Bellack et al., 2009). The guidelines also include recommendations for clinicians on how to involve supportive others in medication adherence such as inviting the family member to appointments with the patient. Respecting confidentiality and only involving others if the patient gave their permission were emphasised.

Guidelines on managing and preventing specific outcomes and behaviours associated with increased CVD risk also include informal support as a strategy to help people manage their health. Smoking guidelines suggest that family or friends can help people who smoke by attempting to quit smoking themselves and providing support and encouragement to quit (NICE 2013a; 2013b). Guidelines on obesity and weight management also suggest that programmes to improve diet should include a number of components, one of which should be involving the family (NICE 2014c; 2014f; 2015a). These guidelines also caution that the views of family members may be a barrier to changing unhealthy behaviours, particularly for vulnerable groups and that social support should be discussed to ensure that a supportive environment exists. Specific ways of involving others are suggested including general encouragement and emphasising the enjoyment gained from shared, social physical activities.

Guidelines on managing harmful drinking suggest that involving families and carers in assessments of alcohol use can help provide a more comprehensive picture of the problems faced by the patient (NICE 2011a). Families and carers should be involved in care planning and treatment to try and help support the person and to maintain a reduction in alcohol use. Confidentiality and information sharing is also tackled with the suggestion that negotiations and discussions on involvement need to be had early on in the treatment process, and that these decisions need to be respected throughout the person's treatment. Negotiations around involving others are also highlighted in the mental health guidelines (NICE 2014a; 2014e).

Behaviour change guidelines highlight that friends and family members can help provide a supportive environment to help people make changes as well as practical and emotional support, positive feedback and rewards and long term encouragement (NICE 2007; 2011b). The guidelines also recognise however that if not effectively managed, informal social support could sometimes lead to “an unhealthy co-dependency, bullying, manipulation or other negative behaviour” (NICE 2011b).

While social support is mentioned in guidelines for individual CVD risk factors, no mention is made in the guidelines for cardiovascular risk management (NICE 2010) and it is acknowledged in guidelines for CVD prevention (NICE 2014b) that further research is required on the effectiveness of CVD prevention programmes involving the families of people at an increased risk of CVD.

1.9 Summary and scope of this thesis

People with SMI are at an increased risk of CVD morbidity and mortality when compared to the general population, and this gap is increasing. There is an urgent need to identify and understand different ways of improving outcomes for the SMI population. While this review of the literature highlights the complexities of defining and measuring social support, evidence that a relationship exists between perceived social support and cardiovascular health related outcomes in the general population is convincing, with high quality evidence suggesting that this relationship may be causal (e.g. social support predicts better health outcomes). Research exists on the link between greater social support and better psychiatric outcomes in people with SMI, however this review has identified a gap in existing evidence of studies that assess the relationship between social support and adherence to treatments and services for improving CVD health outcomes in this population.

Studies on the relationship between social support and CVD health behaviours in the SMI population have produced mixed findings with qualitative studies highlighting a lack of social support as a barrier to participation in physical activity and stopping smoking, and quantitative studies predominantly finding no association between social support and physical activity (Arbour-Nicitopoulos et al., 2017; Leas & McCabe, 2007), diet (Leas

& McCabe, 2007), alcohol use (Schofield et al., 2001; Seo & Min 2005) or smoking (Brunette et al., 2019). Only one study found an association between social contact and physical activity (Daumit et al., 2005), and two studies found some evidence for an association between perceived social support and stopping smoking (Aschbrenner et al., 2015; Ferron et al., 2011), however these studies had many limitations including a lack of validated measures of social support, use of non-global measures of social support and small study samples. Only one study was conducted in a UK health setting (Schofield et al., 2001).

There is evidence for the effectiveness of psychological interventions that involve the family or supportive others on psychiatric outcomes, and national guidelines highlight the importance of involving others in the care of people who are at an increased risk of CVD and who have a diagnosis of SMI. There is however a need to investigate further whether involving supportive others in CVD risk reducing interventions for people with SMI is effective and feasible.

1.10 Context: the PRIMROSE programme

My PhD is embedded within the prediction and management of CVD risk for people with SMI research programme in primary care (PRIMROSE) led by Professor David Osborn, of which I was the programme manager (Osborn et al., 2019). This six year programme of work was funded by an NIHR programme grant for applied research and comprised of three work packages that aimed to identify and reduce CVD risk factors in people with SMI (Appendix 1). My PhD research fits within work packages two and three of the PRIMROSE programme. Work package two involved the development of a primary care based intervention for lowering cholesterol and other CVD risk factors in people with SMI. The PRIMROSE intervention was informed by a systematic review of effective interventions for reducing CVD risk in people with SMI and findings from focus groups and workshops with health professionals, people with SMI, carers and clinical academics. The intervention involved training practice nurses/HCAs to deliver a menu of behaviour change techniques (BCTs) to help people with SMI improve their cardiovascular health. BCTs included how to identify SMART health goals, involve

supportive others, create an action plan, provide positive feedback, record and monitor progress and help people with SMI cope with setbacks. Work package three involved testing the clinical and cost effectiveness of the intervention in a cluster RCT across 76 GP practices in England (Osborn et al., 2018). Throughout the thesis I describe my contribution to the thesis and acknowledge where others contributed to the work.

1.11 Research aims and objectives

This thesis aims to explore i) whether existing social support can be used as a strategy for engagement within CVD risk reducing interventions for people with SMI and ii) if there is a relationship between perceived social support and CVD risk lowering behaviours in an SMI population with elevated CVD risk factors. The specific objectives are to:

1. Systematically assess the evidence base for interventions that involve supportive others to determine if they increase participation in CVD risk reducing behaviours for people with SMI (chapter two).
2. Use the literature and a secondary analysis of focus groups to design and integrate a strategy for involving supportive others into a CVD risk lowering intervention and training programme for practice nurses/HCAs in primary care (chapter three).
3. Investigate whether there is a relationship between perceived social support and participation in CVD risk reducing behaviours for people with SMI in primary care (chapter four).
4. Explore how social support is used as a strategy for engagement with CVD risk reducing behaviours by practice nurses/HCAs and people with SMI within the first appointments of an intervention designed to lower CVD risk in primary care (chapter five).
5. Discuss the findings of the overall thesis and how they relate to further research and clinical practice (chapter six).

Chapter 2 A systematic review of interventions that incorporate existing social support to increase participation in CVD risk reducing behaviours for people with SMI

2.1 Introduction

This chapter begins with a summary of the rationale for investigating the effectiveness of interventions that involve supportive others known to the individual with SMI such as a family member, friend or support worker to increase participation in CVD risk reducing behaviours. These behaviours include adherence to medication, attendance at health service appointments, increased physical activity, healthy eating, stopping smoking and reducing alcohol intake. The methodology for developing and conducting the search is described and the evidence is then identified through a systematic search of electronic databases and trial registries. The results of the search are then presented alongside a quality assessment of the methodology of included studies. The chapter concludes with a summary of the results, strengths and limitations and the implications of the findings from this review for the subsequent work of this thesis regarding the relationship between social support and CVD prevention for people with SMI.

2.1.1 Rationale for investigating the effectiveness of interventions that incorporate existing social support on CVD risk reducing health behaviours

The evidence I reviewed in chapter one of this thesis suggests that there may be a positive relationship between the availability of social support and CVD outcomes in the general population (Holt-Lunstad et al., 2010) and in people with SMI (Aschbrenner et al., 2015, Daumit et al., 2005; Ferron et al., 2011); however in other studies, a relationship was not found (Arbour-Nicitopoulos et al., 2017; Brunette et al., 2019; Leas & McCabe 2007, Schofield et al., 2001; Seo & Min, 2005; van Dam et al., 2005).

Sociological theories such as the main effects model seek to explain the mechanisms by which social support may influence cardiovascular health outcomes. These theories suggest that the relationship between social support and cardiovascular outcomes may

be mediated by facilitating participation in healthy lifestyle activities including adherence to treatments and medications, healthy eating, physical activity, not smoking, and drinking lower levels of alcohol (Dawe, Seinen, & Kavanagh, 2000). A systematic review on levels of social support in the general population found that having access to practical support was related to greater adherence to treatments for a range of health conditions and that adherence was highest for people living in supportive families (DiMatteo, 2004). However, the review excluded people with a psychiatric diagnosis.

While much of the focus has been on observational studies of social support and its relationship to health outcomes, the effectiveness of using existing social support within interventions designed to improve engagement with CVD risk reducing treatments and healthy behaviours has received less attention, particularly in people with SMI. If social support is related to improved CVD health outcomes through supporting the enactment of healthy lifestyle behaviours in the general population, then it should be considered in the design and evaluation of interventions aimed at modifying and encouraging behaviours that help to reduce CVD risk in people with SMI (Perese & Wolf, 2005).

I firstly conducted a scoping review within two electronic databases (PsychINFO and Medline) to identify studies assessing the effectiveness of interventions that incorporated existing social support on adherence to treatments, medications and services specific to CVD risk reduction and health promotion activities (diet, physical activity, smoking, alcohol use, diabetes management, adherence to statins and antihypertensives) for people with SMI. Of 360 papers identified in PsychINFO and 402 papers identified in Medline, no relevant clinical trials were found. I therefore broadened out the outcomes of this review to include adherence to any medications and attendance at any health services for people with SMI, using the assumption that adherence to psychiatric medications and attendance at psychiatric, psychological or other health services might provide relevant information and insight which could then be extrapolated to other behaviours such as adherence to CVD risk reducing medications and attendance at health promotion services.

2.1.2 Aims

In this review chapter, I identified studies of interventions that incorporated existing social support into their design and delivery with the specific aim of improving health enhancing behaviours in people with SMI. I evaluated whether interventions that are delivered to people with SMI and/or their supportive others i) improve adherence to medications, ii) increase attendance at health services and/or iii) increase participation in CVD risk reducing behaviours (healthy eating, physical activity, reduced alcohol use, reduced smoking) in people with SMI.

2.2 Methods

The search strategy for the review question was designed in terms of target population, intervention, comparison and outcome (PICO) measures as specified in The Cochrane Handbook (Higgins & Green, 2011).

2.2.1 Population, Intervention, Comparison and Outcome (PICO) criteria

Population: Adults (aged 18-75 years old) with a diagnosis of SMI (schizophrenia, schizoaffective disorder, persistent delusional disorder, bipolar disorder or other psychosis). Other psychiatric diagnoses were excluded (major depression, anxiety, personality disorders). If a study used a mixed population, it was included if 50% or more of the study population had one or more of the diagnoses listed as inclusions above.

Intervention: Interventions which specified the use of existing social support as an intervention component (e.g. family therapy) or that enlisted supportive others as an aid to engagement or adherence (e.g. a family member attending appointments with their relative) and were delivered to people with SMI and/or their supportive others were included. Existing support was defined as either informal e.g. friends, family, neighbours, or formal e.g. pre-existing paid or unpaid support workers. Only studies involving social support from the person with SMI's existing network were included. Studies testing the provision of additional support were not included, as the focus of this thesis was on existing, not newly formed support networks. For this reason peer support interventions were also excluded.

Comparison: Either 1) any intervention that did not include existing social support or 2) treatment as usual.

2.2.1.1 Outcomes:

i) Adherence to medication

Papers were included if they assessed adherence to any medication or combination of medications (including antipsychotics or antidepressants and non-psychiatric medications such as statins, antihypertensives, stop smoking aids and diabetes medications). The following measures were considered for inclusion in the review:

- Indirect measures of adherence (e.g. pill count, prescription refill rate, electronic monitoring)
- Subjective measures of adherence (e.g. patient self-report, interviews, clinician or relative self-report)
- Direct measures of adherence (drug level assays).

ii) Attendance at health service appointments

Attendance as measured by the number or percentage of attended appointments or non-attendance (DNA) rates over time as recorded by clinicians in medical records or monitoring sheets. Attendance at the following health services were included: psychological therapy, primary care, psychiatric outpatient and community services, and CVD prevention health appointments including weight management groups, dietician appointments, alcohol misuse services, stop smoking services and CVD health checks. Studies that reported only on health service use were excluded if they did not report on actual attendance rates.

iii) Healthy lifestyle behaviours

Studies which included an assessment of healthy lifestyle behaviours were included as follows:

- Diet as measured by self-report questionnaires or food diaries
- Physical activity as measured by pedometers or heart rate monitors, accelerometers or self-report questionnaires or diaries

- Smoking as measured by self-report questionnaires, diaries or carbon monoxide monitoring
- Alcohol use as measured by self-report questionnaires, diaries or blood tests.

2.2.2 Study designs included

Randomised controlled trials testing interventions which incorporated an individual's family or member(s) of their existing support network were included. Case studies, observational studies, single intervention studies with no comparators, non-randomised studies and qualitative studies were excluded. At the first stage of screening, papers with title and abstract written in English were included. Papers were subsequently excluded if the full text was written in a non-English language. There were no time restrictions on the study publication date.

2.3 Search strategy

Searches were conducted in a number of different databases which required search terms to be adapted accordingly. Search terms are described for each database below. Searches included papers published up to and including 31 March 2017.

2.3.1 Electronic database search

I searched the following databases for relevant literature:

- Medline
- Embase and Embase Classic
- PsycINFO
- CINAHL Plus
- Social Policy and Practice
- Web of Science Core Collection

I developed key terms related to the population (severe mental illness), intervention (social support) and outcomes (treatment adherence, attendance at health service appointments and CVD risk lowering health behaviours including, diet, exercise, smoking

and alcohol use) in consultation with an information scientist at the Royal Free Medical Library. Search terms from an existing paper on social support and adherence to treatments in the general population (DiMatteo, 2004) were used to develop the social support and adherence terms for the Medline search. Synonyms and related words were identified for each review component and mapped to appropriate medical subject headings within the Ovid (MedLine, EMBASE, PsycInfo) and CINAHL databases. Free text words were also developed to search the Web of Science and Social Practice and Policy databases. Free text words were then applied to all other databases to identify recent papers which may not yet have been indexed and to ensure complete coverage for the review. The search was firstly tested within MedLine and then adapted according to medical subject heading terms in subsequent databases. The key search terms used to identify papers within each database are presented in Appendix 2. The search was limited to titles, abstracts and key words.

2.3.2 Systematic reviews

I conducted a search for existing reviews within the Cochrane Database of Systematic Reviews (CDSR)). The following search terms were used to conduct a broad search for existing reviews; 1) social support AND schizophrenia 2) social support AND bipolar 3) social support AND severe mental illness 4) social support AND psychosis 5) family AND schizophrenia 6) family AND bipolar 7) family AND severe mental illness 8) family AND psychosis.

2.3.3 Registered clinical trials

I searched the following trial registries for relevant articles;

- Cochrane Central Register of Controlled Trials (CENTRAL)
- International Standard Randomised Controlled Trial Number (ISRCTN) Register (controlled trials)
- ClinicalTrials.gov (US National Institutes of Health service) (clinical trials)
- UK National Institute for Health Research Register (<https://www.ukctg.nihr.ac.uk>)

I searched the Cochrane and ISRCTN Registries using the following combination of terms; 1) social support AND schizophrenia 2) social support AND bipolar 3) social support AND severe mental illness 4) social support AND psychosis 5) family AND schizophrenia 6) family AND bipolar 7) family AND severe mental illness 8) family AND psychosis.

The clinical trials.gov database was searched using the following combination of terms 1) social support AND schizophrenia or bipolar or psychosis or severe mental illness, 2) Family AND schizophrenia or bipolar or psychosis or severe mental illness.

The UKCTG database was searched using the following search term combination: Family OR social support AND schizophrenia OR bipolar OR psychosis OR severe mental illness.

2.4 Data management and study selection

2.4.1 Data extraction

Data were extracted using a modified template from The Centre for Reviews and Dissemination (CRD) guidance for undertaking reviews in health care (University of York Centre for Reviews and Dissemination, 2009) to record methodological (publication, design etc.) and substantive characteristics (participant, setting etc.) of included studies. The data extraction form and the complete list of data extraction items are included in Appendix 3.

2.4.2 Quality assessment

I assessed the methodological quality of included papers using the Cochrane Collaboration's tool for assessing risk of bias (Higgins et al., 2011). This enables an appraisal of internal and external validity through addressing the following five potential areas of bias: selection bias (sequence generation and allocation concealment), performance bias (blinding of participants and study personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete reporting of outcomes) and reporting bias (selective reporting of outcomes). Criteria were rated as having either a 'low', 'high' or 'unclear' risk of bias.

2.4.3 Data synthesis

Since I searched for multiple outcomes and sought to include interventions of varying intensity and content as well as a broad range of outcome measurement tools, it was anticipated that studies would be insufficiently similar to conduct a meta-analysis on the findings and that a narrative synthesis would be more appropriate. Guidance on conducting a narrative synthesis in systematic reviews was used to inform the process (Popay et al., 2005) and involved: a description of the similarities and differences between study characteristics and the direction of effects, consideration of why there might be differences in the direction of effects across studies and a quality assessment of the evidence. To facilitate comparison of effect sizes; continuous variables were converted to standardised mean difference (SMD) and categorical outcomes were converted to proportions/odds ratios (ORs).

2.5 Screening

2.5.1 Electronic database search

A total of 13785 references were retrieved by the search from the Medline, PsychINFO, Embase, CINAHL, Web of Science and Social Policy and Practice electronic databases. Table 2.1 shows the search results for each database and search domain.

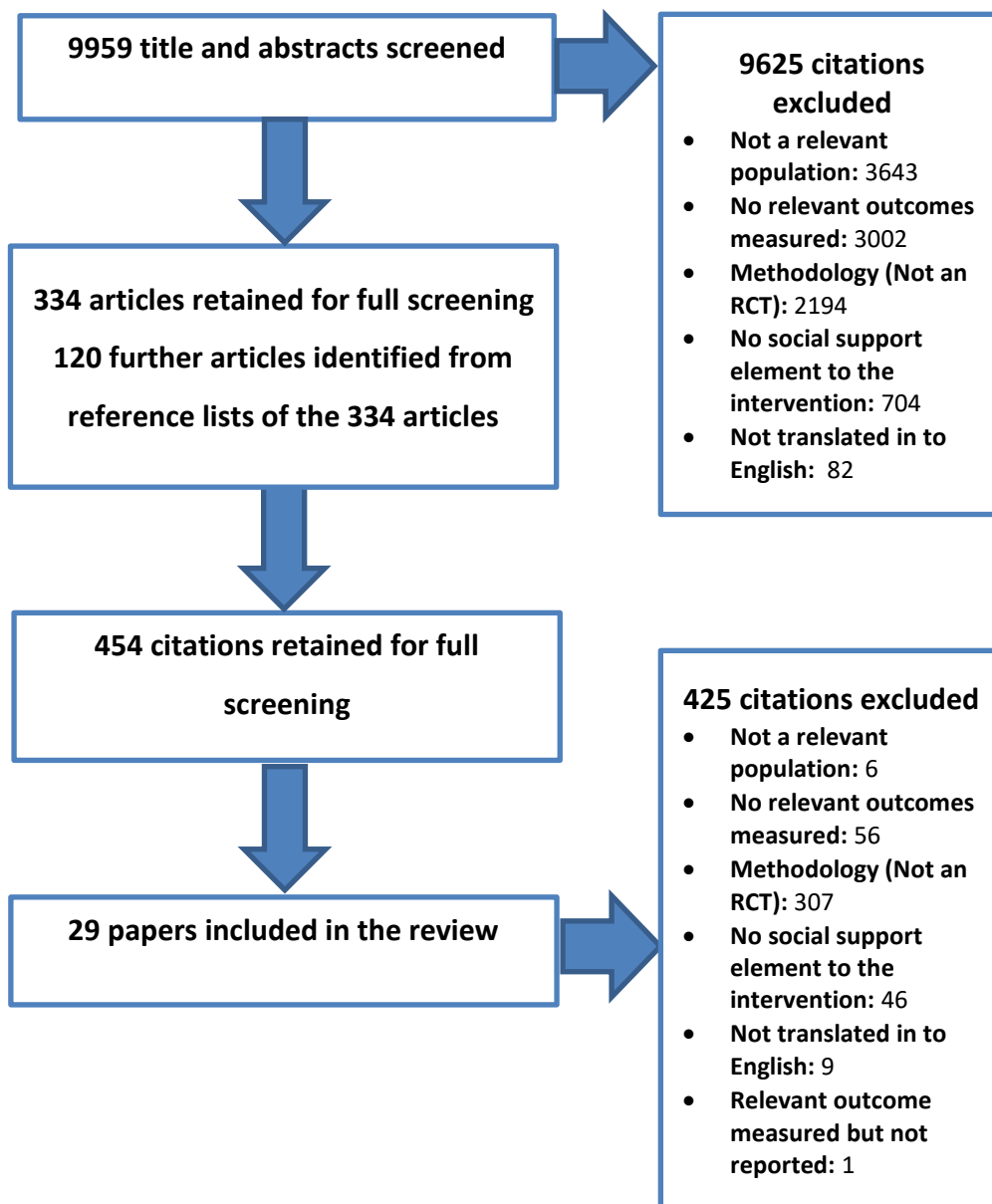
Table 2.1. Number of articles retrieved by the electronic database search

Domain/s	No. of articles retrieved (31 March 2017)					
	MedLine	PsycINFO	Embase	CINAHL	Web of Science	Social Policy and Practice
Population (p)	223202	189709	361163	43554	238575	3557
Intervention (i)	1442886	325729	1795028	479986	1826083	39585
Outcome (o)	1127366	252951	1995738	369262	1258322	16493
(p+i+o)	2798	886	6783	1172	2102	44
No. unique references	13785 - 3826 duplicates removed = 9959					

Retrieved references were exported in to EndNote Version 8. Duplicates identified within and between databases were removed, leaving 9959 unique papers to screen. Two separate copies of the EndNote databases were made and used to independently screen and identify articles meeting the inclusion/exclusion criteria by a researcher (George Salaminios) and myself. Reviewers compared references both retained and excluded from the search and were in complete agreement on 8974 papers (90.1% concordance), with uncertainty around 985 papers. The reviewers discussed any disagreements until consensus was reached resulting in the retention of 334 papers for full screening. I then searched the reference lists of all articles retained for full screening yielding a further 120 articles for potential inclusion that had not been identified by the database search. A total of 454 papers were retrieved for full screening.

Full text reports were obtained and downloaded in to the EndNote database. Full text screening was again conducted independently by a researcher (George Salaminios) and I. We compared references both retained and excluded from the search and were in complete agreement on 100% of papers resulting in 29 studies from the electronic database searches being included in the systematic review.

Figure 2.1 Flow diagram of electronic database search



2.5.2 Cochrane and registered trials

I then searched the Cochrane database of systematic reviews and clinical trial registries for any further evidence that may not yet have been published or indexed in the electronic databases. 1820 papers were identified from the search of systematic review and clinical trial registries, of which 12 citations were retrieved for full screening. Full text reports were obtained and screened against the inclusion/exclusion criteria. Following the full text screen, two trial papers were retained for inclusion in the systematic review. No existing relevant systematic reviews were identified on the

relationship between social support and adherence to any treatment, attendance at health service appointments or participation in healthy lifestyle behaviours in people with SMI, strengthening the justification for carrying out this review. Tables 2.2 and 2.3 show the results from the search of Cochrane databases and clinical trial registries. Figure 2.2 shows the results of these searches combined.

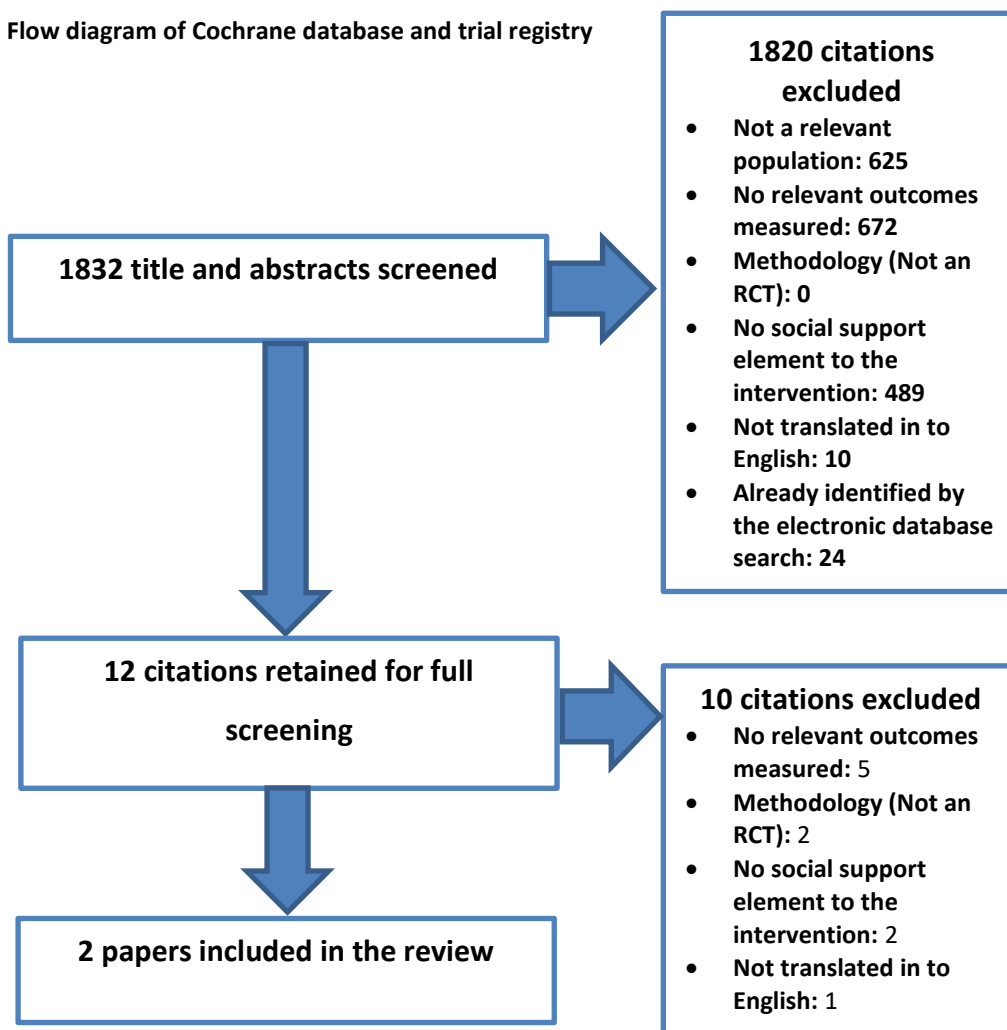
Table 2.2. Results from the search for existing reviews (Retrieved 16 March 2017)

Database	Number of articles identified	Number of new references identified
Cochrane database of systematic reviews	Search 1) 23	Search 1) 0
	Search 2) 3	Search 2) 0
	Search 3) 11	Search 3) 0
	Search 4) 9	Search 4) 0
	Search 5) 28	Search 1) 2
	Search 6) 5	Search 2) 0
	Search 7) 16	Search 3) 0
	Search 8) 13	Search 4) 0

Table 2.3. Results from the search from clinical trials databases (Retrieved 16 March 2017)

Database	Number of articles identified	Number of new references identified
Cochrane Central Register of Controlled Trials (CENTRAL)	Search 1) 325	Search 1) 2
	Search 2) 64	Search 2) 0
	Search 3) 66	Search 3) 1
	Search 4) 141	Search 4) 0
	Search 5) 515	Search 5) 5
	Search 6) 229	Search 6) 1
	Search 7) 44	Search 7) 0
	Search 8) 218	Search 8) 0
International Standard Randomised Controlled Trial Number Register (<u>controlled trials</u>)	Search 1) 30	Search 1) 0
	Search 2) 6	Search 2) 0
	Search 3) 6	Search 3) 1
	Search 4) 27	Search 4) 0
	Search 5) 6	Search 5) 0
	Search 6) 6	Search 6) 0
	Search 7) 2	Search 7) 0
	Search 8) 11	Search 8) 0
ClinicalTrials.gov (US National Institutes of Health service)	Search 1) 2	Search 1) 0
	Search 2) 5	Search 2) 0
	Search 3) 5	Search 3) 0
UK National Institute for Health Research Register (https://www.ukctg.nihr.ac.uk)	Search 1) 16	Search 1) 0

Figure 2.2. Flow diagram of Cochrane database and trial registry searches



2.6 Results

Thirty-one papers reporting randomised controlled trials of interventions involving supportive others compared to either a control group and/or an intervention that did not involve supportive others were included in this review following the electronic database searches, hand searching of reference lists of shortlisted articles for full screening, and clinical trial registry searches. Two of these papers were reports of the same study albeit reporting 12 and 24-month outcomes separately (Miklowitz et al., 2000; Miklowitz et al., 2003).

2.6.1 Study characteristics

Characteristics, intervention descriptions and outcome measures are presented for each study in Table 2.4. The sample size of included studies ranged from 32 to 1268

participants. Twenty-three studies recruited people with schizophrenia or psychosis, five studies recruited people with bipolar disorder and two studies recruited mixed populations of people with schizophrenia or bipolar disorder. The mean age of included participants was 33.2 years old. Just over half of the studies were conducted in outpatient or community mental health settings (n= 16). Four studies were conducted in inpatient and outpatient settings, three in the participant's home and three on inpatient wards. One study was conducted in a voluntary sector setting, one in both an inpatient unit and the patient's home and one in both an outpatient unit and the patient's home. All studies were delivered by mental health professionals apart from one study which did not report the setting or who delivered the intervention.

Most studies were carried out in Europe (n= 11), the USA (n=6) and China (n= 6). Four studies were conducted in South East Asia (Indonesia, Sri Lanka, Thailand and Vietnam). One study was conducted in Australia, one in Pakistan and one in Mexico.

Only ten of the included studies measured an outcome of interest to this review as their primary outcome (nine studies measured medication adherence and one study measured smoking status). The remaining 20 studies measured an outcome of interest to this review as a secondary outcome.

Twenty-three studies reported at least some basic information on the characteristics of supportive others and all involved a family member or partner/spouse in the intervention. A small proportion of participants across two studies identified non-family members as the supportive other including a friend, landlady and ex-partner. Seven studies did not report any supportive other characteristics beyond labelling them as "carers" therefore it was unclear who was involved. No studies reported the involvement of existing formal or paid support workers.

Table 2.4. Characteristics of included studies

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Azrin & Teichner, 1998 USA	<p>Patients N = 39. Male (41%) and female (59%) adults (mean age = 38.5) Diagnosis = schizophrenia (53.8%), bipolar (25.6%), or major depressive disorder (20.5%)</p> <p>Carers Family members.</p>	Community mental health centre	<p>Group 1: Information giving (Medication adherence guideline) plus social support Mode: Individual Length of intervention: 1 appointment Length of session: 1 hour Number of sessions: 1 Care provider: Psychiatrist Participant: Patient and family member</p>	<p>Group 2: Psychoeducation Mode: Individual Length of intervention: 1 appointment Length of session: 1 hour Number of sessions: 1 Care provider: Psychiatrist Participant: Patient</p> <p>Group 3: Information giving (Medication adherence guideline) Mode: Individual Length of intervention: 1 appointment Length of session: 1 hour Number of sessions: 1 Care provider: Psychiatrist Participant: Patient</p>	<p>Psychiatric Medication Adherence Pill count: Count of the number of pills in the participant's possession compared to the number that should have been present if the prescribed number had been used. % compliance = (no. pills taken/no. pills prescribed) 2-month follow up</p>
Barrowclough et al., 2001 England	<p>Patients N = 36. Male (92%) and female (8%) adults (mean age = 31.1) Diagnosis = schizophrenia and substance abuse</p> <p>Carers N = 36 (Parent (66.7%), partner (16.7%), sibling (2.8%), grandparent (2.8%),</p>	Participant's home	<p>Group 1: Integrated intervention (information giving, motivational interviews, individual cognitive behavioural therapy (CBT), family/caregiver intervention) + routine care Mode: Individual Length of intervention: 9-months Length of session: Determined by each caregiver and support worker Number of sessions: 39-45. 18 sessions delivered weekly then</p>	<p>Group 2: Routine care (maintenance neuroleptic medication, and access to mental health services) Mode: Individual Length of intervention: Not specified Length of session: Not specified Number of sessions: Not specified Care provider: Multidisciplinary clinical team Participant: Patient</p>	<p>Psychiatric Medication Adherence Self report - The Drugs Attitude Inventory</p> <p>Substance Misuse Self report "Timeline follow-back" interview</p> <p>Drug and alcohol subscales of the Addiction Severity Index 6-month follow up</p>

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Barrowclough et al., 2001 England	landlady (5.5%) or ex-partner (5.5%).		biweekly Care provider: Support worker, clinical psychologists and nurse therapist Participant: Patient and caregiver		
Bressi et al., 2008 Italy	Patients N = 40. Male (75%) and female (25%) adults (mean age = 29) Diagnosis = schizophrenic disorder Carers Family members.	Psychiatric service for diagnosis and treatment within a general hospital	Group 1: Systemic Family Therapy (psychoeducation, family therapy, systemic questioning, monitoring behaviour tasks, habit formation and information gathering) plus routine care Mode: Individual Length of intervention: 12-months Length of session: 1.5 hours Number of sessions: 12 delivered monthly Care provider: 2 x family therapists who were trained psychologists Participant: Patient and family member	Group 2: Routine care (Drug treatment related to a series of clinical interviews) Mode: Individual Length of intervention: 12-months Length of session: Not specified Number of sessions: Varied with a minimum of 1 interview a month Care provider: Psychiatrist Participant: Patient	Psychiatric Medication Adherence Defined as poor if the patient discontinued therapy prescribed by the treating psychiatrist without discussing with the clinician. Attendance Defined as poor if the patient failed to attend a session with the treating psychiatrist or family therapists without prior notice. 12 & 24-month follow up
Carra et al., 2007 Italy	Patients N = 101. Male (72.3%) and female (27.7%) adults (mean age = 29.8) Diagnosis = schizophrenia	Non-profit, family advocacy and support agency	Group one: Psychoeducation + support group (training on communication, coping skills and mutual support) + standard care Mode: Group Length of intervention: 24-months Length of session: 1.5 hours Number of sessions: 48	Group two: Information group programme (Psychoeducation) + standard care Mode: Group Length of intervention: Not stated Length of session: 1.75 hours Number of sessions: 24 delivered weekly	Treatment Adherence Clinician report: A specifically designed 3 point scale to rate adherence to both psychiatric medication and non-medication treatment. Non-compliance = 3 (refusal of every proposed treatment) 12 & 24-month follow up

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Carra et al., 2007 Italy	Carers Parents (79.2%) or other relative (20.8%).		Care provider: Psychiatrist and key worker (standard care) Participant: Family member	Care provider: Psychiatrist and key worker (standard care) Participant: Family member Group three: Standard care (key worker management and pharmacological interventions) Mode: Individual Length of intervention: Not specified Length of session: Not specified Number of sessions: Not specified Care provider: Key worker and psychiatrist Participant: Patient	
Clarkin et al., 1998 USA	Patients N = 42. Male (59.5%) and female (40.5%) adults (mean age = 47.7) Diagnosis = bipolar Carers Spouse or partner.	Inpatient and outpatient psychiatric services	Group one: Marital intervention + standardized medication Mode: Individual Length of intervention: 11-months Length of session: 1.5 hours Number of sessions: 25. First 10 sessions delivered weekly then bimonthly Care provider: Social workers Participant: Partner and patient	Group two: Standardized medication (mood stabilizer, antidepressant, antipsychotic) Mode: Individual Length of intervention: Not stated Length of session: Not stated Number of sessions: Not stated Care provider: Not stated Participant: Patient	Psychiatric Medication Adherence Patient self-report questionnaire developed for the study Score of 1 = poor to 6 = excellent 11-month follow up
D'Souza et al., 2010 Australia	Patients N = 58. Male (48.3%) and female (51.7%) adults (mean age = 40.1)	Outpatient	Group one: Psychoeducation + routine care Mode: Group Length of intervention: 12-weeks Length of session: 90 mins	Group two: Routine care (Community based case management) Mode: Individual Length of intervention: 60-weeks Length of session: 45 mins	Psychiatric Medication Adherence Pill count: A rater- assessed medication adherence scale (ARS) based on pill count and need for repeat medication prescription

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
D'Souza et al., 2010 Australia	Diagnosis = bipolar Carers Spouse/partner (74.1%), child (11.1%), friend (7.4%), parent (3.7%), sibling (3.7%).		Number of sessions: 12 Care provider: 4x Mental health clinicians Participant: Companion and patient	Number of sessions: Not stated. Weekly with monthly medical review Care provider: Mental health clinician Participant: Patient	0=non-adherence, 1= partial adherence, 2 = full adherence 15-month follow up
Farooq et al., 2011 Pakistan	Patients N = 110. Male (85.5%) and female (14.5%) adults (mean age = 29.5) Diagnosis = schizophrenia (8.8%) or schizoaffective disorder (18.2%) Carers Brother (29.1%), father (24.5%), mother (9.1%), spouse (9.1%), sister (7.3%) child (4.5%), other (10.9%).	Psychiatric out-patients	Group one: Involvement and education of family member in medication taking and usual care Mode: Individual Length of intervention: Not specified Length of session: Not specified Number of sessions: Once a month Care provider: Psychiatrist, psychiatric nurses and a social worker. Participant: Family member and patient	Group two: Routine care (Outpatient setting including medication, out-patient attendance in the psychiatry department and brief counselling) Mode: Individual Length of intervention: Not specified Length of session: Not specified Number of sessions: Not specified Care provider: Psychiatrist, psychiatric nurses and a social worker. Participant: Patient	Psychiatric Medication Adherence Self report (participants and relatives) and pill count Complete adherence = 100% of medications prescribed taken. Partial adherence = medication taken but not every day during a week Non-adherence = missing drugs completely for 1 week+ 12-month follow up
Giron et al., 2010 Spain	Patients N = 50. Male (74%) and female (26%) adults (mean age = 31.5) Diagnosis = schizophrenia	Community mental health centres	Group one: Family intervention + individual counselling + standard treatment Mode: Individual Length of intervention: 24-months Length of session: Not specified Number of sessions: Fortnightly for the first 9-months then monthly	Group two: Individual counselling + standard treatment Mode: Individual Length of intervention: Not specified Length of session: Not specified Number of sessions: Not specified Care provider: Psychiatrist Participant: Patient	Psychiatric Medication Adherence Medical records - number of days without taking medication 24-month follow up

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Giron et al., 2010 Spain	Carers Characteristics not reported		Care provider: Psychiatrists, psychologists, social workers and nurses Participant: Family member and patient		
Guo et al., 2010 China	Patients N = 1268. Male (55%) and female (45%) adults (mean age = 26.3) Diagnosis = schizophrenia (84.6%) or schizophreniform disorder (15.4%) Carers Characteristics not reported	Outpatient	Group one: Psychosocial intervention (psychoeducation, family intervention, skills training, CBT + medication) Mode: Group Length of intervention: 12-months Length of session: One hour Number of sessions: 48 (4 sessions delivered on one day monthly) Care provider: Therapists who had at least two years of clinical experience, psychiatrist Participant: Caregiver and patient	Group two: Medication (Mood stabilizers, benzodiazepines, antidepressants, and anticholinergic medications) Mode: Individual Length of intervention: Not specified Length of session: Not specified Number of sessions: Not specified (Monthly) Care provider: Psychiatrist Participant: Patient	Psychiatric Medication Adherence Patient self- report/clinician report Noncompliance = taking <70% of prescribed medications 12-month follow up
Kopelowicz et al., 2012 USA	Patients N = 174. Male (65.5%) and female (35.5%) adults (mean age = 31.7) Diagnosis = schizophrenia or schizoaffective disorder Carers Family members.	Inpatient and outpatient community mental health centres	Group one: Multifamily group therapy and routine care Mode: Individual + group Length of intervention: 12-months Length of session: 90 mins Number of sessions: 24 (twice monthly) plus 6 hour workshop Care provider: psychiatrists, psychologists, or social workers Participant: Caregiver and patient	Group three: Routine care (community mental health centre, treatment plan, medication and psychiatric rehabilitation) Mode: Individual and group Length of intervention: Not stated Length of session: 20 mins Number of sessions: Monthly Care provider: Case manager, psychiatrist Participant: Patient	Psychiatric Medication Adherence Patient self-report - non-adherent (<50% adherent), partially adherent (50%-80% adherent), and Adherent (>80%) 4, 8, 12, 18 & 24-month follow up

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Kopelowicz et al., 2012 USA			Group two: Multifamily group therapy focused on adherence and routine care Mode: Individual + group Length of intervention: 12-months Length of session: 90 mins Number of sessions: Same as group one Care provider: Same as group one Participant: Caregiver and patient		
Li & Arthur, 2005 China	Patients N = 101. Male (42.6%) and female (57.4%) adults (mean age not reported) Diagnosis = schizophrenia Carers Family members.	Inpatient and home	Group one: Psychoeducation + routine care Mode: Individual Length of intervention: Not specified then 3-months post discharge Length of session: Patient 8 hours, Family member 36 hours in hospital +2hours a month post discharge for both together Number of sessions: Not specified Care provider: Nurse and nurse research assistants Participant: Patient and family member	Group two: Routine care (patients and families could ask staff for information. Educational pamphlets were available in a ward library) Mode: Individual Length of intervention: Not specified Length of session: Not specified Number of sessions: Not specified Care provider: Not specified Participant: Patient	Psychiatric Medication Adherence Self report - interruptions of 1 week or change against advice on a scale of 1–4 3-month follow up

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Merinder et al., 1999 Denmark	<p>Patients N = 46. Male (52.3%) and female (47.7%) adults (mean age = 35.9) Diagnosis = schizophrenia (73.9%), schizoaffective disorder (10.9%), psychotic disorder (4.3%), delusional disorder (2.2%)</p> <p>Carers Characteristics not reported</p>	Community mental health centres	<p>Group one: Psychoeducation Mode: Group Length of intervention: 8-weeks Length of session: Not specified Number of sessions: 8 Care provider: Not specified Participant: Separate groups for patients and relatives</p>	<p>Group two: Routine care (psychopharmacological treatment, psychosocial rehabilitation efforts and supportive psychotherapy) Mode: Individual Length of intervention: Not specified Length of session: Not specified Number of sessions: Not specified Care provider: Not specified Participant: Patient</p>	<p>Psychiatric Medication Adherence Case note review Non-adherence episode = 1+ episode of 14 days non-adherence</p> <p>12-month follow up</p>
Miklowitz et al., 2000 Miklowitz et al., 2003 USA	<p>Patients N = 101. Male (26.6%) and female (63.4%) adults (mean age = 35.4) Diagnosis = bipolar</p> <p>Carers Parents, spouses or sibling.</p>	Inpatient and outpatient	<p>Group one: Family-focused therapy (psychoeducation, communication skills training and problem solving) + pharmacotherapy Mode: Individual Length of intervention: 9-months Length of session: 1 hour Number of sessions: 21 (weekly for 3-months, biweekly for 3-months then monthly for 3-months) Care provider: Therapists Participant: Caregiver and patient</p>	<p>Group two: Routine care (pharmacotherapy with emergency counselling, telephone monitoring and abridged family education) Mode: Individual Length of intervention: 9-months Length of session: Adjusted to patient need Number of sessions: 9-monthly plus two sessions of family education Care provider: Physician Participant: Patient</p>	<p>Psychiatric Medication Adherence Self report checked against physicians' observations and laboratory blood monitoring data. Score of 1-3 where 1 = 100% non-adherence, 2 = partial non-adherence, 3 = 100% adherence</p> <p>12 and 24-month follow up</p>

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Morken, Grawe & Widen, 2007 Norway	Patients N = 50. Male (62%) and female (38%) adults (mean age = 25.1) Diagnosis = schizophrenia (80%), schizoaffective disorder (12%) and schizophreniform disorder (8%) Carers Family.	Participant's home	Group one: Integrated treatment (structured family psychoeducation, social skills training, CBT strategies) + Regular case management Mode: Individual Length of intervention: 24-months Length of session: 1 hour Number of sessions: weekly for 2-months, every third week for 12-months and monthly for 12-months Care provider: Multidisciplinary mental health team Participant: Caregiver and patient	Group two: Regular case management (Antipsychotic drugs, supportive housing and day care, crisis inpatient treatment rehabilitation promoting independent living psychoeducation and psychotherapy) Mode: Individual Length of intervention: Not stated Length of session: Not stated Number of sessions: Not stated Care provider: Not stated Participant: Patient	Psychiatric Medication Adherence Self report, carer report, therapist report, plasma assays and patient records Adherent = up to 1 week without medication Non-adherent = 1 month+ or 4 single weeks+ without medication 12 and 24-month follow up
Ngoc, Weiss & Trung, 2016 Vietnam	Patients N = 59. Male (50.8%) and female (49.2%) adults (mean age = 24.3) Diagnosis = schizophrenia Carers Family.	Inpatient	Group one: Family psychoeducational + drug treatment and monitoring Mode: Individual Length of intervention: Week and a half Length of session: 1.5 hours Number of sessions: 3 Care provider: Psychiatrist, 2x psychologists and 2x nurses Participant: Caregiver and patient	Group two: Drug treatment and monitoring Mode: Individual Length of intervention: Not stated Length of session: Not stated Number of sessions: Not stated Care provider: Physician Participant: Patient	Psychiatric Medication Adherence Self-report using a medication compliance inventory, adapted for Vietnam 0–2 frequency scale, with higher scores indicating higher non-adherence 6-month follow up

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Penn et al., 2011 USA	<p>Patients N = 46. Male (60.9%) and female (39.1%) adults (mean age = 22) Diagnosis = schizophrenia (54%), schizophreniform disorder (28%) or schizoaffective disorder</p> <p>Carers Characteristics not reported</p>	Outpatient	<p>Group one: Psychoeducation, CBT, motivational interviewing and social skills training with self-identified supporter + routine care Mode: Individual Length of intervention: 36-weeks Length of session: Not specified Number of sessions: 36 plus monthly contact with supporter Care provider: Social worker, clinical psychologist, psychiatrist Participant: Caregiver and patient</p>	<p>Group two: Routine care (Early intervention clinic with community outreach, family involvement and psychoeducation and social skills groups) Mode: Individual Length of intervention: Not specified Length of session: Not specified Number of sessions: Not specified Care provider: Social worker, psychiatrist Participant: Caregiver (optional) and patient</p>	<p>Substance Misuse Self report - Alcohol Use Scale (AUS) and Drug Use Scale (DUS) 5 point scale from 1 = No use to 5 = Severe dependence</p> <p>3-month follow up</p>
Petersen et al., 2005 Denmark	<p>Patients N = 547. Male (59%) and female (41%) adults (mean age = 26.6) Diagnosis = schizophrenia (66.2%), schizotypal (14.4%), psychosis (8.2%), delusional disorder (4.6%), schizoaffective (4.6%), psychosis (2%)</p> <p>Carers Characteristics not reported</p>	inpatient and outpatient	<p>Group one: Psychoeducational family treatment (assertive community treatment with family involvement and social skills training) Mode: Group Length of intervention: 18-months Length of session: 1.5 hours Number of sessions: Twice weekly sessions (approx. 156 sessions) Care provider: 2xTherapists Participant: Caregiver and patient</p>	<p>Group two: Routine care (community mental health centre) Mode: Individual Length of intervention: Not specified Length of session: Not specified Number of sessions: Not specified Care provider: Physician, a community mental health nurse, social worker Participant: Patient</p>	<p>Attendance Medical records - discontinuation of treatment for at least a month and discontinuation of treatment despite need</p> <p>12 and 24-month follow up</p>

