



**S mo ki ng C es sa ti on I nt er ve nt i on f or se ve re M en ta l I l l H ea l t h T r i a l  
**(SCIMITAR): a randomised evaluation of a bespoke  
smoking cessation service****

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**Abbreviations**

AE	Adverse Events
BMI	Body Mass Index
BSC	Bespoke Smoking Cessation
CDTQ	Cut Down To Quit
CI	Confidence Interval
CMHT	Community Mental Health Team
CPA	Care Programme Approach
CO	exhaled Carbon Monoxide
CRF	Case Report Form
DMEC	Data Monitoring and Ethics Committee
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders IV
EQ-5D	EuroQol 5D Questionnaire
FTND	Fagerstrom Test of Nicotine Dependence
GCP	Good Clinical Practice
GMS	General Medical Services
GP	General Practitioner
MDD	Major Depressive Disorder
MH-SCP	Mental Health - Smoking Cessation Practitioner
NICE	National Institute for Health and Clinical Excellence
NRT	Nicotine Replacement Therapy
OR	Odds Ratio
PHQ-9	Patient Health Questionnaire-9
PI	Principal Investigator
QALY	Quality Adjusted Life Years
QOF	Quality and Outcomes Framework
QoL	Quality of Life
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
SCIMITAR	Smoking Cessation Intervention for serious Mental Ill Health Trial
SMI	Serious Mental Illness
TMG	Trial Management Group
TSC	Independent Trial Steering Committee

## **1 Introduction**

### **1.1 Summary**

#### **1.1.1 Lay Summary**

Smoking is an important health issue, not just in the general public, but also among people with severe mental illness. A large proportion of patients who have experienced severe mental illnesses, such as schizophrenia or bipolar disorder, smoke. Not only are these patients more likely to smoke, they smoke more heavily, are more addicted to nicotine and are less likely to receive help in quitting, compared to the general population. Smoking is a preventable health hazard, with proven associations with diseases such as cancer and heart disease. Smoking behaviour contributes to the poor physical health of mentally ill patients, increasing their risk of an early death.

The introduction of public smoking bans and other government anti-smoking strategies have highlighted the smoking issue, prompting people to consider giving up smoking. Nicotine is the addictive component of smoking, causing smokers to have extreme difficulty in quitting. Various drugs and services are available to people wanting help to quit. However, these are targeted at the general public and it is not known if and how well these would work in patients with severe mental illness. People with mental health problems do express a desire to stop smoking, but they may require different strategies and greater support to help them quit smoking.

To address this problem, we aim to evaluate a ‘bespoke smoking cessation’ (BSC) service specifically tailored to individual patients with severe mental illness. A mental health nurse or allied health professional will be trained to deliver smoking cessation interventions, and to become the patient’s mental health-smoking cessation practitioner (MH-SCP). They will work with the patient and the patient’s GP or mental health specialist to advise on anti-smoking medication and provide behavioural support in the form of information, support and motivation sessions on cutting down to quit, setting quit dates and maintaining smoking abstinence. They will also regularly check the health and smoking status of the patient. This service is similar to that used in regular smoking cessation services, but with the specific adaptations of support, medication and tailoring support to the individual needs of patients with severe mental illness. This service will be compared to ‘usual care’, i.e. that normally given by the patient’s GP or practice smoking cessation service without any specific adaptations or enhancements for those with mental ill health.

We aim to recruit 100 patients with severe mental illness into the study, who will then be randomly assigned to either the BSC service or usual care. Patients will be followed up for 12 months. At 1, 6 and 12 months they will be requested to complete questionnaires on their smoking status, general and mental health and their satisfaction with specified aspects of the BSC. Patients will also have their smoking status verified by measuring the amount of carbon monoxide in their breath. A selection of participants, MH-SCPs and GPs will be interviewed to obtain their views on whether the BSC service was useful and acceptable.

The results of this trial will provide information on whether the BSC service is effective in helping patients with severe mental illness to stop smoking compared to usual care. It will also establish whether the service is acceptable to the users and cost effective.

## 1.1.2 Professional Summary

### Background

Smoking is highly prevalent amongst patients who have experienced severe mental illness (SMI) despite being a known health hazard associated with numerous diseases such as cancer and heart disease. Patients with SMI smoke more heavily and are more likely to be nicotine dependent compared to the general population. Despite the 'culture' of smoking in mental health services, patients with SMI express a desire to quit smoking. However the services currently available to aid quitting are those which are widely available to the general population but may not be suitable or effective in patients with SMI. Therefore the role of this study is to develop a bespoke smoking cessation intervention specifically targeted at people with SMI with an emphasis on expert, individually tailored and enhanced support provided by a mental health professional trained in smoking cessation therapy (mental health-smoking cessation practitioner, MH-SCP). This initial pilot study will provide information on the introduction of the BSC intervention and give preliminary estimates of effect size, which will inform a subsequent larger trial.

### Aims

The Primary Objective is to establish the clinical effectiveness of a bespoke smoking cessation intervention for people with mental ill health.

The secondary objectives are to establish the acceptability and cost effectiveness of a bespoke smoking cessation intervention for people with mental ill health compared to usual GP care.

### Design

A pragmatic two arm parallel group, individually randomised controlled trial.