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Pitschel-Walz et al., 2006 Germany	<p>Patients N = 236. Male (44%) and female (56%) adults (mean age = 33) Diagnosis = schizophrenia</p> <p>Carers N = 125. (Parent (57%), partner (26%), other (adult child, sibling or friend) (17%)).</p>	Inpatient	<p>Group one: Psychoeducational groups + medication Mode: Group Length of intervention: 5-months Length of session: Patients = 1 hour Relatives = 90 mins Number of sessions: Patients = 8 (4-weekly and 4-monthly) Relatives = 8 biweekly Care provider: Psychiatrists and clinical psychologist Participant: Caregiver and patient (separate groups)</p>	<p>Group two: Routine care (Maintenance antipsychotic medication and outpatient treatment) Mode: Individual Length of intervention: Not stated Length of session: Not stated Number of sessions: At least one appointment a month Care provider: Not stated Participant: Patient</p>	<p>Psychiatric Medication Adherence Psychiatrist rated on a scale of 1-4 (1=very good, 2=good, 3=mediocre or 4=poor) and validated using plasma drug level measurements</p> <p>12 and 24-month follow up</p>
Ran et al., 2003 China	<p>Patients N = 326. Male (39.3%) and female (60.7%) adults (mean age = 43.6) Diagnosis = schizophrenia</p> <p>Carers N = 326. (Parent (29.8%), spouse (53.7%), other (16.6%)).</p>	Community	<p>Group one: Psychoeducational family treatment + drug treatment Mode: Individual + group Length of intervention: 9-months Length of session: 1.5-3 hours Number of sessions: 9-monthly Care provider: Psychiatrists and village doctors Participant: Caregiver and patient</p>	<p>Group two: Drug treatment (haloperidol decanoate (50 - 125mg/month) and/or oral depot) Mode: Individual Length of intervention: 9-months Length of session: Not specified Number of sessions: Not specified Care provider: Not specified Participant: Patient</p> <p>Group three: Control (Medication was neither encouraged nor discouraged) Mode: Individual Length of intervention: 9-months Length of session: Not specified</p>	<p>Psychiatric Medication Adherence Therapist rated. Categorised as either: maintained regular treatment, irregular/discontinued treatment or never/refused treatment 9-month follow up</p>

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Ran et al., 2003 China				Number of sessions: Not specified Care provider: Not specified Participant: Patient	
Rea et al., 2003 USA	Patients N = 53. Male (43%) and female (57%) adults (mean age = 43.6) Diagnosis = bipolar Carers N = 74. (Parent (70.3%), spouse (12.2%), sibling (9.5%), aunt (5.4%) grandparent (1.4%) uncle (1.4%).)	Inpatient	Group one: Family-focused psychoeducational therapy, communication and problem solving skills training + mood-stabilizing medications Mode: Individual Length of intervention: 9-months Length of session: 1 hour Number of sessions: 21: 12-weekly, 6 biweekly, 3-monthly Care provider: 2x therapists Participant: Patient and family	Group two: Individually focused patient treatment, education and problem solving + mood-stabilizing medications Mode: Individual Length of intervention: 9-months Length of session: 30 minutes Number of sessions: 21: 12 weekly, 6 biweekly, 3-monthly Care provider: 1x therapist Participant: Patient	Psychiatric Medication Adherence Psychiatrist rated using a 7-point Likert scale using patients' reports, psychiatrists' observations, and medication blood levels 1 = Full compliance to 7 = Discontinued medication against medical advice 24-month follow up
Reinares et al., 2008 Spain	Patients N =113. Male (46%) and female (54%) adults (mean age = 34) Diagnosis = bipolar Carers N = 113. (Parent (54.9%), partner (39.8%), other (sibling, child) (5.3%).)	Outpatient	Group one: Psychoeducational group + standard care Mode: Group Length of intervention: 12-weeks Length of session: 90 mins Number of sessions: 12 Care provider: Psychologist Participant: Caregiver	Group two: Standard care (outpatient follow-up and pharmacotherapy) Mode: Individual Length of intervention: Not specified Length of session: Not specified Number of sessions: Not specified Care provider: Clinicians Participant: Patient	Psychiatric Medication Adherence Self report, caregiver report and plasma concentrations of mood stabilizers "Good adherence" not defined 12-month follow up

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Rodrigo et al., 2013 Sri Lanka	Patients N =50. Male (36%) and female (64%) adults (mean age = 44.3) Diagnosis = schizophrenia Carers Characteristics not reported	Outpatient	Group one: Assessment and support from a Mental Health Development Officer Mode: Group Length of intervention: Not specified Length of session: Not specified Number of sessions: Monthly Care provider: Mental Health Development Officer Participant: Caregiver and patient	Group two: Standard care (clinical visits, pharmacology management, referral to MHDO if needed) Mode: Individual Length of intervention: Not specified Length of session: Not specified Number of sessions: Not specified Care provider: Medical officer Participant: Patient	Attendance Monthly attendance at clinic visits 12-month follow up
Sari, Suttharangsee & Chanchong, 2014 Indonesia	Patients N =52. Male (66%) and female (34%) adults (mean age = 33.7) Diagnosis = schizophrenia Carers Spouse, parent, sibling or other family member.	Outpatient	Group one: Self-Management, education and counselling with Family Participation Program Mode: Individual Length of intervention: 1 month Length of session: 10-90 mins Number of sessions: 4 mental health education and counselling sessions, 2 telephone follow-ups, and face-to-face follow-up Care provider: Nurse Participant: Caregiver and patient	Group two: Routine care (regular check-ups, medication, and unstructured health education) Mode: Individual Length of intervention: Not specified Length of session: Not specified Number of sessions: Not specified Care provider: Nurse or physician Participant: Patient	Psychiatric Medication Adherence Self report: Medication Adherence Behaviour Questionnaire. Total score ranges from 10-40. A higher score indicates higher medication adherence Follow up time not reported
Strang et al., 1981 UK	Patients N =32. Diagnosis = Schizophrenia Carers Family or partner.	Not reported. Not inpatient as "recently discharged"	Group one: Family Therapy + oral neuroleptic medication or if non-compliant - fluphenazine decanoate injections Mode: Not stated Length of intervention: Not stated	Group two: Individual Supportive Therapy + oral neuroleptic medication or if non-compliant - fluphenazine decanoate injections Mode: Individual Length of intervention: Not stated	Psychiatric Medication Adherence No. changed to depot, pill counts, patient/ family report. Plasma levels. Non adherence defined as taking <50% of prescribed dose

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Strang et al., 1981 UK			Length of session: Not stated Number of sessions: Not stated Care provider: Not stated Participant: Not stated	Length of session: Not stated Number of sessions: Not stated Care provider: Not stated Participant: Not stated	6-month follow up Attendance Number of missed appointments with psychiatrist 6-month follow up
Tantirangsee et al., 2015 Thailand	Patients N =169. Male (98.2%) and female (1.8%) adults (mean age = 35.3) Diagnosis = schizophrenia (80.5%, transient psychotic disorder (10.7%) or psychosis (8.9%). Carers Family members.	Outpatient psychiatric treatment clinics	Group one: Psychoeducation, Motivational Interviewing and family involvement Mode: Individual Length of intervention: 1 session Length of session: 45-75 minutes Number of sessions: 1 Care provider: Psychiatric nurse Participant: Caregiver and patient	Group two: Psychoeducation and Motivational Interviewing Mode: Individual Length of intervention: 1 session Length of session: 30–45 minutes Number of sessions: 1 Care provider: Psychiatric nurse Participant: Patient Group three: Standard care (Substance misuse advice) Mode: Individual Length of intervention: 1 session Length of session: 5 minutes Number of sessions: 1 Care provider: 4 x psychiatric nurses Participant: Patient	Smoking Self-report: Smoking Involvement Score (SIS) low risk [score 0–3], moderate risk [4–14 or high risk [15+] Time-line follow-back interview (TLFB) –No of days and amount of substance use in the last 28 days. 6-month follow up Alcohol As above 6-month follow up

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Valencia et al., 2007 Mexico	<p>Patients N =82. Male (78%) and female (12%) adults (mean age = 29.8) Diagnosis = schizophrenia</p> <p>Carers Family members.</p>	Outpatient	<p>Group one: Psychoeducation, problem solving and communication skills training + family therapy + recreational activities + standard care Mode: Individual + group Length of intervention: 12-months Length of session: 1 hour 15 minutes Number of sessions: 48 Care provider: Family therapists and art teacher Participant: Caregiver and patient</p>	<p>Group two: Standard care (medication management) Mode: Individual Length of intervention: 12-months Length of session: 20 mins Number of sessions: 12-monthly Care provider: 2 x two clinical psychiatrists Participant: Patient</p>	<p>Psychiatric Medication Adherence Self report verified by psychiatrist and medical records</p> <p>Adequate compliance= >80% of prescribed medication taken</p> <p>12-month follow up</p> <p>Attendance (1) patient attendance at sessions (2) intervention completers and drop outs</p> <p>12-month follow up</p>
Van Gent & Zwart, 1991 The Netherlands	<p>Patients N =26. Adults (mean age = 49.5) with bipolar disorder.</p> <p>Carers Partner.</p>	Outpatient	<p>Group one: Psychoeducation + information booklet Mode: Group Length of intervention: Not stated Length of session: Not stated Number of sessions: 5 Care provider: Psychiatrist, social worker. Participant: Partner (with joint homework for patient and partner)</p>	<p>Group two: Control Mode: Not stated Length of intervention: Not stated Length of session: Not stated Number of sessions: Not stated Care provider: Not stated Participant: Not stated</p>	<p>Psychiatric Medication Adherence Serum lithium levels</p> <p>Non-compliance = a difference between tests of more than 0.30 mmol/l in serum lithium levels without changing medication.</p> <p>12-month follow up</p>

Reference and country	Population	Study setting	Intervention group description	Control group description	Outcome measures and follow up period
Xiang, Ran & Li, 1994 China	Patients N =77. Adults (mean age = 40.9) Diagnosis = schizophrenia (89.6%) or affective disorder (10.4%). Carers Characteristics not reported	Community mental health services	Group one: Psychoeducation + drug treatment Mode: Individual + group Length of intervention: Not stated Length of session: Not stated Number of sessions: Family visits, workshops, seminars & supervision Care provider: Not stated Participant: Caregiver	Group two: Drug treatment (injection of haloperidol decanoate (75 mg) Mode: Individual Length of intervention: Not stated Length of session: Not stated Number of sessions: Once monthly Care provider: Not stated Participant: Patient	Psychiatric Medication Adherence Medical records Full compliance = 100% of prescribed medications taken Partial adherence Non-compliance = 0% of prescribed medications taken 4-month follow up
Xiong et al., 1994 China	Patients N =63. Male (68%) and female (22%) adults (mean age = 31) Diagnosis = schizophrenia Carers Family member or partner.	Inpatient and community	Group one: Counselling sessions and family groups Mode: Individual + group Length of intervention: 24-months Length of session: 45 minute counselling and 90 minute group Number of sessions: 24-monthly Care provider: Therapist Participant: Caregiver and patient	Group two: Drug treatment and ad hoc clinic attendance Mode: Individual Length of intervention: Not stated Length of session: Ad hoc Number of sessions: Ad hoc Care provider: Not stated Participant: Caregiver and patient	Psychiatric Medication Adherence Carer report Duration of drug compliance (i.e. time for which the patient took >50% of medication) 18-month follow up
Zhang et al., 1994 China	Patient N =83. Male adults (mean age = 23.8) with schizophrenia. Ethnicity = Chinese Carers Family. Characteristics not reported	Outpatient or participant's home	Group one: Family therapy + standard care Mode: Individual + group Length of intervention: Not stated Length of session: Not stated Number of sessions: 1 every 3-months Care provider: Counsellor Participant: Caregiver and patient	Group two: Standard care (Outpatient appointments and medication prescriptions) Mode: Individual Length of intervention: Not stated Length of session: Not stated Number of sessions: Not stated Care provider: Clinicians Participant: Caregiver and patient	Psychiatric Medication Adherence Self and family report 18-month follow up

*MD= Mean difference, MeD = Median difference, MCD = Mean change difference

2.6.2 Content of interventions and comparators

Interventions ranged from complex and time intensive packages of therapeutic approaches usually involving family therapy, motivational interviewing, cognitive behavioural therapy (CBT), psycho-educational sessions and routine mental health care delivered to the person with SMI and/or their supportive other, to one-off information-giving or psychoeducational sessions with a family member present (See table 2.4 for full details of each study).

Interventions lasted from one hour, one off sessions (Azrin & Teichner, 1998), to fortnightly/monthly sessions over a 24-month period (Carra et al., 2007; Giron et al., 2010; Morken, Grawe & Widen, 2007; Xiong et al., 1994). The majority of studies (n=25) targeted both the patient and supportive other, while four studies targeted the supportive other alone (Carra et al., 2007; Reinares et al., 2008; Van Gent & Zwart, 1991; Xiang, Ran & Li, 1994). In one study it was not specified who was targeted however the intervention included family therapy, suggesting that both the patient and family were involved, while the control condition was supportive therapy delivered to the individual patient (Strang et al., 1981). There was no description in any of the identified studies regarding the extent to which the interventions used social support as a mechanism to increase adherence and engagement with CVD risk reducing behaviours. There was very little information available on how social support was used and incorporated within interventions, beyond a description that the intervention was delivered to the patient and/or their supportive other.

Half of the studies (n=15) focused on individually delivered intervention sessions with the patient and/or supportive other, while eight studies tested group interventions involving patients and supportive others together (D'Souza et al., 2010; Guo et al., 2010; Petersen et al., 2005; Rodrigo et al., 2013); separate groups for patients and supportive others (Merinder et al, 1999; Pitschel-Walz et al., 2006) and groups for supportive others only (Reinares et al., 2008; Van Gent & Zwart, 1991). Six studies used a combination of individual and group sessions for patients and supportive others together (Kopelowicz

at al., 2012; Ran et al., 2003; Valencia et al., 2007; Xiong et al., 1994; Zhang et al., 1994) or supportive others alone (Xiang, Ran & Li, 1994).

In the majority of studies (n=24) the comparator group was treatment as usual involving routine health care and/or medication. It was therefore difficult to separate out the effects of social support from other intervention components in these studies. In three studies (Girón et al., 2010; Rea et al., 2003; Strang et al., 1981), the comparator was individual therapy without the involvement of a supportive other. Only two studies tested the intervention delivered to patients and supportive others against a control group of the same intervention delivered to patients alone (Azrin & Teichner, 1998; Tantirangsee et al., 2015). Both studies included a second control group; one study tested treatment as usual as the second control group (Tantirangsee et al., 2015) while the other study tested psychoeducation delivered to the patient alone (Azrin & Teichner, 1998). One study compared two groups of the same intervention delivered to families and carers against a third group receiving treatment as usual, however one of the intervention groups emphasised adherence strategies in the intervention sessions while the other intervention group did not (Kopelowicz et al., 2012).

2.6.3 Methodological quality of included studies

Most studies were not well-reported; therefore risk of bias was unclear for many aspects of the methodological quality assessment (See Table 2.5 for quality assessment of each study). Twenty-three studies did not report any attempts to conceal allocation status to therapists delivering the intervention and patients receiving the intervention, neither did they acknowledge that blinding of therapists or patients may have not been possible due to the nature of the intervention being tested (i.e. complex time intensive interventions tested against treatment as usual). In five studies, researchers collecting outcome measures were not blind to treatment allocation, and in eight studies, any attempts to blind researchers conducting the outcome assessments were not reported. Only two studies were assessed as at low risk of bias (Farooq et al., 2011; Reinares et al., 2008). Both studies tested psychoeducation delivered to caregivers and patients together against drug treatment and/or routine care delivered to the patient alone. Farooq et al (2011) found greater adherence to medication in the intervention group

compared to control at 12-month follow up while Reinares et al (2008) found no difference in medication adherence between the intervention and control at either 12 or 24-month follow up.

Most studies did not fully report the results of the statistical analyses and in some studies the data and descriptive statistics were missing. The majority of studies did not report baseline data, and it was unclear if analyses of follow up data adjusted for baseline values, therefore the effectiveness of the interventions tested is difficult to interpret.

Just over half of the studies used self-report measures either from patients, supportive others, clinicians or a combination of the three to assess outcomes, which may have resulted in recall bias. Only one study clearly reported on blinding of participants to allocation status and in many cases the intervention was complex and time intensive and compared to routine care therefore blinding of participants was not possible. This may have led to performance bias in those studies relying on self-report measures.

For studies rated as at an unclear risk of bias however, this was due to an absence of information upon which to judge the quality of the study, and does not necessarily reflect poor study design.

Table 2.5. Risk of bias of included studies

Reference	Selection Bias		Performance bias	Detection bias	Attrition bias	Reporting bias	Summary for the study (Red=high risk, Green=low risk, Orange=unclear risk)	Comments on high risk assessments
	Random Sequence Generation	Allocation Concealment	Blinding of participants and personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Selective Reporting		
Azrin & Teichner, 1998	Orange	Orange	Orange	Red	Red	Green	R=2, G= 1, O=3	Assessors of functional outcomes were not blind to treatment allocation. Not all P values reported
Barrowclough et al., 2001	Green	Green	Red	Green	Green	Red	R=2, G= 4, O=0	Patients not blind and not all pre specified outcomes were reported
Bressi et al., 2008	Orange	Orange	Red	Green	Red	Green	R=2, G= 2, O=2	Patients not blind, attrition related to outcome (non-adherent participants removed from analysis)
Carra et al., 2007	Green	Green	Green	Green	Red	Green	R=1, G= 5, O=0	P values not reported
Clarkin et al., 1998	Orange	Orange	Orange	Orange	Red	Green	R=1, G= 1, O=4	High attrition (greater than 10%), reasons not reported Standard deviations not reported
D'Souza et al., 2010	Orange	Orange	Orange	Green	Green	Green	R = 0, G= 3, O=3	
Farooq et al., 2011	Green	Green	Orange	Green	Green	Green	R = 0, G= 5, O=1	

Reference	Selection Bias		Performance bias	Detection bias	Attrition bias	Reporting bias	Summary for the study (Red=high risk, Green=low risk, Orange=unclear risk)	Comments on high risk assessments
	Random Sequence Generation	Allocation Concealment	Blinding of participants and personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Selective Reporting		
Giron et al., 2010	Orange	Orange	Orange	Green	Green	Green	R = 0, G= 3, O=3	
Guo et al., 2010	Orange	Orange	Orange	Green	Red	Green	R=1, G= 2, O=3	Large attrition and unequal 5% more in treatment as usual (TaU). Reasons not given
Kopelowicz et al., 2012	Green	Orange	Orange	Green	Red	Green	R=1, G= 3, O=2	Not all P values reported
Li & Arthur, 2005	Orange	Orange	Orange	Red	Red	Green	R=2, G= 1, O=3	Assessors not blind to treatment, Greater than 10% attrition, higher attrition in TaU. P values not reported
Merinder et al., 1999	Green	Green	Red	Red	Red	Green	R=3 G= 3, O=0	Participants and researchers were not blind to allocation. Greater than 10% attrition
Miklowitz et al., 2000 Miklowitz et al., 2003	Orange	Orange	Red	Orange	Red	Green	R=2 G= 1, O=3	Same therapists delivered both interventions. Patients not blind. Attrition 5% greater in control. Reasons for drop out given but not by group allocation
Morken, Grawe & Widen, 2007	Green	Green	Orange	Green	Red	Green	R=1 G= 4, O=1	P values not reported
Ngoc, Weiss & Trung, 2016	Orange	Orange	Orange	Green	Red	Green	R=1 G= 2, O=3	Attrition greater than 10%, no reasons given

Reference	Selection Bias		Performance bias	Detection bias	Attrition bias	Reporting bias	Summary for the study (Red=high risk, Green=low risk, Orange=unclear risk)	Comments on high risk assessments
	Random Sequence Generation	Allocation Concealment	Blinding of participants and personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Selective Reporting		
Penn et al., 2011	Green	Orange	Orange	Red	Red	Green	R=1 G= 3, O=2	Recruiters and researchers assessing outcomes were not blind to treatment allocation for some outcome measures. P values not reported
Petersen et al., 2005	Green	Green	Orange	Red	Red	Green	R=2 G= 3, O=1	Assessors were not blind to treatment allocation. Greater than 10% attrition and reasons for attrition only reported for some not all lost patients
Pitschel-Walz et al., 2006	Green	Green	Orange	Orange	Red	Green	R=1 G= 3, O=2	Attrition greater than 10%,
Ran et al., 2003	Green	Orange	Orange	Green	Red	Green	R=1 G= 3, O=2	Reasons for attrition not reported in the TaU group. Imbalanced attrition between groups. Not all P values reported
Rea et al., 2003	Orange	Orange	Orange	Green	Green	Green	R=0 G= 3, O=3,	Therapists not blind to allocation
Reinares et al., 2008	Green	Orange	Orange	Green	Green	Green	R=0 G= 4, O=2	
Rodrigo et al., 2013	Orange	Orange	Orange	Orange	Orange	Green	R=0 G= 1, O=5	

	Selection Bias		Performance bias	Detection bias	Attrition bias	Reporting bias		
Reference	Random Sequence Generation	Allocation Concealment	Blinding of participants and personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Selective Reporting	Summary for the study (Red=high risk, Green=low risk, Orange=unclear risk)	Comments on high risk assessments
Sari, Suttharangsee & Chanchong, 2014	Orange	Orange	Orange	Green	Green	Red	R=1 G= 2, O=3	Not all pre specified outcomes were reported Time to follow up not reported
Strang et al., 1981	Orange	Orange	Orange	Orange	Green	Green	R=0 G= 2, O=4	Lack of information to be able to reliably assess bias
Tantirangsee et al., 2015	Green	Green	Red	Green	Red	Red	R=3 G= 3, O=0	Therapists were trained in all procedures. Not all study measures were reported.
Valencia et al., 2007	Orange	Orange	Orange	Green	Red	Green	R=1, G= 2, O=3	Greater than 10% attrition. Reasons for loss not given and numbers slightly higher in TaU. Numbers who were adherent in each group not reported (only %)
Van Gent & Zwart 1991	Orange	Orange	Orange	Orange	Red	Green	R=1, G= 1, O=4	P value not reported
Xiang, Ran & Li, 1994	Orange	Orange	Orange	Green	Orange	Red	R=1 G= 1, O=4	Not all pre specified outcomes were reported
Xiong et al., 1994	Orange	Orange	Orange	Green	Green	Red	R=1, G= 2, O=3	Not all pre specified outcomes were reported
Zhang et al., 1994	Orange	Orange	Orange	Orange	Green	Green	R=0 G= 2, O=4	

2.6.4 Outcomes

The following outcome measures were assessed in the 30 included trials: adherence to psychiatric medication = 25 studies, attendance at appointments with mental health professionals = five studies, substance misuse (including alcohol use) = three studies, combined medication adherence and attendance measures = one study and smoking = one study. Multiple outcomes of interest were assessed in five studies. Only 10 studies assessed an outcome of interest to this review as their primary outcome.

No trials were identified on the pre-specified outcomes of adherence to CVD risk reducing medications, attendance at non-mental health service appointments, healthy eating or physical activity.

2.6.4.1 Adherence to psychiatric medications

Of the 25 studies measuring adherence to psychiatric medications as an outcome, 13 studies found a significant effect in favour of the intervention over the control at all follow up periods (Azrin & Teichner, 1998; Clarkin et al., 1998; D'Souza et al., 2010; Farooq et al., 2011; Guo et al., 2010; Ngoc et al., 2016; Pitschel-Walz et al., 2006; Ran et al., 2003; Sari, Suttharangsee & Chanchong, 2014; Strang et al., 1981; Valencia et al., 2007; Xiang et al., 1994; Zhang et al., 1994), nine studies reported no effect (Girón et al., 2010; Kopelowicz et al., 2012; Li & Arthur, 2005; Merinder et al., 1999; Morken, Grawe & Widen, 2007; Rea et al., 2003; Reinares et al., 2008; van Gent & Zwart, 1991; Xiong et al., 1994), one study found an effect at 12 but not 24-month follow up (Bressi et al., 2008) and one study found no effect at 12-months but did find an effect at 24-month follow up (Miklowitz et al., 2000; Miklowitz et al., 2003;. One study did not report the results of the medication adherence outcome analysis (Barrowclough et al., 2001). For a summary of results please refer to Table 2.6.

Psychiatric medication adherence was targeted as a primary outcome in nine studies (Azrin & Teichner, 1998; Farooq et al., 2011; Kopelowicz et al., 2012; Morken, Grawe & Widen, 2007; Pitschel-Walz et al., 2006; Sari, Suttharangsee & Chanchong, 2014; Strang et al., 1981; Xiang et al., 1994; Xiong et al., 1994) and a secondary outcome in 16 studies (Barrowclough et al., 2001; Bressi et al., 2008; Clarkin et al., 1998; D'Souza et al., 2010; Girón et al., 2010; Guo et al., 2010; Li & Arthur, 2005; Merinder et al., 1999; Miklowitz

et al., 2000; Miklowitz et al., 2003; Ngoc et al., 2016; Ran et al., 2003; Rea et al., 2003; Reinares et al., 2008; Valencia et al., 2007; van Gent & Zwart, 1991; Zhang et al., 1994).

Outcome measurement tools varied greatly across studies and included pill counts (Azrin & Teichner, 1998; D'Souza et al., 2010; Girón et al., 2010), medical records review (Merinder et al., 1999; Xiang et al., 1994), patient self-report (Barrowclough et al., 2001; Clarkin et al., 1998; Guo et al., 2010; Li & Arthur, 2005; Ngoc et al., 2016; Sari, Suttharangsee & Chanchong, 2014), carer self-report (Xiong et al., 1994), patient and carer self-report (Farooq et al., 2011; Zhang et al., 1994), clinician self-report (Ran et al., 2003) or a combination of patient, carer and/or clinician self-report alongside medical records (Kopelowicz et al., 2012; Valencia et al., 2007), pill counts and/or blood monitoring (i.e. drug level assays) (Miklowitz et al., 2000; Miklowitz et al., 2003; Morken, Grawe & Widen, 2007; Pitschel-Walz et al., 2006; Rea et al., 2003; Reinares et al., 2008; Strang et al., 1981; van Gent & Zwart, 1991). In one study, the tool used to measure medication adherence was not described (Bressi et al., 2008).

Reporting of the outcomes also varied across studies with 13 studies reporting the proportion of participants who were adherent to medication (Bressi et al., 2008; Farooq et al., 2011; Guo et al., 2010; Kopelowicz et al., 2012; Li & Arthur, 2005; Pitschel-Walz et al., 2006; Ran et al., 2003; Reinares et al., 2008; Strang et al., 1981; Valencia et al., 2007; Van Gent & Zwart, 1991; Xiang et al., 1994; Zhang et al., 1994), seven studies reporting a mean adherence score (Clarkin et al., 1998; D'Souza et al., 2010; Miklowitz et al., 2000; Miklowitz et al., 2003; Ngoc et al., 2016; Pitschel-Walz et al., 2006; Rea et al., 2003; Sari, Suttharangsee & Chanchong, 2014), and one study reporting the mean proportion of adherence to prescribed medications (Azrin & Teichner, 1998). In two studies, adherence was measured as the average time patients were adherent over the study period (Girón et al., 2010; Xiong et al., 1994) and in one study, adherence was reported as the mean reduction in number of non-adherent episodes (Merinder et al., 1999). One study did not report the results of the analysis (Barrowclough et al., 2001).

Medication adherence as a primary outcome

Six of the nine studies measuring medication adherence as a primary outcome found a significant effect in favour of the intervention group at follow up (Azrin & Teichner, 1998; Farooq et al., 2011; Pitschel-Walz et al., 2006; Sari, Suttharangsee & Chanchong, 2014; Strang et al., 1981; Xiang et al., 1994). The majority of these interventions were psychoeducation or information giving to the participant and/or their supportive other. Three studies found no significant difference between the intervention and control group (Kopelowicz et al., 2012; Morken, Grawe & Widen, 2007; Xiong et al., 1994). In these studies, the interventions were multicomponent therapy or family therapy. For a summary of the results see Table 2.6.

For those studies reporting an effect and the outcome as the proportion of people who were adherent to medication, the difference in adherence at follow up ranged between 21.8%-53.8% greater adherence in the intervention group than the control, with the odds of people being adherent in the intervention group compared to the control ranging from 2.47 to 11.67. Where the outcome was reported as the mean adherence score on a range of self-report questionnaires; the difference between the intervention and control group ranged from a mean score of 0.4 to 5.28 with moderate to large effect sizes reported (0.57 – 1.27).

Psychoeducation/information giving interventions

Four of the six studies that found an effect on adherence to psychiatric medication as the primary outcome tested psychoeducation or information giving to the participant and the supportive other, or to the supportive other alone as the intervention (Azrin & Teichner, 1998; Xiang et al., 1994; Farooq et al., 2011; Pitschel-Waltz et al., 2006). Two of these studies had small sample sizes (Azrin & Teichner, 1998; Xiang et al., 1994) and only one of these studies was rated as being at a low risk of bias (Farooq et al., 2011) (See Table 2.5 for the quality assessment ratings).

Farooq et al (2011) compared psychoeducation delivered in individual sessions to the supportive other and patient together against routine care and found that a significantly greater proportion of people were 100% adherent in the intervention group compared

to the control at 12-months (n=110, 67.3% vs 45.5%, OR=2.47, 95% CI 1.14-5.35, p<0.02). Reporting the relative risk, participants in the intervention group were 1.59 times more likely to adhere to medication than those in the control (95% CI 1.03–2.53).

Xiang et al (1994) tested psychoeducation delivered to the supportive other without the patient in a mixture of individual and group settings against routine care and found that the odds of the patient being 100% adherent to medication were five times greater in the intervention group than the control at four-months (n=77, 47.2% vs 14.6%, OR=5.22, 95% CI 1.76-15.45, p<0.05).

Pitschel-Waltz et al (2006) found that psychoeducation delivered to supportive others and patients in separate group sessions was superior in terms of the proportion of people with 'very good' or 'good' adherence compared to routine care at 24-months (n=236, 80% vs 55%, OR=3.18, 95% CI 1.49-6.79, p<0.01). The mean adherence score for the psychoeducation group at 12-months was also significantly lower than for the routine care group (1.7(0.6) vs 2.1(0.8), d=0.57, 95% CI 0.23-0.92, p=0.003), with lower scores indicating greater adherence. The mean adherence score at 24-month follow up was not reported.

In a small study, Azrin & Teichner (1998) tested an individual one-off, one hour information giving session on medication adherence for patients and supportive others compared with a psychoeducation session delivered to the patient alone and an information giving session delivered to the patient alone. Mean adherence to medication was significantly higher in the information session with patients and supportive others than psychoeducation delivered to the patient alone at two-month follow up (n=39, 95.03%(6.38) vs 73.62%(23.07), d=1.26, 95% CI 0.42-2.10, p<0.01). Adherence did not however significantly differ between the information session with patients and supportive others and the same information session delivered to patients alone (95%(6.38) vs 92%(9.54), d= 0.37, 95% CI 0.41-1.15, p value not reported) suggesting that the information session was the effective component of the intervention rather than the involvement of a supportive other.

Family therapy

Few studies (n=2) studied the effects of family therapy, with mixed findings. One small study (n=32) tested family therapy and medication against individual therapy and medication and found a significant difference between the intervention and control group. 82.4% of the intervention group had greater than 50% adherence to medication compared with 28.6% of the control group at six-months (OR=11.67, 2.13-64.04, $p<0.01$) (Strang et al., 1981). There was no information available on how the intervention was delivered.

One larger study (n=174) compared two groups of family therapy delivered to individuals and carers together in a mixture of individual and group sessions against each other as well as against a third group receiving routine care, however one of the intervention groups focused on adherence strategies while the other intervention group did not (Kopelowicz et al., 2012). There was no significant difference in the proportion of people with >80% adherence at 24-months between the family therapy group and family therapy and adherence strategy group (24% vs 33%, OR=0.67, 95% CI 0.29-1.5, $p=0.20$) or between the family therapy group and control group (24% vs 11%, OR = 2.76, 0.96-7.91, p not reported).

Multi-component interventions

Three small studies that tested interventions comprising of multiple therapeutic approaches were identified, with one study finding an effect in favour of the intervention (Sari, Suttharangsee & Chanchong, 2014) and the other two studies finding no effect (Morken, Grawe & Widen, 2007; Xiong et al., 1994). One small study testing a counselling and family education intervention delivered to the supportive other and patient together in individual sessions against routine care found a significantly greater change in mean adherence score in the intervention group compared to control (n=52, 37.24(2.70) vs 31.96(3.4), $d= 1.72$, 95% CI 1.08 -2.36, $p<0.01$), however it was unclear at what time point the participants were followed up (Sari, Suttharangsee & Chanchong, 2014).

Morken, Grawe & Widen (2007), tested psychoeducation, social skills training and CBT with supportive others and patients together in individual sessions and Xiong et al (1994), tested family group sessions and individual counselling delivered to participants and supportive others together against routine care. Both studies found no significant difference between the intervention and control in the proportion of participants that were adherent to prescribed medications at 12-months (n=50, 70% vs 80%, OR=0.58, 95% CI 0.15-2.24, p not reported) or 24-months (n=50, 67% vs 70%, OR=0.86, 95% CI 0.25-2.91, p not reported) (Morken, Grawe & Widen, 2007) and in the average number of months participants took >50% of prescriptions at 18-months (n=63, 15.1 vs 13.5, d=0.31, 95% CI -0.19-0.81, p not reported) (Xiong et al., 1994).

Medication adherence as a secondary outcome

Of the 16 studies reporting medication adherence as a secondary outcome, eight studies found a significant effect in favour of the intervention group (Bressi et al., 2008; Clarkin et al., 1998; D'Souza et al., 2010; Guo et al., 2010; Ngoc et al., 2016; Ran et al., 2003; Valencia et al., 2007; Zhang et al., 1994), six studies reported no significant difference between the intervention and control group (Girón et al., 2010; Li & Arthur, 2005; Merinder et al., 1999; Rea et al., 2003; Reinares et al., 2008; van Gent & Zwart, 1991) and one study reported a significant effect at 24-month follow up (Miklowitz et al., 2003) but not at 12 months (Miklowitz et al., 2000). One study did not report the results of the analysis (Barrowclough et al., 2001). For a summary of results see Table 2.6.

For those studies that found an effect and reported the outcome as the proportion of people who were adherent to medication, the difference in adherence at follow up between the intervention and control groups ranged from 2.9% to 35% with the odds of people being adherent in the intervention group compared to the control ranging from 2.1 to 10. For studies reporting mean adherence scores, the difference between the intervention and control groups ranged from 0.21 to 2.9 with moderate to large effect sizes reported (0.45-0.94).

Psychoeducation/information giving interventions

Three studies tested psychoeducation delivered to the supportive other and patient in individual sessions (Ngoc et al., 2016), group sessions (D'Souza et al., 2010) and a mixture of individual and group sessions (Ran et al., 2003) and reported a significant effect on medication adherence against routine care, while four studies reported no effect (Li & Arthur, 2005; Merinder et al., 1999; Reinares et al., 2008; van Gent & Zwart, 1991).

Of those studies finding a significant difference between groups, two found that mean adherence scores were significantly greater in the intervention group than the control at six-months ($n=59$, $0.29(0.24)$ vs $0.59(0.5)$, $d=0.77$, 95% CI $0.24-1.30$, $p>0.01$) (lower scores indicated greater adherence) (Ngoc et al., 2016) and at 15-months ($n=58$, $1.2(1)$ vs $0.4(0.7)$, $d=0.94$, 95% CI $0.40-1.48$, $p=0.001$) (D'Souza et al., 2010). The third study ($n=326$) found that the proportion of participants maintaining "regular" adherence as rated by clinicians was significantly greater in the psychoeducation with family group than in a control group without any treatment at nine-months (34.9% vs 5.2%, OR=10, 95% CI 3.78-26.42, $p<0.001$), but not when compared to a medication only group (34.9% vs 32%, OR=1.15, 95% CI 0.66-2.00, p value not reported) (Ran et al., 2003).

Four studies found no significant effect of psychoeducation against routine care delivered to the patient and caregiver together in individual sessions (Li & Arthur, 2005), in separate group sessions for patients and supportive others (Merinder et al., 1999) and to the supportive other only in group sessions (Reinares et al., 2008; van Gent & Zwart, 1991). Li and Arthur (2005), reported no significant difference between groups on the proportion of participants maintaining regular adherence at three-months ($n=101$, 68.2% vs 57.4%, OR=1.59, 95% CI 0.67-3.73, p not reported) (Li & Arthur, 2005) while Merinder et al (1999), found no significant difference on mean adherence scores between groups at 12-months ($n=46$, $0.25(1.26)$ vs $0.68(4.31)$, $d= -0.14$, 95% CI $-0.71-0.44$, $p=0.64$). Neither Reinares et al (2008), nor Van Gent & Zwart (1991), found a significant difference at 12-months between groups in the proportion of participants with good adherence ($n=113$, 86% vs 75%, OR=2.04, 95% CI 0.78-5.34, $p =0.141$)

(Reinares et al., 2008) and (n=26, 78.6% vs 83.3%, OR=0.73, 95% CI 0.1-5.33, p value not reported) (van Gent & Zwart, 1991).

Family therapy

Three studies tested family therapy as the intervention against routine care. Two small studies found an effect in favour of the intervention group (Bressi et al., 2008; Zhang et al., 1994), while one small study found no significant effect (Rea et al., 2003). Bressi et al (2008) found a significantly greater proportion of people were adherent to medication in the systemic family therapy arm delivered in individual sessions to the family and patient together compared to routine care at 12-month follow up (n=40, 100% vs 65%, OR and 95% CI not reported, p=0.009), no difference was found at 24-month follow up (77.8% vs 75%, OR = 1.17 95% CI 0.26-5.24, p=1.000). Zhang et al (1994) found a significant difference in the proportion of people with less than 33% adherence for six days per week in those receiving family therapy compared to routine care at 18-months (n=83, 79.5% vs 56.4%, OR=2.99, 95% CI 1.10-8.16).

One small study tested family therapy delivered to the patient and caregiver together in individual sessions, against individual therapy for the patient alone and found no significant difference between the groups at 24-months and found no significant difference between groups on mean medication adherence scores (n=53, 3.90(2.66) vs 4.13(2.70), d= -0.09, 95% CI -0.63–0.45, p>0.10) (Rea et al., 2003).

Multi-component interventions

Six studies tested combined therapeutic interventions delivered to supportive others and patients together involving a range of approaches including motivational interviewing, psychoeducation, communication skills training and family therapy. Three studies found that the intervention was superior to standard care (Clarkin et al., 1998; Valencia et al., 2007; Guo et al., 2010), while one study found a significantly greater adherence score in the intervention group compared to routine care at 24-months (n=101, 2.77(0.43) vs 2.56(0.48), d=0.45, 95% CI 0.02-0.88, p =0.04) but not at 12-month follow up (analysis not reported) (Miklowitz et al., 2003; Miklowitz et al., 2000).

Effective interventions were delivered to carers and patients together in a mixture of group and individual sessions (Valencia et al., 2007), individual sessions alone (Clarkin et al., 1998; Miklowitz et al., 2003) or group sessions alone (Guo et al., 2010).

One small study (n= 42) reported a significantly greater mean adherence score in the intervention group compared to routine care at 11-months (5.70 vs 5.17, $d = -0.88$, 95% CI not reported, $p=0.008$) with lower scores indicating greater adherence (Clarkin et al., 1998). Two studies reporting the proportion of people who were adherent to medication found that significantly more people in the intervention group were >70% adherent (n=1,268, 97.2% vs 94.3%, OR=2.05, 95% CI 1.15-3.66, $p=0.006$) (Guo et al., 2010) and >80% adherent (n=82, 90% vs 80%, OR & 95% CI not reported, $p<0.05$) (Valencia et al., 2007) at 12-months.

One study found no significant difference in the mean number of days a month that people did not take their medication in a family intervention and individual counselling group compared to individual counselling alone (n=50, 2(5.8) vs 3(8.1), $d = -0.14$ 95% CI -0.70-0.41, $p=0.07$) (Girón et al., 2010), while one study testing a complex intervention of information giving, individual therapy and family therapy delivered in individual sessions to patients and carers together against routine care did not report the results of the medication adherence outcome analysis (Barrowclough et al., 2001).

Table 2.6. Summary of publications on adherence to psychiatric medications

First author	Intervention/control	Outcome	Follow up period	N	Intervention Group		Control Group		Difference at follow up*	Effect size/odds ratio (OR) p value and (95% confidence intervals)
					N	Follow up %/M (SD)	N	Follow up %/M (SD)		
Psychiatric medication measured as a primary outcome										
Azrin & Teichner, 1998	Information giving involving carer/Psychoeducation/Information giving to patient alone	Mean % adherence to prescription	2-month	39	13	95% (6.4)	13	73.6% (23.1)	+21.4%	d= 1.26 p<0.01 (0.42-2.10)
							13	92% (9.5)	+3%	d= 0.37 p=NS (0.41-1.15)
Farooq et al., 2011	Psychoeducation & routine care/Routine care	Proportion of N with 100% adherence	12-month	110	55	37/55 (67.3%)	55	25/55 (45.5%)	+21.8%	OR = 2.47 p<0.02 (1.14-5.35)
Kopelowicz et al., 2012	Family therapy & routine care/Family therapy & adherence training & routine care/Routine care	Proportion of N with >80% adherence	24-month	174	53	13/53 24%	64	21/64 (33%)	-9%	OR=0.67 p=0.20 (0.29-1.5)
							57	6/57 (11%)	+13%	OR = 2.76 p=NS (0.96-7.91)

First author	Intervention/control	Outcome	Follow up period	N	Intervention Group		Control Group		Difference at follow up*	Effect size/odds ratio (OR) p value and (95% confidence intervals)
					N	Follow up %/M (SD)	N	Follow up %/M (SD)		
Psychiatric medication measured as a primary outcome										
Morken, Grawe & Widen, 2007	Psychoeducation, social skills training, CBT & Regular case management/ Regular case management	Proportion of N with less than 1 week without medication	12-month	50	30	21/30 (70%)	20	16/20 (80%)	+10%	OR=0.58 p=NS (0.15-2.24)
			24-month			20/30 (67%)		14/20 (70%)	+3%	OR=0.86 p=NS (0.25-2.91)
Pitschel-Walz et al., 2006	Psychoeducation & medication/Routine care	Mean adherence score	12-month	236	73/125	1.7 (0.6)	62/111	2.1 (0.8)	+0.4	d=0.57 p=0.03 (0.23-0.92)
		Proportion of N with very good/good adherence	24-month			58/73 (80%)		34/62 (55%)	+25%	OR= 3.18 p<0.01 (1.49-6.79)
Sari, Suttharangsee & Chanchong, 2014	Family education and counselling/Routine care	Mean adherence score	Not Reported	52	26	37.24 (2.7)	26	31.96 (3.4)	+5.28	d= 1.72 p<0.01 (1.08-2.36)
Strang et al., 1981	Family therapy & medication/Individual therapy & medication	Proportion of N with >50% adherence	6-month	32	17	14/17 (82.4%)	14/15	4/14 (28.6%)	+53.8%	OR=11.67 p<0.01 (2.13-64.04)
Xiang et al., 1994	Psychoeducation & medication/Medication only	Proportion of N with 100% adherence	4-month	77	36	17/36 (47.2%)	41	6/41 (14.6%)	+32.6%	OR=5.22 p<0.05 (1.76-15.45)

First author	Intervention/control	Outcome	Follow up period	N	Intervention Group		Control Group		Difference at follow up*	Effect size/odds ratio (OR) p value and (95% confidence intervals)
					N	Follow up %/M (SD)	N	Follow up %/M (SD)		
Psychiatric medication measured as a primary outcome										
Xiong et al., 1994	Counselling & family groups/Medication & clinics	Months that N took >50% prescriptions	18-month	63	34	15.1 (4.7)	29	13.5 (5.76)	+1.6	d=0.31 p=0.44 (-0.19-0.81)
Psychiatric medication measured as a secondary outcome										
Bressi et al., 2008	Systemic family therapy & routine care/Routine care	Proportion of N who did not discontinue medication	12-month	40	18/20	18/18 (100%)	20	13/20 (65%)	+35%	OR = unable to calculate due to 100% adherence in intervention arm p=0.009
Bressi et al., 2008	Systemic family therapy & routine care/Routine care	Proportion of N who did not discontinue medication	24-month	40	18/20	14/18 (77.8%)	20	15/20 (75%)	+2.8%	OR = 1.17 p=1.000 (0.26-5.24)
Clarkin et al., 1998	Marital therapy & medication/Medication	Mean adherence score	11-month	42	19	5.70 (NR)	23	5.17 (NR)	+0.53	d=0.88 p=0.008 (Unable to calculate)

First author	Intervention/control	Outcome	Follow up period	N	Intervention Group		Control Group		Difference at follow up*	Effect size/odds ratio (OR) p value and (95% confidence intervals)
					N	Follow up %/M (SD)	N	Follow up %/M (SD)		
Psychiatric medication measured as a secondary outcome										
D'Souza et al., 2010	Psychoeducation & routine care/Routine care	Mean adherence score	15-month	58	27	1.2 (1.0)	31	0.4 (0.7)	+0.8	d=0.94 p=0.001 (0.4-1.48)
Giron et al., 2010	Family therapy & Individual counselling & standard care/Individual counselling & standard care	Mean number of days per month not taking medication	24-month	50	25	2 (5.8)	25	3 (8.1)	+1	d=-0.14 p=0.07 (-0.70-0.41)
Guo et al., 2010	Psychosocial therapy & medication/Medication	Proportion of N with >70% adherence	12-month	1268	633	615/633 (97.2%)	635	599/635 (94.3%)	+2.9%	OR=2.05 p=0.006 (1.15-3.66)
Li & Arthur, 2005	Psychoeducation & routine care/Routine care	Proportion of N maintaining regular treatment	3-month	101	44/46	30/44 (68.2%)	47/55	27/47 (57.4%)	+10.8%	OR=1.59 p=NS (0.67-3.73)
Merinder et al., 1999	Psychoeducation/Routine care	Mean change (reduction) in the number of non-compliance episodes	12-month	46	23	0.25 (1.26)	23	0.68 (4.31)	-0.43	d=-0.14 p=0.64 (-0.71-0.44)
Miklowitz et al., 2003	Family therapy, psychoeducation, communication skills training, problem solving & medication/Routine care	Mean adherence score	24-month	101	31	2.77 (0.43)	70	2.56 (0.48)	+0.21	d=0.45 p=0.04 (0.02-0.88)

First author	Intervention/control	Outcome	Follow up period	N	Intervention Group		Control Group		Difference at follow up*	Effect size/odds ratio (OR) p value and (95% confidence intervals)
					N	Follow up %/M (SD)	N	Follow up %/M (SD)		
Psychiatric medication measured as a secondary outcome										
Ngoc et al., 2016	Psychoeducation & medication/Medication	Mean adherence score	6-month	59	30	0.29 (0.24)	29	0.59 (0.5)	+0.3	d=0.77 p>0.01 (0.24-1.30)
Ran et al., 2003	Psychoeducation & medication/Medication/Control	Proportion of N maintaining regular treatment	9-month	326	125	44/125 (34.9%)	103	33/103 (32%)	+2.9%	OR=1.15 p not reported (0.66-2)
							97	5/97 (5.2%)	+29.7%	OR=10 p<0.001 (3.78-26.42)
Rea et al., 2003	Family therapy & Medication/Individual therapy & Medication	Mean adherence score	24-month	53	28	3.90 (2.66)	25	4.13 (2.70)	+0.23	d= -0.09 p>0.10 (-0.63-0.45)
Reinares et al., 2008	Psychoeducation & standard care/Standard care	Proportion of N with good adherence	12-month	113	57	49/57 (86%)	56	42/56 (75%)	+11%	OR=2.04 p=0.14 (0.78-5.34)
Valencia et al., 2007	Psychoeducation & Family therapy & standard care/Standard care	Proportion of N with >80% adherence	12-month	82	43	n =NR (90%)	39	n = NR (80%)	+10%	OR=1.84 p not reported (0.61-20.38)

First author	Intervention/control	Outcome	Follow up period	N	Intervention Group		Control Group		Difference at follow up*	Effect size/odds ratio (OR) p value and (95% confidence intervals)
					N	Follow up %/M (SD)	N	Follow up %/M (SD)		
Psychiatric medication measured as a secondary outcome										
Van Gent & Zwart, 1991	Psychoeducation & information booklet/Control (Not described)	Proportion of N with a difference between tests of <0.30 mmol/l in serum lithium	12-month	26	14	11/14 (78.6%)	10/12	10/12 (83.3%)	+4.7%	OR=0.73 P=NS (0.1-5.33)
Zhang et al., 1994	Family therapy & standard care/Standard care	Proportion of N with >33% adherence for 6 days per week	18-month	83	39/42	31/39 (79.5%)	39/41	22/39 (56.4%)	+23.1%	OR=2.99 p<0.10 (1.10-8.16)

*A positive sign (+) indicates that the difference at follow up was in favour of the intervention group and a negative sign (-) indicates in favour of the control group

2.6.4.2 Attendance at mental health service appointments

Five studies measured attendance at mental health service appointments as a secondary outcome (Bressi et al., 2008; Petersen et al., 2005; Rodrigo et al., 2013; Strang et al., 1981; Valencia et al., 2007). For a summary of results please refer to Table 2.7. Outcome measurement tools included clinician report (Bressi et al., 2008; Rodrigo et al., 2013; Strang et al., 1981; Valencia et al., 2007) and data taken from medical records (Petersen et al., 2005). One study found a significant effect in favour of the intervention group compared to routine care (Petersen et al., 2005) and four studies found no significant difference between the intervention and control groups (Bressi et al., 2008; Rodrigo et al., 2013; Strang et al., 1981; Valencia et al., 2007).

Family therapy

Two small studies tested family therapy interventions and found no significant difference between the intervention and control groups (Bressi et al., 2008; Strang et al., 1981). Strang et al (1981) tested family therapy and medication against individual therapy and medication and found no significant difference between groups on the proportion of missed appointments with a psychiatrist (n=32, 17.6% vs 46.7%, OR=4.08, 95% CI 0.82-20.38, p<0.10) (Strang et al., 1981). The content of the intervention was poorly described. Bressi et al (2008) (n=40) tested systemic family therapy delivered to patients and caregivers in individual sessions against drug treatment combined with a series of clinical interviews with a psychiatrist, and found no difference in the proportion of participants attending 100% of their respective appointments at 12-month (100% vs 85%, OR and 95% CI not reported, p=0.231) or 24-month follow up (90% vs 85%, OR=1.59, 95%CI 0.24-10.7, p=0.999).

Multi-component interventions

Petersen et al (2006) tested a psychoeducation and social skills training programme delivered in group sessions to supportive others and patients together and found that a higher proportion of participants continued engaging with the intervention for at least a month than participant engagement with routine care appointments at a community mental health centre at 12-month follow up (n=547, 92% vs 78%, OR=3.28, 95% CI 1.91-

5.61, $p < 0.001$) but this difference was not maintained at 24-month follow up (88% vs 86%, OR=1.20, 95% CI 0.68-2.11, $p = 0.06$).

Valencia et al (2007) reported that the proportion of participants attending scheduled appointments was higher in an intervention of family therapy and psychoeducation with individual and group sessions delivered to supportive others and patients together, than the proportion of patients attending routine care (monthly appointments with a psychiatrist) at 12-months ($n = 82$, 87.7% vs 79.5%, OR=1.84, 95% CI 0.61-20.38, p not reported). However, the 95% CI contains 1.0; therefore the null hypothesis cannot be rejected.

There was limited information reported on the content of the interventions tested in the final study (Rodrigo et al., 2013). The intervention consisted of a basic mental health worker service in a developing country with limited resources for mental health care, which assessed the support of a mental health officer for groups of patients and supportive others against standard care. No significant difference in the mean number of clinic visits attended between groups was reported ($n = 50$, 10.1(2.33) vs 9.5(3.53), $d = 0.20$, 95% CI -0.38-0.78, $p = 0.14$).

Table 2.7. Summary of publications on attendance at mental health service appointments

First author	Intervention/control	Outcome	Follow up period	N	Intervention group		Control group		Difference at follow up*	Effect size/odds ratio p value and (95% confidence intervals)
					N	Follow up %/M (SD)	N	Follow up %/M (SD)		
Attendance at mental health service appointments as a secondary outcome										
Bressi et al., 2008	Systemic family therapy & routine care/Routine care	Proportion of N who attended all sessions	12-month	40	20	20/20 (100%)	20	17/20 (85%)	+15%	OR = unable to calculate p=0.231
			24-month			18/20 (90%)		17/20 (85%)	+5%	OR=1.59 p=0.999 (0.24-10.7)
Petersen et al., 2005	Psychoeducation & social skills training/Standard care	Proportion of N not discontinuing treatment for 1+months	12-month	547	263/275	242/263 (92%)	244/272	190/244 (78%)	+14%	OR=3.28 p=<0.001 (1.91-5.61)
			24-month			214/243 (88%)		166/193 (86%)	+2%	OR=1.20 p=0.06 (0.68-2.11)
Rodrigo et al., 2013	Support from a Mental Health Development Officer/Standard care	Mean number of clinic visits (Max= 12)	12-months	50	25	10.1 (2.33)	25	9.5 (3.53)	+0.6	d=0.20 p= 0.14 (-0.38-0.78)
Strang et al., 1981	Family therapy & medication/Individual therapy & medication	Proportion of people attending >80% of appointments with the psychiatrist	6-month	32	17	14/17 (82.4)	15	8/15 (53.3%)	+29.1%	OR=4.08 p<0.10 (0.82-20.38)

First author	Intervention/control	Outcome	Follow up period	N	Intervention group		Control group		Difference at follow up*	Effect size/odds ratio p value and (95% confidence intervals)
					N	Follow up %/M (SD)	N	Follow up %/M (SD)		
Attendance at mental health service appointments as a secondary outcome										
Valencia et al., 2007	Psychoeducation & Family therapy & standard care/Standard care	Proportion of N who completed treatment	12-month	98	49	43/49 (87.7%)	49	39/49 (79.5%)	+8.2%	OR=1.84 p<0.05 (0.61-5.53)

*A positive sign (+) indicates that the difference at follow up was in favour of the intervention group and a negative sign (-) indicates in favour of the control group

2.6.4.3 Adherence to combined treatments (medication and therapy)

One study with 101 participants used a combined clinician self-report measure of adherence to medications and attendance at mental health service appointments as a secondary outcome (Carrà et al., 2006; See Table 2.8). The study compared three groups; a psychoeducation and support group delivered to supportive others, psychoeducation delivered in individual sessions to supportive others, and routine care. Patients in the psychoeducation and support group were 2.8 times more likely to be adherent than those in the individual psychoeducation group at 12-months. (OR = 2.80 $p = 0.027$ CI = 1.12–7.03). There was no significant difference at 24-months (42% vs 32%, OR=2.07, 95% CI 0.79-5.43). No difference was found between the psychoeducation and support group delivered to supportive others, and routine care at 12 (54% vs 36%, OR=1.3, 95% CI 0.42-4.03) or 24-month follow up (54% vs 32%, OR=1.56, 95% CI 0.5-4.9) (Carrà et al., 2006). As the small sample was allocated across three groups, the study may not have had sufficient power to detect a difference.

Table 2.8. Summary of publication on adherence to combined treatments

First author	Intervention/control	Outcome	Follow up period	N	Intervention group		Control group		Difference at follow up*	Effect size/odds ratio p value and (95% confidence intervals)
					N	Follow up %/M (SD)	N	Follow up %/M (SD)		
Adherence to combined treatments (medication and therapy) measured as a secondary outcome										
Carrà et al., 2006	Information giving & additional support group & standard care / Information giving without support group & standard care /Standard care	Proportion compliant with standard care	12-month	101	26	14/26 (54%)	50	14/50 (28%)	+26%	OR = 3 p=not reported (1.12-8.06)
								18/50 (32%)	+24%	OR=2.07 p=not reported (0.79-5.43)
			24-month			11/26 (42%)	25	9/25 (36%)	+6%	OR=1.3 P=not reported (0.42-4.03)
							8/25 (32%)		+10%	OR=1.56 P=not reported (0.5-4.9)

*A positive sign (+) indicates that the difference at follow up was in favour of the intervention group and a negative sign (-) indicates in favour of the control group

2.6.4.4 Alcohol use

Three studies measured alcohol use; all as secondary outcomes using patient self-report questionnaires (Barrowclough et al., 2001; Penn et al., 2011; Tantirangsee et al., 2015). For a summary of results please refer to Table 2.9.

Follow up periods were three to six-months. Two studies used an overall substance misuse measure which incorporated alcohol use (Barrowclough et al., 2001; Tantirangsee et al., 2015), while the third used a measure specific to alcohol use (Alcohol Use Scale) (Penn et al., 2011).

Psychoeducation/information giving interventions

One study tested a single psychoeducation session delivered to supportive others and patients together, patients alone, and routine care and reported a reduction in mean alcohol consumption scores in the psychoeducation and family group compared to routine care at six-months (mean difference= -3.13, $\Delta=1.07$, 95% CI -6.03- -0.23), however the authors did not report the descriptive data and stated that the sample size was too small to make reliable conclusions (Tantirangsee et al., 2015).

Multi-component interventions

Two small studies tested an integrated intervention program of information giving, motivational interviewing and individual CBT with patients and supportive others in individual sessions against routine care (Barrowclough et al., 2001; Penn et al., 2011). Barrowclough et al (2001) measured all substances used by participants, however alcohol was used by the majority of participants (30/36 (83%)), therefore this study was included in the review. There were no significant differences at six-month follow up between groups in the median proportion of days abstinent from all reported substances (20.6% vs 1.1%, no statistical analysis reported), or the most frequently used substance (15.2% vs 8.1%, no statistical analysis reported) (Barrowclough et al., 2001). The median difference on the severity of addiction index was reported as not significantly different between groups; however neither the data nor the statistical

analysis were presented. Penn et al (2011) found no significant difference at three-month follow up between groups on mean scores of severity of alcohol use (1.95 vs 1.67, $d = -0.48$, 95% CI -0.018 – 1.065).

Table 2.9. Summary of publications on alcohol use

First author	Intervention/control	Outcome	Follow up period	N	Intervention group		Control group		Difference at follow up*	Effect size/odds ratio p value and (95% confidence intervals)
					N	Follow up %/M (range/SD)	N	Follow up %/M (range/SD)		
Alcohol use measured as a secondary outcome										
Barrowclough et al., 2001	Psychoeducation & CBT & family therapy & routine care/Routine care	Median change in proportion of days abstinent from all substances	6-month	36	18	20.6% (-35-98)	18	1.1% (-39-80)	+19.5%	Unable to calculate
		Median change in proportion of days abstinent from most frequently used substance				15.2% (-35-98)		8.1% (NR)		+7.1%
Penn et al., 2011	Psychoeducation & CBT & social skills training & routine care/Routine care	Mean score on severity of alcohol use	3-month	46	23	1.95 (0.59)	23	1.67 (0.58)	-0.28	d= 0.48 p=not reported (-0.018-1.065)
Tantirangsee et al., 2015	Psychoeducation with family/Substance misuse advice	Mean alcohol consumption score	6-month	115	58	Not reported	57	Not reported	+3.13	Glass Δ =1.07 p=not reported (-6.03- -0.23)

*A positive sign (+) indicates that the difference at follow up was in favour of the intervention group and a negative sign (-) indicates in favour of the control group

2.6.4.5 Smoking

Only one study with 169 participants assessed smoking, as both a primary and secondary outcome using patient self-report questionnaires and diaries of smoking behaviour (Tantirangsee et al., 2015). Three groups were compared; psychoeducation delivered to the patient and supportive other, psychoeducation delivered to the patient alone, and routine care (substance misuse advice). Scores on the primary outcome of a smoking screening questionnaire (SIS) were significantly lower (lower scores indicated less smoking) for the psychoeducation and family involvement group than routine care (7.16(5.39) vs 9.24(5.24), $d=0.39$, 95% CI 0.02-0.77, $p<0.01$), but not when compared against the psychoeducation delivered to the patient alone group (7.16(5.39) vs 8.25 (5.44), $d=0.20$, 95% CI -0.17-0.57, $p>0.05$).

Participants in the psychoeducation and family involvement group smoked fewer cigarettes per day at six-months than both the psychoeducation delivered to the patient alone group (7.93(6.06) vs 10.68(7.82), $d= -0.4$, 95% CI -0.77- -0.02, $p<0.05$) and routine care group (7.93(6.06) vs 11.65(8.35), $d= -0.51$, 95% -0.89- -0.14, $p<0.01$), but had a similar mean number of smoking days to both the psychoeducation delivered to the patient alone group (24.74(10.86) vs 26.62(2.58), $d= -0.20$, 95% CI -0.57-0.17 and the routine care group (24.74(10.86) vs 26.15(8.4), $d= -0.15$, 95% CI -0.52-0.23, $p>0.05$).

Table 2.10. Summary of publication on smoking reduction

First author	Intervention/control	Outcome	Follow up period	N	Intervention group		Control group		Difference at follow up*	Effect size/odds ratio p value and (95% confidence intervals)
					N	Follow up %/M (SD)	N	Follow up %/M (SD)		
Smoking measured as a primary outcome										
Tantirangsee et al., 2015	Psychoeducation with family/Psychoeducation with patient/Substance misuse advice	Mean score on severity of smoking	6-month	169	58	7.16 (5.39)	54	8.25 (5.44)	-1.09	d= -0.20 p>0.05 (-0.57-0.17)
							57	9.24 (5.24)	-2.08	d=0.39 p<0.01 (0.02-0.77)
Smoking measured as a secondary outcome										
Tantirangsee et al., 2015	Psychoeducation with family/Psychoeducation with patient/Substance misuse advice	Mean number of smoking days per month	6-month	169	58	24.74 (10.86)	54	26.62 (2.58)	-1.88	d=0.23 p>0.05 (-0.14-0.61)
							57	26.15 (8.40)	-1.41	d= -0.15 p>0.05 (-0.52-0.23)
		Mean number of cigarettes smoked per day					54	10.68 (7.82)	-2.75	d=-0.4 p<0.05 (-0.77- -0.02)
							57	11.65 (8.35)	-3.72	d= -0.51 p<0.05 (-0.89- -0.14)

*A negative sign (-) indicates that the difference at follow up favoured the intervention group and a positive sign (+) indicates in favour of the control group

2.7 Discussion

2.7.1 Summary of findings

My systematic review explored the effectiveness of interventions that involved supportive others on adherence to medications, attendance at health services and participation in CVD risk reducing behaviours in people with SMI. The evidence was heterogeneous in terms of interventions tested, comparator populations and outcomes measured, and many studies were small with an unclear risk of bias due to a lack of methodological reporting. There was a lack of conclusive evidence on whether social support worked to improve outcomes mainly because it was not possible to disentangle the effect of social support from the effectiveness of the intervention as a whole package. Also, most of the control groups did not test the same intervention without social support, and the lack of detail on how social support was incorporated into the interventions was poorly described.

The majority of studies assessed the impact of either multi-component therapeutic interventions or psychoeducational approaches that involved supportive others and measured antipsychotic medication adherence as an outcome. Studies that measured medication adherence as a primary outcome showed some promise for psychoeducational approaches that involved supportive others, however the mode of delivery was heterogeneous with the intervention being delivered to patients and supportive others together, separately, in individual sessions and in groups across the different studies.

Only three studies measured outcomes specific to CVD risk reducing behaviours; smoking (Tantirangsee et al., 2015) and alcohol use (Barrowclough et al., 2001; Penn et al., 2011; Tantirangsee et al., 2015). Multi-component interventions comprising of psychoeducation and CBT and psychoeducation with patients and supportive others showed no significant effect on alcohol reduction (Barrowclough et al., 2001; Penn et al., 2011). Psychoeducation was found to have a significant effect on the number of cigarettes smoked when delivered to patients and supportive others together in individual sessions compared to psychoeducation delivered to the patient alone, but had

no effect on number of smoking days, alcohol use or scores on a smoking behaviour questionnaire (SIS) (Tantirangsee et al., 2015).

No studies were identified regarding interventions that involved supportive others to increase adherence to CVD risk reducing medications, attendance at health promotion service appointments, physical activity or to improve diet and, where reported, all of the studies were delivered by mental health professionals in mental health settings.

There were no specific modes of delivery associated with interventions that had a positive effect compared with no effect in terms of the length of intervention (short-term vs long term intensive therapies), group vs individual therapy or length of follow up. In the majority of studies that showed an effect, the intervention targeted the patient and supportive other together, rather than just the supportive other or the patient and supportive other separately; however a number of studies that showed no effect also targeted the patient and supportive other together.

2.7.2 Strengths and limitations of the review

I aimed to identify clinical trials of interventions involving supportive others which measured a broad range of outcomes including adherence to medications, attendance at appointments and participation in CVD risk reducing behaviours in people with SMI. No existing systematic reviews on this topic were identified, strengthening the rationale for conducting the study.

My search strategy was comprehensive including both indexed subject headings and free text terms mapped to specific PICO criteria and an information specialist was consulted to agree the final search terms. The search was conducted across a number of relevant electronic databases and registries and search terms adapted to fit specific database indexing requirements. Eligibility of papers for inclusion in the review was determined by two reviewers and risk of bias of the included studies was systematically assessed using an established assessment tool (Higgins et al., 2011). Where data were available in the included papers, I calculated effect sizes and confidence intervals for each study outcome to enable a comparison between studies.

While this review sought to assess the highest quality evidence and restricted the methodology for inclusion to randomised controlled trials, expanding my inclusion criteria to other methods, such as qualitative research or fidelity work may have led to a deeper understanding of how social support was used within the interventions tested. Broadening out my research questions to identify the mechanisms by which social support may impact on medication adherence and CVD risk reducing behaviours in SMI populations may also have better informed the design of the social support elements of the intervention described in chapter three. I could have also contacted study authors for their intervention manuals to establish the intervention content pertaining to social support.

Synthesis of the results of included studies using meta-analysis was deemed to be unsuitable for my review, as the evidence was heterogeneous in terms of the interventions tested as well as the comparator groups and the way in which outcomes were defined, measured and reported. Definitions of good medication adherence ranged from the proportion of people who took a third or more of their prescribed medications for 6 days per week, to 100% of prescribed medications taken over the follow up period. Other measures included adherence scores on a variety of assessment tools, the proportion of prescribed medications taken, the proportion of time participants adhered to their prescribed medications, a reduction in the number of non-compliance episodes and the proportion of participants who had decreased serum lithium levels between baseline and follow up assessments. The intervention content was poorly described in some studies, which made it difficult to justify comparisons between studies. Only two studies were identified that met the criteria for a suitable control group to allow for the study of the independent effect of social support. Alternative methods have been suggested to deal with comparisons of different interventions, statistical heterogeneity and different metrics of the same outcome including network meta-analysis and Bayesian techniques (Ioannidis, Patsopoulos, & Rothstein, 2008), however these methods were outside of my statistical and methodological expertise.

2.7.3 Strengths and limitations of included studies

All of the included studies were randomised controlled trials with most of the included studies reporting the results of all pre-specified outcomes and describing the randomisation process. A lack of reporting of information meant that many studies were at an unclear risk of bias, however many studies were conducted prior to the development of the quality assessment tool (Higgins et al., 2011) that I used to assess risk of bias when there may have been fewer requirements to report on all areas of bias for publication purposes. Some studies may therefore have been conducted to a higher standard than was reported.

The majority of included studies described the overall theoretical model that formed the basis of the intervention, intervention content and delivery mode, however the way in which supportive others were incorporated into the interventions being tested was not clearly described, and a lack of a suitable comparator groups meant that it was often not possible to isolate the effect of social support from the therapeutic interventions as a whole. It may have been that interventions were simply delivered to both the patient and supportive other rather than exploring how supportive others could help patients during and in between intervention sessions. The control conditions in many of the included studies were often poorly described and labelled only as routine or standard care. The control group may have also involved supportive others in routine care, however this was often not reported.

To be able to adequately assess the value of social support within interventions, future studies should test the effectiveness of interventions which incorporate social support against the same intervention without social support as a specified intervention component. Only two studies included in my review compared the intervention delivered to patients and supportive others against a control group using the same intervention without social support (Azrin & Teichner, 1998; Tantirangsee et al., 2015). Both studies found that interventions delivered to the patient and supportive other were not superior to the same intervention delivered to the patient alone on medication adherence, alcohol use and all but one outcome of smoking (number of cigarettes smoked), however both studies were flawed. Azrin & Teichner (1998) recruited a small

sample of 39 participants (13 participants allocated to each group) therefore the study may have been underpowered to detect a difference between groups and it was unclear whether allocation was concealed and how randomisation to groups was conducted. Tantirangsee et al (2015) reported that the number of participants using alcohol was too small to make a reliable estimate of effect; therefore full outcome data were not reported. Therapists were trained to deliver all procedures, which could have resulted in contamination between groups.

A number of studies were conducted in countries with limited mental health services and resources which acted as the control group. The impact of any new intervention may therefore be smaller when the intervention is delivered in countries with established health services. A meta-epidemiological assessment across a range of health conditions and treatments supports this assumption, finding some evidence for greater effect sizes in low income compared to high income countries (Panagiotou, Contopoulos-loannidis, & Ioannidis, 2013). Alternatively the control group in resource poor settings possibly consisted of more than usual care because participants were recruited and tested in a research study, which could explain the lack of difference in outcomes between the intervention and control groups in some of these studies. The variability of health care settings across different countries also makes it difficult to generalise the results to UK settings and there may also have been cultural differences across countries in how families were involved in supporting people with SMI as identified in a study comparing Asians, Asian Americans and European Americans in the USA (Kim, Sherman, & Taylor, 2008).

Most studies had very limited information on the nature or strength of the relationships between supportive others and participants. Previous evidence suggests that it is the quality of social relationships that might be important in impacting positively on health outcomes, and that relationships that are not supportive can have little or even a negative impact on health (Holt-Lunstad et al., 2010; Barth, 2010). It may have been that the strength of the relationships between people with SMI and their supportive others in studies that found no effect were weak or even dysfunctional, however family members or friends with weak relationships may have been less likely to attend intervention appointments. There was no evidence that the studies included in this

review explored social support with participants in the intervention arm to determine whether or not a person felt supported by those in their network and to decide who might be the best person to involve in their care.

2.7.4 Conclusion

My systematic review aimed to explore the effectiveness of interventions that involved supportive others on outcomes of medication adherence, attendance at health service appointments and participation in CVD risk reducing behaviours in people with SMI. The evidence was heterogeneous and many studies were small with an unclear risk of bias. There was a lack of conclusive evidence on the impact of social support on outcomes due to a lack of reporting on how social support was used within interventions, and a lack of appropriate comparator groups.

Psychoeducational approaches that involved supportive others showed some effect, however the way in which the interventions were delivered to supportive others was heterogeneous.

Interventions that included supportive others and addressed adherence to CVD risk reducing medications, attendance at health promotion service appointments, physical activity and diet were absent from the literature.

The studies identified by this review highlight the challenges of isolating the impact of social support within complex interventions for people with SMI and the need to describe and assess how social support is embedded and used by people with SMI and health professionals within intervention delivery. The next study in my thesis aims to address this limitation by describing how involving supportive others was incorporated as a strategy for engagement into the design of an intervention (PRIMROSE trial) for reducing CVD risk in people with SMI using evidence from focus groups, workshops with experts and a review of NICE clinical guidelines.

Chapter 3 Development of social support components to enhance a practice nurse/HCA led intervention to lower CVD risk in people with SMI

3.1 Introduction

In this chapter, I describe the process of developing and incorporating a social support strategy into a CVD risk reducing intervention for people with SMI in primary care (PRIMROSE). I coordinated the development of the overall intervention manual and training programme, which was then tested as part of work package three of the PRIMROSE programme: a cluster randomised controlled trial assessing the clinical and cost effectiveness of an intervention for reducing CVD risk in people with SMI and raised CVD risk factors in primary care (Osborn et al., 2016; Osborn et al., 2018). The full manual can be accessed online: www.ucl.ac.uk/primrose

In section 1.7 of my literature review, I identified two small studies that investigated the feasibility of delivering an augmented 12-week partner support intervention to engage family members and friends in diet and physical activity for people with SMI (Aschbrenner et al., 2016; Aschbrenner et al., 2017c). Partner-support intervention sessions included education on the influence of family and friends on health behaviours, an overview of the different ways supportive others could be involved including practical support and making changes together, agreeing shared health goals and positive encouragement and feedback. The partner support intervention was however tested as a separate “add on” intervention and was delivered to a small sub-set of study participants after they had participated in a clinical trial assessing the effectiveness of a health promotion programme, rather than as an integrated component.

Very little information was identified in the literature and in my systematic review on how social support was integrated and how it might be used within interventions to improve adherence to treatments and engagement in CVD health behaviours in people with SMI. The findings from my systematic review highlighted the challenges of isolating the impact of social support within complex interventions for people with SMI and the

need to better describe and assess how social support is embedded and subsequently used by patients and health professionals to inform the future design of research in this area.

Medical Research Council (MRC) guidelines recommend that the development of new health interventions should be informed by a review of existing evidence, and the identification and/or development of an appropriate theory to explain how and why a proposed intervention is expected to impact on health outcomes (Craig et al., 2008). This evidence should then be supplemented with new qualitative research, for example interviews with stakeholders responsible for developing, delivering or receiving a proposed intervention to determine whether or not it is feasible and acceptable.

There have been some relevant examples of the intervention development process documented and published in academic journals. Hardeman et al (2005) combined psychological theory with information about the epidemiology of type 2 diabetes to develop an intervention to encourage people at risk of type 2 diabetes to be more physically active. This included systematic reviews, expert meetings with researchers and practitioners, focus groups and interviews with the target population, and a survey of attitudes towards increasing physical activity. Similarly the development process of an intervention to reduce weight gain in people with schizophrenia included a literature review of effective interventions to reduce weight gain in people with SMI, development of a theoretical framework informed by the literature review, and consultations, focus groups, and interviews with clinicians and people with SMI (Carey et al., 2018; Holt et al., 2018).

These examples of intervention development described in the literature, mirror the process that I followed for coordinating the development of the overall PRIMROSE intervention (Osborn et al., 2018). Based on the preliminary work presented in chapters one and two of this thesis, it was agreed by the wider study team that a social support component had the potential to be integrated within the PRIMROSE intervention. How I went on to develop the social support components of the intervention is the focus of this chapter.

I firstly decided to explore further, the data I collected in focus groups and workshops as part of the development work (work package two) for the PRIMROSE intervention, as well as conduct additional workshops and a review of national clinical guidelines. My focus was to identify recommendations for involvement; barriers to, and facilitators for involving supportive others in the promotion of CVD risk reducing behaviours for people with SMI, in order to determine the most promising components of involving supportive others in a CVD risk lowering intervention for people with SMI in primary care (the PRIMROSE intervention).

I firstly analysed data collected in a focus group study with people with SMI, health professionals and family carers that aimed to identify barriers and facilitating factors for lowering CVD risk in people with SMI in primary care and subsequently informed the development of the PRIMROSE intervention. I led all aspects of the focus group study including ethical approval and site set up, participant recruitment, data collection, analysis and write up. In my original analysis of the data (Burton et al., 2015), I identified that social support was a potential strategy for improving and maintaining engagement with primary care and health behaviours. I decided to explore and analyse this theme further for the purpose of this thesis. I subsequently mapped the themes to the social support mechanisms specified by Thoits, 2011 to inform the development of social support elements to include in the intervention.

I also organised workshops with people with SMI, clinical and academic experts and facilitated discussions around what strategies for CVD risk prevention in people with SMI needed to be included in the PRIMROSE intervention. The input of support workers and family carers emerged from these discussions as a potential strategy to encourage engagement with health behaviours in people with SMI. I subsequently organised additional workshops with family carers for the purpose of this thesis to explore their perspectives on supporting their relatives with SMI to engage in healthy lifestyle behaviours.

I then mapped the findings from the workshops and recommendations taken from national clinical guidelines to the themes identified in my secondary analysis of the focus

groups (Table 3.3). I used the findings to make recommendations for social support components that could be integrated into the PRIMROSE training programme and intervention manual. I then used these recommendations to develop the social support components of the intervention which are described in section 3.6.

3.2 Focus group study

3.2.1 Introduction and aims

I conducted focus groups to explore perceived barriers and facilitators to lowering CVD risk in people with SMI in primary care. Social support emerged as a key theme for improving engagement with health services and health behaviours in my original analysis of the data (Burton et al., 2015). I conducted a secondary analysis on the focus group data to provide a more detailed and in depth analysis of the role social support might play in improving engagement in CVD risk lowering behaviours and services for people with SMI. I developed the following research questions for my secondary analysis:

- How can existing social networks help people with SMI engage in CVD risk lowering treatments and behaviours?
- What are the barriers to involving existing social networks and how might this hinder engagement in CVD risk lowering treatments and behaviours?

3.2.2 Method

Data Collection

I developed different topic guides for health professionals, patients, and carers. The topic guide for health professionals aimed to identify the conditions needed for them to effectively lower CVD risk for people with SMI. It was informed by a published Theoretical Domains Framework (TDF), which was developed to help identify the key factors that are involved in influencing health professional behaviour change (Cane, O'Connor & Michie, 2012; Michie et al., 2005). The framework was used to develop

questions that would help explore the necessary components required for health professionals to effectively lower CVD risk for people with SMI. The topic guide for health professionals can be found in Appendix 4.

Topic guides for patients and carers aimed to elicit information on the extent to which health behaviours are explained by capability, motivation and/or having the opportunity to perform these behaviours and questions were developed using a general model for understanding behaviour – the COM-B model (Capability Opportunity Motivation – Behaviour) (Michie, van Stralen, & West, 2011). The topic guide for patients and carers can be found in Appendix 5.

The topic guides were reviewed by a multidisciplinary team including Health Psychologists, a Lived Experience Researcher, Psychiatrist, Medical Sociologist and a GP. I obtained further feedback from a Lived Experience Advisory Panel (LEAP), a group of people with SMI and carers tasked with supporting and critiquing the overall PRIMROSE programme of work set up through the charity Rethink – Mental Illness (Gray, Larsen & Faulkner, 2013). Topic guides for the CMHT group remained the same as those for the primary care health professional groups; however in addition to the topic guides, I also shared with them the themes that had been raised in the focus groups with patients and primary care health professionals about their role in helping people with SMI to engage in healthy lifestyle behaviours. This was to allow them to validate or challenge the perspectives from other groups on what their role should be in providing support or facilitating the involvement of supportive others. This enabled the exploration of key issues and barriers to implementation from different health care provider perspectives, the challenges they might face and how they might work together to ensure the effective delivery of CVD preventative health care to people with SMI.

Procedure

I obtained ethical approval for the study which was granted by the London - Camden and Islington National Health Service (NHS) Research Ethics Committee (11/LO/1475) (Appendix 6). I obtained approvals from local research and development departments

in Camden, Hampshire, Northamptonshire and Nottinghamshire where recruitment to the study took place.

Each focus group lasted approximately one hour and all group discussions were audio digitally recorded. I facilitated or co-facilitated all of the focus groups. Twelve groups were run by a facilitator and observed by a co-facilitator. The remaining two groups contained three and two participants; therefore it was felt appropriate that I facilitated those groups without a second researcher present.

All groups followed the same procedure. At least one week before the focus group, potential participants were sent a participant information sheet (Appendices 7 & 8). Before each focus group began, I asked participants to sign an informed consent form (Appendix 9) and to complete a questionnaire on their individual characteristics. Participants were then prompted to introduce themselves to each other, and the facilitator asked the groups to identify current practice and experiences of the management of CVD risk for people with SMI using the relevant topic guide.

Patients were paid £20 for their time at the end of the group session. Practices were reimbursed for health professional time, or nurses attending in their own time were reimbursed with a £20 gift voucher.

Participant recruitment and characteristics

I recruited 75 participants to one of 14 focus groups between March and August 2012. Focus groups with forty-three health professionals and 20 patients were conducted in GP practices or community mental health settings in Camden, Hampshire, Northamptonshire and Nottinghamshire. Two groups were also run with seven carers and five people with SMI recruited through the Mental Health Research Network (MHRN) now referred to as Clinical Research Networks (CRNs). The groups consisted of between two and eight people (mean group size of five people). Target groups for recruitment were: GPs, practice nurses, people with SMI, carers and mental health workers in community mental health teams (CMHTs).

Participants were initially approached by the Primary Care Research Network (PCRN) and Mental Health Research Network (MHRN) (CRNs). An invitation to participate in the study and a study information sheet were mailed out to GP practices, with a request for expressions of interest to coordinate the study in their locality. Practices expressing an interest were asked to host the focus groups at their surgery and coordinate a mail out of study information to GPs and practice nurses from GP practices within their locality.

Twenty people with a diagnosis of schizophrenia, bipolar disorder or schizoaffective disorder were recruited through study invitation mail outs from GP practices or via an approach about the study from staff working in community mental health services.

Five lived experience experts were also recruited through a mail out to the MHRN North and South London experts by experience email list to take part in a focus group at the MHRN West London offices. An additional group with carers was run for the purpose of this thesis, in order to explore carer perspectives and the feasibility of carer involvement in lowering CVD risk for people with SMI. Seven carers were recruited through a mail out to existing support networks at Rethink - Mental Illness.

The composition of each focus group is presented in Table 3.1.

Table 3.1. Focus group composition

Participants	Number of groups	Number of participants
Patients	5	25
Practice nurses	3	13
General practitioners	2	11
Practice nurses and general practitioners	1	5 GPs 3 Practice Nurses
Community mental health staff	2	11
Carers	1	7
TOTAL	14	75

Focus group participants were predominantly white British, female and aged 28-68 years old (average age 49 years old). Just over half of the people with SMI were unemployed and single. Participant characteristics are presented in Table 3.2

Table 3.2. Focus group participant characteristics

Group	Patients (N = 25)	Carers (N=7)	Practice Nurses (N=16)	General Practitioners (N=16)	CMHT staff (N=11)	Total (N=75)
Mean Age (Range)	49 (31-68)	55 (32-66)	52 (42-68)	46 (28-60)	44 (29-51)	49 (28-68)
Gender:						
Female	16 (64%)	7 (100%)	16 (100%)	11 (69%)	9 (82%)	59 (79%)
Male	9 (36%)	0%	0%	5 (31%)	2 (18%)	16 (21%)
Ethnicity:						
White British	16 (64%)	6 (86%)	12 (75%)	11 (69%)	10 (91%)	55 (73%)
White Other	2 (8%)	0 (0%)	3 (19%)	1 (6%)	0 (0%)	6 (8%)
Black African	3 (12%)	1 (14%)	0 (0%)	0 (0%)	1 (9%)	5 (7%)
Indian	1 (4%)	0 (0%)	1 (6%)	3 (19%)	0 (0%)	5 (7%)
Asian Other	2 (8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (3%)
Black Caribbean	1 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)
Mixed Asian and African	0 (0%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)	1 (1%)
Unemployed	14 (56%)	1 (14%)	n/a	n/a	n/a	n/a
Marital status						
Married/in relationship	9 (36%)	4 (57%)	n/a	n/a	n/a	n/a
Single	13 (52%)	0 (0%)	n/a	n/a	n/a	n/a
Divorced	3 (12%)	1 (14%)	n/a	n/a	n/a	n/a
Missing data	0 (0%)	2 (29%)	n/a	n/a	n/a	n/a

Original data analysis

All focus group recordings were transcribed verbatim by an external transcription company (Virtual Outsourcing). I then listened to each recording, edited any spelling

mistakes, added any audible missing dialogue and omitted any remaining identifiable information such as names and locations.

I imported the transcripts and associated field notes into QSR International's NVivo9 qualitative software package (QSR International Pty Ltd, 2015) to aid analysis. Two researchers (Dr Lou Atkins, health psychologist and Dr Ben Gray, lived experience researcher) and I independently coded the content of the first four transcripts. Any disagreements in coding were discussed until a draft coding framework was generated. The final coding framework was developed through an iterative process as further transcripts were analysed and until saturation was reached. The multidisciplinary team reviewed and finalised the coding framework and a subset of transcripts was shared with the team to ensure that the team were familiar with the original data.

The content of these codes was then reviewed and consolidated into three main categories. The original data were synthesised in thematic charts illustrating each main theme, their corresponding sub-themes and supporting quotes. Data were analysed using the Framework Analysis Method (Ritchie & Spencer, 1993).

Analysis proceeded through five main stages (Pope, Ziebland, & Mays, 2000): 1) familiarisation with the transcripts, 2) identification of a coding framework, 3) application of the coding framework to the data, 4) charting the data and 5) interpretation of themes and associations.

Secondary data analysis

To address the research questions for my thesis, a secondary analysis was performed on the data to explore in greater depth the role of involving supportive others to lower CVD risk in people with SMI. I revisited the original transcripts and coded any instances where social support was discussed by the participants. I then created a coding framework and grouped these codes into themes. The coding framework and examples of supporting quotations that mapped to each code were shared and discussed with my supervisory team to ensure the findings aligned with their interpretations of the data. The resulting themes were then mapped to the key strategies and barriers identified in the original

analysis of the focus groups to provide a more thorough understanding of how involving supportive others may either help or hinder people with SMI to lower their CVD risk. Finally, any additional themes relevant to involving supportive others that did not map to the themes identified in the original analysis, but that were important considerations for lowering CVD risk in people with SMI in primary care settings were identified.

3.2.3 Results

In my original analysis of the data, three main themes emerged as important considerations for delivering CVD risk lowering interventions for people with SMI in primary care: 1) Existing procedures for CVD risk management in SMI 2) Perceived barriers towards lowering CVD risk and 3) Strategies to facilitate lowering CVD risk (Burton et al., 2015).

Perceived barriers to implementation included negative perceptions of people with SMI, difficulties accessing services, non-attendance at appointments, difficulties managing a healthy lifestyle and a lack of awareness around working with increased CVD risk and SMI. Suggested strategies to improve CVD risk management included: involving supportive others, improving patient engagement with services, continuity of care, providing positive feedback in consultations and goal-setting.

My secondary analysis of the data found that participants identified both informal support from family and friends and formal support from health professionals as important. Social support was identified as a strategy for i) increasing patient engagement with services and ii) helping people with SMI to manage a healthy lifestyle. Social support was also identified as an important component for promoting continuity of care across different services. Barriers to involving supportive others included i) concerns around maintaining confidentiality and ii) the absence of supportive others. These themes are explored below with accompanying quotes from the data.

Formal and informal support

Social support for people with SMI was considered to be provided by two distinct groups; formal or professional relationships with mental health workers or support workers and/or informal or natural support provided by family members, partners or friends.

Some patients discussed the importance of involving family members or partners in their health care, both in terms of monitoring engagement in treatment regimens and providing general care and support:

“It doesn’t take account of people that are in relationships and partnerships. Because I’m hearing everybody talk, and I’m not hearing anyone say that, ‘My partner helps me with my medication,’ or, you know. Everyone is talking as a single individual entity, and there’s no, ‘My mother cares for me,’ or, ‘My brother cares for me, my partner cares for me.’ What about that.....that aspect?”
(FG1-Patient3)

Patients discussed the role of mental health and support workers in enabling them to access physical health care, attend health appointments and encourage healthy lifestyle behaviours.

“I have a CPN, and she encourages me to go for diabetes tests and stuff like that, so I have blood tests now and again”. (FG1-Patient5)

Some patients described these formal caring relationships as practically helpful and in one case the support worker was seen as a friend:

“The Council pay (for the support worker). I’m technically her employer and it isn’t that kind of relationship at all. (We’re) Good friends and we get on and do things together. She’s been brilliant at getting me out of the flat because that was what my problem was. I stay in the flat, go out for half an hour to Sainsbury’s. I’d just stay at home and wait to die basically, is what I was doing. She’s come on the scene and bang, we’re exercising and getting out”. (FG4–Patient2)

Research aim one: how can existing social networks help people with SMI engage in CVD risk lowering treatments and behaviours?

Almost all of the discussions on involving supportive others identified that involving informal and formal carers could be a useful way of helping people with SMI lower their CVD risk. The majority of discussions on involving supportive others focused on how they could help facilitate suggested strategies and remove potential barriers to lowering CVD risk in this population. Three themes were identified: improving engagement with services and reducing non-attendance, continuity of care, and managing a healthy lifestyle.

Improving engagement with services and reducing non-attendance

Most focus group participants discussed the role of formal and informal supportive others in reminding patients to attend primary care appointments, accompanying them to appointments and being available for health professionals to contact in the event that a patient did not attend an appointment.

Health professionals and patients felt that mental health workers could help their patients attend appointments, either by accompanying them to the GP practice, or through access to a named key worker in the event that a patient did not attend, to establish why this might be and to help rearrange appointments:

"It's just a thing about the appointment... if somebody within secondary mental health services, it would be helpful for that to be copied in, because that helps keep the whole picture, doesn't it? Because then that person can perhaps encourage you to go." (FG1-Patient2)

"If the key worker brings them, they might be happy to come along, so that's another way of trying to get access to them." (FG3-GP2)

While most mental health professionals acknowledged that part of their role was to accompany patients to GP appointments, one clinical psychologist felt that this was "a bit of a cop out" and that GPs were "passing the buck" (FG14CLINPSY2) on building

relationships with their patients by relying on mental health workers to encourage engagement.

Some patients felt that it was important to involve informal carers in attending primary care appointments and being involved in treatment decisions:

“And would you want them (carer) to be involved in this check with you...?” (Facilitator)

“Definitely, come to appointments with me, talk to the doctor, talk to the nurse, be involved in a very real way.” (FG1-Patient3)

GPs did not discuss the role of informal carers and there were some negative views towards carers attending appointments with patients. Some practice nurses felt that having carers within consultations could sometimes be difficult if the carer was attempting to make decisions on behalf of their relative. In the example below the practice nurse perceived that the patient did not agree with the carer’s request:

“There was definitely an incident not so long ago, a carer that had come in with somebody, was like, ‘Oh, no, they’ve got to be done, they’ve got to be done,’ and we’re like, ‘We can’t force anything. If they’re happy for us to do it, we’ll do it, but we’re not forcing anything on anybody’.” (FG2-PracticeNurse1)

Some informal carers also reported that their role as partner, parent or friend could be undermined by health professionals:

“It’s a constant battle because I’ve found I was described as the ‘dominant mother’ on my daughter’s record, which I thought, ‘Oh right, thanks,’ because I was trying to get some services for her because she kept saying, ‘No, I’m fine, I’m this, I’m that’.” (FG9-Carer7)

Continuity of care

In the original analysis of the focus group data, I identified continuity of care between the patient and the same primary care based health professional as an important strategy for keeping patients engaged in CVD risk lowering behaviours and services

(Burton et al., 2015). Continuity of care provided by mental health professionals was also described as important, with some primary care health professionals stating that mental health workers could have a bigger influence on patient behaviour than they could hope to achieve because they had more regular and consistent contact with the patient:

“Someone who has got a care coordinator within the community mental health team, they would probably see them much more frequently than they would see their doctor, so whether they would be good people to kind of address their physical health as well, in terms of the continuity and the trust and knowing how to take on that particular patient's state of mind at the time, it would be an interesting view”. (FG10-GP7)

Primary care professionals also described the close relationship between mental health workers and people with SMI as a facilitator for encouraging patients to engage in activities to improve their health:

“Maybe if they involved with us more, because the patients know their key workers better, they probably have created a relationship there, they might listen to their key worker. The key worker, then instigating a move to the practice or booking an appointment, and coming along with them on one of those days to have a check or to have the bloods”. (FG3-GP2).

The importance of involving informal carers who are in frequent contact and who had detailed knowledge of the person with SMI was also described by some patients, particularly around the monitoring of their mental health:

“Luckily I’m living with my mum still and she can see my change in moods and how I’m affected by them. She’s got to realise that I need to go through that. By having small snapshots they can only see you at one particular time in your mood cycle, so basically you can say, ‘Oh yes, I’m up.’ But their version of up is different from your version of up, or down”. (FG4-Patient1)

Managing a healthy lifestyle

Family members and friends were identified by patients and mental health professionals as being influential in helping to promote messages about how to improve health:

"I think involving carers is important because if they have specific carers, maybe a mother that is looking after somebody with diabetes, is on a huge amount of medication, (it is) about educating or looking at diet, symptoms to look for, do they have regular screening? So they need to be involved in that process." (FG11-CPN2)

Some patients gave examples of supportive others helping them to participate in physical activities:

"My friends take me to the gym every day and that's all what I do, really. I play football with my son and that". (FG12-Patient6)

Practice nurses and carers also described examples of supportive others helping people eat more healthily and participate in light exercise, while GPs felt that mental health workers had an important role to play in encouraging healthy lifestyles for people with SMI:

"I have a lot of patients with mental health asking for referrals, because their friends or their family have been referred to the gym or they've been referred to health trainers and said, 'Well, that's working for them. Can I do it?' So it's quite useful". (FG2-PracticeNurse2)

"I think what I would like to see is everybody singing from the same health hymn sheet, and so even if the CPNs aren't going to do the work, that they should be reinforcing good stopping smoking, weight, and saying, 'That's really good,' or, 'We'll take you along,' or, 'Have you got your medication?' or whatever, and I think some support from them who are seeing them far more often would be very useful actually." (FG5-GP7)

Family carers and support workers were seen as supportive in helping patients to make healthy changes to their lifestyle, however some GPs and practice nurses felt that mental health professionals encouraged the enactment of unhealthy behaviours by using this as a strategy for building relationships with their patients. This in turn could have a potentially negative impact on the patient's cardiovascular health:

“The only thing about secondary care is sometimes perhaps they condone things like smoking because it's so important to establish a rapport, and it may not be right that the same person is sort of being their friend, if you like, and encouraging conversation and then saying, 'Hmm, but you mustn't smoke’’. (FG10-GP7)

Overall, family carers were unified in their experiences of being involved in supporting the health of their relatives regardless of age and relationships and there were no noticeable differences in experiences of patients who were supported by different people e.g. partners or parents.

Research aim two: what are the barriers to involving existing social networks and how might this hinder engagement in CVD risk lowering treatments and behaviours?

Barriers to involving the social network included concerns around maintaining patient confidentiality and an absence of social support.

Concerns around maintaining patient confidentiality

Concerns were raised by primary care health professionals on sharing confidential information with informal carers without first asking the patient:

“You can't necessarily contact the carer to follow up non-attenders unless you get consent from the client. But if you're talking about like (a) partner or something you can't necessarily be contacting them and saying, ‘Your husband didn't come for his thing.’ (FG13- Practice Nurse1)

Carers however viewed this lack of sharing of information as frustrating and discussed the negative impact this might have on the person they cared for:

“I think for myself, because I'm a friend, a peer support, so I had a difficulty from there where they've seen that I've been there with her since the age of 15, it's been over 10 years, but I had a difficulty. They say, 'Well, you're not next of kin, you're not a relative. You're not really blood related so we can't even talk to you.' And even though her parents would give the permission and they've written a letter out, because her parents are elderly now, they're in their eighties, so

they can't take the stress of looking after her. I've been doing that all this time. There's times when this bubbles up and they won't allow me to go any further and I feel that I'm stuck.....And she will ask for my help and she will say to them, but they will say no, they can't". (FG9-Carer1)

The carers group did however acknowledge that some patients may not want their carer to be involved in treatment decisions and in some cases, it was appropriate to respect an individual's autonomy:

"But then you've got to look at it on the other side, because quite a lot of service users don't want their carers or relatives involved, so the GPs have got a fine line to work out which ones".(FG9-Carer4)

Patient confidentiality was not raised as an issue or concern in the focus group discussions with people with SMI.

Absence of social support

While most of the discussions on involving supportive others were about who could be involved and how, it was acknowledged by some that not everyone had a close relationship:

"I now just about prefer community, living in (the) community, although in hospital there are always people around. I get lonely in the evening. I get very lonely in the evenings". (FG7-Patient3)

"Well, it is, and mostly they don't have friends, so that's another problem and it's difficult to go somewhere on your own, so again, you need that support. You need a buddy or a carer or friend, or something, somebody to help". (FG9-Carer4)

It was also acknowledged that not everyone with SMI had access to a mental health worker so formal support may not be available for everyone:

"Actually, there's an awful lot of patients on the SMI register that don't have any contact with secondary care at all, to be fair". (FG6-Practice Nurse2)

3.2.4 Summary and interpretation of findings from focus groups on social support

My secondary analysis suggests that the involvement of supportive others is important for addressing barriers to achieving a healthy lifestyle identified by the focus groups, however the analysis also identified concerns from health professionals and barriers to involvement raised by family carers that need to be addressed.

Supportive others were seen as important promoters of patient engagement to assist with monitoring attendance at appointments. Communication of healthy lifestyle options not just from GPs and practice nurses but by carers and mental health workers who could reinforce messages outside of time limited consultations was seen as important for successful behaviour change.

There was however discord between patient, GP and carer opinions of involving family or friends in their care. Patients discussed how they would want to involve informal carers in their care, however GPs did not mention informal carers at all and some nurses and carers described negative experiences of involvement of family members and friends in consultations. Given the desire to involve informal carers from patients, a possible lack of awareness on this subject from GPs and the difficulties described by practice nurses and informal carers, this is an important consideration for training both in terms of prompting conversations with patients to determine if there is anyone they would like to involve as well as exploring how they might be most effectively involved. For example, if an informal carer is perceived as being overbearing within consultations, it may be useful for both the patient and health professional to decide on alternative ways of involving them. Identifying strategies to improve communication between primary care health professionals and informal carers may also help to improve primary care staff confidence in working with people with SMI.

Involving supportive others appeared to be an important component for increasing engagement and adherence to treatments and services. One person with SMI described how his mother helped monitor his mental health and could help provide a more comprehensive view of his behaviour. A fluctuating state in mental health is likely to

have an impact on a person's ability to manage their physical health and engage with health services. Involving carers in providing additional information on mental or physical health states could potentially help health professionals understand how poor mental health impacts on the ability to participate in healthy behaviours and to consider how best to adapt and manage this.

3.3 Workshops to develop the content of the PRIMROSE intervention including social support

I shared the findings from my original analysis of the focus group data with academic and clinical experts and people with SMI in a series of workshops. The purpose of the workshops was to aid the development of the PRIMROSE intervention and training programme components. This section reports on key findings and themes that arose specifically on the involvement of supportive others in CVD risk reducing interventions for people with SMI.

I also facilitated three additional workshops with family carers of people with SMI for the purpose of this thesis to explore their experiences and suggestions for involvement in supporting their relatives to participate in healthy lifestyle activities and their experiences of accessing primary care with their relative with SMI.

3.3.1 Lived Experience Advisory Panel (LEAP) recommendations

I ran a workshop with a group of eight people with SMI and carers with lived experience of mental and physical health problems to obtain their views on what should be included in the PRIMROSE intervention for lowering CVD risk in people with SMI. Discussions around social support were limited, however LEAP members felt that coordination between community psychiatric nurses (CPNs), carers and primary care nurses was important to build trust and communication between people working in health services and those being cared for. Closer collaboration and joint working between primary care and mental health teams was also suggested to encourage continuity of care and integrated physical and mental health support.

Offering training to informal carers to identify and use strategies to help people with SMI change unhealthy behaviours and adhere to CVD risk reducing medications was also discussed, however there were concerns for those who lacked support and who might not have a carer to “nudge” them into going to their GP practice if required.

3.3.2 Recommendations from workshops with academics and clinicians

I coordinated three workshops at University College London (UCL) involving 17 academics with backgrounds in psychology, psychiatry, primary care, medical statistics, health economics, medical sociology and nursing. The workshops explored the findings from the focus groups, recommendations from the LEAP and evidence from the literature review, to identify effective interventions for lowering CVD risk for people with SMI in primary care, how to improve engagement of people with SMI with primary care and what to include in a training programme for practice nurses and HCAs working to lower CVD risk in people with SMI in primary care.

The workshops raised a number of recommendations specific to the use of social support for people with SMI in primary care and CVD risk lowering interventions. The group queried whether patients with SMI would engage with specialist services such as smoking cessation or weight management programmes and involving mental health workers or carers was suggested as a way of encouraging engagement with those services. It was also suggested that the patient could identify a key person, which could be a carer, family member, friend, mental health worker or support worker, at the initial consultation with the practice nurse to help with adherence and engagement. Guidance could be developed for the practice nurse on how to approach the subject of involving others and how they might be involved. Finally it was suggested that the practice nurse should ask the patient which health behaviour they would prefer to change (e.g. medication taking, diet, physical activity, smoking cessation, alcohol use), identify their support mechanisms for change and identify who could help monitor progress with making changes.

3.3.3 Carer support groups

I presented the rationale and aims of this thesis to three existing Rethink –Mental Illness carer support groups and obtained their feedback on involving supportive others in primary care and CVD risk lowering services.

One carer reported a negative experience of working with their GP practice and felt that it was a battle to get the medication change she thought was needed for her son. The carer talked about “arguing” with the GP until they finally agreed to change the medication. Other members of the groups reported positive experiences around decision making between themselves, the GP and the person they cared for. There was a feeling among the groups that using social support to improve access to health services was already part of their experience, as they as carer’s were already heavily involved in their loved ones care as advocates; however the groups acknowledged that there was not a consistent approach to involving others and that this was often carer, rather than health professional led. The main concern raised by the groups was for those who did not have anyone to advocate for them and that there may be a group of people with SMI who do not have carers, friends or mental health professionals to advocate for them. The group suggested that future work should look at targeting those who do not have a supportive other to evaluate whether peer support or buddying schemes might help them to improve their lifestyle, however this lies outside the scope of this thesis.

The groups agreed that supportive others should only be involved if the person with SMI wanted them to be involved. One carer’s experience was of her daughter having a good relationship with the GP practice and not wanting her mother to be involved.

Another concern was if the person with SMI wanted the carer to be involved in attending appointments with them but the carer did not have time for this. The group felt that involving supportive others in lowering CVD risk was not just about supporting attendance at primary care appointments but also about encouraging a healthy lifestyle at home or accompanying relatives to participate in leisure activities in their spare time. Allowing flexibility of involvement was seen as an important consideration.

3.4 Recommendations from NICE clinical guidelines regarding social support in managing cardiovascular risk

A full review of NICE clinical guidelines for people with SMI and on the promotion of cardiovascular health behaviours and prevention of CVD in the general population was conducted in chapter one, section 1.8 of this thesis to identify how social support might be used to improve engagement with health services, treatments and healthy behaviours. The guidelines suggested that families and friends should be given opportunities to be involved in treatment and care decisions for people with SMI and for people who need to improve their cardiovascular health. A summarised version of these findings is presented below with the emphasis on practical recommendations for involving supportive others to improve engagement with CVD risk reducing behaviours.

Guidelines on smoking suggested that family or friends can help people who smoke by attempting to quit smoking themselves and providing support and encouragement to quit (NICE, 2013a; 2013b). Obesity and weight management guidelines also suggested that programmes to improve diet should involve the family. Suggestions included the benefits of general encouragement and emphasis on the enjoyment gained from shared, social physical activities (NICE, 2006; 2014c; 2014d; 2014f; 2015a). Caution around involving the family of vulnerable groups was however given with the suggestion that social support should be discussed and not assumed, to ensure that a supportive environment exists.

Guidelines on alcohol use recommended involving families and carers in alcohol use assessments to help provide health professionals with a more comprehensive picture of the problems faced by the patient (NICE, 2011a). Families and carers should try and support the person to maintain a reduction in alcohol use. Confidentiality and information sharing was also addressed with the suggestion that discussions on involvement need to be had early on in the treatment process with the patient, and that these decisions need to be respected throughout the person's treatment.

Behaviour change guidelines highlighted that friends and family members can provide practical and emotional support, positive feedback and rewards and long term

encouragement (NICE, 2007; 2011b). The guidelines also recognised however that if not effectively managed, informal social support could sometimes lead to negative behaviours such as unhealthy co-dependency or manipulation (NICE, 2011b).

3.5 Theoretical considerations

In chapter one I identified a number of theoretical models that have been used to describe how social connections have an impact on mortality and morbidity. Only one paper was identified which attempted to describe the psychosocial mechanisms by which social ties have an impact on health behaviours and psychological wellbeing (Thoits, 2011). The findings from the focus groups mapped to three out of seven of these mechanisms: social comparison, social control and companionship. These three mechanisms informed the development of the key components of the social support strategy. Table 3.3 describes these three mechanisms.

Table 3.3. Psychosocial mechanisms considered in the development of the social support strategy

Mechanism	How might it influence health?
Social comparison	Participation in normative health behaviours occur as a result of comparisons with similar others in the social network or group. Risky or unhealthy behaviours may also be modelled by the social network.
Social control	Members of the social network explicitly attempt to influence, encourage or monitor participation in healthy behaviours
Companionship	Connections to others gives opportunity for participation in joint social activities which may include healthy lifestyle activities, which in turn impacts positively on mental health

3.6 Bringing together the evidence

In this section, I bring together the evidence from the secondary analysis of the focus groups, workshops with experts and the review of NICE clinical guidelines to form key recommendations for involving supportive others in primary care CVD risk reducing interventions for people with SMI. These recommendations were then used as the basis for the social support elements of the PRIMROSE intervention.

3.6.1 Key recommendations

i) People with SMI should be given a guided choice on how to involve others in their care

Focus groups, workshops and policy all emphasised that involving supportive others was to be encouraged but should only happen if appropriate and if the person with SMI agreed. Suggestions for involvement ranged from helping patients to attend health appointments, positive encouragement to achieve a healthy lifestyle and practical support through participation in shared health behaviours such as physical activity, stopping smoking and healthy eating.

How can this be implemented?

Training with practice nurses and HCAs should emphasise that decisions about how to involve supportive others in helping to lower CVD risk should be patient led. Practice nurses/HCAs should be trained to suggest appropriate and relevant ways of involving supportive others but be mindful that this is ultimately the decision of the patient. This could range from supportive others offering reminders or assistance to help the person with SMI attend intervention appointments or take their medication, through to how supportive others might help them achieve a healthier lifestyle specific to the CVD risk factors that they present with, including stopping smoking, eating a healthy diet or increasing their physical activity.

ii) Ask patients for their permission before others are involved in their care

Focus groups with practice nurses identified concerns around patient confidentiality as well as some experiences of what they perceived to be overbearing carers speaking on behalf of patients in consultations, while some carers felt that it could be a struggle to be involved in health decisions. NICE guidelines suggest that open discussions should be had with patients and their carers to negotiate and agree confidentiality and information sharing at the beginning and throughout the patient's treatment, while the workshops with lived experience experts and carers emphasised the importance of asking patients to identify who should be involved in their care rather than imposing the involvement of others on to them.

How can this implemented?

Training with practice nurses and HCAs should emphasise that the identification of a supportive other by the patient is in keeping with patient centred care and shared decision making. Training practice nurses to have open discussions about involving others and how they might be involved from the beginning of the intervention, and revisiting this at each consultation, as well as having written confirmation of who should be involved, may help to address concerns raised by practice nurses in the focus groups about breaching confidentiality when sharing information with others. Discussions should explore involving both informal carers such as family members, partners or friends and formal carers such as support workers and mental health professionals.

iii) Identify those with low social support or unsupportive others and strategies to overcome this

Focus groups and carer workshops raised concerns that not everyone has a supportive other to help them attend appointments or monitor their health. Focus groups and policy also acknowledged that some relationships may have a negative influence on behaviour such as people with SMI and their supportive others smoking together.

How can this implemented?

Practice nurses and HCAs could research initiatives in the local area which may help to increase social contacts for people with SMI, for example identifying group programmes for physical activity, such as walking groups. Discussions within consultations should also involve identifying potentially unsupportive others who may have a negative influence on the patient's behaviour, and explore strategies for managing these relationships. An intensive intervention with regular contact between the patient and practice nurse may also result in the practice nurse acting as a supportive other.

Table 3.4 presents the main findings from each source (focus groups, workshops and policy review) mapped against the key themes identified in the secondary analysis of the focus groups and the relevant psychosocial mechanisms of how social support impacts health identified by Thoits, 2011. Suggestions on how these findings informed the

incorporation of social support in to a primary care based CVD risk reducing intervention and training programme are also presented.

Table 3.4. Evidence from focus groups, workshops and clinical guidelines

Themes: Secondary analysis of focus groups	Evidence			How to incorporate social support in to the intervention and training programme
	Focus groups (<i>psychosocial mechanism</i>)	NICE clinical guidelines	Workshops	
Improving engagement with services and reducing non-attendance	<p>Primary care staff should have access to a named mental health worker so that they can contact them, establish why they might not have attended, and help rearrange appointments (<i>4 health professionals</i>) (<i>social control</i>)</p> <p>Mental health workers and carers could accompany patients to appointments and remind them to attend (<i>5 patients, 1 carer, 16 health professionals, however 3 practice nurses felt it was distracting having care workers in the consultation and one mental health worker felt it was a "cop out" to rely on them</i>) (<i>social control</i>)</p>	<p><i>Service user experience in adult mental health</i></p> <p>When people are contacted for mental health service appointments it should be explained that a family member, carer or advocate can attend with them if they wish for all or part of the time</p>	<p><i>LEAP</i></p> <p>Coordination between CPNs, carers and primary care nurses is needed to build trust and engagement with community based care</p> <p><i>Clinical academic experts</i></p> <p>Involve mental health workers and informal carers to help encourage engagement with primary care</p>	<p>Ask the patient at their first appointment if they would like anyone to accompany them to their appointments. Prompt the health provider to ask the patient if they would be happy for them to contact them to help follow up. Follow up with supportive others at subsequent appointments if needed and if the patient has agreed</p> <p>Suggest to the patient at their first appointment that they discuss the study with their supportive others and explore whether they could help remind them of their appointment times</p>
Difficulties managing a healthy lifestyle associated with lowering CVD risk	<p>Motivation and self-management of CVD risk factors could be increased by positive influence of friends and family or physical health peer support groups (<i>13 patients, 4 health professionals, 2 carers</i>) (<i>social comparison; companionship</i>)</p>	<p><i>Type 2 diabetes: prevention in people at high risk</i></p> <p>Encourage involvement of others who offer emotional, information, planning or practical support to help make changes in physical activity and diet, and</p>	<p><i>LEAP</i></p> <p>Prescribe healthy lifestyle choices based on individual hobbies and interests to encourage</p>	<p>Explore with the patient at the first appointment, who is in their social network and whether they would like to involve them in the study or not.</p>

Themes: Secondary analysis of focus groups	Evidence			How to incorporate social support in to the intervention and training programme
	Focus groups <i>(psychosocial mechanism)</i>	NICE clinical guidelines	Workshops	
<p>Difficulties managing a healthy lifestyle associated with lowering CVD risk</p>	<p>Mental health workers and informal carers can help monitor adherence to medications by reminding patients to take it (1 patient, 1 health professional) <i>(social control)</i></p> <p>Mental health workers and informal carers can remind patients to have blood tests (3 carers, 3 health professionals) <i>(social control)</i></p> <p>Mental health workers and informal carers can help patients monitor progress with their behavioural goals (4 health professionals, 2 patients, 1 carer) <i>(social control)</i></p> <p>Mental health workers and informal carers can act as advocates for patients when they are accessing primary care services (5 patients, 3 carers, 2 health professionals)</p>	<p>to help participants achieve behaviour change goals</p> <p>Physical activity: exercise referral schemes Provide social support during interventions to encourage adherence and long-term physical activity</p> <p>Obesity: identification, assessment and management Multicomponent interventions (e.g. diet change, targeted advice, family involvement and goal setting). Discuss sources and benefits of support. Encourage a partner to support them</p> <p>Preventing excess weight gain Communication of benefits of maintaining a healthy weight e.g. enjoyment from shared, social physical activities. Behaviour-change should include social support/making changes to the social environment</p>	<p>regular physical health monitoring</p> <p>Training of carers to help patients change behaviour and adhere to statins</p> <p>Coordination between CPNs, carers and primary care nurses to build trust</p> <p>Group intervention would work for some people - peer support in changing behaviours. Peer group support meetings every 2-months</p> <p>Clinical academic experts Peer support groups - Although raised by patients as a strategy for CVD risk monitoring, it was felt this would not</p>	<p>Suggest to the patient at their first appointment that they discuss the study with their supportive others and explore with them how they can get involved e.g. remind them to monitor taking their medications or have health checks, monitor progress with achieving their behavioural goals</p> <p>Include social support in the action plan so that it clear who will be involved and how</p> <p>Emphasise to the patient why involving supportive others can be helpful – that positive encouragement and support is rewarding which helps motivation</p>

Themes: Secondary analysis of focus groups	Evidence			How to incorporate social support in to the intervention and training programme
	Focus groups (<i>psychosocial mechanism</i>)	NICE clinical guidelines	Workshops	
Difficulties managing a healthy lifestyle associated with lowering CVD risk		<p>Behaviour change: individual approaches Advise and arrange for supportive others to provide practical help, emotional support, praise or reward. Help maintain long-term change by ensuring they have the social support they need</p> <p>Behaviour change: general approaches Select interventions that motivate and support people to recognise how social contexts and relationships may affect behaviour. Identify and plan for situations that might undermine changes they are trying to make</p> <p>Smoking: acute, maternity and mental health services Carers, partners, family and friends can help protect people from smoking at home including attempts to stop, stopping or changing their own smoking and providing encouragement</p>	<p>be feasible for the intervention and would be too resource intensive to set up.</p> <p>The patient could identify a key person (carer, family member, friend, mental health worker, support worker) at the initial consultation to help with adherence and engagement. Guidance could be developed around how the person could be involved</p> <p>Ask the patient which behaviour they would like to change and what their support mechanisms for change would be – identify who can help monitor progress</p>	

Themes: Secondary analysis of focus groups	Evidence			How to incorporate social support in to the intervention and training programme
	Focus groups (<i>psychosocial mechanism</i>)	NICE clinical guidelines	Workshops	
Difficulties managing a healthy lifestyle associated with lowering CVD risk		<p>Smoking: harm reduction Relapse is associated with lack of help to stop</p> <p>Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence If the patient agrees, families and carers should have the opportunity to be involved in treatment decisions. Encourage and support all to keep an up-to-date list of prescribed medications</p> <p>Alcohol-use disorders: diagnosis, assessment and management of harmful drinking Encourage families and carers to help support and maintain change. Discuss the impact of alcohol misuse and provide information on how families and carers can support the patient. Develop individualised care plans with the patient, families, carers and other staff</p>	<p>Carer workshop Not just about supporting attendance at primary care appointments but also about encouraging a healthy lifestyle at home or accompanying their relative in leisure activities in their spare time. Flexibility of involvement is an important consideration</p>	

Themes: Secondary analysis of focus groups	Evidence			How to incorporate social support in to the intervention and training programme
	Focus groups (<i>psychosocial mechanism</i>)	NICE clinical guidelines	Workshops	
Difficulties managing a healthy lifestyle associated with lowering CVD risk		<p>Schizophrenia Discuss the use of alcohol, tobacco, prescription and non-prescription medication and illicit drugs with the patient, and carer if appropriate</p> <p>Bipolar disorder Develop an ongoing relationship with the person and their carers. Discuss alcohol, tobacco, prescription and non-prescription medication and illicit drug use with the person, and their carer if appropriate</p>		
Patient confidentiality	<p>Share mental health worker contact details with practice staff if a patient is in crisis or needs mental health support (8 health professionals)</p> <p>Share appointment details, test results and treatment plans across agencies (2 patients, 4 health professionals)</p>	<p>Alcohol-use disorders: diagnosis, assessment and management of harmful drinking Negotiate with the patient and their family or carer about their involvement in care and the sharing of information; make sure the patient's, families and carer's right to confidentiality is respected</p>	<p>Carer workshop Supportive others should only be involved if the patient wants them to be involved.</p>	<p>In the patient recruitment materials – make it explicit that they will be asked if their treatment plan can be shared with friends, family or support workers</p> <p>Always seek the patient's permission before supportive others are involved in their care</p>

Themes: Secondary analysis of focus groups	Evidence			How to incorporate social support in to the intervention and training programme
	Focus groups (<i>psychosocial mechanism</i>)	NICE clinical guidelines	Workshops	
Patient confidentiality		<p>Schizophrenia Give copies of advance decisions and statements to the person, their health worker, and significant others if the person agrees. Negotiate about how information will be shared. Include carers in decision-making if the patient agrees.</p> <p>Bipolar disorder Negotiate how decisions will be shared. Foster a collaborative approach. Encourage development of advance statements when stable, in collaboration with carers if possible. Regularly review information sharing. Include carers in decision-making if the person agrees.</p> <p>Service user experience in adult mental health Discuss and encourage if and how carers are to be involved. Negotiate confidentiality/sharing of information; explain how families or carers can help</p>		

Themes: Secondary analysis of focus groups	Evidence			How to incorporate social support in to the intervention and training programme
	Focus groups (<i>psychosocial mechanism</i>)	NICE clinical guidelines	Workshops	
Patient confidentiality		with treatment plans; ensure that no services are withdrawn because of carer involvement, unless clearly agreed with everyone.		
Consideration of those who lack social support and of negative influences of family and friends	<p>Lack of access to a support worker (3 health professionals)</p> <p>Lack of family or friends (4 health professionals, 1 patient, 1 carer)</p> <p>Family or friends being a negative influence on healthy behaviours (2 patients) (<i>social comparison</i>)</p> <p>Not wanting family or friends involved (3 carers)</p> <p>Mental health staff might encourage and participate in unhealthy behaviours with the patient (e.g. smoking) to maintain engagement (2 health professionals) (<i>social comparison</i>)</p>	<p>Obesity: identification, assessment and management</p> <p>Explore barriers to lifestyle change including family and community member views. Tailoring advice to address family and community member views is particularly important for people from BAME, vulnerable and those at increased risk for weight gain groups.</p> <p>Service user experience in adult mental health</p> <p>Patient's may be ambivalent or negative towards family for different reasons, including as a result of the mental health problem or prior experience of violence or abuse</p>	<p>LEAP</p> <p>Not everyone has a carer to remind them to go to the doctor</p> <p>Carer workshops</p> <p>What about those who do not have anyone? Peer support or buddying schemes could be offered</p>	<p>Explore and introduce alternative support for people who do not identify anyone such as community groups</p> <p>Explore negative influences on the patient's behaviour and how they might manage this</p>

Themes: Secondary analysis of focus groups	Evidence			How to incorporate social support in to the intervention and training programme
	Focus groups (<i>psychosocial mechanism</i>)	NICE clinical guidelines	Workshops	
Consideration of those who lack social support and of negative influences of family and friends		<p><i>Behaviour change: individual approaches</i></p> <p>Social support could help people to make changes. However social support from non-professionals could lead to an unhealthy co-dependency, bullying, manipulation or negative behaviour</p>		

3.7 Social support components of the PRIMROSE intervention

I coordinated the development of a manual (available for download at: www.ucl.ac.uk/primrose) and training programme to enable practice nurses or healthcare assistants to deliver a CVD risk lowering behavioural intervention to patients with SMI in primary care. The intervention consisted of between 8-12 appointments delivered over a six-month period. The practice nurse or HCA worked with recruited patients to set goals to improve aspects of the patient's physical health and monitored progress with achieving goals through the use of a health goal plan. This section presents the components of social support that I developed and integrated in to an intervention and training programme for practices nurses and HCAs working with patients with SMI to lower their CVD risk based on the evidence presented in section 3.6.

I developed a dedicated Help Sheet on "*Involving Supportive Others*" (See figure 3.1) for the intervention manual as a possible strategy in its own right for engaging people with SMI. The content of the help sheet was informed by the themes identified by the focus groups and the corresponding mechanisms linking social support to health proposed by Thoits, 2011, as well as practical considerations identified by workshops and policy. Table 3.5 presents the social support help sheet content mapped to these mechanisms as well as other areas of the manual that were informed by these mechanisms.

Table 3.5. Psychosocial mechanisms mapped to social support content of intervention manual

Mechanism	How was this used within the intervention manual and training programme
Social comparison	Situations in which patients might not identify a supportive other or identified family or friends as a negative influence on their CVD risk reducing behaviours were explored with practice nurses/HCAs as part of the training programme. They were asked to consider what they might do in those scenarios, and options such as referring the patient to a community group and exploring with the patient how they might manage those negative influences were discussed.
Social control	<p>A prompt for practice nurses/HCAs to explain that involving supportive others can help encourage behaviour change was included in the social support help sheet</p> <p>Suggestions on involving supportive others in encouraging or monitoring participation in healthy behaviours such as accompanying appointments and monitoring adherence to medications was included in the social support help sheet</p> <p>Eight CVD risk factor help sheets were developed with clinical recommendations on how to lower various CVD risk factors such as raised cholesterol, raised blood pressure, diabetes, weight, smoking and alcohol use. I included the following statement within each help sheet: “Encourage the patient to get support from family and friends. Positive support and encouragement is rewarding and tends to increase the frequency with which the behaviour is performed.”</p>
Companionship	Suggestion to involve supportive others in shared activities that promote health such as physical activity was included in the social support help sheet

Figure 3.1. Help sheet on involving supportive others in a CVD risk lowering intervention in primary care

HELP SHEET 7: INVOLVING SUPPORTIVE OTHERS

Why involve supportive others?

- Patients benefit from involvement of supportive others such as carers, family, friends and mental health workers in their care, who can help to encourage behaviour change.

How to involve supportive others:

At the first appointment: Ask the patient if they would like to involve someone in their care. This could be their carer, family member, mental health worker, friend and/or support worker. It could be more than one person.

- Explain that involving others may make it easier for them to achieve their goals
- Discuss ways in which this person could be involved e.g.
 - o Accompany them to appointments
 - o Remind them of their appointments
 - o Help them to take their medication
 - o Help them to monitor progress with their goal
 - o Identify activities that could be done together to help them achieve their goal (e.g. exercise together/cook meals or go food shopping together)
- If they would like someone involved, ask if you can invite them to the appointments.
- If they do not want the person to come to the appointments, ask if you can contact the person to discuss how they can help.
- Document who will be involved and how in the 'MY HEALTH GOAL' plan. This is important as you should only involve supportive others in the patient's care if the patient has agreed to this.

I also developed practical aids and prompts to remind the practice nurses/HCAs to initiate conversations with patients about involving their social networks in supporting behaviour change. These included:

i) Adding a prompt to a summary flow chart to be used at every appointment or placed on the wall of the consulting room to remind health providers to involve supportive others as a way of engaging patients to attend appointments

ii) The creation of appointment flow charts to guide health providers to discuss involving supportive others in their first appointment with each patient. The health provider was prompted to ask: *“Would the patient like to involve anyone else and in what way? (This could be one or more people, including their mental health worker, family member or friend). Record how they would like them to be involved in the 'MY HEALTH GOAL' plan. Record their contact details in the patient’s medical records.”*

iii) A reminder within the appointment flowcharts for practice nurses/HCAs to involve supportive others in any subsequent appointments using the following text: *“If the patient would like to involve others in their care, contact them to explain the study and to agree their level of involvement based on patient preference and the person’s availability. Tell them the appointment date and time and discuss progress. Invite them to the appointment only if the patient has agreed. If the patient has agreed for you to contact their mental health worker, ask if they are aware of any specialist physical health services available for patients with SMI – Add these to your Local Resource Directory (pg. 30-32).”*

Practice nurses/HCAs were then reminded to follow up supportive others: *“If the patient wanted their supportive other to attend but they were unable to, ask if you can phone them to discuss progress made and how the patient would like to be supported. Invite them to attend the next appointment if the patient requests this.”*

iv) At the final appointment the practice nurse/HCA was reminded: *“If the patient would like someone to attend the final appointment with them, contact this person to inform them of the date and time. Explain that this is the last appointment for the intervention. If they cannot attend, discuss how they can support the patient going forward.”* Practice nurses/HCAs were again reminded to follow up supportive others: *“If the patient wanted their supportive other to attend but they were unable to, ask if you can telephone them to discuss progress made and how the patient would like to be supported”.*

v) Eight help sheets on different behaviour change techniques (BCTS) that could be used to help health providers maintain engagement with patients in the intervention were developed and incorporated into the intervention manual. I added a section on involving supportive others within the Help Sheet on creating action plans, in which the nurse/HCA was instructed to develop an action plan with the patient which included who they would involve in achieving their goal and how this person would be involved. At the first appointment, the health provider encouraged the patient to set a goal and complete an action plan detailing how they would achieve the goal. I developed two sections in the health plan to document who would be involved in helping them to achieve their goal and how (Figure 3.2).

Figure 3.2. My health goal plan: social support sections

MY HEALTH GOAL PLAN

With whom I am going to do it:

.....

.....

How I will be supported by the people listed above:

.....

.....

ix) I developed a frequently asked questions' section in the manual. One of the concerns raised by the focus groups was around non-attendance and disengagement with services. The advice for practice nurses in this scenario was given as: *“Leave a message with your name and contact details and ask the patient to call you back. Reassure them that everything is okay and that you are calling to rearrange the appointment. If the patient does not call back after a few days and they have identified a supportive other (e.g. carer, family member, mental health worker, friend), contact this person and ask if they have any information or have had any recent communication with the patient.”*

3.8 Discussion

3.8.1 Summary of findings

I drew upon the MRC framework for the development of complex interventions (Craig et al., 2008) to develop the social support component of the PRIMROSE intervention. I conducted an initial analysis of data collected from fourteen focus groups and identified social support as a key strategy for reducing CVD risk in people with SMI which was published in the journal PLOS One in 2015 (Burton et al., 2015). I then explored the theme of social support further in a secondary analysis of the focus group data and mapped these themes to theoretical constructs of how social support impacts health outcomes identified by Thoits, 2011. I shared the findings from the focus groups with clinicians, academics, family carers of people with SMI and lived experience experts in facilitated workshops to explore the most important components of an intervention for reducing CVD risk in people with SMI in primary care. Social support was identified as a strategy for increasing the uptake of CVD risk reducing behaviours in people with SMI in primary care. I conducted a review of national clinical guidelines to identify policy recommendations for involving supportive others in health care for people with cardiovascular risk factors and people with SMI.

I brought the evidence together from the focus groups, theory, workshops and a review of national guidelines and formulated three key recommendations on how social support could be incorporated into a CVD risk reducing intervention for people with SMI in primary care. These recommendations included giving patients' a guided choice of how to involve others in their care; always asking for the patient's permission before others are involved in their care and identifying people with low social support or unsupportive others and exploring strategies to overcome this.

I then incorporated the recommendations into a training programme and intervention manual for practice nurses and healthcare assistants who were participating in work package three of the PRIMROSE programme.

3.8.2 Reflexivity

My influence as a researcher interested in social support and as the facilitator of the workshops with people with SMI, clinicians, academics and family carers to determine the key components of the PRIMROSE intervention may have biased the discussions towards more favourable conversations about social support as a strategy for improving engagement with CVD risk reducing behaviours. The discussions were however based on evidence from the overall findings from the focus groups and broader reviews of the literature on interventions for reducing CVD risk in SMI populations (Osborn et al., 2019). The discussions also involved stakeholders from diverse clinical backgrounds including psychiatrists, psychologists, nurses and general practitioners as well as people with SMI and family carers, with the aim of eliciting different experiences and opinions from my own stance as an applied health services researcher. The findings from the overall analysis of the focus groups helped to strengthen my decision to pursue the link between social support and CVD health behaviours as the focus for my thesis, however my preconceptions about the benefits of social support on health outcomes may have also influenced my secondary analysis. I did however seek to identify disconfirming evidence within the data and found instances where social support could be perceived as a negative influence as well as positive. I also discussed preliminary themes with my supervisory team and obtained their feedback on the findings.

3.8.3 Strengths and limitations

I included a diverse range of stakeholder views including people with SMI, family carers, researchers and primary care and mental health professionals and triangulated their views against national policy recommendations for involving family, friends and support workers in CVD risk prevention for people with SMI. These views were used to formulate a social support strategy that sought to highlight the strengths identified by a sample of relevant stakeholders on involving existing members of the social network in promoting healthy lifestyle behaviours for people with SMI, as well as identify and overcome the potential challenges involved. I considered theory and used different qualitative methodologies

including focus groups, facilitated workshops and a clinical guidelines review to determine how to involve supportive others in CVD risk prevention for people with SMI.

The focus groups were conducted in GP practices and services across urban and rural areas with a diverse range of stakeholders from different backgrounds and a range of views expressed, making the findings applicable to UK primary care.

Questions and findings put to the focus groups and workshops with clinicians and academics were not specific to social support and how supportive others could be involved in improving healthy behaviours; rather they explored overall barriers and strategies to reducing CVD risk in people with SMI in primary care. There were therefore limitations to conducting a secondary analysis on data collected with alternative research aims in mind and not all of the data were relevant. Nevertheless, social support emerged as a strategy for engagement without direct probing, and where involvement of supportive others was raised, I followed up these discussions with further questioning. This theme was discussed by all fourteen focus groups suggesting that it was viewed as an important strategy for the successful engagement of people with SMI in primary care based interventions.

3.8.4 Conclusion

Harnessing existing social support emerged as an important strategy for engagement in healthy lifestyle behaviours for people with SMI, however some concerns were raised including the importance of maintaining confidentiality and exploring and offering choice rather than assuming the involvement of others as a uniform approach for all. These findings were incorporated into a training programme and manual for practice nurses/HCAs to help them explore how social support might be enlisted and used in consultations with people with SMI recruited to the PRIMROSE intervention.

In chapter four of this thesis, I explore the importance of social support further, by analysing whether baseline perceptions of social support were associated with increased participation in CVD risk reducing behaviours in a cohort of participants with SMI and raised

CVD risk factors who were recruited to the PRIMROSE trial. In chapter five, I will then go on to explore how the social support strategy described in this chapter was used in consultations between practice nurses/HCAs and people with SMI who were recruited to the PRIMROSE trial.

Chapter 4 Perceived social support and CVD risk reducing behaviours for people with SMI: longitudinal and cross sectional secondary analysis of the PRIMROSE trial data

4.1 Introduction

In this chapter I present the results of a secondary analysis of the PRIMROSE trial data which aimed to explore associations between perceived social support and CVD risk reducing behaviours in a sample of people with SMI and raised CVD risk factors. I presented the findings of this work at the 62nd Annual Scientific Meeting of the Society for Social Medicine in September 2018 (Burton, Walters, & Osborn, 2018) and I have submitted the findings for publication in a peer reviewed journal (Burton et al., 2019).

The outcome data analysed in this chapter were collected as secondary outcomes for work package three of the PRIMROSE programme: a cluster randomised controlled trial assessing the clinical and cost effectiveness of an intervention for reducing CVD risk in people with SMI and raised CVD risk factors in primary care (Osborn et al., 2016; Osborn et al., 2018). I conceived and designed the additional components of the trial related to the role of social support and its relationship to CVD health behaviours, and the independent variable (perceived social support) was collected for the purposes of this thesis. I was the trial manager for the project and oversaw the running of the trial through the NIHR CRNs. I developed and delivered the training of CRN research nurses in all study procedures including questionnaire administration. Where activities were undertaken by CRN nurses or the trial coordinator, this is stated in sections “4.3.5 Recruitment Procedures” and “4.3.6 Data Collection”.

In chapter one I reviewed the literature on the relationship between different types of social support and cardiovascular health outcomes. Research with the general population suggests that the more social support that people have, the better their outcomes in terms of CVD morbidity and mortality, with more complex measures of social support assessing

the quality of relationships being the most promising predictor, rather than received support or simple measures such as living alone or marital status (Holt-Lunstad et al., 2010).

A small number of qualitative studies have identified social support as a facilitator for physical activity (Bassilios et al., 2014; Firth et al., 2016; Fogarty & Happell, 2005) and quitting smoking (Heffner et al., 2018) in people with SMI and very little quantitative evidence exists that assesses the association between social support and non-psychiatric related health outcomes in people with SMI, specifically key cardiovascular health behaviours of physical activity (Arbour-Nicitopoulos et al., 2017; Daumit et al., 2005; Leas & McCabe, 2007), diet (Leas & McCabe, 2007), smoking (Aschbrenner et al., 2015; Brunette et al., 2019; Ferron et al., 2011) and alcohol use (Schofield et al., 2001; Seo & Min 2005). No studies were identified on whether social support was associated with greater attendance at CVD health related appointments or adherence to CVD risk reducing medications.

Given the limited number of studies that have assessed whether an association exists between perceived social support and CVD health behaviour outcomes in SMI populations; I conducted a secondary exploratory analysis on the PRIMROSE trial data to test for this association (Osborn et al., 2016; Osborn et al., 2018).

4.2 Aims and hypotheses

I aimed to explore whether an association existed between a self-report measure of perceived functional social support and six key CVD risk reducing behaviours identified by NICE clinical guidelines on cardiovascular disease risk assessment and reduction (NICE, 2014b). The primary outcome was attendance at PRIMROSE intervention appointments as measured by clinician report. I chose this as my primary outcome as it is an essential first step to accessing care and CVD risk reducing support, and no existing research was identified on primary care appointment attendance in SMI populations. Secondary outcomes were adherence to CVD medications, physical activity, diet, alcohol use and smoking as measured through patient self-report. The International Physical Activity

Questionnaire (IPAQ) (Craig et al., 2003) used to measure physical activity, produced two scores; one for physical activity and one for sedentary behaviour; while the Dietary Instrument for Nutrition Education (DINE) (Roe et al., 1994) used to measure food intake produced three scores related to fat, fibre and unsaturated fat consumption rather than one overall score.

4.2.1 Primary hypothesis

Higher perceived social support measured by the Medical Outcomes Study - Social Support Survey (MOS-SSS) (Sherbourne & Stewart, 1991) at baseline is associated with attendance at a greater number of primary care intervention appointments over a six-month period.

4.2.2 Secondary hypotheses

Higher perceived social support measured by the MOS-SSS (Sherbourne & Stewart, 1991) at baseline is associated with:

- i) greater adherence to CVD risk reducing medications as measured by higher scores on the Morisky Medication Adherence Scale (MMAS-8)³ (Berlowitz et al., 2017; Morisky et al., 2008; Morisky & DiMatteo, 2011) at baseline
- ii) higher levels of physical activity as measured by a higher total metabolic equivalent of task (MET) minutes score and a lower amount of time spent sitting as measured by the International Physical Activity Questionnaire (IPAQ) (Craig et al., 2003) at baseline
- iii) lower fat, higher fibre and higher unsaturated fat scores on the Dietary Instrument for Nutrition Education (DINE) (Roe et al., 1994) at baseline,

³ The MMAS (8-item) content, name, and trademarks are protected by US copyright and trademark laws. Permission for use of the scale and its coding is required. A license agreement is available from Donald E Morisky, 14725 NE 20th St Bellevue, WA 98007, USA; dmorisky@gmail.com

- iv) lower levels of alcohol consumption as measured by lower scores on the Alcohol Use Disorders Identification Test (AUDIT) (Saunders et al., 1993) at baseline,
- v) being a current non-smoker at baseline

4.3 Method

4.3.1 Study design

I conducted a secondary exploratory analysis of data collected as part of the PRIMROSE trial (Osborn et al., 2016; Osborn et al., 2018). I tested for an association between perceived social support at baseline and attendance at primary care intervention appointments at six-month follow up. Cross sectional analyses were also conducted to assess whether there were associations between perceived social support and secondary outcomes of CVD health behaviours including self-reported adherence to CVD risk reducing medications, physical activity, diet, alcohol use and smoking at baseline.

4.3.2 Participants and setting

The sample consisted of patients aged 30-75 years old who were on the SMI register in 76 GP practices I recruited to the PRIMROSE trial (Osborn et al., 2016; Osborn et al., 2018). GP practices were recruited if they had a practice nurse or healthcare assistant (HCA) who could deliver the intervention if they were randomised to the intervention group; and if they had an SMI register containing 40 or more patients. All recruited participants met the following inclusion criteria:

- i) on the SMI GP practice register with a diagnosis of schizophrenia, persistent delusional disorder, schizoaffective disorder, bipolar affective disorder, psychosis, psychotic depression or other psychotic disorder,

ii) raised total cholesterol above 5 mmol/l **OR** raised total cholesterol/ HDL cholesterol ratio above 4 mmol/l **AND** one or more of the following risk factors: BMI >30 kg/m², current smoker, blood pressure >140mmHg systolic and/ or >90mmHg diastolic on two or more consecutive occasions, HBA1c of 42-47mmol/mol (6.0–6.4%), diabetes, hypertension,

iii) able to give written informed consent,

iv) agreed to be contacted by a researcher.

Participants were excluded from the study if they met one or more of the following criteria:

i) too acutely unwell defined as currently in an inpatient unit or accessing a crisis service,

ii) primary diagnosis of an organic mental health problem and/ or severe cognitive impairment,

iii) life expectancy of less than six-months,

iv) pregnant at baseline,

v) pre-existing CVD.

4.3.3 Research instruments

I selected validated instruments to include in the data collection in order to measure the pre-specified outcomes of interest to the trial and to my secondary data analysis for my PhD. I designed questions to elicit smoking behaviours with input from a health psychologist specialising in smoking intervention trials; Dr Hazel Gilbert, and I created an attendance spreadsheet template to record the number of primary care intervention appointments that each patient in the intervention group attended. I added the MOS-SSS measure (Sherbourne & Stewart, 1991) and demographic data relating to social support in to the data collection specifically for the purpose of my PhD. All data were collected at baseline, six and 12-month follow up by research nurses employed by the NIHR CRN, apart from appointment attendance which was collated by health providers. I have only used the data collected at baseline, and the six-month appointment attendance data in this analysis.

4.3.3.1 Demographics and descriptive data

Data collection included sex, ethnicity (Office for National Statistics, 2011), date of birth, marital status, social network size measured using a single question asking the participant to indicate “about how many close friends and close relatives do you have (people you feel at ease with and can talk to about what is on your mind)?” (Sherbourne & Stewart, 1991), whether the participant had a mental health support worker, living arrangements (living alone versus living with family, friends or others), employment status (unemployed versus employed (full or part time employment or in full or part time education)), and Townsend deprivation score (Townsend, Phillimore & Beattie, 1988). The deprivation score is calculated through the participant’s post code which is mapped to one of five levels of deprivation, with one indicating the least deprived area and five indicating the most deprived. Each level of deprivation is calculated using four variables: unemployment, non-car ownership, non-home ownership and household overcrowding. Primary psychiatric diagnosis was taken directly from the participant’s GP medical record.

4.3.3.2 The Medical Outcomes Study - Social Support Survey (MOS-SSS)

In my review of the literature in chapter one, I identified that measures of perceived and functional social support better predict health outcomes than measures of received or structural support in general populations. I therefore chose the MOS-SSS (Sherbourne & Stewart, 1991) as it is a validated and widely used measure of the perceived availability of functional support (Berkman & Glass, 2000). The MOS-SSS has also been validated in a population of 2,987 adult (18+ years old) patients with chronic conditions such as hypertension, coronary heart disease, depression and diabetes (Sherbourne & Stewart, 1991) and has been used to assess perceived social support in populations with schizophrenia (Fulginiti & Brekke, 2015; Rungruangsiripan et al., 2011).

The MOS-SSS is a patient self-complete questionnaire which includes 19 items designed to assess how often different types of functional social support are available to the participant if they need it using a five point Likert scale ranging from 1 “none of the time” to 5 “all of

the time". The scale includes four subscales with statements to assess perceptions of i) emotional/informational support e.g. "Someone who understands your problems", ii) tangible support e.g. "Someone to help with daily chores if you were sick", iii) affectionate support e.g. "Someone who shows you love and affection" and iv) positive interactions e.g. "Someone to do something enjoyable with". An additional item asks participants how often they have: "Someone to do things with to help you get your mind off things". An overall functional support index score is generated by calculating the average score across the 19 items in the scale. The range for the overall score is 1-5 which can be converted so that the lowest possible score is 0 and the highest possible score is 100 using the following formula:

$$100 \times \frac{(\text{observed score} - \text{minimum possible score})}{(\text{maximum possible score} - \text{minimum possible score})}$$

The authors report that the measure is reliable (Cronbach alpha coefficient = 0.97 for the overall support index) and stable over time (one year stability coefficient = 0.78) (Sherbourne & Stewart, 1991).

4.3.3.3 Patient attendance at intervention appointments

Data on attendance at intervention appointments were collected for intervention group participants only. I developed an appointment attendance template for practice nurses/HCAs delivering the intervention to complete for every recruited patient at their GP practice. Practice nurses/HCAs were asked to indicate on the spreadsheet whether or not an appointment was scheduled, and subsequently attended or not attended by each participant recruited at their GP practice (Appendix 10). I coordinated and monitored the return of the templates by asking providers to email or fax the attendance sheets to me on a monthly basis. I then collated all data on an excel spreadsheet. Providers were asked to deliver a minimum of eight and a maximum of 12 appointments to each patient over a six-month period.

4.3.3.4 Morisky Medication Adherence Scale (MMAS-8)

Adherence to medication was measured using a validated questionnaire, the Morisky Medication Adherence Scale (MMAS-8) (Morisky et al., 2008; Morisky & DiMatteo, 2011). The scale was chosen because it has been widely used in research with hypertensive and diabetic populations (Berlowitz et al., 2017; Huang, Shiyanbola, & Smith, 2018; Tan & Chang, 2014). It is a patient self-complete questionnaire that can be used to ask participants about specific medication use and was administered in this study to ask participants specifically about their adherence to CVD risk reducing medications such as statins, antihypertensives, metformin, stop-smoking medication and/or diabetic medications. The scale contains eight questions; the first seven of which are yes/no responses and the final item is a 5-point Likert response. A score between 0 and 8 for each participant is possible with a score of <6 indicating low adherence, 6 to <8= moderate adherence and 8= high adherence (Morisky et al., 2008). The questionnaire was found to be reliable (Cronbach's alpha = 0.83) and valid when compared against the MMAS-4 (PCC = 0.64; p<0.05) (Tan & Chang, 2014).

4.3.3.5 International Physical Activity Questionnaire (IPAQ)

Physical activity was assessed using the International Physical Activity Questionnaire (IPAQ) short form (Craig et al., 2003). This scale was chosen as it is a widely used self-complete questionnaire which has been validated in people with schizophrenia (Duncan et al., 2017; Faulkner, Cohn, & Remington, 2006). Also the questionnaire has been shown to demonstrate good test-retest reliability, and reasonable concurrent and criterion validity (Craig et al., 2003) and It is structured so that it gives separate scores in three domains: walking, moderate intensity activity and vigorous intensity activity. It is scored by multiplying the number of minutes the domain is carried out by the frequency per week. This can further be multiplied by the metabolic equivalent of task (MET) minutes to get a score in terms of MET minutes per week. There are standard MET minutes for each domain: Walking = 3.3 MET minutes, Moderate physical activity = 4.0 MET minutes and Vigorous physical activity = 8.0 MET minutes. From these, a total score in terms of MET minutes per week is calculated. Based on the MET minutes, the score can then be categorised into:

- a) Medium activity consisting of three or more days of vigorous-intensity activity of at least 20 minutes per day, or five or more days of moderate-intensity activity and/ or walking of at least 30 minutes per day, or five or more days of any combination of moderate intensity or vigorous intensity, moderate intensity activities or walking that achieves a minimum total physical activity of at least 600 MET minutes per week.
- b) High activity consisting of vigorous-intensity activity on at least three days and accumulating at least 1500 MET minutes per week or seven days of any combination of walking, moderate or vigorous intensity activities accumulating at least 3000 MET minutes week
- c) All other activity is categorised as low activity.

The last question on the IPAQ asked participants to indicate how much time they spent sitting on a typical day during the last seven days.

4.3.3.6 Dietary Instrument for Nutrition Education (DINE)

Diet was assessed using the Dietary Instrument for Nutrition Education (DINE), a validated food frequency questionnaire which is administered as a structured interview by the researcher and takes approximately 20 minutes to complete (Little et al., 1999; Roe et al., 1994). The DINE was chosen for this study as it was developed and validated in a sample of 206 primary care attenders in the UK and has been used to assess dietary behaviour in previous research studies with people with SMI (Martina et al., 2003; Osborn, Nazareth, & King, 2007b; Ryan et al., 2004). A study validating a range of dietary assessment tools in 101 participants recruited from primary care (half of whom had one or more risk factors for CVD), found that the DINE was moderately correlated with a seven day food diary (fat = 0.51, unsaturated fat=0.47 and fibre=0.46). (Little et al., 1999).

Questions were asked on the frequency that 19 specific foods were eaten by the participant, organised into fat, fibre and unsaturated food groups. Separate overall scores were then

calculated for each food group with a higher score on each respective food group (fat, fibre and unsaturated fat) indicating a greater intake of that specific food group:

a) Fat scores:

Low fat score = a score of <30 equivalent to <83 grams per day.

Medium fat score = 30-40 equivalent to 84-122 grams per day.

High fat score = >40 equivalent to >122 grams per day

b) Fibre scores:

Low fibre score = a score of <30 equivalent to <20 grams per day.

Medium fibre score = 30-40 equivalent to 21-30 grams per day.

High fibre score = >40 equivalent to >30 grams per day

c) Unsaturated fat scores:

Low unsaturated fat score = <5

Medium unsaturated fat score = 6 to 9

High unsaturated fat score = >10

The questionnaire does not allow for an overall dietary score to be calculated.

4.3.3.7 Alcohol Use Disorders Identification Test Consumption (AUDIT)

Alcohol use was measured using the Alcohol Use Disorders Identification Test (AUDIT) (Saunders et al., 1993), a questionnaire which was administered as a structured interview by the researcher. The AUDIT questionnaire was chosen for this study as it has been validated and found to be reliable in studies involving people with SMI (Dawe et al., 2000; Maisto et al., 2000) and it is widely used in UK clinical practice to assess whether a patient is at risk of alcohol misuse problems. The first three questions measure the frequency and quantity of alcohol intake such as “how often do you have a drink containing alcohol.” Participants first completed these first three questions (Alcohol Use Disorders Identification Test-Consumption; AUDIT-C), and if a participant scored five or more indicating a higher

consumption of alcohol, they were then asked an additional seven questions on the full AUDIT questionnaire. These additional questions focus on the perceived consequences of the participant's alcohol use such as "How often during the last year have you had a feeling of guilt or remorse after drinking?" If a participant scored less than five on the AUDIT-C, a score of 0-5 was their final score. Possible scores ranged from 0-40 and were categorised as follows: A score of 0-7 = lower risk, 8-15 = increasing risk, 16-19 = higher risk and 20+ = possible dependence.

4.3.3.8 Smoking

Participants were asked their current smoking status and were given the following pre-specified answers to choose from: a) non-smoker, b) ex-smoker, c) light smoker (9 or less cigarettes a day), d) moderate smoker (between 10-19 cigarettes a day), e) heavy smoker (20 or more cigarettes a day). Following discussions with an expert in smoking cessation research (Dr Hazel Gilbert), answers were converted into a binary outcome and participants were categorised as either i) current smokers (comprising light, moderate and heavy smokers) or ii) non-current smokers (comprising both non and ex-smokers).

4.3.4 Ethical considerations

Data collection was approved by the City Road and Hampstead Research Ethics Committee (Reference No: 12/LO/1934, 10 January 2013) as part of the PRIMROSE trial NHS ethics committee application (Appendix 11). I wrote and submitted the application for the trial and attended the ethics committee meeting alongside my second PhD supervisor, Professor Kate Walters, where the application was discussed and subsequently approved.

Prior to the recruitment of GP practices and patients, I obtained local NHS approvals from research and development (R&D) departments in the following areas: Avon primary care collaborative, Leicester City clinical commissioning group, Lincolnshire community health services NHS trust, North and Central London research consortium (Noclor), Northamptonshire research and development service, North of England commissioning

support unit, North West Coast clinical commissioning group, Norfolk & Suffolk primary & community care research office, South London CRN, Wessex primary care research support service and West Midlands primary care research management and governance business support service and CRN: West Midlands, research support team.

4.3.5 Recruitment procedures

I contacted local CRNs to identify eligible GP practices to participate in the study. Once a GP practice had submitted an expression of interest to the CRN I then contacted the lead GP and practice manager at the interested site to arrange a site initiation visit. At the site initiation visit, I presented the research study aims and trained all practice staff with responsibilities for the conduct of the study at the site in the study procedures, and answered questions from the site team. For approximately one third of the recruited GP practices, site initiations was delegated to the PRIMROSE trial coordinator, Samira Heinkel (SH), whom I trained in all study procedures.

Following the site initiation visit, either SH or I ran a computerised search designed in collaboration with colleagues at the Camden and Islington NHS Foundation Trust research governance office (Noclor) to identify potentially eligible participants for the study from the GP practice system. The search was conducted with the GP practice administrator and focused on identifying potentially eligible participants specifically from the GP practice Quality Outcomes Framework (QoF) SMI register which contained all patients within the practice that had a diagnosis of SMI including schizophrenia, bipolar disorder and psychosis.

Following the search, all potentially eligible participant details were entered on to a screening log (excel spreadsheet) which was passed on to the lead GP to check each patient against the inclusion and exclusion criteria. Patients who were excluded by the GP were subsequently removed from the screening log. All remaining patients on the screening log were sent a study leaflet and letter inviting them to express their interest in taking part in the study, a reply slip for patients to indicate whether or not they were interested in taking

part in the study, and a stamped addressed envelope for patients to post the reply slip back to the practice.

Patients who were interested in taking part in the study but who needed to be assessed for eligibility were contacted by the GP practice to attend an eligibility screen with a healthcare assistant or practice nurse who I (or SH) had trained in the study procedures. Screening was undertaken using usual practice procedures and equipment for blood tests (cholesterol and HBA1c) and clinical measures (BMI, blood pressure, smoking status). If following the screening the patient was eligible and interested in the study, their details were passed to the local CRN research nurse who contacted them to arrange to take written informed consent and conduct the baseline assessment at the patient's local GP practice. For patients who were already eligible because they had received a routine health screen in the previous three-months, their details were passed directly to the local CRN research nurse who contacted them to arrange the written informed consent and baseline assessment appointment at their local GP practice. At least one week prior to the consent and baseline assessment meeting, the full patient information sheet (PIS) (Appendix 12) was sent out by the CRN research nurse to the patient.

Any patients who did not return the reply slip within two weeks of the letter being sent were followed up with a telephone call from a member of staff at the GP practice who had been trained in the research study procedures (usually a practice nurse or healthcare assistant) to determine if they were interested in taking part. If they were interested, they were either invited to the practice for a full eligibility screen if required, or if they already met the eligibility criteria, their details were passed on to the local CRN research nurse who contacted them to arrange the consent and baseline assessment appointment. See Appendix 13 for the consent form template.

All patient responses to the study invitation letter and whether or not a patient was interested and eligible following the eligibility screening were recorded on the screening log by the GP practice. I asked GP practices to email me fortnightly with an anonymised version

of the screening log so that I could monitor recruitment and help troubleshoot if practices were having difficulties identifying and recruiting participants.

Once recruitment had ceased at the site, the GP practice and all recruited patients within the site were then randomised to either receive the PRIMROSE intervention or routine GP practice care. The randomisation process will not be described in detail here and a description can be found in the trial publication (Osborn et al., 2018) however it is important to mention that randomisation occurred for the purpose of this study, as the primary data analysis on the impact of social support on attendance at appointments was conducted on the intervention sample only (as the control group did not receive the intervention). I conducted all other analyses on the baseline data, treating the intervention and routine GP practice care groups as one sample.

4.3.6 Data collection

Data for this study were collected by research nurses working in CRNs across England, apart from the primary outcome of attendance at appointments which was collated by practice nurses or HCAs based in recruited GP practices who were delivering the intervention (described in section 4.3.3.3 above).

I developed the study procedure training and delivered this to the CRN research nurses. The training covered all aspects of recruitment and assessment procedures including taking informed consent from patients, data collection tools and data entry. I was the main point of contact for any data collection queries.

Data were collected by CRN research nurses at the baseline assessment from three sources i) the participant's medical record (diagnosis), ii) a written case report form comprising of questionnaires that were administered and completed by the research nurse (demographics, AUDIT, DINE and smoking questions) and iii) a self-complete patient questionnaire booklet containing the IPAQ, MMAS-8 and MOS-SSS questionnaires.

I trained the research nurses on how to use and input data into a web based online secure database hosted by Sealed Envelope (<http://www.sealedenvelope.com>). I designed, edited, built and tested the questionnaire forms for the database and built in range checks, consistency checks and for any closed questions, added all possible answer options plus “other” where appropriate. The checks were built in to the database to minimise the risk of data entry errors, mainly the inputting of illegal values.

Once the last participant had been recruited to the study, baseline data entry was checked by both myself and the Trial Statistician (Dr Louise Marston) before analysis. If problems were identified, I liaised with the relevant CRN research nurse responsible for that particular data entry error to check the source data, made a direct request to the GP practice to fax the source data to me, or if neither of those approaches were successful I visited the GP practice to directly check the source data in the medical records or questionnaires. I entered any corrections onto the web based system where identified and added notes containing the reason for any corrections to ensure there was an audit trail for any changes made.

4.3.7 Statistical methods and data analysis

I used Stata Version 14 (StataCorp, 2015) to carry out the statistical analyses. Summary statistics for all variables were produced. For continuous variables, the mean and standard deviation or median and interquartile range were computed as appropriate. Summary statistics for categorical or binary variables were reported as frequency and percentage within each category.

Continuous independent and dependent variables were explored for normality using histograms and, following modelling, residual plots were generated. Unadjusted analyses were then performed between the independent variable of perceived social support as measured by the MOS-SSS questionnaire and each pre-specified dependent variable using random effects logistic regression for binary outcomes. Negative binomial regression was

used for count outcomes that were over dispersed. The analyses accounted for clustering as a random effect at the level of the GP practice.

4.3.7.1 Independent variable

Perceived social support was measured using the MOS-SSS and consisted of continuous data as no validated cut off points for categorising the data were specified in the literature. This was confirmed via email by the authors of the MOS-SSS.

4.3.7.2 Primary outcome - attendance at appointments

The number of primary care intervention appointments attended consisted of count data; however following an exploration of the data I deemed it inappropriate to use Poisson regression models due to the data being over dispersed (Gardner, Mulvey, & Shaw, 1995); the variance (17.52) in the number of appointments attended was over 3 times greater than the mean (5.25). A negative binomial regression model was therefore used to model the relationship between perceived social support and primary care intervention appointments attended.

4.3.7.3 Secondary outcomes

Adherence to CVD medication

A binary outcome was created using established thresholds (Morisky et al., 2008) to test a combined group of participants classified as either moderate or high medication adherers (a score of 6 to 8) against participants classified as low adherers to medication (a score of <6). Random effects logistic regression was used to analyse the association between perceived social support and high/moderate adherence versus low adherence to CVD medication.

Physical activity

Random effects logistic regression was used to analyse the association between perceived social support and physical activity categorised into moderate or vigorous activity versus

low activity. Data on the amount of time spent sitting were positively skewed and because a validated categorisation of time spent sitting has not been defined by the authors of the questionnaire, data were divided into tertiles representing the lowest, moderate and highest amount of time spent sitting (Margiotta et al., 2018). Random effects logistic regression was used to analyse the association between perceived social support and time spent sitting on a typical day in the last seven days categorised as a short amount of time spent sitting versus a moderate and high amount of time spent sitting.

Diet

A binary outcome was created using established thresholds (Roe et al., 1994) to test a combined group of participants with a medium or high score against participants with a low score on each of the three food intake groups (fat, fibre and unsaturated fat) as measured by the DINE questionnaire. Random effects logistic regression was used to analyse the association between perceived social support and i) low fat scores versus high/medium fat scores versus, ii) high/medium fibre scores versus low fibre scores and iii) high/medium unsaturated fat scores versus low unsaturated fat scores.

Alcohol use

Due to the small number of participants categorised as high risk (7/320, (2.2%)) or possibly dependent (21/320, (6.6%)) alcohol users, these two categories were combined with the moderate risk alcohol use group (51/320, 15.9%), to create an increased risk of alcohol use category. Random effects logistic regression was used to analyse the association between perceived social support and risk of alcohol use grouped into two categories: low risk vs moderate, high risk or possible alcohol dependency.

Smoking

Random effects logistic regression was used to analyse the association between perceived social support and being an ex/non-smoker (non-current smoker) versus current smoker.

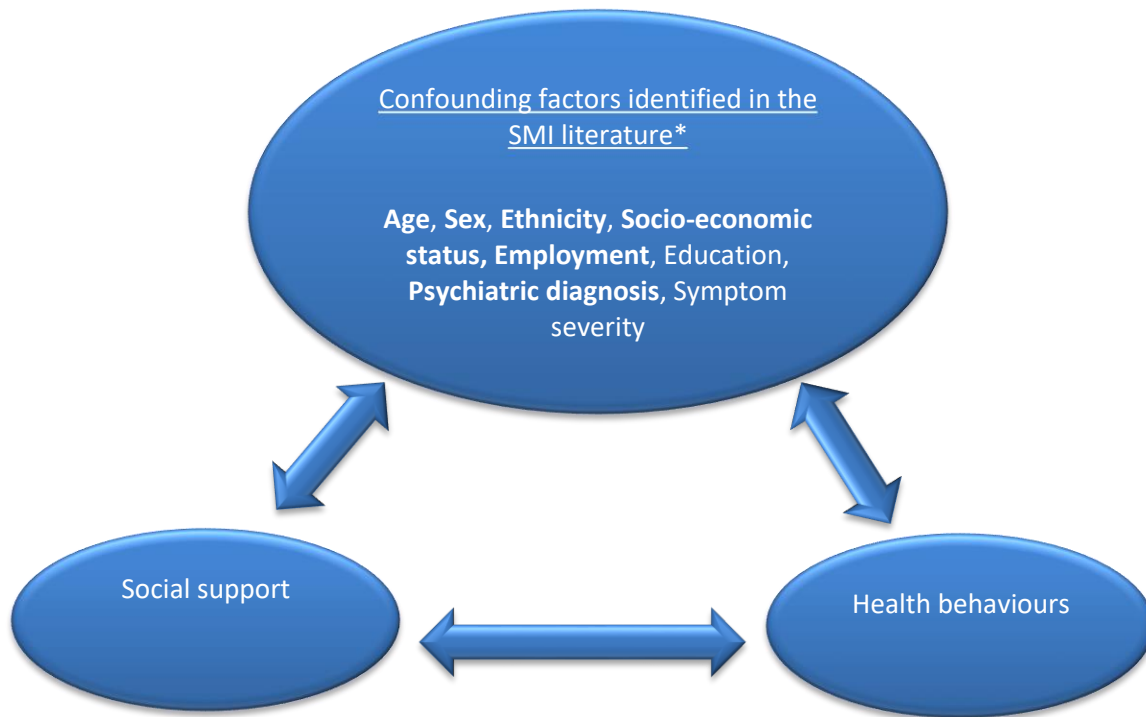
4.3.7.4 Missing data

The amount of missing data for the independent and dependent variables was explored and a low proportion of missing data was identified. The largest amount of missing data was for the IPAQ total MET minutes score which six out of 326 participants did not complete (1.8% missing data). Complete case analysis was therefore the main analysis for the study.

4.3.7.5 Adjusting for potentially confounding variables

Following the unadjusted analyses, six demographic variables of interest were entered in to the models. Demographic variables included sex, age, ethnicity, psychiatric diagnosis, deprivation and employment status. The decision to include these variables in the analyses was based on a review of the literature on predictors of social support in people with SMI presented in “section 1.4” of this thesis. There was some evidence to suggest that sex (Aschbrenner et al., 2013; Thorup et al., 2006), age (Smyth et al., 2015; Thorup et al., 2006), ethnicity (Aschbrenner et al., 2013; Smyth et al., 2015), employment (Smyth et al., 2015) and psychiatric diagnosis (Pinfold et al., 2015) were associated with social support in SMI. Studies have found that sex (Daumit et al., 2005) age (Arbour-Nicitopoulos et al., 2017; Vancampfort et al., 2016) and psychiatric diagnosis (Daumit et al., 2005) were also predictors of physical activity in people with SMI, and demographic factors found to be predictors of smoking in SMI populations included age (Aschbrenner et al., 2015; Ferron et al., 2011) and ethnicity (Brunette et al., 2017).

Figure 4.1 Confounding factors of the relationship between social support and health outcomes identified in the SMI literature



**Those highlighted in bold were part of the data collection for this study*

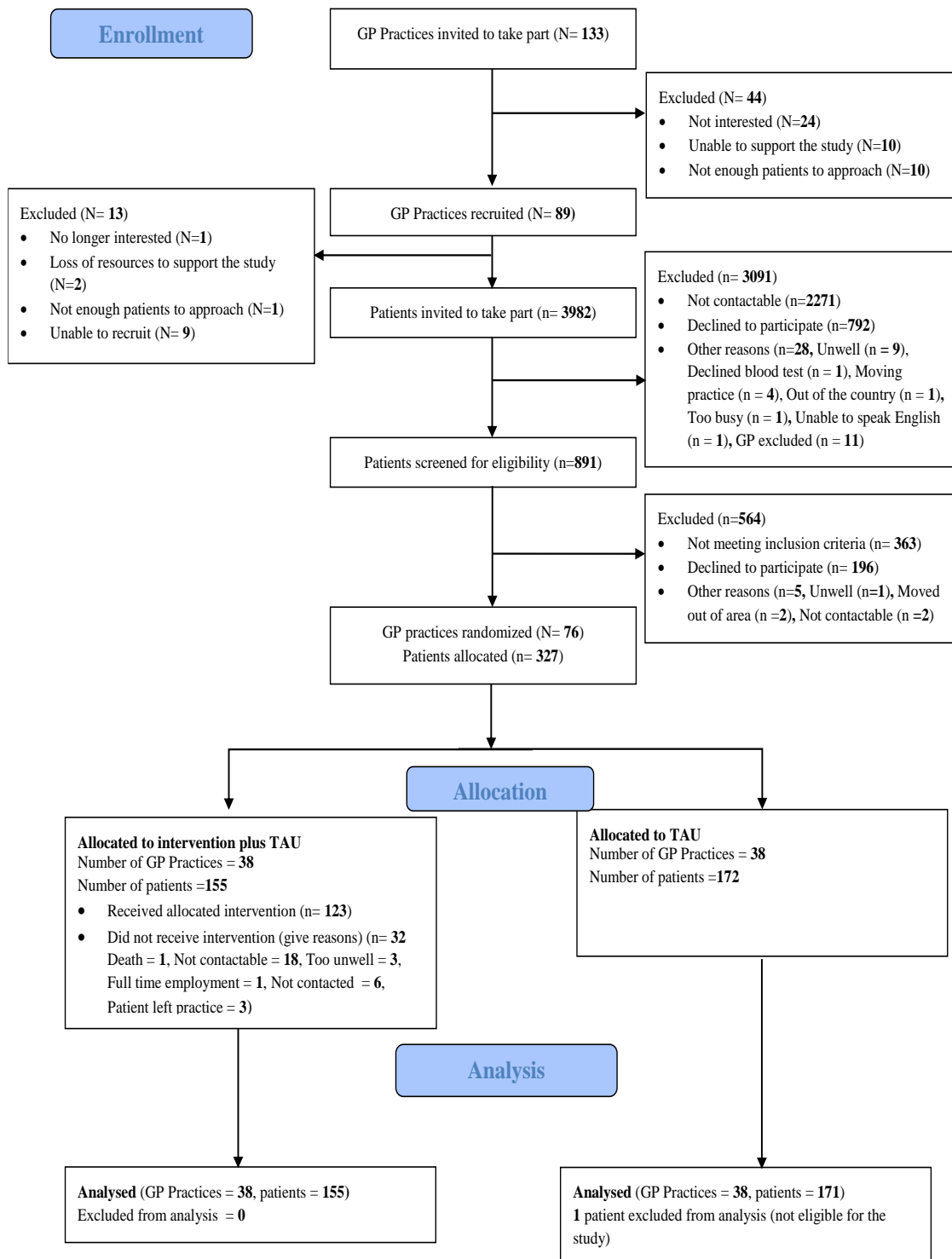
No studies were found on demographic factors that may influence attendance at appointments, adherence to CVD risk reducing medications, diet or alcohol use in SMI. Area deprivation (Townsend, Phillimore & Beattie, 1988) was also included in the analyses as a proxy indicator for individual socio-economic status that may have an impact on both social support and CVD health behaviours (i.e. those from deprived areas may have less social support and participate in fewer CVD risk reducing behaviours than those from less deprived backgrounds).

4.4 Results

4.4.1 Descriptive analysis

327 participants were recruited to the study across 76 GP practices with a mean of 4.3 patients and a range of one to 10 patients recruited per GP practice. 155 participants were randomised to the intervention group and 172 to treatment as usual. One patient in the treatment as usual group was found not to be eligible for the study and was therefore removed from the analysis. The analysis on the primary outcome (attendance at intervention appointments) was conducted on the intervention group sample only; there were no data on intervention appointment attendance in the control group sample as they did not receive the intervention. All other analyses were performed on the combined baseline data from both the intervention and usual care groups treated as one cohort. Figure 4.2 shows the flow of GP practice and participant recruitment for the trial from which the data were taken.

Figure 4.2 Recruitment flow diagram



Original source: Osborn D, Burton A, Hunter R, Marston L, Atkins L, Barnes T, et al. (2018). Clinical and cost-effectiveness of an intervention for reducing cholesterol and cardiovascular risk for people with severe mental illness in English primary care: a cluster randomised controlled trial. *The Lancet Psychiatry*, 5(2), 145-54.

4.4.2 Study sample

Characteristics of the intervention sample on which the primary analysis was conducted can be found in Table 4.1. The mean age of participants was 50.9 years old, with 67 (43.2%) men randomised to the intervention group. 134/155 (87%) participants were White, 11/154 (7.1%) were Black, 5/154 (3.2%) were Asian and 4/154 (2.6%) indicated that they were of “other” ethnicity. 60/136 (44.1%) were in the most deprived Townsend deprivation quintile and 71/155 (45.8%) were unemployed. 66/154 (42.9%) participants were single, while 59/154 (38.3%) were married or cohabiting. 83/155 (53.5%) lived with other people, while 72/155 (46.5%) lived alone. 54/155 (34.8%) participants had a primary diagnosis of schizophrenia or schizoaffective disorder, 71/155 (45.8%) had a diagnosis of bipolar disorder and 30/155 (19.4%) had a diagnosis of other psychosis. The mean number of family and friends within the participant’s social networks was 4.3 and 73/155 (47.1%) had a mental health support worker.

Characteristics of the overall study sample on which the secondary analyses were conducted can also be found in Table 4.1. The mean age of participants was 50.8 years old, with 155 (47.5%) men taking part in the study. 289/325 (88.7%) participants were White, 16/325 (4.9%) were Black, 10/325 (3.1%) were Asian and 10/325 (3.1%) indicated that they were of “other” ethnicity. 112/255 (34.4%) were in the most deprived Townsend deprivation quintile and 147/326 (45.1%) were unemployed. 133/324 (41.1%) participants were single, while 123/324 (38.0%) were married or cohabiting. 187/326 (57.4%) lived with other people, while 139/326 (42.6%) lived alone. 105/326 (32.2%) participants had a primary diagnosis of schizophrenia or schizoaffective disorder, 159/326 (48.8%) had a diagnosis of bipolar disorder and 63/326 (19.0%) had a diagnosis of other psychosis. The mean number of family and friends within the participant’s social network was 4.2 and 132/326 (40.5%) had a mental health support worker.

Table 4.1. Characteristics of the trial sample

Variable	Intervention group (n=155)		Overall sample (n=326)	
	n/N or mean	Percent or SD	n/N or mean	Percent or SD
Gender				
Male	67/155	43.2	154/326	47.2
Age	50.9	10.0	50.8	9.9
Ethnicity				
White	134/154	87.0	289/325	88.9
Black	11/154	7.1	16/325	4.9
Asian	5/154	3.2	10/325	3.1
Other	4/154	2.6	10/325	3.1
Townsend Deprivation				
1 =Least deprived	22/136	16.2	39/255	15.3
2	7/136	5.1	18/255	7.1
3	17/136	12.5	28/255	11
4	30/136	22.1	58/255	22.7
5 – Most deprived	60/136	44.1	112/255	43.9
Marital Status				
Single	66/154	42.9	133/324	41.1
Married or cohabiting or civil partners	59/154	38.3	123/324	38.0
Separated or divorced or civil partners	25/154	16.2	59/324	18.2
Widowed	4/154	2.6	9/324	2.8
Living arrangements				
With others	83/155	53.5	187/326	57.4
Lives alone	72/155	46.5	139/326	42.6
Employment				
Unemployed	71/155	45.8	147/326	45.1
Primary diagnosis				
Schizophrenia/schizoaffective	54/155	34.8	105/326	32.2
Bipolar	71/155	45.8	159/326	48.8
Other psychoses	30/155	19.4	62/326	19

Variable	Intervention group (n=155)		Overall sample (n=326)	
	n/N or mean	Percent or SD	n/N or mean	Percent or SD
Social support				
MOS-SSS	52.4	25.2	56	25.1
No. of friends and family	4.3	4.5	4.2	4.0
Mental health support worker	73/155	47.1	132/326	40.5
Primary outcome - appointment attendance				
Number of intervention appointments attended	5.2	4.2	N/A	N/A
Secondary outcomes				
MMAS-8 (CVD prevention medication)				
High and moderate medication adherence	N/A	N/A	103/145	71
Low medication adherence	N/A	N/A	42/145	29.0
IPAQ (Physical activity)				
Low activity	N/A	N/A	140/320	43.8
Moderate and vigorous activity	N/A	N/A	180/320	56.3
Sitting total MET minutes (Median and IQR)	N/A	N/A	360	(240, 480)
DINE (Diet)				
Fat intake				
Low fat intake	N/A	N/A	155/326	47.6
Medium/high fat intake	N/A	N/A	171/326	52.4
Fibre intake				
Low fibre intake	N/A	N/A	156/326	47.9
Medium/high fibre intake	N/A	N/A	170/326	52.1
Unsaturated fat intake				
Low unsaturated fat intake	N/A	N/A	16/326	4.9
Medium/high unsaturated fat intake	N/A	N/A	310/326	95.1
AUDIT (Alcohol)				
Low risk drinkers	N/A	N/A	247/326	75.8

Variable	Intervention group (n=155)		Overall sample (n=326)	
	n/N or mean	Percent or SD	n/N or mean	Percent or SD
Moderate, high risk or possible dependence	N/A	N/A	79/326	24.2
Smoking status				
Non-smoker	N/A	N/A	166/326	50.9
Current smoker	N/A	N/A	160/326	49.1

4.4.2.1 Independent variable – social support

Data on the independent variable of perceived social support (MOS-SSS) were available at baseline for 154/155 (99.4%) participants in the intervention sample and 325/326 (99.7%) participants in the overall sample. One participant did not complete all of the questions therefore a total score on the MOS-SSS could not be computed. There were no available rules for handling missing data for this instrument; therefore, the participant was excluded from the analysis. The mean perceived social support score for participants randomised to the intervention group was 52.39 (SD=25.23) with a range of 2.63 to 100. The average MOS-SSS score per GP practice in the intervention group ranged from 30.92 to 82.46 with a mean of 53.80 (SD=13.53). The full sample mean at baseline was 55.96 (SD=25.08) with a range of 2.63 to 100. The average MOS-SSS score per GP practice ranged from 30.92 to 89.91 with a mean of 56.93 (SD=13.93).

4.4.3 Perceived social support and appointment attendance

Data on the primary outcome of attendance at appointments were available for all intervention sample participants. The number of appointments attended ranged from 0-14 with a mean of 5.46 (SD=4.13) appointments attended per patient and a mean of 5.31 (SD=3.03) appointments attended per GP practice. 123/155 (79.4%) patients attended one or more appointments while 32 (20.6%) patients did not attend any appointments. The main reasons for non-attendance were that the GP practices were unable to contact the patients to arrange the appointment (17/32 (53.1%)), followed by GP practices making no

attempt to contact the patients (6/32 (18.8%)). Reasons for non-attendance for all 32 patients are presented in Table 4.2.

Table 4.2. Reasons for patients not attending any appointments

Reasons for non-attendance	Number (%) of patients
Nurse unable to make contact	17 (53.1)
Never contacted by the practice	6 (18.8)
Moved to a different practice	3 (9.4)
Too unwell	2 (6.3)
Died soon after baseline assessment	1 (3.1)
Out of the country	1 (3.1)
Full time employment	1 (3.1)
Did not want to come in to the surgery	1 (3.1)
Total	32

An unadjusted negative binomial regression analysis was conducted to assess the relationship between social support and attendance at primary care appointments. For a one point increase in score on the MOS-SSS, the rate of appointments attended increased by 0.05% (incident rate ratio=1.005). This was significant at the 5% level (95% CI 1.000 to 1.011, p=0.05).

When age and sex were entered into the model, the association between social support and attendance at primary care appointments was weakened and no longer significant (IRR=1.005, 95% CI 0.999 to 1.010, p=0.09). There remained no significance when all demographic variables (sex, age, ethnicity, psychiatric diagnosis, deprivation and employment) were entered into the fully adjusted model (IRR=1.003, 95% CI 0.998 to 1.009, p=0.25).

Table 4.3. Unadjusted and fully adjusted analyses of the association between perceived social support and attendance at appointments

	Appointment Attendance (n=155)
Unadjusted analysis+	1.005 (1.000-1.011; p=0.05)
Adjusted for sex and age	1.005 (0.999-1.010; p=0.09)
Fully adjusted analysis^	1.003 (0.998-1.009; p=0.25)

+Data are change in each outcome variable (incident rate ratio (IRR)) for a one-point increase in perceived social support as measured by the MOS-SSS (95% CI; p value)

^Fully adjusted model includes sex, age, ethnicity, psychiatric diagnosis, deprivation and employment status

4.4.4 Perceived social support and secondary outcomes of CVD risk reducing health behaviours

An association between perceived social support and being a moderate/high adherer to CVD medications compared to being a low adherer was identified. Higher perceived social support was associated with lower odds of being in the moderate/vigorous physical activity group in the fully adjusted analysis but not in the unadjusted analysis or analysis adjusted for sex and age. No significant associations were detected between perceived social support and any other pre-specified secondary outcomes (sedentary behaviour, diet, alcohol use, or smoking). The results of the unadjusted and adjusted analyses can be found in Table 4.4

Table 4.4. Unadjusted and adjusted analyses on the association between perceived social support and secondary outcomes

	Medication Adherence (MMAS-8) n=145	IPAQ Physical Activity n=320	IPAQ Time spent sitting n=322	DINE Score Fat n=326	DINE Score Fibre n=326	DINE Score Unsaturated Fat n=326	AUDIT Score n=326	Smoking status n=325
Unadjusted analysis ⁺	1.039, (1.018-1.060; p=0.00)	0.993, (0.984-1.002 p=0.13)	1.003, (0.993-1.013; p=0.56)	1.000, (0.990-1.009; p=0.91)	1.003, (0.995-1.012; p=0.47)	1.002, (0.980-1.025; p=0.87)	1.004, (0.994-1.015; p=0.43)	1.006, (0.997-1.014; p=0.22)
Adjusted for sex and age	1.041, (1.019-1.063; p=0.00)	0.993, (0.998-1.002; p=0.14)	1.003, (0.993-1.013; p=0.56)	0.999, (0.990-1.008; p=0.83)	1.003, (0.994-1.012; p=0.55)	Analysis not performed [#]	1.004, (0.993-1.015; p=0.51)	1.005, (0.996-1.004; p=0.30)
Fully adjusted analyses [^]	1.042, (1.015-1.070; p=0.00)	0.989, (0.978-1.000; p=0.05)	1.005, (0.993-1.017; p=0.41)	0.996, (0.985-1.008; p=0.54)	0.998, (0.987-1.009; p=0.73)	Analysis not performed [#]	1.004, (0.991-1.017; p=0.58)	1.002, (0.991-1.013; p=0.68)

*MMAS-8=Morisky Medication Adherence Scale, IPAQ=International Physical Activity Questionnaire, DINE=Dietary Instrument for Nutrition Education, MET=metabolic equivalent of task, AUDIT=Alcohol Use Disorders Identification Test

+Data are change in each outcome variable (odds ratio) for a one-point increase in perceived social support as measured by the MOS-SSS (95% CI; p value)

[^]Fully adjusted models include sex, age, ethnicity, psychiatric diagnosis, deprivation and employment status

[#] Due to the small number of participants categorised in the low unsaturated fat intake group (16/326), it was not possible to conduct the adjusted analyses

4.4.4.1 Adherence to CVD medications

145/326 (44.5%) participants completed the Morisky Medication Adherence Scale (MMAS-8) at baseline in relation to prescribed medications for CVD risk. 42/145 (29%) participants were categorised as low adherers, 60/145 (41.4%) participants were categorised as moderate adherers and 43/145 (29.7%) participants were categorised as high adherers. A combined category of moderate and high adherers was created and compared against low adherers. The mean score on the MOS-SSS for high adherers was 63.59 (SD 23.96), for moderate adherers it was 62.39 (SD 26.07) and for low adherers it was 42.98 (SD 23.13). For moderate and high adherers combined, the mean MOS-SSS score was 62.89 (SD 25.01).

The unadjusted random effects logistic regression analysis found that for a one point increase in perceived social support, the odds of being in the moderate/high adherence to medication group compared to the low adherence group increased by 3.9% (OR =1.039, 95% CI 1.018 to 1.060, p=0.00).

The association between perceived social support and being a moderate/high medication adherer vs low adherer when adjusted for sex and age (OR=1.041, 95% CI 1.019 to 1.063, p=0.00) and when fully adjusted for sex, age, ethnicity, psychiatric diagnosis, deprivation and employment remained significant (OR=1.042, 95% CI 1.015 to 1.070, p=0.00).

4.4.4.2 Physical activity

Data on the total metabolic equivalent of task (MET) minutes per week were available for 320/326 (98.2%) participants. The median total MET minutes per week was 1344 with an interquartile range of 371 to 3464 MET minutes. 140/320 (43.8%) participants had low activity levels and 180/320 (56.3%) had moderate or high activity levels. The mean score on the MOS-SSS for participants with low physical activity was 58.65 (SD 25.75) and for moderate and vigorous physical activity combined, the mean score on the MOS-SSS was 54.34 (SD 24.31).

Random effects logistic regression was used to model the association between scores on the MOS-SSS and physical activity. The results of the unadjusted analysis found that for a one point increase in perceived social support as measured by the MOS-SSS, the odds of being in the moderate/vigorous physical activity category decreased by 0.7% compared to the low physical activity category. The association between perceived social support and physical activity was not significant (OR=0.993, 95% CI 0.984 to 1.002, $p=0.13$).

There remained no significant association between social support and physical activity when adjusted for sex and age (OR=0.993, 95% CI 0.998 to 1.002; $p=0.14$), however when sex, age, ethnicity, psychiatric diagnosis, deprivation and employment were entered into the model, the association became significant (OR=0.989, 95% CI 0.978 to 1.000; $p=0.05$).

Data on the amount of time spent sitting on a typical day in the last seven days were available for 322/326 (98.8%) participants. The median amount of time spent sitting was 360 minutes (6 hours per day) with an interquartile range of 240 to 480 minutes. The moderate and highest amount of time spent sitting were combined and compared against the lowest amount of time spent sitting. The mean score on the MOS-SSS for participants who spent the least amount of time sitting (270 minutes or less) was 57.04 (SD 22.94) and for participants who spent the most amount of time sitting (271 minutes or more), the mean score on the MOS-SSS was 55.55 (SD 26.23).

Random effects logistic regression was used to model the association between scores on the MOS-SSS and categorised sedentary behaviour (time spent sitting). The unadjusted analysis found that for a one point increase in perceived social support, the odds of being in the low sedentary behaviour group (the group that spent the least amount of time sitting) increased by 0.3% compared to the high/moderate sedentary behaviour group. The association between perceived social support and sedentary behaviour was not significant (OR=1.003, 95% CI 0.993 to 1.013, $p=0.56$).

There remained no significant association between perceived social support and time spent sitting when adjusted for sex and age (OR=1.003, 95% CI 0.993 to 1.013, $p=0.56$).

and sex, age, ethnicity, psychiatric diagnosis, deprivation and employment status (OR=1.005, 95% CI 0.993 to 1.017, p=0.41).

4.4.4.3 Diet

Data on fat, fibre and unsaturated fat intake were available for 326/326 (100%) participants at baseline.

Random effects logistic regression was used to model the association between scores on the MOS-SSS and the odds of i) having a low fat diet versus a medium/high fat diet and ii) having a medium/high fibre diet versus a low fibre diet and iii) having a medium/high unsaturated fat diet versus a diet low in unsaturated fat. Each outcome was entered in to a separate analysis model.

4.4.4.4 Fat scores

155/326 (47.6%) participants were categorised as having a low fat intake and 171/326 (52.4%) were categorised as having a medium or high fat intake. The mean score on the MOS-SSS for those with a low fat diet was 55.78 (SD 26.37) and for those with a medium/high fat diet the mean score on the MOS-SSS was 56.12 (SD 23.94).

For a one point increase in perceived social support as measured by the MOS-SSS, the odds of having a diet low in fat decreased by 0.05%. The association between perceived social support and fat intake was not significant (OR=1.000, 95% CI 0.990 to 1.009, p=0.91).

There remained no significant association between perceived social support and fat intake when adjusted for sex and age (OR=0.999, 95% CI 0.990 to 1.008, p=0.83) and sex, age, ethnicity, psychiatric diagnosis, deprivation and employment (OR=0.996, 95% CI 0.985 to 1.008, p=0.54).

4.4.4.5 Fibre scores

156/326 (47.9%) participants were categorised as having a diet low in fibre while 170/326 (52.1%) participants had a medium or high fibre intake. The mean score on the

MOS-SSS for those with a diet low in fibre was 54.90 (SD 24.75) and for those with a medium/high fibre diet the mean score on the MOS-SSS was 56.94 (SD 25.41).

The results of the unadjusted logistic regression analysis found that for a one point increase in perceived social support as measured by the MOS-SSS, the odds of having a medium/high fibre diet increased by 0.3%. The association between perceived social support and fibre intake was not significant (OR= 1.003, 95% CI 0.995 to 1.012, p=0.47).

There remained no significant association between perceived social support and fibre intake when sex and age (OR=1.003, 95% CI 0.994 to 1.012, p=0.55) and sex, age, ethnicity, psychiatric diagnosis, deprivation and employment were all entered into the model (OR=0.998, 95% CI 0.987 to 1.009, p=0.73).

4.4.4.6 Unsaturated fat scores

16/326 (4.9%) participants had a low intake of unsaturated fats and 310/326 (95.1%) had a medium or high intake of unsaturated fats. The mean score on the MOS-SSS for those with a diet low in unsaturated fat was 54.91 (SD 22.39) and for those with a medium/high unsaturated fat diet the mean score on the MOS-SSS was 56.01 (SD 25.24).

The unadjusted analysis found that for a one point increase in perceived social support as measured by the MOS-SSS, the odds of having a medium/high unsaturated fat intake increased by 0.2%. The association between perceived social support and unsaturated fat intake was not significant (OR=1.002, 95% CI 0.980 to 1.025, p=0.87). Due to the small number of participants categorised in the low unsaturated fat intake group (16/326), it was not possible to conduct the analysis adjusted for sex and age, or a fully adjusted analysis.

4.4.4.7 Alcohol use

Data on alcohol use were available for 326/326 (100%) participants at baseline. 247/326 (75.8%) participants reported that they were low risk drinkers and 79/326 (24.2%) participants reported that they were moderate risk drinkers, high risk drinkers or possibly alcohol dependent. The mean score on the MOS-SSS for low risk drinkers was

56.59 (SD 26.04) and for moderate, high risk or possibly alcohol dependent drinkers, the mean score on the MOS-SSS was 53.98 (SD 21.81).

Random effects logistic regression was used to model the association between scores on the MOS-SSS and categorised risk of alcohol use. The results of the unadjusted analysis found that for a one point increase in perceived social support as measured by the MOS-SSS, the odds of being in the low risk alcohol group increased by 0.4% compared to the moderate, high risk and dependent categories combined. The association between perceived social support and risk of alcohol use was not significant (OR=1.004, 95% CI 0.994 to 1.015, p=0.43).

There remained no significant association between perceived social support and alcohol use when adjusted for sex and age (OR=1.004, 95% CI 0.993 to 1.015, p=0.51) and sex, age, ethnicity, psychiatric diagnosis, deprivation and employment (OR=1.004, 95% CI 0.991 to 1.017, p=0.58).

4.4.4.8 Smoking

Data on smoking status were available for 326/326 (100%) participants at baseline. 160/326 (49.1%) participants reported that they were smokers and 166/325 (50.9%) participants reported that they were ex or non-smokers. The mean score on the MOS-SSS for current smokers was 54.2 (SD 24.08) and for non/ex-smokers the mean score on the MOS-SSS was 57.64 (SD 25.97).

Random effects logistic regression was used to model the association between scores on the MOS-SSS and the odds of being a non/ex-smoker versus a smoker. The results of the unadjusted logistic regression analysis found that for a one point increase in perceived social support as measured by the MOS-SSS, the odds of being a non/ex-smoker increased by 0.6%. The association between perceived social support and smoking status was not significant (OR=1.006, 95% CI 0.997 to 1.014, p=0.22).

There remained no significant association between perceived social support and smoking status when adjusted for sex and age (OR=1.005, 95% CI 0.996 to 1.004, p=0.30)

and sex, age, ethnicity, psychiatric diagnosis, deprivation and employment (OR=1.002, 95% CI 0.991 to 1.013, p=0.68).

4.5 Discussion

4.5.1 Summary of findings

This study tested whether there was an association between perceived social support and attendance at primary care appointments in a population with SMI and raised CVD risk factors. My secondary hypotheses tested whether there was an association between perceived social support and self-reported adherence to CVD risk reducing medications, physical activity, sedentary behaviour, smoking and alcohol use.

The study found a significant association between perceived social support and attendance at primary care intervention appointments showing that a 10% increase in perceived social support was associated with a 5% increase in the appointment attendance rate (IRR=1.005, p=0.05, 95% CI 1.000 to 1.011). However when the model was adjusted for sex, age, ethnicity, diagnosis, deprivation and employment, this association decreased to 3% and was no longer significant (IRR=1.003, p=0.25, 95% CI 0.998 to 1.009).

A stronger association between perceived social support and adherence to CVD medication was identified, with the odds of being in the moderate/high medication adherence group compared to the low adherence group predicted to increase by 3.9% with a one point increase in perceived social support (OR=1.039, p<0.001, 95% CI 1.018 to 1.060). This association remained significant following adjustment for all socio-demographic variables (OR=1.042, p=0.002, 95% CI 1.015 to 1.070). Thus; a 10 point increase in score on the MOS-SSS increased the odds of higher adherence by 42%.

There was no association between social support and physical activity in the unadjusted analysis or the analysis adjusted for sex and age, however when psychiatric diagnosis, ethnicity, deprivation and employment status were entered into the model, the result became significant with higher perceived social support associated with lower odds of

being in the moderate/vigorous activity group compared to the low physical activity group (OR=0.989, 95% CI 0.978 to 1.000; p=0.05). There was no association between perceived social support and sedentary behaviour, diet, alcohol use or smoking status.

The finding that higher perceived social support was associated with greater adherence to CVD risk reducing medications and attendance at appointments in the unadjusted analysis suggests that social support may be important in helping people with SMI to adhere to CVD risk reducing treatments and services. The association between social support and appointment attendance should however be treated with caution as the effect disappeared in the adjusted analyses. The association between higher perceived social support and lower odds of being in the moderate/vigorous physical activity group in the fully adjusted analysis but not the unadjusted analysis or the analysis adjusted for age and sex should also be treated with caution and would need confirming in further work.

The finding that social support was associated with adherence to medications and attendance at appointments but not, diet, smoking or alcohol use may have been because medication adherence and appointment attendance are discrete events and may therefore be more easily supported by family or friends. Attending appointments and taking medication are behaviours that directly impact on the individual and that do not require the supportive other to make changes to their own behaviour beyond encouragement and monitoring, whereas support with physical exercise, diet, alcohol use and smoking may require changes in behaviour by both the participant and the person supporting them.

The sub-group of participants who completed the questionnaire on adherence to CVD risk medications (and were therefore on some form of medication to lower their CVD risk) appeared to be more likely to participate in healthy lifestyle behaviours than those who did not complete the questionnaire. A lower proportion of participants completing the medication adherence questionnaire were smokers (43.4% vs 53.6%), moderate to high risk alcohol users (20% vs 27.6%), had a moderate to high fat diet (50.3% vs 54.1%) and were less likely to be sedentary (63.6% vs 67.6%) than those who did not complete

the questionnaire, however a higher proportion had a low fibre diet (51% vs 45.3%). This group may have therefore been more engaged with their health and health services and therefore more likely to be prescribed preventative medications, or they may have had more severe health problems to warrant a prescription and made changes to their lifestyles in response. The impact of perceived social support on health behaviours may be different for people who are more engaged with their health or who have greater CVD morbidity; however, the reasons for this are unclear and the mechanisms for this warrants further research.

4.5.2 Strengths and limitations

This was the first known study seeking to identify an association between perceived social support and multiple CVD risk reducing behaviours in people with SMI and raised CVD risk factors in a UK primary care setting. My primary data analysis was longitudinal with baseline social support hypothesised to predict PRIMROSE intervention appointment attendance at six-month follow up and validated questionnaires that have been used in previous studies with people with SMI and in primary care based studies were used to assess both social support (Sherbourne & Stewart, 1991) and secondary outcomes (Craig et al., 2003; Morisky et al., 2008; Saunders et al., 1993; Roe et al., 1994).

Study design

The primary outcome of appointment attendance was collected by practice nurses and HCAs delivering the PRIMROSE intervention and data return was monitored regularly throughout the intervention delivery period, rather than waiting until the end of the study to request the data. Practice nurses/HCAs were encouraged to return the appointment attendance spreadsheet to me every time an intervention appointment was scheduled and attended or not attended to ensure accurate recall. Appointments were also audio recorded and the date recorded on the audio files, and the number of audio files returned for each participant was used to corroborate the number of appointments indicated as attended or not on the spreadsheets.

The study was a secondary analysis of data collected as part of a cluster randomised controlled trial aimed at testing the effectiveness of a primary care based intervention to reduce CVD risk, with the primary outcome in the main trial being total cholesterol levels (Osborn et al., 2018). The study may therefore not have been sufficiently powered to detect an association between social support and CVD risk reducing health behaviours, particularly for appointment attendance as the analysis was only conducted on the intervention group and therefore the sample was smaller. This may help to explain why an association between social support and appointment attendance was found in the unadjusted but not adjusted analyses. Multiple hypothesis testing also increases the risk of chance findings (Bellmunt-Montoya, 2019) which may explain the observed association between perceived social support and CVD risk reducing medication adherence.

Reverse causation cannot be ruled out for the association between perceived social support and adherence to CVD medications as the analysis was cross sectional. However while it is plausible that being adherent to some CVD risk reducing medications such as diabetic medications has a positive impact on physical health which may in turn increase the ability to participate in meaningful relationships and social networks, being non-adherent to statins and antihypertensive medications may have a limited impact on symptoms and every day functioning.

In further analysis, it would be possible to additionally test for associations between baseline social support and six and 12-month secondary outcomes, adjusting for treatment allocation, to determine whether perceived social support had an impact on outcomes over time and to explore whether treatment allocation affected the association between baseline perceived social support and secondary outcomes. The decision to conduct a cross sectional rather than prospective analysis on the secondary outcomes was made however because this was an exploratory analysis to identify areas for further research, the PRIMROSE intervention had no overall effect on behavioural outcomes from baseline to six and 12-month follow up (Osborn et al., 2018), and data collection was more complete for the baseline assessments than at follow up (attrition rate at 12-month follow up =11%) (Osborn et al., 2018).

Sources of bias

The size of the sample meant that I was only able to adjust the analysis for a limited number of confounding variables (Harrell, 2015). There may have been additional confounding variables present that were not measured in the dataset. Unmeasured variables such as education (Aschbrenner et al., 2013), individual socioeconomic status (Muller et al., 2007), severity of symptoms (Giacco et al., 2012) and negative symptoms (Tsai et al., 2011) are possible factors that may influence both an individual's perceived level of social support and their participation in CVD risk reducing behaviours.

While all potentially eligible participants on SMI registers within participating GP practices were invited to take part in the study, selection bias may have occurred at various steps in the recruitment process. GPs were asked to check study invitation lists to ensure participants met basic inclusion/exclusion criteria before being invited to take part in the study. This may have resulted in GPs excluding participants whom they deemed would not engage with the study. Of the 3,982 participants who were invited to take part in the study, 891 were interested in participating (a response rate of 22%) (Osborn et al., 2018). While a number of those who did not respond may not have been eligible for the study, there may have been something different about participants who were not contactable or who did not want to take part compared to those who did participate, for example those who agreed to take part may have been more open to changing their behaviour than those who declined. The demographics of the recruited study sample were however similar to a large primary care sample of 38,824 people with SMI from 430 English GP practices (Osborn et al., 2015). This included comparable ages (51 years vs 49.5 years), sex (47% of both samples were male), diagnosis of schizophrenia (32.2% vs 34.8%), heavy alcohol use (8.8% vs 9%) and smoking (49% of participants were current smokers in both samples).

There were however some differences with more participants in the current sample living in the most deprived areas (44% vs 23% participants) and having a diagnosis of bipolar disorder (48.8% vs 26%), while fewer participants in this study sample had a diagnosis of other psychosis (19% vs 29%). While a high proportion of my PRIMROSE

study sample identified as White (88.9%) this was only slightly higher than the UK population (86%) (Office for National Statistics, 2011). There were less Asian people in this study (3.1% vs 7.5% of the UK population) and slightly more black people (4.9% vs 3.3% of the UK population).

The independent variable and all of the secondary outcomes in this analysis were collected through patient self-reported measures. These measures are subjective and patients may over-emphasise their participation in desirable health behaviours such as medication adherence, physical activity or healthy food intake, and under report undesirable behaviours such as smoking and alcohol use. 56.3% of the current study sample reported moderate or high activity levels which seemed high, however this was much lower than reported in a large sample of the UK general population (n=398,984, moderate or high physical activity = 81.5%) (Cassidy et al., 2017) and mirrored findings from a previous study with people with SMI where 60.8% of participants were categorised in the moderate to high activity group (n=2,407) (Stubbs et al., 2018). Inaccurate reporting of health behaviours may have masked an association between social support and health behaviours. Research in general population samples have found both under and over reporting of physical activity when compared to objective measures (Prince et al., 2008) and the under reporting of alcohol use in one off interviews when compared with recording alcohol consumption in a daily diary (Boniface, Kneale, & Shelton, 2014). In addition, a systematic review has found that overweight people under-reported their food intake (Wehling & Lusher, 2017).

Participants were asked about adherence to all of their prescribed CVD medications, rather than specific medications such as statins or metformin. It may have been difficult for participants taking multiple CVD medications to accurately respond to the questionnaire if they adhered to each of their CVD medications differently. There is evidence to suggest however that adherence rates are comparable for statins, diabetic medications and antihypertensives in people with schizophrenia (Dolder, Lacro, & Jeste, 2003; Piette et al., 2007) and that being on a greater number of prescribed medications has no impact on medication adherence rates (Dolder et al., 2003). A study with 76

people with bipolar disorder however found that self-report adherence rates were poorer for statins than for antihypertensive or diabetic medications (Levin et al., 2017).

Generalisability of findings

Data were collected in a pragmatic trial on people with SMI and CVD risk factors in primary care. While those who participate in research may not necessarily be representative of the population; this study sample was drawn from 76 GP practices across diverse rural and urban settings in England. There were also very few missing data in the study, therefore the analyses were representative of the sample and a complete case analysis was conducted.

The primary outcome of interest in this study was attendance at primary care intervention appointments developed for a research trial, as it was felt that this was an important indicator of engagement in a CVD risk reducing service overall. Attendance at research intervention service appointments might not be the same as routine clinical care (e.g. GP or practice nurse appointments), as research participants may have been more motivated to attend due to being involved in the research study. The intervention appointments were however delivered by practice nurses and HCAs working in GP practices, rather than researchers employed on the study, and were concerned with testing the delivery of a new potential service for people with SMI within routine primary care.

Participants in the sample all had raised cholesterol and at least one other risk factor for CVD as this was part of the inclusion criteria for entry into the trial from which the data for this study were collected. The results may therefore not necessarily apply to the influence of social support on uptake of CVD risk reducing behaviours in those classified at lower risk, but for whom preventative CVD activities could still be beneficial. Future research should include all people with SMI who are at risk of CVD, in particular, criteria should be broadened to include those who not only have raised cholesterol but who may still be at an increased risk of CVD because they have one or multiple other CVD risk factors (e.g. obesity, hypertension, smoking and/or diabetes). This would also mean that

a higher proportion of younger adults with SMI may be eligible to take part than in the current study.

4.5.3 Conclusion

The results of this study suggest that perceived social support may be an important facilitator for adherence to CVD risk reducing medications and is potentially important for attendance at health appointments, however alternative strategies may be needed to increase physical activity, improve diet and reduce smoking and alcohol intake in people with SMI.

Findings from this study further support the rationale for incorporating social support into CVD risk reducing interventions to improve engagement and adherence. In the next chapter, I will explore how social support was used as a strategy by practice nurses/healthcare assistants and patients with SMI to promote engagement with CVD risk reducing goals within first intervention appointments in the PRIMROSE trial.

Chapter 5 How was the social network of people with SMI used to promote CVD risk reducing behaviours in primary care appointments?

Thematic analysis of audio recordings from the PRIMROSE trial

In chapter three, I used the findings from a review of national health policy and analysis of focus groups and workshops with key stakeholders to develop and incorporate social support components in to the PRIMROSE intervention manual and training programme for healthcare assistants/practice nurses (health providers) in primary care. In this chapter, I qualitatively assess whether these social support components were used by health providers and patients within their initial primary care intervention appointments in the PRIMROSE trial. I focus my analysis on the content of discussions that occurred around the involvement of the patient's existing social network in helping or inhibiting them to participate in CVD risk reducing behaviours. The data analysed in this chapter were collected as part of work package three of the PRIMROSE programme to assess health provider fidelity to the PRIMROSE study manual and training programme (Osborn et al., 2019), however the research aims and analysis presented in this chapter were not part of the original PRIMROSE study aims.

My systematic review in chapter two found limited available evidence of the effectiveness of interventions that used existing social support to reduce CVD risk behaviours in people with SMI. Only three low quality studies were identified, with little information on how supportive others were involved in the interventions that were tested. The findings identified a need to explore the nature of social relationships and social support further in people with SMI, and to determine if social support can be harnessed within physical health promotion interventions. Involving supportive others was also identified as a strategy for improving engagement and adherence to CVD risk reducing treatments and services for people with SMI in the qualitative literature reviewed in chapter one (section 1.7.2), and in the focus groups and workshops reported in chapter three.

5.1 Study aims

To explore how social support was discussed within first appointments within the PRIMROSE intervention focusing on the:

- type of support identified by people with SMI
- ways in which supportive others could support people with SMI to participate in CVD risk reducing behaviours
- potential problems and barriers to involving supportive others

5.2 Methods

5.2.1 Study setting and sample

I conducted a qualitative thematic analysis of transcribed audio-recordings of all received first intervention appointments between health providers and patients with SMI who were participating in the intervention arm of the PRIMROSE study. All appointments took place at the patient's GP Practice. I decided to focus my analysis on all first appointments for which an audio-recording was received as it was in the first appointment that the health providers were prompted to explore and establish the involvement of supportive others with their patients to help them achieve their health goals.

5.2.2 Procedures

I obtained ethical approval to audio-record appointments from the City Road & Hampstead – London National NHS Research Ethics Committee (Reference Number 12/LO/1934; Appendix 11) as part of the study approvals for the PRIMROSE trial. I provided health providers with written participant information sheets (Appendices 12 & 14) and obtained signed informed consent (See Appendix 15 for the health provider consent form template) to audio record the appointments from each health provider at the first intervention training day. Informed consent was taken from patients at their baseline assessment meeting with the CRN research nurses (See chapter four section 4.3.5 Recruitment procedures for further details).

Health providers attended a two day training programme on how to deliver the intervention according to a written manual. The training was delivered by myself, a practice nurse with mental health expertise, a health psychologist and a lived experience advisor. The training and manual included information on eight BCTs that health providers could use within intervention appointments to assist each patient to set and monitor progress with goals around reducing their CVD risk. These techniques included setting a behavioural goal, monitoring and reviewing progress with goals, developing an action plan, giving positive feedback, helping the patient cope with setbacks, forming habits and involving supportive others for which I developed and incorporated a help sheet (Please see figure 3.2) into the manual for the purpose of this thesis.

At the first intervention training day, I provided each health provider with a digital audio-recorder and an intervention delivery manual containing instructions on operating the audio recorder and on saving and sending audio files to the study team via a secure data transfer system (Data Safe Haven) managed by UCL. Health providers were asked to audio-record all intervention appointments with patients who consented to this aspect of the study and complete an appointment attendance monitoring sheet every time a patient was scheduled to attend and attended, or did not attend an intervention appointment. I coordinated all aspects of data collection and management alongside the trial coordinator (SH). This included both myself and SH liaising with providers on a weekly basis to ensure that audio files and appointment monitoring sheets were returned. Health providers were also asked to report any reasons for failing to audio-record the appointments if applicable.

As audio files were received, either myself or SH sent them electronically to a UCL approved external transcription company (Way With Words) where they were transcribed verbatim for analysis purposes. Once the transcript had been returned to me, I listened to the corresponding audio-recording whilst reading through the transcript to check and correct any transcribing errors and to remove all references to names, places and any other identifying information from the transcript. Audio files and transcripts were securely stored in separate folders on password protected UCL computers. The folders were only accessible to the PRIMROSE study team, and the audio

files were subsequently deleted once transcribed. All personal data pertaining to patient characteristics and contact details was stored on the UCL Data Safe Haven (IDHS), separately from audio files and transcripts. Anonymised transcripts will be electronically stored for 20 years following completion of the study in accordance with UCL's archiving policy.

5.3 Data analysis

I entered all first appointment transcripts into QSR International's NVivo11 qualitative software package (QSR International Pty Ltd, 2015) for coding and analysis purposes. All instances where social support, supportive others or relationships with others were mentioned or discussed were highlighted in the text of each transcript. I then used inductive (Thomas, 2006) thematic analysis to code and analyse the highlighted sections of text based on the following six analysis phases identified by Braun & Clarke (2006): familiarising myself with the data; generating initial codes; searching for themes; reviewing themes; defining and naming themes; and writing up the findings (Braun & Clarke, 2006).

I used the constant comparison method of coding to generate initial codes and analyse the data (Starks & Brown Trinidad, 2007). I began by open coding to examine, compare and categorise the data, followed by axial coding to reorganise the data based on emerging relationships among the categories. Finally I employed selective coding of the data to identify and describe the core categories of involving existing social support and social networks in an intervention for reducing CVD risk in people with SMI.

A random sample of 10% of appointment transcripts were coded independently by a second researcher, Suzan Hassan. Suzan and I met to discuss the codes and agree the final coding framework to ensure reliability of coding. Codes were then organised into emerging themes which I shared with my supervisory team. We discussed the data and themes, and explored the interpretation and implications of the findings.

5.4 Results

5.4.1 Sample characteristics

155 patients with SMI and elevated CVD risk factors in 38 participating GP practices were randomised to receive the PRIMROSE intervention (Osborn et al., 2018). In three of the 38 GP practices, the original health provider allocated to provide the intervention left the practice and a new health provider received training, therefore 41 health providers were trained to deliver the intervention.

123/155 patients attended a first appointment. Where a patient did not attend their first scheduled appointment but attended subsequent appointments, the first subsequent appointment attended was classed as the first appointment. First appointment audio files were received from 27/41 (65.9%) health providers for 72/123 (58.5%) intervention patients. Table 5.1 lists the reasons why first appointment audio files were not received for the 51/123 (41.5%) intervention patients who attended their first appointment.

Table 5.1. Reasons for missing first appointment audio files

Reason audio file was not received	Number (%) of patients
Patient did not consent to audio-recording	22 (26.2)
Health provider felt it inappropriate to record	14 (16.7)
Health provider forgot to record	6 (7.1)
Device failed to record	4 (4.8)
Health provider did not have access to the device	3 (3.6)
Audio file corrupted	2 (2.4)
Total	51 (100)

Table 5.2 shows the characteristics of patients for whom the first appointment was recorded compared to the overall intervention sample characteristics. There were slightly fewer females (50% vs 56.8%) and single people (37.5% vs 43%) and slightly more divorced/separated people (23.6% vs 16%) in the first appointment sample (n=72) than in the overall intervention sample (n=155) from which the first appointment sample came from.

Table 5.2. Patient characteristics of the first appointment and PRIMROSE trial intervention samples

Characteristics	First appointment sample n(%) (n=72)	Intervention sample n(%) (n=155)
Female	38 (50)	88 (56.8)
Mean age	51.2	51
Ethnicity		
White	63 (87.5)	134 (87.0)
Black	5 (6.9)	11 (7.1)
Asian	2 (2.8)	5 (3.2)
Other	2 (2.8)	5 (3.2)
Psychiatric diagnosis		
Schizophrenia	25 (36.1)	54 (34.8)
Bipolar	33 (47.2)	71 (45.8)
Other psychoses	14 (16.7)	30 (19.4)
Marital status		
Single	28 (37.5)	66 (42.9)
Married/cohabit/civil	25 (36.1)	59 (38.3)
Divorced/separated	17 (23.6)	25 (16.2)
Widowed	2 (2.8)	4 (2.6)
Deprivation		
1= Least deprived	10 (14.7)	22 (16.2)
2	4 (5.9)	7 (5.1)
3	7 (10.3)	17 (12.5)
4	16 (23.5)	30 (22.1)
5= Most deprived	31 (45.6)	60 (44.1)
Unemployed	33 (45.8)	71 (45.8)
MOS-SSS Score (mean)	51.3	52.4

Table 5.3 shows the characteristics of health providers for whom the first appointment was recorded compared to the overall intervention sample characteristics. A larger proportion of health providers had previous research experience (48.1% vs 31%) and there were more practice nurses (51.9% vs 43.9%) and fewer healthcare assistants (44.4% vs 53.7%) in the first appointment sample than in the overall intervention sample.

Table 5.3. Health provider characteristics of the first appointment and PRIMROSE trial intervention samples

Characteristic	First appointment sample n(%) (n=27)	Intervention sample n(%) (n=41)
Health providers		
Practice nurse	14 (51.9)	18 (43.9)
Healthcare assistant	12 (44.4)	22 (53.7)
GP	1 (3.7)	1 (2.4)
Female	26 (96.3)	39 (95.1)
Mean age	46.1	45.7
Ethnicity		
White	25 (92.6)	39 (95.1)
Asian	2 (7.4)	2 (4.9)
Years as a practice nurse/HCA (Mean)	11.4	10.6
Previous research experience	13 (48.1)	16 (39)

5.4.2 Who was in the patients' social network?

Table 5.4 presents the type of relationships identified and discussed by patients during their intervention appointments. The social networks of patients included a range of different people with friends being mentioned by the highest number of patients (30/72, 41.7%) closely followed by children (28/72, 38.9%) and a partner (28/72 38.9%). Other relationships that were described during consultations included siblings, parents, health professionals, grandchildren, the family of the patient's partner, ex-partners, band mates, work colleagues, a casual partner, a neighbour and a cleaner. In four cases the relationship of the patient to the supportive other was not specified. Eight people described not having their family close by, while three people mentioned that their family lived close and were easy to access support from if needed. Sixteen (22.2%) patients mentioned having a pet; in most cases a dog, and often in the context of the patient discussing walking or running. Only three (4.2%) patients stated that they did not have anybody in their social network and did not at any point during their appointment mention the presence of family or friends.

44/72 (61.1%) of patients identified a supportive other to help them to achieve their health goals. Involving a partner was the most popular choice chosen by 25/72 (34.7%) patients, followed by children (11/72, 15.3%), pets (11/72 15.3%), friends (10/72, 13.9%) and mental health professionals (8/72, 11.1%). Twenty-eight (38.9%) patients did not identify anyone to support them.

Almost all patients who identified having a partner decided to involve them to help support their health goals (25/28, 89.3%). Only a third of patients who spoke about friends (10/30, 33.3%) and work colleagues (2/6, 33.3%) set a health goal that involved their support, with siblings (1/14, 7%) and in-laws (0/3, 0%) being the least likely to be enlisted as the supportive other.

Table 5.4. Relationship types identified in the patient’s social network

Relationship to the patient	N/72 (%) of patients who identified the person	N/72 (%) of patients who chose the person to support them
Friend	30 (41.7)	10 (13.9)
Child	28 (38.9)	11 (15.3)
Partner	28 (38.9)	25 (34.7)
Pet	16 (22.2)	11 (15.3)
Parent	15 (20.8)	6 (8.3)
Sibling	14 (19.4)	1 (1.4)
Mental health professional	8 (11.1)	3 (2.8)
Grand child	7 (9.7)	3 (2.8)
Work colleague	6 (8.3)	2 (2.8)
Relationship unclear	4 (5.6)	1 (1.4)
Other^	4 (5.6)	2 (2.8)
In laws	3 (4.2)	0 (0.0)
Nobody	3 (4.2)	26 (36.1)
Total	166*	101*

*Some patients identified more than one supportive other therefore the total exceeds 72.

^ Ex partner, cleaner, neighbour

5.4.2.1 Identifying health behaviours

The most popular health behaviours were around weight loss, with a focus on how supportive others could assist the patient to increase their physical activity or improve their diet. Half of the patients however either involved nobody, or a pet, in increasing physical activity, while just under a third did not involve anyone in helping them improve their diet. For those who did identify someone, just under a third indicated their partner.

Seventeen patients explored stopping smoking, with a quarter of those who chose this indicating that they would like to do it alone. Of those who identified a supportive other, a small number identified a partner, child, grandchild or friend to support them, either directly or indirectly, for example one patient spoke about not smoking when their grandchildren were visiting.

A small number of providers and patients discussed attendance at health appointments related to smoking, weight or the intervention itself, with the most popular choice of support being a partner. Providers and patients rarely discussed alcohol intake, or medication adherence and of the four patients who did explore medication adherence, three felt that they did not need any support with this. Table 5.5 shows the CVD risk reducing behaviours that were discussed in the appointments, the frequency with which the behaviour was chosen and who was identified as the supportive other for each behaviour.

Table 5.5. CVD risk reducing behaviours and relationship of supportive others who were identified to support each behaviour

Relationship to patient	CVD risk reducing behaviours						Total
	Increase exercise	Improve diet	Reduce or stop smoking	Appointment attendance	Monitor medication adherence	Reduce alcohol use	
Nobody	9	10	4	1	3	1	28~
Partner	5	9	3	7	0	1	25
Child	5	4	2	0	0	0	11
Pet	11	0	0	0	0	0	11
Friend	3	3	2	1	0	1	10
Health professional	2	1	0	1	0	0	4*
Parent	1	1	1	2	1	0	6
Grand child	2	0	2	0	0	0	4+
Work colleague	0	2	0	0	0	0	2
Other	0	0	2	0	0	0	2
Sibling	0	1	0	0	0	0	1
Relationship unclear	1	0	0	0	0	0	1
In laws	0	0	0	0	0	0	0
Total	39	31	16	12	4	3	105[§]

~1 patient did not want to involve anyone in attending appointments or in improving their diet and one patient did not want to involve anyone in improving diet or increasing exercise.

*1 patient chose to involve their support worker in both attending appointments and exercise

+1 patient stated that their grandchild encouraged them to be both physically active and stop smoking

§Some patients identified more than one supportive other therefore the total exceeds 72.

5.4.3 Provider adherence to the social support strategy

The majority of health providers adhered to the study manual and encouraged the patient to explore for themselves who to involve and how to involve them in helping them to achieve their health goals. This was often in the form of a direct question from the provider to the patient, with the patient then deciding that they would either like to involve a particular individual or work on their health goals alone:

PROVIDER17: And do you have anyone that can support you in this, do you think?

PATIENT17126: In the walking?

PROVIDER17: Yes, like give you a support, say okay, you're doing great. That's nice.

PATIENT17126: Yes, I think if I talk to my daughter, then I have a goal worth something

PROVIDER17: So your daughter?

PATIENT17126: Yes.

However in a small number of appointments, the health provider did not give the patient choice, and, following an exploration of the patient's social network, the health provider

decided on behalf of the patient who should be involved and how, without confirming with the patient if this is what they wanted:

PROVIDER33: Try for two weeks? That's fine. With whom? So you're going to do it with colleagues at work. So you can ask your friend to support you as well. Okay. So, now, this is week one. So starting from today which is Wednesday... Well, actually, no, you can start from next week because you're doing it on a Monday.

PATIENT33109: Okay, next Monday. Okay.

In two cases, the decision to involve a supportive other in the intervention was made prior to the first appointment, with a family member (a mother in one case and a husband in the other) attending with the patient. Discussions revolved around how the individual who was present could support the patient, with limited exploration of the patient's wider social network:

PROVIDER31: Two to three weeks. With who?

HUSBAND31146: With me.

PROVIDER31: Well, so, you're going to do it with your husband, aren't you?

PATIENT31146: Yes.

PROVIDER31: Okay, so, you're going to be supported by your husband, aren't you, because he's, you've already said.

Only one provider did not initiate any discussions around involving members of the patient's social network, despite the patient mentioning a sister who had given her information about healthy eating and that she walked with her dogs.

5.4.4 Qualitative thematic analysis

Six main themes on involving supportive others to promote CVD risk reducing behaviours were identified from the analysis: i) motivators for behaviour change, ii) social contact, iii) monitoring progress with health goals, iv) benefits to the supportive other v) supportive others as a barrier to achieving a healthy lifestyle and vi) support for those who have no-one. Each theme is presented below with supporting quotations taken from the appointment transcripts.

5.4.4.1 Motivators for behaviour change

A number of patients discussed ways in which their supportive others could be, or were already involved in motivating them to achieve a healthier lifestyle. This included i) doing things together, ii) providing positive feedback on behaviour, iii) being concerned about the patient's health and iv) the presence of family and friends as positive role models.

Doing things together

The majority of patients and health providers discussed a range of benefits to sharing a new activity with someone else including company, mutual support and practical support. Most conversations focused on weight loss, and how supportive others could help the patient to increase their physical activity, such as providing company on walks or participating in sporting activities together:

PATIENT17119: I have something to do every day. Yesterday I met my social worker. It was a bit wet... we usually go out. He does badminton.

PROVIDER17: So you play badminton as well. You're quite active as well, aren't you? Lots going on.

PATIENT 17119: I play badminton maybe once a week, an hour. It's very nice.

PROVIDER17: So you have a chat with him and then you go and play badminton together.

PATIENT17119: Yes.

Other activities that were discussed by a small number of patients included going to sports clubs or going out dancing together:

PATIENT31111: We do go mo'jiving once a week and we often go out on the Saturdays. So, during the week, for three hours' dancing, he's spinning me this way and spinning me that way and I'm sweating buckets and drinking and drinking. So, we do have exercise together and I can go for the three hours.

Some patients explored how supportive others might be involved in helping them to stop smoking. This included health providers and patients exploring whether the patient and family member could stop smoking together:

PROVIDER37: Do you think it would help if you were both trying to give up together?

PATIENT37109: Yes, I think so, yes. Well, it definitely would because, you know, if someone's smoking there, then the other wants to, don't they?

PROVIDER37: Yes, I mean you could both make appointments together or you could both, you know, that might help.

PATIENT37109: Yes.

Health providers explained the benefits of making healthy lifestyle changes with family or friends including having someone to talk to who might be able to give alternative advice on accessing and achieving healthy lifestyle options, and making the patient feel that they weren't alone if they faced difficulties:

PROVIDER86: Okay. And did you want to include somebody with you to help you, to walk along with you, to give you some support?

PATIENT86105: I don't know whether my husband would, because it depends if he'll go out at the same time as what I do. That's the only thing, if it's a morning. I mean, if I try and work it in that...

PROVIDER86: Yes, because that would be nice, wouldn't it? If you had a bit of company.

PATIENT86105: Yes.

PROVIDER86: If you've got somebody at the side of you, you'd feel more like you...

PATIENT86105: Somebody there, yes. That's right.

PROVIDER86: Yes, exactly. You know, and then, the times when you feel, oh, I don't really want to go, they, sort of, spur you on, as well, wouldn't they?

PATIENT86105: Yes. They can... Yes, actually. Yes. The motivation isn't it, yes.

In some cases, doing things together meant family members or friends providing practical support including help with transportation to get to a leisure centre for swimming activities, to go shopping or to attend health service appointments and group meetings:

PATIENT73166: Yes, so tonight, and because I have fear of getting on public transport, but on a Wednesday, a friend of mine, [name] goes to the same (Alcoholics Anonymous) meeting, and he's picked me up for years, since 2009, so he'll pick me up and he'll take me home again.

Providing feedback on behaviour

Both health providers and patients raised the importance of positive feedback from family or friends to help keep patients motivated to maintain changes to unhealthy

behaviours. In some cases, patients volunteered that they were confident that their family or friends would provide them with positive feedback:

PATIENT35142: Yes. And also [name of partner] is great at being able to, she has a great quality of being able to keep you in line but not feel like you're getting told off, you know so she's good at encouragement, so, yes, she'll be great for that, the encouragement.

In a number of appointments, health providers encouraged their patients to enlist the support of family or friends who were unable to directly support the patient in achieving their health goals by obtaining positive feedback from them:

PATIENT13193: Yes. My other son lives in <name of place> so, isn't really...

PROVIDER 13: Big trek. Well, there's no reason they can't, sort of, support you on the phone and, you know.

PATIENT13193: Yes.

PROVIDER 13: And say, well done.

PATIENT13193: Yes.

PROVIDER 13: And how you're getting on.

PATIENT13193: Yes.

As well as providing positive feedback, providers and patients explored examples of supportive others directly challenging the patient's participation in negative health behaviours such as smoking and drinking alcohol:

PROVIDER31: If he can support you, as well.

PATIENT31125: Oh, yes, he will.

PROVIDER31: And say to you, look, you really, really do not need this cigarette.

PATIENT31125: Yes, he has said that to me.

PROVIDER31: Has he?

PATIENT31125: Yeah

PROVIDER31: And just say, put it out. That's really good because sometimes you just need that bit of support, and sometimes hearing it from someone else you think, yes. You know what? He's really right because I don't really fancy this.

PATIENT31125: That's what goes through my head.

Concerns about the patient's health

A few patients described how their supportive others had raised concerns about their health and that this was a motivating factor for them to try and change their unhealthy

behaviours. Family or friends had raised concerns around the patient developing long term health conditions in the future, or even dying as a result of participation in unhealthy behaviours. The potentially negative impact on others, of continuing to engage in unhealthy behaviours, seemed to be a motivating factor for patients to change:

PROVIDER16: Will she be pleased if you give up?

PATIENT16108: My wife will be pleased, yes, because she hasn't said as much but I know it's something that plays on her mind but, she has to watch her Mum die because of this (smoking).

PROVIDER16: Shakes you up a bit, doesn't it?

PATIENT16108: Most of which I've managed to stop doing apart from that one thing.

PROVIDER16: It's not easy, not easy at all. Okay, so yes it would be good for your wife to see you trying again as well.

PATIENT 53127: I said bless you, you're really thinking about my cholesterol and he was like yes, well obviously because it's going to affect your life and you know so he's being...

PROVIDER53: Well it's great. So you've got somebody who's being supportive.

PATIENT 53127: Yes, he really is, yes.

Positive role models

Providers and patients explored the positive and reinforcing health behaviours of family and friends, and how these behaviours could be used to influence the patient's own behaviour. Some of these behaviours, such as having a restricted diet and only being able to cook low fat or low sugar meals were a consequence of the supportive other having a long term health condition such as diabetes or heart disease, and successfully making changes to manage their conditions:

PROVIDER 85: So when you eat at home, like, is your wife very conscious? Does she prepare your meals for you?

PATIENT 85112: Yes, I mean, she's a diabetic.

PROVIDER 85: Oh, right.

PATIENT 85112: So, you know, she's quite conscious as well of eating well

In other cases, the supportive other simply enjoyed eating healthy foods or didn't smoke, which led to the patient eating healthy meals or not smoking in the presence of their family member or friend. Other family members or friends simply wanted to lose weight or stop smoking, and patient's discussed how the behaviour of their supportive other had helped them to make changes to their own lifestyle:

PATIENT88102: We, my wife joined a fitness club, so we joined them, we've been eating more healthier than...

PROVIDER88: Yes. Have you ever thought about any of those types of things, like weight loss groups or that type of thing?

PATIENT88102: Well, I've been... My wife goes, so I've been doing what she's been doing.

PROVIDER88: So you sort of tagged on to what she's done is some ways, yes.

PATIENT88102: Well, I think it's better because I've been eating a bit healthier. It seems to be a better thing.

The provision of fruit and vegetables by family members and friends also provided opportunities for patients to eat more healthily:

PATIENT37109: My daughter that lives at home works with fruit and veg, so she brings me in free fruit and veg all the time. So I do, every day, I try to eat.

PROVIDER 37: You're lucky.

PATIENT37109: I know. I've got all this healthy food, haven't I?

PROVIDER 37: Yes, wow.

PATIENT37109: And I do, every night, eat one piece of fruit because I think she's bringing it home free, it's only going to be chucked out if I don't eat it. And, to tell the truth, I've started enjoying it again.

PROVIDER31: Maybe within the food, cut the crisps out and have more healthier things so you can just nit-pick at healthier things, if that makes sense?

PATIENT 31125: I have, not Satsumas. What's the other ones? Clementines. My friend, he buys them over there. And I have one, maybe two of them a day.

5.4.4.2 Social contact

For some patients, simply having contact with others was the main motivating factor for participating in healthy lifestyle activities. A small number of patients identified social contact as the key motivating factor for participating in physical activities, both in terms of bringing friends or family together as well as an opportunity for meeting new people:

PATIENT85112: I don't particularly enjoy going to the gym. The social side's quite good actually but now, you know, you go up to the University and you meet different people so that's quite good but I don't particularly enjoy it. I have to drag myself there sometimes.

However a minority of patients also explored their fear of people and of going outside as a barrier to exercise. One patient discussed her fear of going to the gym because being surrounded by noise and people caused her stress. Health providers responded to these concerns by providing alternative strategies such as exercises that could be done at home, and in one case the health provider explored the patient's social isolation and provided encouragement to use exercise as a means of going out and meeting people. This advice however seemed to have little impact on the patient:

PROVIDER17: Okay. So you want to increase some exercise?

PATIENT17126: Yes.

PROVIDER17: Which will, I think will be very good for you, so not only you'll go out more, and maybe open up a little bit to the outside world...

PATIENT17126: Yes.

PROVIDER17: And maybe socialise, a little bit more as well, will make you feel more confident. So, because now, Winter is coming, you don't want to lock yourself indoors, and...

PATIENT17126: I quite like Winter, I don't feel bad in the Winter.

5.4.4.3 Monitoring behaviours and outcomes

The involvement of family members and friends in monitoring the patient's behaviours and health outcomes in relation to achieving their goals was also raised. This included discussions around how supportive others were already involved in monitoring the enactment of health behaviours such as the number of cigarettes the patient smoked, the amount and type of food they were eating and support with monitoring weight:

PROVIDER13: And if you find that you're at the gym and you get on the scales before you go in each time or each week and you want to record that, then you can do that too. But know that scales are going to be different wherever you go.

PATIENT13106: Yes I usually rely on my care co-ordinator weighing me every two weeks.

Making changes to diet was frequently explored by providers and patients and involved discussions around how family members or friends could support the patient to monitor their unhealthy food intake:

*PATIENT33106: The sugary content in other things, I'm reading to make sure I'm okay with...
And the wife is helping us out tremendously,
PROVIDER33: Oh brilliant
PATIENT33106: By separating what I need and what I don't need.
PROVIDER33: Oh that's good. So she's been really, really helpful for you.
PATIENT33106: She's very helpful.*

*PROVIDER53: Sometimes people want partners or carers involved. Or some people are just
happier to do it themselves, to be managing their own food and their own intake.
PATIENT53109: It would probably be good, as my partner's quite good at managing my food.
PROVIDER53: Yes?
PATIENT53109: Anyway so it would be quite good to get her involved, as well.*

Patients and providers also explored how supportive others could help with monitoring progress with the health goals they set within the appointments, such as the patient sharing the changes that they were planning on making to their behaviour with their supportive other, so that they could help them keep on track:

*PROVIDER70: That's really good if you've got a friend who understands you as well.
PATIENT70122: Yes, and he'll always pitch in, you know, stay off that cider, don't have cider.
PROVIDER70: Yes, so, what you need to say to [name of friend] then is tell him
PATIENT70122: I'll tell him what I've agreed*

In a small number of appointments, the health provider actively encouraged the patient to speak to their family member or friend about the conversations they had had within the appointments to try and enlist their support in achieving their health goals. This included general advice to go away and explore with supportive others how they might be able to help the patient achieve their health goals as well as more directive approaches, for example advising the patient to ask family and friends to tell them not to smoke if they saw them with a cigarette, not to provide or encourage unhealthy food intake or to reduce portion sizes if the supportive other cooked for them:

*PROVIDER70: Right, okay, so portion sizes... so what could you change, how could you
change your behaviour in regard to portion size? So say, for example, you weren't cooking
and your partner was doing the cooking?
PATIENT70116: Yes.
PROVIDER70: Would you be able to say to him, give me a smaller plateful, please.
PATIENT70116: Yes.*

Only one patient said that they were supported to help monitor adherence to their medication, with his mother supporting him to take psychiatric medication. The remaining patients either chose not to or did not have anyone who could support them:

PROVIDER16: Are you on your own at home, or do you live with anybody?

PATIENT16104: I live with my daughter and her boyfriend, and my dog.

PROVIDER16: Right, okay. I was going to say, can they, perhaps, help remind you to... do you actually physically need reminding? Did you want to get anyone else involved with reminding you to have this (diabetes) tablet?

PATIENT16104: No, I should be all right. I'll stick a note on my cupboard, from now on.

5.4.4.4 Benefits to family and friends

The most frequently discussed reason for involving supportive others was the perceived health benefits to not just the patient, but to their family member or friend. In the majority of these discussions, the supportive other's health was raised as a concern by the patient, with the patient perceiving that their loved one would also benefit from losing weight, stopping smoking or reducing their alcohol intake, either because they participated in unhealthy behaviours or because they had long term health conditions such as diabetes or heart problems:

PROVIDER52: Could he do with losing a bit (of weight)?

PATIENT52103: Yes, he could.

PROVIDER52: So you could do it together, couldn't you?

PATIENT52103: He could do with it a lot, yes. [husband] could, yes. He has a lot of health problems, physically like, my husband.

In a small number of cases, having children or grandchildren was cited as a key motivating factor for stopping or reducing smoking, both in terms of wanting to remain healthy for them, as well as the potential dangers to them of passive smoking:

PATIENT41112: Basically, I generally want to stop. I mean, obviously, I've been taking a lot of walks and stuff, because they've (daughter and grandchild) been there, because I haven't been smoking in the flat, while the baby's there.

5.4.4.5 Supportive others as a barrier to achieving a healthy lifestyle

A number of patients mentioned that their family or friends acted as a barrier to them achieving a healthy lifestyle, and sometimes made it difficult for them to modify

unhealthy lifestyle behaviours. This included family or friends encouraging or participating in unhealthy behaviours with the patient (e.g. poor diet, alcohol use or smoking), a lack of interest or support from family or friends to make changes, and smoking and alcohol use being used as a social activity with friends and family. Disruption to family routine or relationships and the poor health of family members which subsequently either had a direct negative impact on the patient's ability to focus on their own health, or meant that they were left without any support were also discussed.

Encouraging and participating in unhealthy behaviours together

Examples of work colleagues, friends and family members actively encouraging poor diet choices and smoking were described by a number of patients:

PROVIDER11: Do you think your colleagues would come on board with that?

PATIENT11104: Well, <work colleague's> a bit of a tease because he knows I want to lose weight and sometimes he's my spanner in the works.

PROVIDER11: He can be a bit jealous, maybe, of your efforts?

PATIENT11104: Maybe. I don't know, but (he) can be the spanner in the works because he's the one that will, you know, I'll be going well for a few weeks, then he'll say, well, I've bought you a biscuit or a—like, a feeder—I've bought you something.

Health providers sometimes tried to tackle these negative influences by suggesting that the unsupportive other could be brought on board to help:

PROVIDER 16: So if you could buy the single. You know in multipack you get the singles, then you're less likely, perhaps, than buying a big (chocolate) bar that you start, and then you have to finish. Do you think that might...?

PATIENT16115: Usually my friend and I – I live with like my girlfriend – usually I have half of it, and she has like half.

PROVIDER 16: Okay, so do you think she'll help you? Do you think she'll help encourage you?

PATIENT16115: Yes, she's quite willing to like lose weight, as well, I think

In other cases the health provider directly explored how the patient might try to enlist the help of the unsupportive other, for example by encouraging the patient to speak to their family or friend about the health goals that they had chosen:

PROVIDER11: Because that's not saying no. It's not saying never; it's just saying, not today. Tomorrow, let's go to the bakery.

PATIENT11104: Yes, I've just got to be more assertive with him. Yes, that's fine.

PROVIDER11: Shall we give that a whirl?

PATIENT11104: We'll give that a whirl.

Lack of encouragement and support

In some cases, a lack of encouragement or support from family or friends to participate in healthy activities made it difficult for the patient to sustain their own healthy lifestyle. This was particularly the case when patients were trying to maintain a healthy diet or participate in physical exercise:

PATIENT13106: My partner's coming with me, but he's a bit more difficult to motivate to get in a gym, he kind of, he wants to sit on his bike and read a book and it's like, you know you've got to put some effort in babe.

PROVIDER13: I suppose part of it is getting him there with you, because if he's there with you that's a start, and you're going for you and I know he's supporting you and you're probably trying to support each other. So getting him through that door is a starting point. And if he chooses to sit on his bike while you do your stuff well, you're going to have to give him that maybe.

A range of responses were given by health providers to situations where family or friends offered little encouragement or support to patients including acknowledging that a lack of support was difficult but then providing no further advice; to exploring why supportive others may be behaving in this way and suggesting alternative goals that the patient felt that their family or friend would support them with.

In instances where health providers did explore a perceived lack of encouragement or support from the patient's family or friends, these was more likely to result in the patient modifying their health goal to align with something that their family member or friend would be more likely to support, or for the patient to persist with their original health goal and work on it alone. In the example below, a decision was made by the patient to work on dieting alone following a discussion about how her husband did not support her dieting preferences:

PATIENT80114: Yes. And my other half, bless him, has... We've been on all the diets that he wants to go on, and I go on them with him, but he doesn't particularly want to do anything that I want to do, because it doesn't...

PROVIDER80: You mean changing eating habits and things?

PATIENT80114: Yes.

PROVIDER80: Or different meals plans, or something like that.

PATIENT80114: Yes. And he's... If he's convinced about it, it's fine and we'll go that way, and... But he is very good at pooh-poohing anybody else's ideas...

In a minority of cases the potential pitfalls of relying on others to assist with healthy lifestyle activities were identified, with patients describing examples of friends initially being involved in healthy lifestyle activities and then subsequently letting them down. In one case this did not stop the patient from attending their Slimming World Group, however they did not seem to find the group useful:

PATIENT80114: One of the girls at work said, would I go with her? And I went with her the one time, and then she never turned up again, so you think well what am I doing here?

PROVIDER80: Yes, that's right, because it would have been more encouragement for you, as well as for her, wouldn't it? If you'd both continued to have gone together.

PATIENT80224: I think so, yes.

PROVIDER80: Sometimes you just need that little bit of motivation, as well, don't you?

PATIENT80224: Yes, well I went for about, six, seven, eight weeks, something like that.

PROVIDER80: Oh, right. Well, that was good. Yes?

PATIENT80224: But didn't do very much, so....

One participant discussed walking with a friend but fitting this activity around the friend's schedule. The provider used this information to encourage the patient to attempt to carry out physical activities both with their friend, but also on their own to avoid becoming dependent and being let down:

PATIENT53104: So that's when I fit in with her as well sort of thing we kind of get together. So, again, it just depends. I can't set days because, you know, that might be off the cuff, she's like, are you free? Yes, let's do it and I'll drive over there and we do our walk kind of thing.

PROVIDER53: What I would say is that sounds great. It's a good plan. Sounds like it works for you. However, it does put your activity in somebody else's hands to an extent.

PATIENT53104: Hmm.

PROVIDER53: So what I would say is if you're going to say three times a week, if she hasn't phoned and you haven't managed to set yourself up one, you may have to... are you comfortable to do that walk... a walk on your own?

PATIENT53104: Yes, yes, yes

Smoking and alcohol as social activities

Alcohol use and smoking with family and friends were experienced as positive social activities by some patients. Alcohol was used as a way to unwind with friends and partners, and some patients raised concerns that by stopping drinking or smoking, this would reduce their social contact with others. In all cases, the health provider acknowledged that maintaining these social connections and activities was important. In the health provider response below, the patient had previously described a close network of friends who drank together and who had been supportive of each other during recent difficult times, and so the provider tailored advice on alcohol to drinking alone:

PROVIDER70: So, I mean, at the moment do you want to carry on... you obviously want to carry on meeting your friends and having a drink with them is something that's quite important, so, you want to leave that as it is?

PATIENT70122: Yes.

PROVIDER70: So, then it would be looking at the other times that you drink. Is there any way we can set some, kind of, a target? Do you think there's any way you could cut down on the amount you drink when you're not seeing your friends? So, these are times when you're on your own.

In some of those incidences, the health provider attempted to explore alternative options with the patient on how to reduce rather than completely stop their alcohol intake, for example cutting down at home rather than in the pub:

PROVIDER85: Right. Now, where would you feel more happy to reduce?

PATIENT85112: At home probably.

PROVIDER85: At home?

PATIENT85112: Because I take my father-in-law out because he likes to go out and he's 89, so I take him out.

PROVIDER85: Right. Okay. So if you, perhaps, stopped having the beer at home, that wouldn't be a problem for you?

PATIENT85112: Well, I'll see. I'll do it because I've agreed to take part so I'll do it, yes.

In other cases the health provider acknowledged that reducing alcohol or smoking in social situations with friends was difficult but then did not explore further how the patient might be able to make positive changes:

PATIENT65102: I don't know. I suppose its friends and alcohol, stuff like that.

PROVIDER65: Okay, so Wednesday night is pub night, is it? How will you manage at the pub with no cigarettes? Oh, I suppose you're smoking tonight.

PATIENT65102: Well, I have to play it by ear and just go for it.

PROVIDER65: See how you go then and then I'll see you next week won't I? And then we can see how you're getting on.

These discussions usually ended with the patient identifying a different family member or friend to those with whom they socialised with, to help the patient maintain social connections while still making progress with their health goal outside of these social situations.

Preferences and routines of supportive others

Another difficulty identified by a minority of patients was a reliance on the preferences and daily routines of their supportive other. In some cases the patient ate unhealthy foods because they liked different foods to their partner, which led to the patient cooking their own unhealthy convenience meals, and in other cases they ate unhealthy food due to their children's or partner's preferences:

PATIENT 93129: When [name] was with me – I mean, we never lived together or anything like that – but he stopped with me a week here and a week there when he was becoming ill. And then I'd go up to eat out and have my dinner, so while we were doing that all he wanted was roast dinners. I had to cook a bloody roast dinner at dinnertime every day.

PROVIDER93: Oh god.

PATIENT 93129: And I thought, this is getting ridiculous. And I knew I wasn't supposed to eat roast potatoes and I kept eating them. And there was a lot of them.

A barrier to being able to plan and have time to cook healthy meals or do physical activity together was if the supportive other had a change in daily routine. If the routine was disrupted, this could result in ordering a take away or cooking an unhealthy meal that was convenient, as in the case below where the patient's partner was away from home:

PROVIDER 53: Is there anybody else that you want to rope in to help you with this? Is there anybody or is it something that you feel you can do by yourself?

PATIENT53127: I probably can do it on my own. My partner has been brilliant.....He's been saying right we're going to start eating healthy and he's been going out and getting all the stuff and he came home the other night and he said I've got roasted vegetables, I've got corn chicken meat and I'm going to do brown rice with it. And I was like brilliant. And then he was away yesterday and I was working and didn't get home until about eight with the kids and I thought do you know what I've been really good all week I'm going to have steak bake and some chips.

Health providers tended to acknowledge that different preferences and disruptions in daily routines were difficult and in some cases attempted to get the patient to think about alternative options:

PROVIDER 13: How often do you have a takeaway during the week?

PATIENT13193: Two or three times, two or three times probably.

PROVIDER 13: And would that be the same, roughly, every week?

PATIENT13193: Yes. Not every week, no, just depends. If [husband's] got a very late appointment, we don't have them, but if he's got an early appointment, sometimes I'll do that.

PROVIDER 13: Right, okay, I see. Because it's easier, maybe?

PATIENT13193: Yes it is.

PROVIDER 13: Yes, okay. So, do you think you would cut down having your takeaways?

PATIENT13193: I would, yes.

PROVIDER 13: How would you think you would?

PATIENT13193: I personally, get fed up with them to be honest, I mean I had one the other week and it was a dreadful takeaway, you know, and it wasn't cheap.

PROVIDER 13: Yes, so, you could save yourself a bit of money as well.

PATIENT13193: Yes.

PROVIDER 13: And get something that you would cook from home?

PATIENT13193: Yes.

Ill health of family or friends

A trigger for some patients to relapse into unhealthy behaviours was stress caused by the ill health of family members or friends. In some cases this meant that the patient began smoking again after quitting, and for others, diet plans were discarded:

PATIENT93129: It was just all upheaval with him, really, because it was... He went to live with his daughter last December and it was just before that that he got dementia. And I couldn't cope; he was quite bad. He was playing up a hell of a lot and that was when I went off the diet I was on.

PROVIDER93: So hence that could be why there's such a difference, isn't it?

PATIENT93129: It all ties up now, I can see it now.

In some cases, the ill health of a relative or partner profoundly affected the patient's ability to focus on the intervention and their motivation to identify a health goal to work on:

PATIENT31109: I have a very sick grand-daughter, I haven't got time for other goals around my illness, you know, and being hyper-manic and at the moment slightly depressed, so I'm not really in the mood.

In all cases where the poor health of a relative was described as being stressful to the patient, the health providers listened and acknowledged the challenges that this brought.

Some patients also described having a lack of practical support for participating in physical activities or doing the food shopping because their family member or friend was unwell, which in turn impacted on their ability to lead a healthy lifestyle:

PROVIDER13: And maybe if there's someone you can go with, tag along with.

PATIENT13170: Yes. I mean, you know, the thing is, like, not being rude, but a lot of my mental health friends that aren't particularly well, we make all these arrangements and then it all goes a bit, like, oh we're not doing it, because of blah, blah, and... You know?

PROVIDER13: So you're the one that motivates everybody else, normally?

PATIENT13170: I try, and it doesn't always happen then. And, like, I'm the one that needs... If that person said to me, right, come on, we're going, we're going, and I didn't feel like it, I think I'd feel a bit more like, all right, I'm going to let them down if I'm not, so, like, get up and do it. Do you know what I mean?

5.4.4.6 Support for those who have no-one

In the majority of cases where the patient did not involve others in supporting their health goals, they had previously described the presence of relationships with a number of people including friends, parents, children, siblings and in a small number of cases

partners. For many of these patients; following an exploration by the health provider on who to involve, the patient explicitly expressed a desire to work on their health goals alone and chose not to involve anyone:

PROVIDER53: Is there anybody that (you) feel you want to involve in this process? Do you want anybody else with you? Is there anybody who can help you meet your goals?

PATIENT53101: No I can do it on my own. I want to do it on my own

Some patients however described living at a distance from their friends or family as a barrier to involving them:

PROVIDER89: Do you have friends or family or you if you need some support?

PATIENT89159: Well my family, my family's about 100 miles away.

PROVIDER89: Okay.

PATIENT89159: I've got some friends though yes so.

PROVIDER89: Okay.

PATIENT89159: But most of them are working, so I can't really ask them so.....

A small number of patients stated that they were alone or felt lonely:

PATIENT93129: Because it's long nights on your own and... As I say, I see my daughter quite often; I'm lucky. But if I didn't have her I wouldn't see anybody.

PROVIDER93: You've got no other friends, you've got...? Do you go to any clubs or...?

PATIENT93129: I've got family. Yes I do, I do, but, I mean, nobody would come to the house.

PROVIDER93: And see you at home.

PATIENT93129: No, not just on the spare sort of, you know. It would be lovely to have a visitor.

In most instances, the health provider elicited information from participants about being alone or feeling lonely by asking questions about the support the patient might have available to them. Sometimes, the health provider then went on to discuss alternative support mechanisms for those who spoke about being lonely, or for those who were unable to identify anyone to help them achieve their goal. This included offering referrals to a stop smoking service that offered one-to-support over the phone and to walking groups:

PROVIDER89: Like I said, in this area they do have some (walking) groups that started, that you can just join, but you just told me that you don't.....

PATIENT 89159: No I'd rather do it on my own, I'd rather do it on my own.

PROVIDER89: In your own time okay. So I think that's very good, how do you feel about all this?

PATIENT89159: oh that's okay, I'll give it a bash, I'll give it a bash.

In some cases the health provider went on to identify themselves as the supportive other:

PROVIDER51: So how long are you going to do it for? You're going to do it for two weeks and you're going to do it on your own, aren't you?

PATIENT 51103: That's right.

PROVIDER51: But I am on the phone.

PATIENT 51103: That's right, yes.

PROVIDER51: And I'll just put in here... it says here how will I be supported by the people listed above so I'm just going to put [practice nurse name] will support me, okay?

PATIENT 51103: Yes, yes

While some health providers explored the possibility of accessing a health trainer or support groups with patients who did not identify any support, one health provider seemed reluctant to explore this option, perhaps due to a lack of service funding or because the participant did not meet the criteria to qualify for a free service. The patient expressed a desire for help to lose weight by accessing a personal trainer, however even though the patient returned to the topic on three separate occasions during the appointment, their requests went ignored and the health provider changed the subject:

PROVIDER17: Okay. Let's write this down. So, lose weight. Anything else?

PATIENT17119: I'd like to get maybe a personal trainer. I don't know, a person not to pay, like, you know. I don't have much money.

PROVIDER17: And do you take your... are you on statins? Do you take tablets for cholesterol?

Most patients who described feelings of loneliness or being alone chose to set health goals that did not involve others following an exploration by the health provider of their social network. In one case where the patient described being lonely but also being married with children and having a friend, the provider did not directly explore how these existing relationships might have been harnessed or why they might not have been utilised:

PROVIDER88: Are you going to do that by yourself or would you like to involve somebody else?

PATIENT88103: That would be... I don't have anyone else to involve.

PROVIDER88: Okay. So just to think long term, there might be things that present themselves in the future where someone else does want to get involved, where you'd say absolutely fine, but you know, just hold on to that thought. And how are you going to be supported to do it? Well again that might be from your own personal motivation, but if you can think of anyone else who can help you do that, you know, that's something to think about....

PATIENT88103: Other than Slimming World....

For another patient, the provider seemed to decide for the patient that they would work on their goal alone:

PROVIDER16: And, I mean, have you got anyone that supports you? Have you got anyone that can help encourage you, or are you... are you just live on your own?

PATIENT16118: I live alone, yes.

PROVIDER16: Right, okay, so you're doing it by yourself, then. And we've decided twice a week? Is that all right?

PATIENT16118: Twice a week, yes. That's fine.

5.5 Discussion

5.5.1 Summary of findings

I qualitatively assessed how social support was explored in first intervention appointments between practice nurses/HCAs and people with SMI who also had raised CVD risk factors. Social support was largely delivered as intended with providers exploring with patients who was in their social network, how they were currently involved and making suggestions for how they could be involved going forward in a generally collaborative way.

The majority of people who identified having a partner involved them in their health goals, usually because they lived with the person and prepared meals together or because they already participated in some form of activity together. No particular relationship types were identified as being more supportive than others. Patients described examples of work colleagues, friends, partners, parents and adult children as

negative influences on their behaviour while others described them as supportive and encouraging in helping them to achieve their health goals. Just over a third of patients did not want or did not have anyone to help them to achieve their health goals.

Social support was described by patients and health providers as a motivating factor for making positive changes either through companionship, providing encouragement and feedback and acting as positive role models. In some cases however supportive others made it difficult for patients to live healthier lifestyles either through participating in unhealthy lifestyles themselves or through incompatible routines or their own ill health. A small number of patients described being lonely and three patients did not identify anyone in their social networks.

5.5.2 Interpretation of findings

Previous research has highlighted the challenges for health professionals, in particular GPs, in exploring the social networks of people with SMI in terms of work pressures and lack of knowledge around solutions for those who are isolated (Pinfold et al., 2015). My study has however demonstrated that following a brief training programme, practice nurses/HCAs were able to instigate conversations about social support in the context of supporting patients to achieve CVD risk reducing health goals. The majority of patients were guided by health providers to identify at least one person in their social network who they wanted to involve in helping them to achieve their health goals.

There was however a heterogeneity evident in the consulting styles of the health providers which appeared to influence how successfully social support was addressed. Some health providers gave their patient's freedom to explore and make decisions for themselves, without questioning those decisions further, while others took a more directive approach and were more involved in influencing the patient's decision on who and how to involve supportive others. For a small number of patients, requests to involve others were ignored by the provider, or providers decided on behalf of the patient who would support them, often putting themselves forward as the supportive other with little discussion around whether the patient wanted this.

In other instances, providers decided for the patient that a family member or friend mentioned earlier in the consultation would be involved, or that the patient would work alone. This seemed to occur when there was a tension between what the patient was saying (I have nobody to involve or I do not want to involve anyone) and what the provider was trying to achieve (identifying and involving a supportive other). This tension may have occurred because providers were attempting to deliver what they perceived to be rigid instructions in the intervention manual to involve supportive others, rather than an optional strategy to help engage people. It may also have occurred because some health providers felt uncomfortable exploring social support with participants whose social relationships were not supportive, or if participants identified that they were lonely. While there have been no previous studies on interactions between practice nurses and people with SMI around physical health care, previous work has identified tensions between psychiatrists and people with schizophrenia when discussing psychotic symptoms (McCabe et al., 2002). In this study, psychiatrists often avoided answering difficult questions and were reluctant to engage with patient concerns.

Resolving this tension is an important consideration for future training, and adaptations may be required to make clearer that the involvement of supportive others should be a choice rather than a required element of the service. There may have also been too much focus in the intervention manual and training programme on harnessing positive relationships rather than offering health providers guidance on how to navigate negative relationship experiences or identify alternative support for those who had none. Future training should focus on exploring with patients whether a support network exists, whether it is appropriate to involve others and what to do for those who need extra support.

Previous research has identified three ways in which health professionals can support the social networks of people with SMI (Pinfold et al., 2015), the first being to facilitate the person in building social connections through referral to support groups and encouragement to access these resources. While mental health professionals in this previous study were comfortable referring people on to these groups, GPs were cautious

about the effectiveness of these groups and also lacked knowledge of local services to refer people to. The second role was helping people to maintain their existing social connections, particularly during times of mental ill health, and the final role was simply as an active member of the person's social network in their own right. This previous study did not explore the role that practice nurses or HCAs might play, however some similarities were identified in my analysis. Most practice nurses/HCAs seemed aware of support services relevant to particular health goals such as health trainers, walking groups, stop smoking or weight management support groups, however very few responded to admissions of loneliness or lack of support. It may be that they lacked the confidence and knowledge to suggest services that could simultaneously address both healthy lifestyle behaviours and lack of support. Training programmes should emphasise the need to identify and become familiar with wider support services that people with SMI may be able to access in the community if they are lonely or socially isolated. In a small number of cases in my study, the practice nurses/HCAs put themselves forward to act as the supportive other for those who did not identify anyone, reinforcing the finding from Pinfold et al (2015) that health professionals may have an important role to play within the patient's social network.

Thoits (2011), described seven psychosocial mechanisms through which members of an individual's social network might impact on health including social comparison, social control, purpose and meaning, self-esteem, sense of control, companionship and perceived social support. Three of these mechanisms fed into the development of the social support strategy as described in chapter three and were subsequently demonstrated within the consultations; social comparison, social control and companionship. The main motivating factor for involving family or friends identified by both patients and health providers was that they could offer positive feedback to help motivate patient's to monitor progress and achieve their health goals. This aligns with social control, where members of the social network attempt to influence, encourage or monitor healthy behaviours. Companionship was also frequently discussed as important in having someone to participate in physical activities or to stop smoking with, as described in the sub theme "doing things together".

A third of patients described the behaviour of their family or friends as a negative influence on their own health behaviours either through active encouragement of unhealthy eating, smoking or alcohol use or through a lack of interest in supporting the patient to make changes to their lifestyle. This demonstrates that social comparison was occurring for some of the participants whose social network members were participating in risky or unhealthy behaviours and serving as negative role models to the patient (Thoits, 2011). Another form of social comparison was demonstrated when patients spoke of the need for their supportive other to improve their own health as a potentially motivating factor to involve them in the participation of healthy lifestyle activities as well as when patients spoke about their relatives or friends as positive role models in terms of being healthy eaters or non-smokers.

Having purpose and meaning in relation to relationships with others was discussed within consultations, albeit less frequently and usually for those fulfilling parental or grandparent roles, and who subsequently wanted to avoid unhealthy behaviours for the health of their children (e.g. smoking). In other cases participants described that their partners were worried about their health and that this was a motivating factor for them to make changes.

Mechanisms of self-esteem and sense of control were less likely to emerge within the consultations. These concepts may have emerged in later consultations as the participants became more familiar with the health providers and shared more information about their lives, or it may be that these mechanisms are not relevant for people with SMI. Previous research has suggested that people with SMI are less likely to have reciprocal relationships and are more likely to report relationships from which they receive support but do not offer support back (Meeks & Murrell, 1994). This suggests that self-esteem and sense of control may be less important for explaining the link between social ties and health behaviours in people with SMI.

Previous research has identified that people with SMI rely more on formal support and have more health and social care professionals in their social networks (Bengtsson-Tops & Hansson, 2001; Giacco et al., 2012). Only 8/72 (11.1%) participants identified a mental

health worker as being in their social network in this study. This may have been because participants in my sample were community dwelling and less likely to be in touch with, or had less frequent contact with mental health services, whereas in other studies, samples were recruited from secondary mental health services. It may also be because health professionals traditionally provide emotional support focused around the person's mental health (Bengtsson-Tops & Hansson, 2001), rather than practical support to help them engage in healthy lifestyle activities.

There was very little discussion around the provision of emotional support by supportive others. This was possibly because the social support components of the intervention guided the health providers to explore practical ways in which supportive others could help improve the physical health of participants and meet their CVD risk reducing health goals, rather than support them with their mental health. It may be that emotional support was explored in later consultations as the health providers and patients became more familiar with each other.

5.5.3 Strengths and limitations

This was the first known study to qualitatively assess the content of consultations between primary care health providers and patients with SMI to explore how social support was used in determining and supporting behavioural goals aimed at reducing CVD risk factors. Given the lack of description of how social support was used within interventions identified in my systematic review, this study makes an important contribution to the field in shedding some light on how social support interventions are delivered in practice. Assessing the content of consultations has its advantages over interviews as the interactions were happening in real time and provided an accurate record of the content of the appointments, as opposed to using pre-specified questions to elicit how social support was used within appointments that require patients and health providers to independently recall their past experiences. One limitation of this methodology however was the inability to probe and ask the participant's direct questions about their experiences of social support outside of the context of the intervention appointment.

A potential limitation of the study was the amount of missing audio files, with 51/123 first appointments not recorded. It is therefore not known how supportive others were involved for 41.5% of the sample. Practice nurses were over represented in the sample and healthcare assistants under represented when compared to the overall intervention sample. This could have been because practice nurses were more comfortable than healthcare assistants at recording their appointments. A higher proportion of health providers who returned the audio files had been involved in previous research and were possibly more comfortable with adhering to study procedures than those with no previous research experience. This is a consideration for future training in research studies to ensure that different health provider experiences are recorded and acknowledged, and that those who require more support with delivering the research procedure aspects of an interventional study are identified and offered additional support.

The presence of the audio recorder may have also had an influence on the behaviours and conversations between patients and health providers. Some health providers raised concerns in the training session about being recorded, however I attempted to reassure them that they were not being judged on their performance, but that the recordings would be a helpful record of what was delivered in practice and could be used to help modify and improve the intervention, materials and training programme for future use. Nevertheless, future studies seeking to collect data on intervention delivery should provide structured training, support and reassurance to health providers on the use and purpose of recording appointments.

There were some differences between the patient study sample and the overall intervention sample from which it came from, with an over-representation of divorced/separated people in this study sample. One explanation could be that people who had previously had a partner but no longer had that support were more invested in the study and in the appointments, and therefore more likely to agree to potentially intrusive study procedures such as audio-recording. There was however also an under-representation of single people and females. It may be that these groups felt more

uncomfortable with having their conversations recorded, however this is speculative and the reasons why this might be are unclear.

I chose to conduct a thematic analysis of the data to determine how social support was used within consultations, however the dataset also lends itself well to an analysis of communication styles and interactions between health providers and patients, and how these interactions might have had an impact on decisions to involve supportive others or not. This would have required additional training and supervision in conversation analysis and was beyond the scope and aims of this thesis.

As a researcher interested in social support and how this was used within the intervention appointments, I may have had biases towards positive social support in my analysis and interpretations. I did however identify a range of negative aspects of social support and a proportion (10%) of the transcripts were independently coded by a second researcher with whom I compared codes and discussed and resolved any discrepancies. I also shared my preliminary findings with my supervisory team and discussed and agreed the final themes with them.

5.5.4 Conclusion

This study suggests that practice nurse/HCAs can be trained to explore the social networks of people with SMI and how to involve them in supporting patients to make changes to unhealthy lifestyle behaviours. Further training may be needed to help practice nurses/HCAs guide their patients to make these decisions for themselves, rather than deciding on behalf of the patient who should be involved and how. Involving supportive others were seen as helpful for supporting patients to engage in healthy lifestyle behaviours through providing positive feedback, helping to monitor progress with goals, companionship and modelling their own positive behaviours. A third of patients chose not to involve others or had limited social networks, and a third reported that family or friends were a negative influence on their behaviour. In some instances, practice nurses/HCAs may be an important resource for identifying and supporting patients with SMI who have limited social networks and referring them on to community services or by supporting the patient themselves.

In the next chapter I discuss the findings from my overall thesis, ideas for future research and implications for clinical practice.

Chapter 6 Discussion of overall findings

A summary discussion has been included after each individual chapter within this thesis in which the strengths and limitations for each study have been considered. In this chapter, I will bring together the findings of the thesis, consider the meaning and implications of the overall findings of my thesis, and discuss future directions for research and clinical practice.

6.1 Summary of main findings

I conducted a systematic review on the effectiveness of interventions that incorporated social support on improving adherence to medication, attendance at health service appointments and participation in CVD risk reducing behaviours in people with SMI. Psychoeducational interventions that involved supportive others showed some promise in significantly increasing medication adherence and significantly reducing the number of cigarettes smoked compared to control groups, however the evidence was not conclusive. Multi-component interventions of psychoeducation and CBT with patients and supportive others showed no significant effect on alcohol reduction. No trials were identified that measured adherence to CVD risk reducing medications, attendance at health promotion service appointments, physical activity or diet as outcomes. Studies were heterogeneous making it difficult to compare effectiveness, and the majority were at a low or unclear risk of bias. It was not possible to isolate the impact that social support had on outcomes and none of the studies described how social support was used within the interventions other than reporting that a supportive other was present. All of the identified studies took place in mental health settings and were delivered by mental health professionals.

The lack of available evidence on social support interventions in primary care settings targeting people with SMI and CVD risk factors identified in my systematic review, as well as the finding from the focus groups that social support was identified as a potentially useful strategy for improving engagement with CVD risk reducing behaviours in people with SMI led me to develop and incorporate a social support strategy into the

PRIMROSE intervention (Osborn et al., 2018). I conducted a secondary analysis of focus groups, workshops with key stakeholders and a review of national clinical guidelines and used the findings to formulate three key recommendations which formed the basis of the strategy: i) give patients a guided choice on involving others in their care, ii) ask the patient's permission before involving others in their care and iii) identify those without support and formulate strategies to overcome this.

I then conducted longitudinal and cross sectional analyses on data collected within the PRIMROSE trial (Osborn et al., 2018), to test my hypotheses that perceived social support would be associated with attendance at primary care intervention appointments, adherence to CVD risk reducing medications, increased physical activity, healthier diet, being a non-smoker and lower alcohol use. I found a significant association between perceived social support and attendance at primary care intervention appointments in unadjusted (IRR=1.005, 95% CI 1.000-1.011) but not adjusted analyses (IRR=1.003, 95% CI 0.998-1.009), and a significant association between perceived social support and adherence to CVD medication in both unadjusted (OR=1.039, 95% CI 1.018-1.060) and adjusted analyses (OR=1.042, 95% CI 1.015-1.070). In the fully adjusted analysis, I found that as perceived social support increased, the odds of being in the moderate/vigorous activity group decreased (OR=0.989, 95% CI 0.978 to 1.000; $p=0.05$). This association was not significant in the unadjusted analysis or the analysis adjusted for age and sex. I found no association between perceived social support and sedentary behaviour, diet, alcohol use or smoking status.

In my final study, I explored the extent to which social support was delivered in the PRIMROSE trial using thematic analysis of all audio-recorded first appointments. I found that it was feasible for health providers to explore the social networks of their patients and make suggestions for how to involve them in achieving CVD health related goals. Most patients identified a family member or friend to help them work on their health goals and social support was described by patients and health providers as a motivating factor for making positive changes to health, either through companionship, positive feedback or supportive others acting as positive role models. However just over a third

of patients chose not to involve anyone or did not identify anyone to help them, and just under a third reported that family or friends were a negative influence on their health. In these cases, healthy lifestyle changes were made difficult for patients either because supportive others were engaging in unhealthy lifestyles themselves, had incompatible routines or had their own health problems which hindered their ability to participate in healthy lifestyle activities.

6.2 Interpretation of findings

6.2.1 Social support interventions for increasing participation in CVD risk reducing behaviours

The most commonly tested interventions that involved supportive others and which showed some promise on improving adherence to psychiatric medications identified in my systematic review were psychoeducation or information giving approaches. While there was very little information available on the social support content of these interventions, it could have been that they incorporated a social skills or social relationships training element. A previous review on interventions to tackle loneliness in people with SMI found that psychoeducation can be used to highlight the importance of social support and maintaining meaningful relationships for staying well, alongside education on mental illness and medication taking (Mann et al., 2017). I incorporated an educational element into my social support strategy to guide health provider explanations about the importance of social support and why it might be useful for making changes to lifestyle behaviours, and my qualitative analysis demonstrated that some, but not all health providers went on to explore these benefits with their patients. In particular, health providers seemed to find it difficult to navigate conversations about social support when people were unable to identify someone to support them. This element of the training could therefore be strengthened

There was a distinct lack of social support interventions identified in the literature that aimed to tackle CVD risk reducing behaviours in people with SMI. Despite the epidemiological evidence linking social support to improved CVD morbidity and mortality in the general population (Holt-Lunstad et al., 2010), social support is either

not being included as a strategy within multicomponent interventions for CVD risk management in SMI, or intervention content is not being fully described in publications. In a RCT of structured lifestyle education aimed at weight reduction in people with SMI, the option for participants to bring friends, relatives or carers to their group sessions was removed following feedback from intervention development work (Holt et al., 2018). It was not clear why this decision was taken as the development work was based on one small focus group in which people with SMI said that they would be happy to bring a friend or support worker, but not a relative to their sessions (Carey et al., 2018). Rather than remove the option, it would have been informative to offer the participant's choice and monitor if this was taken up or not.

While I successfully incorporated social support into the PRIMROSE intervention and the overall fidelity of delivery of the manual was moderate (67.7% of intervention manual-specified activities delivered as intended) (Osborn et al., 2019), this did not translate into improved cardiovascular health outcomes in the PRIMROSE trial (Osborn et al., 2018). This may have been because the trial was powered to detect a difference in cholesterol, however most of the goals that were set within intervention appointments were related to increasing physical activity and improving diet, which may have some impact on cholesterol but not as large an effect as initiating statin prescriptions and improving statin adherence. My finding in the analysis of appointments that around a third of participants in the intervention group did not want to involve others, had nobody to involve, or reported the negative influences of others on their health suggests that a third of my sample may not have felt supported, which could have weakened any potential overall effect of involving supportive others on health outcomes.

6.2.2 Associations between perceived social support and CVD risk reducing behaviours

This was the first known study to assess the relationship between social support and CVD health behaviours in an SMI population recruited from primary care. My finding of an association between perceived social support and self-reported adherence to CVD risk reducing medication adds to the small body of literature that has identified associations between social support and adherence to psychiatric medications in people

with SMI (Ramirez-Garcia et al., 2006; Glick et al., 2011; Magura, Rosenblum, & Fong, 2011; Seo & Min, 2005; Tham et al., 2018) and social support and adherence to CVD risk reducing medications in non-SMI populations with elevated CVD risk factors (Gu et al., 2017; Magrin et al., 2015). This is the first known study to assess the relationship between social support and adherence to CVD risk reducing medications in an SMI population and the association suggests that supportive others have a potentially important role to play in supporting medication taking. The mechanisms for this relationship could be through the presence of practical support for medication taking via supervision, monitoring or collection of prescriptions by family members (Scheurer et al., 2012), and/or approval of medication taking from family or friends, which was found to be important for pharmacological smoking cessation adherence in people with SMI (Aschbrenner et al., 2015) and antipsychotic medication adherence (Kozuki & Schepp, 2005).

My finding of an association between perceived social support and attendance at intervention appointments in unadjusted but not adjusted analyses requires further exploration. It could be that my analysis was underpowered to detect a difference once multiple variables were added into the model, or that there is no true benefit of social support on appointment attendance once confounders such as age and sex are taken into account. It is plausible for example that middle aged people may be more likely to have a long term supportive partner than younger participants and might also be more likely to attend health appointments. Very few studies were identified on the relationship between social support and attendance at health appointments in SMI populations. Only one previous study found an association between social support and attendance at smoking cessation appointments (Aschbrenner et al., 2015), while one study found no association between social support and attendance at diabetes outpatient clinics (Gunzler et al., 2017). Evidence in the general population however suggests that greater social support was related to attendance at preventative CVD screening appointments (Hoebel et al., 2014; Petrova et al., 2015).

My finding that higher perceived social support was associated with lower physical activity in my fully adjusted analysis but not in the unadjusted analysis or the analysis

adjusted for age and sex should be treated with caution. This may be a chance finding and does not align with existing qualitative literature which suggests that people with SMI identify a lack of social support as a barrier to physical activity (Firth et al., 2016; (Muralidharan et al., 2016; Bassilios et al., 2014; Klingaman et al., 2014; Yarborough et al., 2016).

My finding that perceived social support was not associated with diet, smoking and alcohol use mirrors findings from previous studies identifying a lack of association between different measures of social support (including emotional support, satisfaction with relationships, and adequacy of social support in terms of resources provided) and health behaviours in people with SMI (Arbour-Nicitopoulos et al., 2017; Brunette et al., 2019; Gunzler et al., 2017; Leas & McCabe, 2007; Seo & Min, 2005). Findings in the general population have however shown that higher perceived social support is related to increased participation in healthy lifestyle activities (Croezen et al., 2012; Gu et al., 2017; Hoebel et al., 2014; Magrin et al., 2015; Murray et al., 2013; Petrova et al., 2015). This discrepancy between SMI and non-SMI populations requires further investigation. It could be that perceived support is somehow different in SMI populations and may therefore have less impact on health behaviours than in the general population. Previous qualitative work with people with SMI has however cited a lack of social support as a barrier to stopping smoking (Aschbrenner et al., 2017a; Heffner et al., 2018) and a relationship has been shown between perceived social support and improved mental health outcomes (Degnan et al., 2018; Doyle et al 2014; Wang et al., 2018). It could also be that different types of support, such as received support or size of network are more important to people with SMI compared to the general population. Social network size was found to be important for mental health outcomes in people with SMI (Degnan et al., 2018), however further work is needed to determine whether received or structural support is important for CVD health outcomes in this population.

6.2.3 Exploration of social support within first PRIMROSE intervention appointments

While my quantitative study did not find an association between greater perceived social support and a healthier diet or greater participation in physical activity, the goals that were set in the first appointments in my qualitative study focused on involving family, friends or support workers in physical activity or diet. This may have been because health providers and patients were more comfortable with discussing goals around weight management than for example CVD risk reducing medications, especially if nurses/HCAs were not trained or authorised to prescribe medications. It may also be that weight loss (and therefore diet and exercise) was a greater priority for people with SMI (Vandyk & Baker, 2012), than other risk factors, as participants were able to choose which areas they wanted to work on. Health providers may have also been reluctant to involve supportive others in appointment attendance and may therefore have not actively suggested this. Involving supportive others in consultations was a concern raised by the practice nurses in my focus group study (Burton et al., 2015), with suggestions that they sometimes found this difficult to manage, and, only 12/72 health providers explored the possibility of involving family or friends in appointment attendance.

While a key finding from my secondary analysis of focus groups was that primary care health professionals advocated for involving mental health workers in supporting appointment attendance or having them as a contact to identify non-attenders (Burton et al., 2015), only one patient chose to involve a mental health support worker in supporting them to attend their appointments. This may have been because my sample had less contact with mental health services than primary care providers may have expected. Research suggests that up to a third of people with SMI are seen only in primary care and do not have contact with secondary mental health services (Reilly et al., 2012). Alternatively it may be that mental health professionals do not provide this level of support to their patients. In the focus group study, mental health professionals raised concerns that primary care providers were “passing the buck” for physical health

care of people with SMI, by expecting them to attend services with them (Burton et al., 2015)

The finding in my thematic analysis of first appointments; that a number of patients did not identify a supportive other, or spoke of family or friends as being a negative influence in their lives, suggests that a substantial sub group of my sample did not feel supported by their social networks. This finding is corroborated by my quantitative study, where the mean score on the MOS-SSS was 56; similar to MOS-SSS scores reported in previous studies with people with schizophrenia (Fulginiti & Brekke, 2015; Rungruangsiripan et al., 2011) and bipolar disorder (Lauder et al., 2015), however much lower than MOS-SSS scores reported in non-SMI populations including a mean score of 70.1 in people with chronic conditions in the USA (Sherbourne & Stewart, 1991) and a mean score of 80.9 in cancer patients in the UK (Haviland et al., 2017). Previous research has also found that approximately a third of people with SMI reported a lack of emotional support as well as small and un-diverse social networks (Bengtsson-Tops & Hansson, 2001; Pinfold et al., 2015)

The average number of people in the social networks of my study sample was 4.7; much lower than has been reported in previous studies with SMI populations (Albert et al., 1998; Palumbo et al., 2015). This may have been because previous work was conducted in populations who were in contact with mental health services, whereas my sample was recruited from primary care. It may be that having extra support from mental health services allows people to maintain their social connections and also means that mental health professionals are included within these networks. Only 40% of my sample had a mental health support worker which is lower than reported in previous work (Reilly et al., 2012). This lower number of people in touch with mental health services in my sample could be due to a reduction in service provision due to austerity and budget constraints (Cummins, 2018), or my sample may have been healthier or more stable in their mental health than the sample in the previous study, and therefore less likely to be in contact with mental health services.

Previous work has found that people with SMI identified their GPs and mental health workers as part of their social network and those who had known them for longer reported feeling close to them, that the relationship had a positive effect on their wellbeing and they felt significantly more satisfied with their social networks (Pinfold et al., 2015). The value of continuity of care for people with SMI has been emphasised by qualitative studies, with ongoing personal relationships reported to facilitate trust and be central for mental health recovery (Biringer et al., 2017). Previous work in non-SMI populations has also found that nurse led interventions significantly improved perceived social support in intervention groups compared to controls for people with chronic heart disease (Cui et al., 2019) and diabetes (Azami et al., 2018; Spencer-Bonilla et al., 2017). An analysis of qualitative interviews conducted with a sub sample of PRIMROSE health providers and patients found that some patients and staff had formed close relationships and that this had a positive impact on engagement with the intervention (Hassan et al 2019).

For the purpose of this discussion chapter, I went back to my data and explored the stability of the MOS-SSS score over time in the PRIMROSE samples. I found that perceived social support scores increased in the intervention group (from 52.39 at baseline to 58.98 at six-month follow up) compared to the control group (59.18 at baseline and 60.78 at six-follow up). At 12-month follow up (six-months after the end of the intervention period), perceived social support scores decreased slightly in the intervention group (55.17) and remained stable in the controls (59.45). This suggests that participants may have missed the contact with intervention providers and may have felt less supported once the intervention ended. These findings taken together might suggest that those who are in regular contact with a consistent health professional may feel more supported in general, with my thesis demonstrating that practice nurses/HCAs may have a key role to play in encouraging people with SMI to explore and use their existing support networks to maintain healthy behaviours, as well as offering to act as a supportive other in their own right for those who do not have anyone in their network to support them.

6.3 Strengths and limitations of overall thesis

The strengths and limitations of each individual study contained within this thesis are described at the end of each study chapter. Here I describe some of the strengths and limitations of the body of work as a whole.

A major strength of this thesis was that it was embedded within a wider programme of work, with the aims, methods and analysis plans developed prospectively rather than retrospectively. I was able to develop my ideas alongside the PRIMROSE programme and incorporate my aims, methods and data collection tools into each work package. Part of the inspiration for this thesis emerged from the focus groups that I conducted in 2012 as part of the earlier PRIMROSE development work. It was in these focus groups that discussions around social support emerged as a strategy to help improve engagement with primary care and CVD risk reducing behaviours. I was then able to explore this finding further through literature and policy reviews to ensure that social support was integrated into the development of the PRIMROSE manual and training programme, as well as incorporate additional data collection tools into the main trial before the trial commenced, so that I could explore the link between social support and health behaviours. I was also able to develop the aims for my qualitative study on social support within first intervention appointments before the data were collected.

Embedding my thesis within a wider programme of work also had some limitations. I had to carefully plan my work around the programme timescales to ensure that each element of my thesis was incorporated into the development work and the data collection for the main trial, and I had to limit the amount of additional data that I collected in order to minimise burden on the participants completing the assessments. Also one key limitation to this work was the difficulty in isolating the impact of social support on health outcomes both in terms of measuring associations between social support and health outcomes and teasing out the specific effects of social support within multi-component interventions. It was not, for example, possible within the wider programme of work to impose an experimental design that compared the PRIMROSE intervention with social support against the PRIMROSE intervention without social

support. Also, the samples described in chapters four and five of my thesis had all been recruited to take part in a trial of a new CVD risk reduction service (PRIMROSE), which might have made them unrepresentative of the population of people with SMI in general. I would not however have had the time or resources to recruit a new sample specifically for my PhD.

The process of developing health interventions needs to be described with sufficient detail to enable clinicians to implement effective interventions in practice, as well as allow researchers to test and advance published research findings (Hoffmann et al., 2014). However, a review of 137 non-pharmacological interventions tested within clinical trials found that only 39% of reported studies described the intervention well enough for it to be replicated (Hoffmann, Erueti, & Glasziou, 2013), despite CONSORT guidelines recommending that intervention components should be described for replication purposes (Moher et al., 2010) and the availability of established guidelines to support researchers to report intervention content (Hoffman et al., 2014).

A strength of my thesis was that I followed the MRC guidelines on complex intervention development (Craig et al., 2008) and conducted focus groups, workshops and carried out a review of current interventions and national health policy, considering theoretical models for social support and health to guide the development of a social support component to the intervention. I described the content of this strategy in detail and how it was incorporated into the PRIMROSE intervention and the manual is available to download online: www.ucl.ac.uk/primrose. I then went on to evaluate how this strategy was implemented within a large qualitative dataset of first intervention appointments.

While the evidence base is growing for interventions aimed at improving the cardiovascular health of people with SMI (Druss et al., 2017; Gaughran et al., 2017; Gilbody et al., 2019; Holt et al., 2018; Westman et al., 2019), none of these interventions described involving the social networks of people with SMI to help improve engagement with healthy lifestyle behaviours. One study did however acknowledge the importance of social comparison as a motivating factor for behaviour change and suggested that future research might deliver weight reduction interventions to family members and

patients together (Holt et al., 2018). My thesis is therefore a first attempt at developing, incorporating and describing how health professionals might be guided to explore social networks within interventions aimed at helping people with SMI participate in CVD risk reducing behaviours. This approach to actively investigating the involvement of supportive others could be adapted and incorporated into future interventions for people with SMI and raised CVD risk factors. Liu and colleagues (Liu et al., 2017) recognised that social support was a potentially important element of any multilevel intervention that seeks to improve CVD health outcomes in this population, both in terms of harnessing existing support through family interventions as well as developing new connections through peer support programmes.

6.4 Future research

6.4.1 Further exploration of the current dataset

Further exploratory analysis on the observational dataset might help to isolate the potential impact of perceived social support at baseline on my primary outcome of appointment attendance at six-month follow up. Attendance could be categorised as attendance at no appointments versus attendance at one or more appointments to determine any effect of additional perceived support from the health provider on subsequent attendances. Alternatively, a supplementary analysis could control for perceived social support at six-month follow up to tease out any potential effect of the practice nurse/HCA on perceived social support and appointment attendance. Perceived social support scores could be categorised into low versus high support to examine the distribution of intervention uptake, particularly among those with low perceived social support.

Social support made up a small part of the overall intervention appointments in my qualitative study, and as a result, the focus of discussions was not only on social support, but included a range of strategies designed to engage the participant. A large amount of the data were therefore not included in my analysis as it was not relevant to the aims of my study. Future work could analyse this dataset in full to determine which behaviour change strategies were perceived to be most useful to participants and which strategies

used by health providers in the first appointments were related to subsequent appointment attendance. This was however too broad a question for the current thesis.

Further exploration of the follow up intervention appointments would determine the potential impact of involving supportive others on progress with health goals over time, and whether decisions made in the first appointment about involving supportive others were followed through, adapted or subsequently ignored in later appointments. The PRIMROSE trial found that psychiatric inpatient admissions were reduced in the intervention group compared to the control group (Osborn et al., 2018) and further analysis of subsequent appointments may help to unpick this finding and determine whether practice nurses/HCAs were offering emotional support to their patients and participating in discussions about mental health. Very few discussions around mental health and emotional support occurred in the first appointments, however as the intervention progressed and the relationships between the health providers and patients developed, emotional needs may have been more readily explored, which might then help to explain the reduction in admissions in the intervention group.

Conversation or discourse analysis techniques would be a useful lens with which to further explore interactions, negotiations and decision making processes between health providers and participants (Maynard & Heritage, 2005) to determine how they navigated discussions around involving supportive others and how their communication styles may have influenced the decision making process. Further research focusing on the interactions and conversations that emerge when supportive others are present in health appointments would also help to determine both the positive impact and the potential difficulties their presence may bring to the consultation. Both of these suggested areas of future work could inform training programmes for health providers to enhance their communication skills (Pilnick et al., 2018) and help them navigate potentially difficult interactions with patients and their family members.

Further secondary analyses of first appointments could explore the nature of the relationships being formed between health providers and patients, whether the support being provided by the health provider led to attendance at subsequent appointments

and how support was provided over time by the health provider. This question would be best explored through either a conversation analysis to understand how different conversational styles may have influenced attendance (e.g. directive vs passive, negotiations of different viewpoints, agreements and disagreements) or an exploration of the wider literature on therapeutic relationships and attachment theory to develop an analysis framework which could then be applied to first and subsequent appointments to see if different relationship styles were present, how these relationships may have affected outcomes, and how relationships between health providers and patients may have changed and developed over time.

Linking the appointment data to outcomes would also be a useful next step to determine if those who involved supportive others in working on their health goals in the intervention group had improved health outcomes at follow-up than those who did not involve them.

6.4.2 Further work on social support and health outcomes

Future quantitative work could assess the relationship between perceived social support and objective measures of health behaviours such as a pedometer to measure physical activity, carbon monoxide monitor to measure smoking and pill counts or prescription records to measure adherence to medications rather than self-report measures. Future research should seek to recruit a larger sample size in a bespoke cohort, representative of the wider population of people with SMI. It would for example be informative to impose fewer inclusion criteria to test the relationship between social support and CVD risk reducing health behaviours in people with SMI, for example people who have one or more CVD risk factors, rather than specifying that they have to have raised cholesterol and one other risk factor.

While there may have been a small effect of social support on appointment attendance, this association was not detected once confounders were accounted for in the analysis. This association should therefore be explored further in a larger sample of people with SMI and raised CVD risk factors.

Further RCTs could explore the effectiveness of CVD risk reducing interventions that encourage the use of social support or aim to improve relationships in people with SMI to help them to participate in healthy lifestyle behaviours. Any future trials of health interventions augmented with social support should specify a control group that tests the same health intervention without social support as a component in order to isolate the impact of involving supportive others. Future interventions could explore whether delivering CVD health interventions jointly to patients with SMI and their supportive others might help with enlisting their support by directly tackling the potentially negative influences of family and friends on the patient's health behaviours. Delivering interventions in this way without offering flexibility however would exclude patients who do not identify anyone in their network or who actively want to pursue health goals on their own. Further qualitative work would also allow for an in depth exploration to aid our understanding of how supportive others can be most usefully involved and in what contexts for CVD risk reduction for people with SMI.

To date, a number of recent studies in the field of CVD risk reduction for people with SMI have tested the effectiveness of behavioural interventions on CVD health outcomes (Druss et al., 2017; Gaughran et al., 2017; Holt et al., 2018), one of which was the PRIMROSE trial (Osborn et al., 2018). None of the interventions were superior to routine care on reducing CVD risk factors such as weight, smoking, HBA1c or cholesterol, and only the PRIMROSE trial explicitly reported social support as an intervention component (Osborn et al., 2018). Further work is urgently needed to identify effective intervention components that tackle the increasing health inequalities that people with SMI face in terms of their cardiovascular morbidity and mortality (Hayes et al., 2018).

6.5 Implications for clinical practice

6.5.1 The role of primary care in assessing support needs

The finding that perceived social support was associated with adherence to medications highlights the potential importance of involving supportive others in supporting medication taking and in identifying those who have low social support to help prevent disengagement and non-adherence to treatments.

National Clinical Guidelines suggest that involving supportive others in appointments can help build a more comprehensive picture of the patient and their health needs. While only two patients brought a family member to their first intervention appointment in my qualitative study, in both appointments, the supportive other offered information about the patient's health and lifestyle which may not have emerged had the patient attended the appointment alone. Decisions were ultimately reached that involved the family member agreeing to support the patient to achieve their chosen health goal, however occasional conflicts did occur, which may be difficult for health providers to manage in clinical settings, where consultation time is limited and where they may lack the skills to manage conflict. This potential issue was also raised by health professionals in the focus groups described in chapter three of this thesis (Burton et al., 2015). Nevertheless consulting the patient and family member or friend together should be considered as a strategy for engagement in primary care consultations and in decisions around medication and medication adherence for people with SMI.

The finding that perceived social support was not associated with participation in any other healthy lifestyle behaviours in people with SMI suggests that relying on social support alone, without further intervention, may not be effective in changing lifestyle behaviours in this population. Health practitioners may need to do more to help people with SMI understand the benefits of involving supportive others and explore with them the different ways that they can be involved to help promote participation in physical activity, healthy eating, stopping smoking and reducing alcohol intake.

As demonstrated by my development work and in my qualitative analysis, patients may choose not to involve anyone to support them to make changes to their health, they may not feel supported by people in their social networks, or supportive others may even have a negative influence on health behaviours such as alcohol use, smoking and diet. It is therefore important for clinicians to explore the nature of patient relationships and involve them only as an optional component of health interventions. In my qualitative study however, while some health providers identified and explored alternative mechanisms of support for those who had nobody, or for those who chose

not to involve others in supporting them, other health providers seemed uncomfortable when faced with these conversations and avoided or moved on to a different topic. Training should be provided to improve primary care health provider confidence in discussing potentially upsetting or difficult topics with patients and in identifying local resources for isolated patients to access. Providing primary care services with information on community or voluntary services and support groups to refer people to who present as lonely might assist health providers to grow in confidence in having these potentially difficult conversations.

This thesis originally set out to investigate the impact of positive aspects of social support on CVD health behaviours in people with SMI and whether these relationships could be used to help people live healthier lifestyles, rather than address loneliness or negative support. My finding however that perceived social support scores on the MOS-SSS were lower than for general populations in other studies, and that a third of my qualitative sample chose not to involve anyone in helping them to achieve their health goals either because of the presence of unsupportive others or because they did not have anyone to involve warrants further investigation of how best to support those with limited social networks. It may be that closer management by health providers is required for those patients lacking sufficient support systems to overcome the challenges associated with making healthy lifestyle changes.

There has been a growing interest and body of literature on the negative impact of loneliness on health outcomes in SMI populations and interventions that aim to tackle this (Mann et al., 2017). In previous literature, a number of people with SMI have reported the presence of health professionals as an important part of their social networks (Bengtsson-Tops & Hansson, 2001; Pinfold et al., 2015). In a sample of 150 people with SMI, 42% reported that these relationships had existed for over five years (Pinfold et al., 2015). For those who have limited support from family or friends, continuity of care from health professionals may play an important role for those who are lonely or have limited contact with friends or family. In the PRIMROSE trial, while the intervention did not have an impact on physical health outcomes, the number of psychiatric admissions in the intervention group was significantly lower than in the control at 12-month follow up (Osborn et al., 2018). While we do not know the

mechanism for this finding, it is possible that those in the intervention group felt more supported by having increased and continuous (fortnightly to monthly) contact with a named practice nurse/HCA over a six-month period which may have reduced their need for inpatient care.

While my thesis set out to explore the impact and availability of existing support, one unexpected finding was that a number of practice nurses/HCAs offered to act as the supportive other themselves. Previous work has described the evolution of the nursing role from one of being clinical and detached, to a more informal partnership with the patient and family which can be seen as a form of befriending (Perese & Wolf, 2005). Training should emphasise that primary care health providers are a potentially vital source of support for patients with SMI who do not identify anyone in their social network or who have low perceived social support, particularly those who are not in receipt of mental health services. Recent evidence suggests however that continuity of care is being eroded in primary care (Close et al., 2018), and while GPs have acknowledged the importance of social networks in recovery of people with SMI, barriers to facilitating these networks included work pressures, lack of knowledge on existing support services, administrative bureaucracy and diminishing resources and services (Perese & Wolf, 2005; Pinfold et al., 2015). Nevertheless all but one practice nurse/HCA in my qualitative study were able to explore social networks within their consultations and most health providers offered continuous appointments to participants within the PRIMROSE trial (Osborn et al., 2018). Support might therefore be best tailored to the needs of both the health provider and the patient through a stepped approach. Simple algorithms could be developed that encourage the health provider to consider different options for involving others depending on the individual patient's circumstances. Consultations could begin with an exploration of the patient's social network and a plan to involve others if support is identified; troubleshooting of negative influences and targeting both the supportive other and patient to make changes together if possible. Health providers could then assess support needs and, if needed, explore potential group activities or community services for onward referral to increase access to social support for people with SMI, as well as meet their health needs. Only in those cases where no support is available and support services may not be suitable, the

health provider could then offer to provide more intensive support directly to the patient.

6.5.2 Alternative models of care to help those with limited support

My qualitative analysis of first intervention appointments identified that for some patients, access to social support to help them participate in healthy lifestyle behaviours is limited. Social prescribing is an emerging service that could bridge the gap between socially isolated individuals and community services and relieve the workload of primary care practitioners (Drinkwater, Wildman, & Moffatt, 2019). NHS England describes social prescribing as the presence of a support worker who holistically assesses people's health and wellbeing and puts them in touch with local community services that provide practical and emotional support (NHS England, 2019). It is recommended for people with long term conditions, mental health problems and people who are socially isolated, however evidence for the effectiveness of social prescribing is currently lacking as it is a relatively new concept (Husk et al., 2019). It has been suggested that primary care networks will however be given funding to employ a full time social prescriber from 2019 onwards (Drinkwater et al., 2019) and plans to evaluate these schemes are evolving (NHS England, 2019).

A collaborative care model whereby a mental health worker is situated within GP surgeries to support the healthcare needs of people with SMI is another promising model of care that is currently being tested (Baker et al., 2019). Mental health professionals may be well placed to enhance existing social networks and provide direct social support to improve both physical and mental health outcomes in this population.

Peer support interventions whereby an individual with lived experience is employed to support people with the same health problem through their recovery, are receiving further attention. Peer support was recommended by lived experience advisors to the PRIMROSE study as a resource to encourage engagement with CVD risk reducing behaviours (Gray, Larsen & Faulker, 2013), however this was beyond the remit of my thesis as my focus was on exploring and using existing support. Peer interventions have

however shown some promise in supporting recovery and reducing psychiatric inpatient admissions in people with SMI, however they had no impact on loneliness or social network size at 18-month follow-up (Johnson et al., 2018). Two studies were identified that tested peer support interventions for people with SMI and targeted their physical health, with one study finding that those in a peer led health recovery group had improved quality of life but not improved diet or medication adherence compared to controls at six-months (Druss et al., 2018). A small feasibility study focusing on both psychiatric and physical comorbidities in ten older adults (60+) with SMI and medical comorbidities tested a peer supported digital app which included modules to support recovery and illness management (Fortuna et al., 2018). One module was dedicated to building and using social support to help self-management. The study found pre/post-test improvements in both psychiatric and chronic health condition management as well as increased perceived social support from baseline to three-month, post intervention follow-up (MOS-SSS=46.13 at baseline, 53.53 at follow-up).

Interventions that directly educate people with SMI on how they can best use their existing social support networks to help manage their own health as well as build new connections or access support from a peer support worker or health professional are worth further investigation. Future interventions should harness existing support networks as well as identify those who have limited social support and who may benefit from contact with supportive peers.

6.6 Key recommendations for a new social support intervention for supporting CVD risk reduction in people with SMI

The social support elements of the intervention developed for the purpose of this thesis were part of a broader intervention that incorporated a number of behaviour change strategies for practice nurses and HCAs to help people with SMI reduce their CVD risk. Future interventions could focus more specifically on how existing social networks might help or hinder people with SMI to achieve healthier lifestyles. In Table 6.1 and in the text below I summarise the intervention components that should be retained or developed further as part of the learning from my PhD, as well as additional intervention

components suggested by the wider literature that could be considered in the design of a new social support intervention to help people with SMI reduce their CVD risk.

Table 6.1. Key recommendations for a new social support intervention for reducing CVD risk in people with SMI

Retain component from the current intervention	Develop intervention component further	New intervention component
Ask who is in the patient's social network and explore how they can be involved at the first appointment	Map the patient's social network to identify the presence of positive, negative and neutral influences at the first appointment. Revisit the social network in subsequent appointments	Involve a peer supporter (Johnson et al., 2018; Druss et al., 2018) and/or refer to social prescribing initiatives (Drinkwater, Wildman, & Moffatt, 2019) for those who lack support
Optional component for the supportive other and patient to attend appointments together	Deliver intervention appointments to both the patient and supportive other unless the patient does not consent to this.	Peer supporter to attend the intervention appointments with the patient (8)
Record who should be involved and how on the action plan	Health professionals explicitly share action plans with supportive others (with patient consent)	Health professional explicitly share action plans with peer supporter (with patient consent)

The findings from my analysis of first intervention appointments suggest that health professionals are able to have structured conversations with patients about their social networks and how they might support healthy lifestyle changes. Rather than a specific focus on who can help however, a new intervention should go further by training health professionals to explicitly map the patient's social network at the beginning of the intervention and to identify whether each member of the patient's network is a positive, neutral or negative influence for CVD risk reducing behaviours. This would help the health professional and patient to map who should be involved and how, and determine whether the behaviour of the supportive other also needs to be targeted by the intervention.

As a number of patients in my study identified a lack of support to improve their health, the initial appointment should involve a direct exploration of the presence of any negative social contacts. Strategies should then be developed and used by the health professional to mitigate these influences (e.g. identification of alternative support mechanisms or delivery of the intervention to the patient and relative together). Action plans could be explicitly shared with supportive others so that progress towards goals is monitored together, and appointments could be set up so that the patient and supportive other meet with the health professional together to explore their involvement and progress.

The wider literature suggests that peer support (Johnson et al., 2018; Druss et al., 2018) and/or social prescribing (Drinkwater, Wildman, & Moffatt, 2019) are promising initiatives for people who lack social contacts. Further research should assess the feasibility of including these initiatives within a new intervention as potentially alternative support mechanisms for those who lack a supportive network.

6.7 Conclusions

Social support may be an important facilitator for adherence to CVD medications; however, there was no evidence for an association between greater perceived social support and greater physical activity, healthier diet, being a non-smoker or lower alcohol use, and limited evidence for an association with greater attendance at appointments, which disappeared on adjustment for potential confounding factors.

A clear gap in the literature was identified of high quality studies of interventions that involved supportive others and targeted non-psychiatric outcomes in people with SMI, specifically adherence to CVD risk reducing medications, attendance at health promotion services and interventions to increase physical activity, reduce smoking and alcohol use and improve diet. Further work is needed to identify the effectiveness of social support within interventions aimed at improving health behaviours in people with SMI that are evidence and theory based and clearly describe how social support is integrated and used within interventions. There is a need for health interventions to

isolate the effect of social support on health behaviours by testing them against a control group of the same intervention without the social support component.

I developed and embedded social support as a strategy for engagement within the PRIMROSE intervention for improving CVD risk factors in people with SMI in primary care. These strategies were based on the premise that patients with SMI should be given a guided choice over involving supportive others in their care and how to involve them. Health providers were able to deliver these strategies in the majority of their first appointments with patients. Further communication skills training and the provision of information on community services and local support groups would enable health providers to identify people without social support or people with negative influences in their lives and equip them to explore alternative support mechanisms to enable them to better self-manage their physical health.

Existing social support could be targeted within CVD risk reducing interventions to help increase uptake and engagement, in particular for adherence to CVD risk reducing medication. Alternative interventions that provide additional support from peers or paid health or social workers may be needed to provide support for people with SMI who have low perceived social support. Primary care health providers have a potentially important role in providing social support to people with SMI who have limited social networks.

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**Appendix 1: Overview of the PRIMROSE programme work packages
(PGfAR RP-PG-0609-10156)**

Work Package Title	Summary
<p>Work package 1: development and validation of a risk model for predicting cardiovascular disease events in people with severe mental illnesses.</p>	<p>A CVD risk prediction tool was developed and validated for people with SMI using data from The Health Improvement Network (THIN) UK primary care database. The cost-effectiveness of the tool was also evaluated.</p>
<p>Work package 2: development of a practice nurse-/health-care assistant-led intervention for lowering levels of cholesterol and reducing cardiovascular disease risk in people with severe mental illnesses.</p>	<p>Focus groups and systematic reviews were used to inform the design of the PRIMROSE intervention and training programme.</p> <p>Differences in statin prescriptions in primary care were investigated between 25,246 people with SMI and 125,825 people without SMI in the UK THIN database. The effectiveness of statins for primary prevention of CVD was also investigated.</p>
<p>Work package 3: evaluation of a practice nurse-/health-care assistant-led intervention for lowering levels of cholesterol and reducing cardiovascular disease risk in people with severe mental illnesses in primary care – a cluster randomised controlled trial.</p>	<p>The clinical and cost-effectiveness of the PRIMROSE intervention was tested in a cluster randomised controlled trial with 326 people with SMI recruited from 76 GP practices. Fidelity to the intervention manual was assessed through analysis of a random 20% of audio transcribed intervention appointments.</p>

Appendix 2: Systematic review search terms: themes and corresponding medical subject headings and free text terms for each database

DATABASE: OVID MEDLINE (2798)	
MEDICAL SUBJECT HEADINGS	FREE TEXT
Theme 1: Severe mental illness	
Schizophrenia Psychosis Bipolar disorder Paranoid affective psychosis Psychotic disorders Mood disorders Paranoid disorders	Schizoaffective Schizo-affective delusional adj disorder\$ Bipolar adj2 disorder\$ Manic adj depress\$ Severe adj mental adj illness\$ Psychotic Psychos?s Schizophren\$ Affective adj disorder\$
Theme 2: Social support	
Social support Family Social network Friends Caregiver Parents Spouses Siblings Support worker	Carer\$ Unpaid adj2(care or support) Informal adj2(care or support) Social adj (network\$) Social adj (support) Caregiver\$ (family OR friend\$ OR spouse OR partner OR parent\$) adj4 support\$ Natural adj support Formal adj support
Theme 3: Adherence	
Patient compliance Treatment refusal Health care utilization Physical activity Exercise Diet Smoking cessation Health Behaviour	(Treatment OR medication\$ OR patient) adj2 (complian\$2 OR refusal OR adher\$3) Attend\$ adj3 (clinic\$1 OR appointment\$) Attend\$ adj3 service Health adj service\$ adj2 utiliz\$ Health adj service\$ adj2 utilis\$ health adj service\$ adj2 us\$3 physical adj activity diet healthy adj eating alcohol stop adj smoking health adj behavio\$ behavio\$ adj change

DATABASE: EMBASE and EMBASE CLASSIC (6783)	
MESH TERMS	FREE TEXT
Theme 1: Severe mental illness	
Schizophrenia	Schizoaffective

Bipolar disorder Psychosis Mood disorder Delusional disorder Schizoaffective psychosis Affective psychosis Manic psychosis	Schizo-affective delusional adj disorder\$ Bipolar adj2 disorder Manic adj depress\$ Severe mental illness\$ Psychotic Psychos?s Schizophren\$ Affective adj disorder\$
Theme 2: Social support	
Social support Family Social network Caregiver	Carer\$ Unpaid adj2(care or support) Informal adj2(care or support) Social adj (network\$) Social adj support Caregiver\$ (family OR friend\$ OR spouse OR partner OR parent\$) Natural adj support Formal adj support
Theme 3: Adherence	
Patient compliance Treatment refusal Health care utilization Physical activity Exercise Diet Alcohol Smoking cessation Health Behaviour Behaviour Change	(Treatment OR medication\$ Or patient) adj2 (compliance\$2 OR refusal OR adhere\$3) Attend\$ adj3 (clinic\$1 OR appointment\$) Attend\$ adj3 service\$ Health adj service\$ adj2 utilize\$ Health adj service\$ adj2 utilize\$ health adj service adj2 use\$3 physical adj activity diet healthy adj eating alcohol stop adj smoking health adj behavior\$ behavior\$ adj change

DATABASE: PSYCINFO (886)	
MESH TERMS	FREE TEXT
Theme 1: Severe mental illness	
Schizophrenia Bipolar disorder Psychosis Schizoaffective disorder Affective disorders	Schizoaffective Schizo-affective Delusional adj disorder\$ Bipolar adj2 disorder\$ Manic adj depress\$ Severe adj mental adj illness\$ Psychotic Psychos?s Schizophren\$ Affective adj disorder\$
Theme 2: Social support	

Social support Family Parents Spouses Siblings Friendship Significant others Social networks Caregivers	Carer\$ Unpaid adj2(care or support) Informal adj2(care or support) Social adj (network\$) Social adj support Caregiver\$ (family OR friend\$ OR spouse OR partner OR parent\$) adj4 support\$ Natural adj support Formal adj support
Theme 3: Adherence	
Treatment compliance Client participation Treatment refusal Health care utilization Physical activity Exercise Diets Smoking cessation Health Behaviour Behaviour Change	(Treatment OR medication\$ OR patient) adj2(complian\$2 OR refusal OR adher\$3) Attend\$ adj3 (clinic\$1 OR appointment\$) Attend\$ adj3 service\$ Health adj service\$ adj2 utiliz\$ Health adj service\$ adj2 utilis\$ health adj service adj2 us\$3 physical adj activity diet healthy adj eating alcohol stop adj smoking health adj behavio\$ behavio\$ adj change

DATABASES: CINAHL (1172)	
MESH TERMS	FREE TEXT
Theme 1: Severe mental illness	
Schizophrenia Bipolar disorder Schizoaffective disorder Psychotic disorders Affective disorders, psychotic Psychosis Delusional disorder Severe mental illness	Schizoaffective Schizo-affective Delusional disorder* Bipolar W2 disorder* Manic depress* Severe mental illness* Psychotic Psychos?s Schizophren* Affective disorder*
Theme 2: Social support	
Social support Caregiver Social networks Family or friends or friendship or relationships Carers Parents Spouse Siblings	Carer* Unpaid AND (care or support) Informal AND (care or support) Social network* Caregiver* (family OR friend* OR spouse OR partner OR parent*) W4 support* Natural support Formal W1 support

Significant others	
Theme 3 Adherence	
Medication adherence	(Treatment OR medication* Or patient) W2 (complan* OR
Medication compliance	refusal OR adher*)
Patient compliance	Attend* W3 (clinic* OR appointment* OR health service*)
Treatment refusal	Attend* W3 service
Appointment adherence	Health service* W2 utiliz*
Appointment attendance	Health service* W2 utilis*
Physical activity or exercise	Health service* W2 us*
Diet	physical W1 activity
Alcohol	healthy W1 eating
Smoking cessation	alcohol
Health Behaviour	stop W1 smoking
Behaviour Change	

DATABASES: Web of science (2102 results) and SPP (44)	
MESH TERMS	FREE TEXT
Theme 1: Severe mental illness	
	Schizophren* Bipolar adj2 disorder\$ Manic adj depress\$ Psychos?s Schizo affective Schizo-affective Delusional adj disorder\$ Severe mental illness\$ Psychotic Affective disorder
Theme 2: Social support	
	Social adj support Social adj network\$ Caregiver\$ Family OR friend* OR partner Or spouse OR parent* Carer\$ Unpaid adj2 (care or support) Informal adj2 (care or support) Natural adj support Formal adj support Support adj worker
Theme 3: Adherence	
	((Treatment or medication\$ or patient) adj2 (complan\$2 or refusal or adher\$3)) Patient adj compliance Attend\$ adj3 clinic Attend\$ adj3 service\$ Appointment attendance Health service attendance Health adj service\$ adj2 utiliz\$ Health adj service\$ utils\$ Health adj service\$ us\$3

	physical adj activity exercise diet healthy adj eating alcohol stop adj smoking health adj behavio\$ behavio\$ adj change
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Appendix 3: Systematic review data extraction form

1.General Information			2.Study Characteristics			3.Participant Characteristics					
Date of extraction	Complete Reference	Country	Study aims	Study design	Recruitment procedures	Unit of allocation	Participant population	Number of participants	Participant inclusion/exclusion criteria	Response rate	Carer population

4. Intervention and Setting			5. Outcome Measures							
Study setting	Description of the intervention	Relationship of supportive other	Primary outcome measure	Length of follow up	Secondary outcome measures	Analysis (Statistical techniques used)	Results - Primary outcome	Results - Secondary outcomes	Conclusions	Quality of evidence

Appendix 4: Health provider topic guide for the focus group study



Managing cardiovascular risk for people with severe mental illness: A focus group study: The PRIMROSE Programme.

Topic Guide

1. Introduction (5 mins)

The aim of this study is to explore your experiences and views on screening, identifying and managing cardiovascular disease risk in patients with severe mental illness. Your views today will help us to design a practice nurse led service and training programme that is acceptable and practically deliverable in the primary care setting. The service aims to reduce the risk of patients with severe mental illness developing cardiovascular disease. The cost effectiveness of the service will be tested and evaluated in a clinical trial over a period of one year.

We have consulted with a group of experts in cardiovascular disease and mental health to identify some of the key components that the service may include. This will help guide our discussion today, however we are interested in what you think the service should look like, your role is in delivering such a service, your views on the role of the practice nurse and how the service could be integrated in practice.

We are interested in all of your thoughts today, so please share any positive or negative views on the proposed service and training programme, what it might include and how it would work in practice.

Do you have any immediate thoughts/comments or questions before we start?

- b) anonymity of presentation of results
 - Introduce digital audio recorder
 - Stress confidentiality
 - Set ground rules

2. Introduce participants (10 mins) Start recording

a) *Introductory exercise, (whether participants want to use their first names or surnames, title or a pseudonym)*

b) *Ask each participant to say a little bit about themselves: What is their background/special interest. Why they agreed to come*

c) *Brief introduction to cardiovascular disease and SMI - Emphasise the need to explore and understand how to deliver this in real world primary care settings. Emphasise targeted screening and service at potentially a younger age than the general population.*

3. Knowledge and decision processes (15 mins)

- a) Talk me through how you currently screen for and manage CVD risk (in patients with SMI)
Opportunistic or in CVD clinic? – For people with current CVD or risk factors?
Annual physical health check for people on SMI register?
How often? What tests?
GP vs. nurse roles?
Access to supporting services (accessible stop smoking, exercise, diet or weight management for people with SMI?)
- b) When you have a consultation with a patient with severe mental illness, would you screen for and manage CVD risk?
- If not what are the reasons for this?
- c) Which CVD risk-reducing interventions do you think currently work (for this group)?
- d) Which CVD risk-reducing interventions do you think are less effective (for this group)?
- e) What do you think a practice nurse led service for screening, identifying and managing CVD risk in SMI patients should include?

4. Main discussion (60 mins)

Use the handout and feedback from Qn 3d to guide the group

A. Professional roles and identity

- a) What do you see as your role in screening and managing CVD risk in SMI patients?
What should the GP do? What should the nurse be responsible for?
- *How should the prescription of medications be organised between nurse and GP?*
- *Should/could it all be nurse delivered?*
- *How should/could tasks be divided? e.g. joint appointments?*
- *Who should the first appointment be with?*

- b) What support structures should be in place for practice nurses?
to screen and manage CVD risk?
to work with patients with SMI?

Arrangements and protocols for supervision/emergency situations/practicalities

B Beliefs about capabilities

- a) How confident would you feel in having a practice nurse led service for patients with SMI in your practice?
- *Are there any specific concerns around SMI patients?*
- *Are there any specific concerns about the service being run by nurses?*
- b) What, if any difficulties do you think your practice might have in running the service with patients with SMI?
- *If difficulties are identified, what would make it difficult?*
- c) What might help your practice overcome these difficulties?
- *(practical support, supervision, knowledge)*

C. Skills

a) What (if any) training and support would be helpful in working with SMI patients to enable your practice to run the service?

b) What training might nurses require?

Talking about severe mental illness/mental state examination or mental health risk assessment?

Talking about CVD risk/managing risk in SMI

c) How should this training be delivered?

Service user involvement?

Practical issues eg Location, timing etc

How long/over what period of time/before the trial begins/refresher training

Manuals/materials?

d) How should support be provided after the training period?

Manual/other materials/website?

Links via email/telephone/personal visits to practice?

Any other ideas?

D. Optimism

a) Do you think it is possible to achieve an effective practice nurse led service for patients with SMI in current circumstances?

E. Beliefs about consequences

a) What do you think the benefits might be of a practice nurse led service for patients with SMI?

- For staff? For patients?

-

b) What do you think the disadvantages might be of a practice nurse led service for patients with SMI?

- For staff? For patients?

F. Reinforcement

a) What factors might encourage screening and management of CVD risk for SMI patients (earlier than the general population)?

- Targets/ performance indicators

- Financial/ remuneration

- Motivation for people with SMI to attend?

- Any other factors?

G. Intentions

a) Having discussed the service would you offer it to patients with SMI if you had the opportunity to do so?

H. Memory, attention and decision processes

a) Are there any circumstances for which you might decide to exclude a patient with SMI from receiving the service?

- *Particular patients?*
- *Reasons why?*

b) Are there any circumstances in which you might forget to implement it?

I. Environment and resources

a) What resources are currently available in your practice that might facilitate a practice nurse led service to screen for and manage CVD risk in SMI patients?

Availability of nurse/reception/admin time to set up a service.

b) What additional resources might be required? c) Are there any competing tasks or time constraints that might influence whether a patient with SMI is referred to the service?

- *(resources, needs of patient/ other patients, availability of equipment/space)*

d) How often should cardiovascular risk reviews take place for people with SMI?

- *For those with identified risk factors for CVD?*
- *For those not yet identified as at risk?*
- *How feasible is this? Resources and time constraints*

e) How long should appointments be? (Initial and follow-up?)

f) How should patients be invited to take part?

- *Mail-out SMI register, all at once? In batches? Opportunistic?*

g) How can the practice encourage people to attend? (Eg text messages, reinforcement?)

- *What would you need to enable you to do this? (Eg posters, computer 'pop-ups')*

h) How would you manage non-responders/DNAs?

J. Behavioural regulation

b) Do you have systems that you could use for monitoring whether or not you/the practice nurse have carried out a review with SMI patients and provided subsequent follow up?

- *If not what would be useful?*
- *Prompts/reminders for invitation and monitoring - how would these prompts appear?*
- *How should information be recorded and monitored?*
- *Draw upon experiences in other long term condition management – e.g. diabetes.*

K. Social influences

a) What might help or hinder the implementation of a practice nurse led service?

- *Team attitudes (on SMI?)*
- *Team working – GP and nurse roles*

- *Organisational influences*

L. Emotions

a) Would you feel comfortable having a practice nurse led service for patients with SMI in your practice?

- *if no - why?*
- *What might help you overcome this concern?*

5. Conclude discussion (10 minutes)

I just want to finish by summarising the discussion and bring you back to the original list containing the service

- Are there any components on the list that you feel should not be on there?
- Is there anything that is not currently on the list that you feel should be part of the service?
- Are there any other comments?

|

GP Group handout:

1. Suggested GP input in to the intervention

1. Identify all people with SMI on the practice list (Administrator, Practice nurse or GP?)
2. Invite all people with SMI on the practice list to attend a cardiovascular screening appointment (Administrator, Practice nurse or GP?)
3. Screen patient for cardiovascular disease risk factors, including arranging blood tests (Practice nurse or GP?)
4. Prescribe statin
5. Refer the patient to a practice nurse led service
6. Authorise referrals/refer patients with risk factors to external services (e.g. dietician, exercise on prescription, smoking cessation).

2. Suggested components of a practice nurse led intervention for reducing CVD risk in patients with severe mental illness in primary care

1. Identify all people with SMI on the practice list (Administrator, Practice nurse or GP?)
2. Invite all people with SMI on the practice list to attend a cardiovascular screening appointment (Administrator, Practice nurse or GP?)
3. Screen patient for cardiovascular disease risk factors including health measurements (BP, weight, waist circumference, blood tests), (Health care assistant, Practice nurse or GP?)
4. Provide health information and lifestyle advice (such as diet, weight, smoking, alcohol use) (Practice nurse)
5. Identify one key behaviour change goal with the service user (Practice nurse)
6. Refer to support services as required by the individual (e.g. smoking cessation) (Practice nurse)
7. Organise prescription of statin
8. Follow up with psychiatrist/GP if problems with antipsychotic medication are flagged by the service user (adherence/side effects/adverse effects)
9. Arrange follow up and monitoring of risk factors, adherence to statins, attendance at support clinics or participation in behaviour change interventions.
10. Identify non attenders and follow up.

Appendix 5: Patient and carer topic guide for the focus group study



Managing cardiovascular risk in people with SMI: A focus group study: The PRIMROSE Programme.

Topic Guide

1. Introduction (5 mins)

a) *nature and purpose of research*

Firstly, thank you very much for coming and taking part in this discussion today, we really appreciate you giving up your time to talk to us. Please be honest and open about your views on this area, there are no right or wrong answers so any thoughts or comments you have please feel free to share them with the group. Thank you.

The aim of this discussion is to explore your experiences and views on how you feel health care is managed in GP practices for patients with mental health problems. Your views today will help us to design a service carried out by nurses working in GP practices, which you would find acceptable and useful. The service will be aimed at supporting people with mental health problems to reduce the risk of them gaining weight, developing heart disease, diabetes and stroke. We will be testing whether the service that we develop works in a future study.

Do you have any immediate thoughts/comments or questions before we start?

b) *anonymity of presentation of results*

- Introduce digital audio recorder
- Stress confidentiality
- Set ground rules

2. Background (10 mins) Start recording

- *Introductory exercise, (whether participants want to use their first names, last name and title or a pseudonym) Ask people to write on badge/sticker*
- *Ask each participant to say a little bit about their experiences as a service user and their health*
- *Brief introduction to key issues in cardiovascular disease and MH – Emphasise 1) the need to explore and understand how to deliver CVD risk screening and management in GP practices for patients with SMI. 2) health inequalities for people with SMI. 3) Brief introduction of policy, evidence and potential treatments (medication, support services and early intervention)*

3. Accessing services (Opportunity) (15 mins)

- a) What are your experiences of accessing your GP or nurse at your GP surgery?
- b) What has worked well?
- c) What hasn't worked well?

4. Capability (15 mins)

- a) What would you like to know about the risks of developing heart disease, stroke or diabetes?
- b) What sorts of things are you doing to look after your physical health?
- c) What services have you accessed to look after your physical health?

5. Opportunity (15 mins)

- a) What support would you need to be able to attend a nurse led service?
 - Practical/social (carers, family and friends)
 - health team (CMHT, GP, practice nurse, psychiatrist)
- b) What would the GP practice need to do to make it easier for you to take part in the service?

6. Motivation (45 mins)

Introduce hand out to group members – brief description of each stage. Check the group understand and/or have any questions

- a) If this service was available, would you want to take part in it? (*Refer to handout*)
 - How often would you attend follow up appointments if risks were identified? (*Initial appointment, screening, reviews, monitoring prescriptions and taking medication, re-assessment after medication is prescribed etc*)?
- b) Is there anything you would not want to do?
 - If yes why?
- c) Is there anything that might help you to take part in the service?
 - What might make it easier?
 - What might make it difficult?
- d) Is there anything that is not included that you think should be?
 - What? Why do you think it is important?
- e) If the evidence suggests that people with mental health problems should have access to medication for preventing heart disease, stroke or diabetes sooner than the general population:
 - What would you think about this?
- f) Would you take medications (such as statins) if you were at risk of developing heart disease?
 - if not/unsure why not? What might make you change your mind? – e.g. information on benefits/side effects
- g) Would you take this medication (e.g. statins) if the prescription was organised for you by the practice nurse?
 - If not why not?
 - What might help you to take statins from the practice nurse?
 - Would you take statins if your GP prescribed them to you?

7. Conclude discussion (10 minutes)

I just want to finish by summarising the discussion and run through some of the key issues you have discussed today. *Ask each participant in turn:*

- Is there anything that has not been discussed that you think is important to bring up now regarding this service?
- Is there anything that I have just mentioned that you think isn't important and should not be a key part of the service?
- Are there any other comments/questions or ideas?

Thank participants; reimburse them for their time and travel expenses; ask if they have further questions about the study.


/

Focus Group Handout

What might a practice nurse led intervention for reducing the risk of heart disease and stroke look like? It might include the following:

1. Be invited by your GP or nurse at your GP surgery to attend an appointment for health screening
2. Confirm with the GP practice that you can or can't attend the health screening appointment
3. Have a health check with your nurse or GP which may include the following things:
 - a. Having your blood pressure taken
 - b. Answering questions on foods you like to eat, how often or not you exercise why you might find exercising difficult, how often you might drink alcohol, whether you smoke and if you do how often and whether you know of any history of heart disease in your family.
 - c. Getting yourself weighed whilst you are there
 - d. Having your waist measurements taken
 - e. Having a blood test
4. You could be given health information and advice by the nurse which might include:
 - a. what you can do and what support might be available to help you reduce your weight
 - b. types of exercise you might like to do
 - c. support to help you cut down or give up smoking
 - d. support on cutting down or giving up drinking alcohol
5. Discuss taking medication (such as statins) to reduce the risk of developing heart disease, stroke or diabetes
6. Think about one key healthy choice you would like to make with the help of the nurse. This could be to help you cut down or give up smoking, eating healthier, losing weight or being more active
7. Discuss whether you would find it helpful to be referred to and attend appointments with specialist services or a support group if you feel that extra support would help. (For example a stop smoking service/group)
8. Attend follow up appointments with the practice nurse to monitor your physical health

Appendix 6: Ethical approval for the focus group study


National Research Ethics Service
NRES Committee London - Camden & Islington
REC Office
Maternity, Level 7
Northwick Park Hospital
Watford Road
Harrow
HA1 3UJ
Telephone: 020 8869 5446
Facsimile: 020 8869 5222

20 October 2011

Dr David Osborn
Senior Lecturer
University College London (UCL)
Charles Bell House
67-73 Riding House Street
London W1W 7EJ

Dear Dr Osborn

Study title: Prediction and management of cardiovascular risk for people with severe mental illness. A research programme and trial in primary care (PRIMROSE Programme).

REC reference: 11/LO/1479

Thank you for your letter of 19 October 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

This Research Ethics Committee is an advisory committee to London Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter	Letter to Ms Braley from Dr Osborn	24 August 2011
Investigator CV	CV for Dr David Osborn	01 August 2011
Other: CV for Ms Alexandra Burton		01 August 2011
Other: Letter to Dr Osborn from Rajinder Flora		30 September 2010
Other: Topic Guide - Service Users	1	27 June 2011
Other: Topic Guide - GPs	1	27 June 2011
Other: Topic Guide - Practice Nurses	1	27 June 2011
Other: Letter of Invitation - SU Mixed Group	2	19 October 2011
Other: Letter of Invitation - Service Users	2	19 October 2011
Other: Letter of Invitation - Staff	2	19 October 2011
Other: Email to Ms Braley from Ms Burton		19 October 2011
Other: Email to Ms Braley from Ms Burton		19 October 2011
Participant Consent Form: Primrose FG Consent Form	1	20 June 2011
Participant Information Sheet: CMHT Staff Information Sheet	2	19 October 2011
Participant Information Sheet: Service User - Mixed Group Information Sheet	2	19 October 2011
Participant Information Sheet: Nurse Information Sheet	2	19 October 2011
Participant Information Sheet: Service User Information Sheet	2	19 October 2011
Participant Information Sheet: GP Information Sheet	2	19 October 2011
Protocol	1	17 June 2011
REC application	83710/242854/1/461	08 August 2011
Referees or other scientific critique report	NIHR Peer Review Form (Reviewers 1-9)	
Referees or other scientific critique report	Primrose Peer Review	10 August 2011
Response to Request for Further Information	Letter to Ms Braley from Dr Osborn	19 October 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/LO/1479

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely



**Ms Stephanie Ellis
Chair**

Email: louise.braley@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Ms Angela Williams, Camden and Islington NHS Foundation Trust

Appendix 7: Health provider participant information sheet for the focus group study



**Information to participate in a research project:
Managing cardiovascular risk for people with severe mental illness: A focus group study: The PRIMROSE Programme.**

We are inviting you to take part in a research study. The information which follows tells you about the research and what will happen if you decide to take part. It is very important that you understand what is in this leaflet before agreeing to take part.

It is YOUR choice whether or not you take part.

Please ask any questions you want about the research and we will try our best to answer them.

▪ **Why have you been invited to take part in the research?**

We are asking you to take part in this research as you are a General Practitioner (GP) caring for people with severe mental illness.

▪ **What is the purpose of the research?**

People who have a severe mental health illness may be at higher risk of cardiovascular disease than the general population. The aim of this research is to explore your experiences of managing the physical health of patients with severe mental illness and to ask for your views on how this might be improved. We are interested in hearing what you think of this so that we can develop a training package for practice nurses and an intervention to help reduce the risk of cardiovascular disease in people with severe mental health illness. We will speak to GPs, nurses and service users with severe mental illness on this subject.

▪ **Who is organising the study?**

The study is being run by researchers at University College London (UCL). Camden and Islington NHS Foundation Trust are the lead NHS organisation for the study. The study has been funded by the National Institute for Health Research (NIHR) and is part of a five year programme grant.

▪ **What will happen to me if I take part?**

If you participate in the research, it will involve you discussing the topic in either a focus group with approximately nine other GPs or a mixed group of GPs and practice nurses. Two researchers will conduct the focus group which should last for a maximum of two hours. At the beginning of the discussion we will present background information on severe mental illness and cardiovascular disease to get you thinking about some of the key issues. We will also share with you a proposed intervention which will guide the main discussion. We will ask you your views on the proposed intervention and how this might be implemented in practice.

▪ **What will happen to the information you provide?**

During the focus groups, the discussion will be digitally audio-recorded and will be used to make recommendations on the type of intervention that might be used in primary care to reduce the risk of cardiovascular disease in people with severe mental illness. All information gathered during the study will be strictly confidential and any information about you will be anonymised after the focus group discussion so that you cannot be

recognised from it. You will be asked to respect the privacy of all individuals within the group and maintain confidentiality by not disclosing any of the information discussed outside of the group setting. Confidentiality will only be broken in the event of a disclosure of malpractice or if a disclosure is made which indicates that a participant or other individual is at serious risk. In the event of a disclosure of malpractice, the individual's employer will be informed.

All information will be stored in a secure locked filing cabinet and will not be used for any other research purposes. The only people who may see information about your part in the study are members of the research team. If you require more information about the study you may contact the researcher (At the bottom of this information sheet).

- **Are there any possible risks of taking part in this study?**

There are no identified risks of taking part in this study.

- **What are the possible benefits of taking part?**

You may value the opportunity to reflect on your experiences of managing the physical health of patients with severe mental illness. The information you provide will help us to develop an intervention to manage the risk of cardiovascular disease which we will implement with practice nurses working in GP surgeries as part of a clinical trial.

- **What if something goes wrong?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

In the event that something goes wrong and you are harmed during this study there are no special compensation arrangements. However, Camden and Islington NHS Foundation Trust as the legal sponsor of this study will give sympathetic consideration to claims for non-negligent harm suffered by a person as a result of a study, or other work supported by Camden and Islington NHS Foundation Trust.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any adverse events you may have experienced due to your participation in the research, the normal National Health Service complaints mechanisms are available to you. Please ask the researcher (contact details below) if you would like more information on this. Details can also be obtained from the Department of Health website: <http://www.dh.gov.uk>

- **Has the research been approved by an appropriate research ethics committee**

The research study has been reviewed and approved by National Research Ethics Committee London – Camden & Islington

Thank you for taking time to consider participating in this study. If you agree to take part, you will be given a copy of this information sheet and a copy of the signed consent form.

Further information can be obtained from:

Research Associate: Miss Alexandra Burton

Address: Charles Bell House, 67-73 Riding House Street, London, WC1W 7EJ

Telephone number: 02076799031

Email: a.burton@ucl.ac.uk

Appendix 8: Patient participant information sheet for the focus group study



**Information to participate in a research project:
Managing the risk of heart disease in people with mental health problems: A focus
group study: The PRIMROSE Programme.**

Please read this information carefully before signing the consent form. We are inviting you to take part in a research study. The information which follows tells you about it and what will happen if you decide to take part. It is very important that you understand what is in this leaflet before agreeing to take part.

It is YOUR choice whether or not you take part. If you choose not to take part this will not disadvantage you in any way

Please ask any questions you want about the research and we will try our best to answer them.

- **Why have you been invited to take part in the research?**
We are asking you to take part in this research as you have a mental health problem and may also suffer from heart disease or related physical health problems. You may also have an interest in how your physical health needs are cared for by your General Practitioner (GP).
- **What is the purpose of the research?**
People who have a mental health problem may be at higher risk of developing heart disease or having a stroke. They may also be less likely to have their physical health needs assessed by their GP. The aim of this research is to explore your experiences of how your physical health is managed by your GP or practice nurse and ask for your views on how this might be improved. We are interested in hearing what you think of this so that we can develop a training package for practice nurses and a service to help reduce the risk of heart disease and stroke in people with mental health problems.
- **Who is organising the study?**
The study is being run by researchers at University College London (UCL). The research team contact details are at the bottom of this information sheet. Camden and Islington NHS Foundation Trust are the lead NHS organisation for the study. The study has been funded by the National Institute for Health Research (NIHR) and is part of a five year programme grant.
- **What do I do if I take part?**
If you participate in the research, it will involve you taking part in a group discussion with eight service users. Two researchers will conduct the group discussion which should last for a maximum of 90 minutes. At the beginning of the discussion we will present background information on heart disease and stroke to get you thinking about some of the key issues. We will also share with you a proposed service which will guide the main discussion. We will ask you your views on the proposed service and how this might work in practice. You will be paid for your time and travel costs.
- **What will happen to the information you provide?**
The group discussion will be digitally audio-recorded and will be used to make recommendations on the type of service that might be used in primary care to reduce the risk of heart disease and stroke. All information gathered during the study will be strictly

confidential and any information about you will be deleted after the discussion so that you cannot be recognised from it. You will be asked to respect the privacy of all individuals within the group and maintain confidentiality by not discussing any of the information you hear outside of the group setting. Confidentiality will only be broken if something is said which suggests that a participant or another individual is at serious risk.

All information will be stored in a secure locked filing cabinet and will not be used for any other research purposes. The only people who may see information about your part in the study are members of the research team. If you require more information about the study you may contact the researcher (*Details at the bottom of this information sheet*).

- **Are there any possible risks of taking part in this study?**
There are very few risks involved in taking part. If you feel uncomfortable during the discussion, you can leave at any time. A researcher will be available to help you. You will continue to receive appropriate care and treatment if you take part in the study.
- **What are the possible benefits of taking part?**
You may value the opportunity to talk about your health and the issues that may be involved in reducing the risk of heart disease and stroke in people with mental health problems. The information you provide will help us to develop a service to manage the risk of heart disease and stroke in people with mental health problems which will be delivered by practice nurses working in GP surgeries. |
- **What if something goes wrong?**
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

In the event that something goes wrong and you are harmed during this study there are no special compensation arrangements. However, Camden and Islington NHS Foundation Trust as the legal sponsor of this study will give sympathetic consideration to claims for non-negligent harm suffered by a person as a result of a study, or other work supported by Camden and Islington NHS Foundation Trust.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any adverse events you may have experienced due to your participation in the research, the normal National Health Service complaints mechanisms are available to you (contact details below). If you would like more information on this details can also be obtained from the Department of Health website: <http://www.dh.gov.uk>

- **Has the research been approved by an appropriate research ethics committee**
The research study has been reviewed and approved by National Research Ethics Committee London – Camden & Islington

Thank you for taking time to consider taking part in this study. If you agree to take part, you will be given a copy of this information sheet and a copy of the signed consent form. If you would like a copy of the final summary report of the research please give your details to the researcher who will send you the information once the study is complete.

Further information can be obtained from:

Researcher: Miss Alexandra Burton

Appendix 9: Consent form for the focus group study



Managing cardiovascular risk for people with mental health problems: a focus group study: The PRIMROSE Programme. Participant Consent Form

Version Number: 1
Name of Researcher: Alexandra Burton



(The participant should complete the whole of this sheet himself/herself)
Please circle "YES" or "NO"

Have you read the participant information sheet (Dated 19/10/2011 Version 2)?	YES	NO
Have you had the opportunity to ask questions and discuss the study?	YES	NO
Have you received satisfactory answers to all your questions?	YES	NO
Who have you spoken to?	<input type="text"/>	

Do you understand that your participation is voluntary, and that you are free to withdraw from the study: at any time; without having to give a reason?	YES	NO
Do you agree to the focus group discussion being audio recorded?	YES	NO
Have you been told that strict confidentiality will be maintained:	YES	NO
Do you agree to take part in this study	YES	NO
Do you wish to receive a summary of the research findings?	YES	NO

<input type="text"/>	<input type="text"/>	<input type="text"/>
Name of participant	date	signature
<input type="text"/>	<input type="text"/>	<input type="text"/>
Name of person taking consent (if different from researcher)	date	signature
<input type="text"/>	<input type="text"/>	<input type="text"/>
Researcher	date	signature

Appendix 10: PRIMROSE appointment attendance record

Provider ID:												
Practice ID:												
Score as follows: 1 = Patient attended 0 = Patient did not attend n/a = Patient was not scheduled to attend												
	Appointment											
Patient ID	1	2	3	4	5	6	7	8	9	10	11	12

Appendix 11: Ethics approval for the PRIMROSE trial



Health Research Authority NRES Committee London - City Road & Hampstead

Bristol Research Ethics Committee Centre
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 01173421339
Facsimile: 01173420445

10 January 2013

Dr David Osborn
Reader in Community Psychiatric Epidemiology
University College London
67-73 Riding House Street
London
W1W 7EJ

Dear Dr Osborn

Study title:	Prediction and management of cardiovascular risk for people with severe mental illnesses. A clinical trial in primary care. (PRIMROSE)
REC reference:	12/LO/1934
IRAS project ID:	116410

Thank you for your letter of 08 January 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Miss Georgina Castledine, nrescommittee.london-cityroadandhampstead@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

A Research Ethics Committee established by the Health Research Authority

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		15 November 2012
Covering Letter		08 January 2013
Investigator CV		30 October 2012
Other: Summary CV for Student		01 August 2011
Other: Letter of invitation - Practice Managers	1	31 October 2012
Other: Screening Appointment Letter	1	31 October 2012
Other: Letter to mental health key worker	1	01 November 2012
Other: Letter to Carer	1	01 November 2012
Other: PG Standard Contract Cover Letter		30 September 2012
Other: Programme grants for applied research - peer review form		23 April 2012
Other: Letter of invitation - Service Users	2	08 January 2013
Participant Consent Form: Patient Consent Form	1	30 October 2012
Participant Consent Form: Practice Staff Consent form	1	30 October 2012
Participant Information Sheet: Practice Staff Information Sheet	2	08 January 2013
Participant Information Sheet: Service User Information Sheet	2	08 January 2013
Protocol	1	02 November 2012
REC application	3.4	20 November 2012
Response to Request for Further Information		08 January 2013

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed

A Research Ethics Committee established by the Health Research Authority

guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

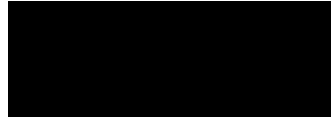
12/LO/1934

Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

Yours sincerely



Mr Hari Jayaram
Vice Chair

Email: nrescommittee.london-cityroadandhampstead@nhs.net

Enclosures: "After ethical review – guidance for researchers" [\[SL-AR2\]](#)

Copy to: *Ms Lynis Lewis*
Ms Angela Williams, North Central London Research Consortium

Appendix 12: Patient participant information sheet for the PRIMROSE trial



Managing cardiovascular risk for people with mental health problems: The PRIMROSE Trial

Information to participate in a research project

Please read this information carefully before signing the consent form. We are inviting you to take part in a research study. The information which follows tells you about it and what will happen if you decide to take part. It is very important that you understand what is in this leaflet before agreeing to take part. Please talk to others (friends, relatives, your mental health team or your doctor) about it if you want.

It is YOUR choice whether or not you take part. If you choose not to take part this will not disadvantage you in any way

Please ask any questions you want about the research and we will try our best to answer them.

- **What is the purpose of the research?**

People who have a mental health problem may be at higher risk of developing heart disease or having a stroke. They may also be less likely to have their physical health needs assessed by their GP. The aim of this research is to test a service delivered by a practice nurse or healthcare assistant that aims to reduce risk factors associated with heart disease or having a stroke. We want to compare the experiences of people who take part in the service with those who receive usual care from their practice nurse or healthcare assistant over a period of 1 year. This type of research is called a 'randomised controlled trial'.

- **What is a randomised controlled trial (RCT)?**

A randomised controlled trial (RCT) is the best type of research to test whether a new service is really helpful. To find out whether the service helps, we need to make comparisons between patients who receive the service and those who do not. General practices taking part in the study will be randomly allocated to one of two groups: One group of practices will continue to care for their patients in the usual way and the other group will be given specific training to provide advice and treatment plans to patients to reduce risk factors for heart disease and stroke.

- **Why have I been invited to take part in the research?**

The general practice that you are registered with has agreed to take part in the study. We are asking you to take part in this research as you have a mental health problem and your GP or practice nurse has identified that you may have some of the risk factors for developing heart disease or stroke in the future.

- **What will happen if I agree to take part in the research?**

1. A researcher from the study team will collect some basic medical information about you from your medical notes and will arrange for you to have a blood test to measure your cholesterol and glucose if you have not had one in the last 3 months. This data will be treated confidentially and recorded anonymously. The researcher will also ask you some questions about your mental health and the health services you have accessed recently and whether or not you would like your mental health worker and/or carer to be told you are participating in the research. You will be asked for your consent to give a saliva sample for future genetic research purposes. This will be to determine whether there is any DNA variation relevant to mental health and physical health outcomes. The sample will be stored at UCL laboratories or collaborating centres. You do not have to give this sample and it will not affect your participation in the study if you choose not to.
2. If your GP practice is chosen to provide the service, you will be invited to attend an initial appointment in which a treatment plan will be developed between you and the practice nurse or healthcare assistant. You will be asked if this treatment plan can be shared with your mental health key worker and/or carer. You will then be asked to attend regular appointments with your practice nurse or healthcare assistant to monitor your physical health over a 6 month period. Each consultation will be audio recorded so that the research team can assess whether the practice nurse or healthcare assistant is delivering the service properly and this will inform future training for nurses and healthcare assistant.
3. You will be invited to complete basic health assessments at 6 and 12 months after your initial appointment. This will include measuring your blood pressure, height, weight and waist size and asking you questions on smoking and alcohol use. A small sample of 10 ml of blood will also be taken from your arm to measure your cholesterol and glucose. At 12 months after your initial appointment you will also be asked questions about your mental health, health service use, medication use and satisfaction with services.
4. If your GP practice is *not* chosen to provide the service, you will continue to receive normal care. You will be invited to complete the basic health assessments described above at 6 and 12 months after your initial appointment. At 12 months after your initial appointment you will also be asked questions about your mental health, health service use, medication use and satisfaction with services.

- **Do I have to participate?**

No. It is entirely up to you to decide whether or not you want to take part. If you decide to take part, you will be given this information sheet to keep and you will also be asked to sign a 'consent form'. If you decide to take part, you will be free to stop at any time without giving a reason. Whether you decide to take part or not, or stop once the study has started, it will not affect the standard of your care or your rights in any way.

- **Will my participation be kept confidential?**

Yes. All information about you will be kept confidential and will be recorded anonymously. You will not be identified in any report or publication of the research findings.

- **Who is organising and funding the study?**

The study is being run by researchers at University College London (UCL). Camden and Islington NHS Foundation Trust are the lead NHS organisation for the study. The study is funded by the National Institute for Health Research's Programme Grants for Applied Research Programme (RP-PG-0609-10156)

- **Will I be paid to take part?**

To compensate for your time and travel expenses, you will receive £20 for completing the first and the final assessment and £10 for the 6 month follow up. You will receive a maximum of £50 for taking part in the research. You will be asked to sign a form to say that you have received this payment for taking part in the research.

- **What if something goes wrong?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

In the event that something goes wrong and you are harmed during this study there are no special compensation arrangements. However, Camden and Islington NHS Foundation Trust as the legal sponsor of this study will give sympathetic consideration to claims for non-negligent harm suffered by a person as a result of a study, or other work supported by Camden and Islington NHS Foundation Trust.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any adverse events you may have experienced due to your participation in the research, the normal National Health Service complaints mechanisms are available to you. If you would like more information on this, details can also be obtained from the Department of Health website: <http://www.dh.gov.uk>

- **Has the research been approved by an appropriate research ethics committee?**

The research study has been reviewed and approved by National Research Ethics Committee – City Road and Hampstead (REC Ref: 12/LO/1934)

Thank you for taking time to consider taking part in this study. If you agree to take part, you will be given a copy of this information sheet and a copy of the signed consent form. If you would like a copy of the final summary report of the research please give your details to the researcher who will send you the information once the study is complete.

Further information can be obtained from:

Researcher: Miss Alexandra Burton

Address:

Telephone number:

Email:

Lead investigator: Dr David Osborn

Appendix 13: Patient consent form for the PRIMROSE trial

<insert local header>



Managing cardiovascular risk for people with mental health problems: The PRIMROSE Trial Consent Form

(The patient should complete the whole of this sheet himself/herself)
Please circle "YES" or "NO"

I have read the participant information sheet (Dated: Version:)	YES	NO
I have had the opportunity to ask questions and discuss the study	YES	NO
I understand that my participation is voluntary, and that I am free to withdraw from the study: at any time; without having to give a reason; without affecting my future medical care, or legal rights	YES	NO
I agree to the consultations with my GP/practice nurse being audio recorded	YES	NO
I agree for relevant sections of my medical notes to be looked at by responsible individuals from the PRIMROSE research team. I give permission for these individuals to have access to my medical records.	YES	NO
I agree to donate a saliva sample for future research purposes. I consent for my DNA to be used in the study of genes involved in mental health and physical health	YES	NO
I agree to my mental health key worker being told that I am participating in the research	YES	NO
I agree to my carer being told that I am participating in the research.	YES	NO
I agree to take part in this study	YES	NO
I agree to be contacted after the study to discuss taking part in further research related to this project	YES	NO
I wish to receive a summary of the research findings	YES	NO

Name of participant	date	signature

Name of person taking consent	date	signature

Participant Identification number							

Appendix 14: Health provider participant information sheet for the PRIMROSE trial



Managing cardiovascular risk for people with mental health problems: The PRIMROSE Trial

Information to participate in a research project

Please read this information carefully before signing the consent form. The information which follows tells you about the research and your role in the study.

Please ask any questions you want about the research and we will try our best to answer them.

- **What is the purpose of the research?**

People who have severe mental illnesses are at higher risk of developing cardiovascular disease. The aim of this research is to test a new service in general practice that aims to reduce cardiovascular disease risk factors, tailored for people with severe mental illnesses. We want to compare the experiences of people who take part in the service with those who receive usual care from their GP or practice nurse over a period of 1 year. We will test the cost effectiveness of the service in a cluster randomised controlled trial.

- **Why have I been invited to take part in the research?**

The general practice that you work for has agreed to take part in the study. We are asking you to take part in this research as your practice cares for patients with severe mental illnesses.

- **What will happen if I agree to take part in the research?**

1. If the GP practice you work for is chosen to provide the service, you will be offered two days of training. You will be invited to attend a training workshop where you will learn about the study and how to deliver the intervention. You will be asked to fill out a brief training evaluation form. You will be given an intervention manual which describes each stage of the intervention in detail. We will ask you to audio record each appointment that you have with each patient who is part of the trial so that the research team have information on what was delivered in practice. This information will be used to inform the future training of practice nurses.
2. If the GP practice you work for is *not* chosen to provide the service, you will continue to provide care as normal. You will receive information leaflets on physical health care for people with severe mental illnesses. You will be offered the training once the study is finished.

- **Will my participation be kept confidential?**

Yes. All information about you will be kept confidential and will be recorded anonymously. You will not be identified in any report or publication of the research findings.

▪ **Who is organising and funding the study?**

The study is being run by researchers at University College London (UCL). Camden and Islington NHS Foundation Trust are the lead NHS organisation for the study. The study is funded by the National Institute for Health Research's Programme Grants for Applied Research Programme (RP-PG-0609-10156).

▪ **Has the research been approved by an appropriate research ethics committee?**

The research study has been reviewed and approved by National Research Ethics Committee - City Road and Hampstead. REC Ref. 12/LO/1934.

If you would like a copy of the final summary report of the research please give your details to the researcher who will send you the information once the study is complete.

Further information can be obtained from:

Researcher: Miss Alexandra Burton

Address:

Telephone number:

Email:

Lead investigator: Dr David Osborn

Address:

Telephone number:

Email:

|

Appendix 15: Health provider consent form for the PRIMROSE trial



Managing cardiovascular risk for people with severe mental illnesses: The PRIMROSE Trial

Participant Consent Form



(The participant should complete the whole of this sheet himself/herself)

Please circle "YES" or "NO"

I have read the participant information sheet (Dated: 17/10/13 Version: 4)	YES	NO
I have had the opportunity to ask questions and discuss the study	YES	NO
I agree to my consultations with patients who are part of the study being audio recorded	YES	NO
I agree to take part in the study	YES	NO
I agree to be contacted after the study to discuss taking part in further research related to this project	YES	NO
I wish to receive a summary of the research findings	YES	NO

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Name of participant

date

signature

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Name of person taking consent

date

signature