### Patients

100 Patients who have experienced severe mental illness (such as schizophrenia and bipolar disorder) who are current smokers, but express an interest in stopping smoking or cutting down to quit smoking. Patients will be recruited by:

1. GP referral or referral after identification from electronic GP records ('database screening')
2. Primary care referral after their annual health check
3. Referral from Care Programme Approach and Community Mental health Teams
4. Self-referral by advertisements in outpatient departments, mental health clinics and day centres

### Interventions

Patients will be randomised to receive either a bespoke smoking cessation service or usual care by their GP or mental health specialist.

1. Bespoke Smoking Cessation service

The patient will be assigned a mental health professional (nurse or allied mental health professional) trained to deliver smoking cessation interventions (mental health-smoking cessation practitioner, MH-SCP) who will work with the patient and patient's GP or mental health specialist to provide an individually-tailored smoking cessation service. This will be based around current NICE guidelines<sup>1</sup> for smoking cessation services and specific treatment recommendations issued jointly by the Royal Colleges of General Practitioners and Psychiatrists<sup>2</sup>. Guideline-recommended treatments will include behavioural support

sessions managed by the MH-SCP specifically for patients with SMI and the facilitation of guideline-recommended smoking cessation pharmacotherapies delivered by their general practitioner (in line with NICE guidance). In essence, the MH-SCP will provide a service similar to current smoking cessation services (working within current National guidance on smoking cessation), with enhanced levels of contact and support tailored to the needs of the SMI patient.

## 2. Usual care

The patients' GP or mental health specialist will be given advice to follow current NICE guidelines for smoking cessation. This will be in line with general guidance that is offered to all smokers in primary care, with no specific adaptation or enhancement in relation to SMI. This may include pharmacotherapies to aid smoking cessation access to self help materials and referral to local NHS stop smoking clinics, which may not be specific for SMI.

## Outcomes

The primary outcome measure will be smoking cessation at 12 months post-recruitment as verified by expired CO measurements.

Other smoking-related outcome measures will include:

- Reduction in number of cigarettes smoked
- Fagerstrom test of nicotine dependence<sup>3</sup>
- Motivation to Quit questionnaire<sup>4</sup>
- If successfully quit smoking, the number of cessation attempts and the periods of cessation.

General mental health as measured by:

- PHQ-9<sup>5</sup>
- SF-12<sup>6</sup>

## Measures of cost effectiveness

- EuroQol EQ-5D<sup>7</sup>
- Health Economics/Service utilisation Questionnaire

## Other measures

- Body Mass Index
- Acceptability, fidelity and adherence with smoking cessation programme, as measured by patient treatment records kept by MH-SCPs, qualitative interviews of intervention and control participants, MH-SCPs and GPs.

## 1.2 Background

### 1.2.1 Smoking behaviour amongst people with severe mental illness

People with severe mental illnesses (SMI), such as schizophrenia and bipolar disorder are more likely to smoke<sup>8</sup> and to smoke more heavily<sup>9</sup> than the general population. The point prevalence of smoking amongst those with SMI has been estimated to be between 58% and 90%<sup>8 10</sup>. The presence of mental ill health is associated with an elevated risk of smoking by a factor of 2.7 (95% CI, 2.4-3.2)<sup>11</sup>. Smokers with SMI are more nicotine-dependent; more likely to become medically ill; and less likely to receive help in quitting, compared with the general population<sup>12</sup>. There are several reasons why people with SMI are more likely to smoke. They:

- begin smoking at a higher rate before diagnosis or treatment for SMI<sup>13</sup>, compared to smokers without SMI.
- smoke each cigarette more intensely, extracting more nicotine per cigarette<sup>9 14</sup>.
- are much less likely to receive advice to quit smoking from their GP<sup>10</sup> or mental health specialist<sup>15</sup>.

People with SMI have a lot of time on their hands, and smoking is part of the ‘culture’ of mental health services (both amongst staff and patients). In addition, people with SMI often lack self-esteem and see the future as ‘bleak’; as a consequence, they may not be motivated to look after their physical health<sup>12</sup>. Many people with severe mental illness are also misinformed about the risks and benefits of smoking versus nicotine dependence treatment<sup>16 17</sup>. They often fear and overestimate the medical risks of nicotine replacement therapy<sup>18</sup>. Many believe smoking relieves depression and anxiety<sup>19</sup> (although nicotine actually is anxiogenic). Nicotine may also improve some aspects of cognitive dysfunction in schizophrenia, which could be a disincentive for patients to quit smoking<sup>20</sup>.

Smoking contributes to the general poor physical health of those with SMI; in the UK the standardised mortality rate (SMR) for all causes of death for people with schizophrenia was 289 (95% CI 247–337), a threefold increase in mortality compared with the population of England and Wales<sup>21</sup>. Although people with SMI are more likely than the general population to smoke, there is evidence that this is less likely to be recorded in primary care records or to be acted on for these patients than for the general population<sup>22</sup>. Burns & Cohen<sup>23</sup> found that, although the annual general practice consultation rate was significantly higher than normal for people with serious mental illness (13–14 consultations a year compared with about 3 a year for the general population), the amount of data recorded for a variety of health promotion areas including smoking advice was significantly less than normal. It is within this context that a number of policy initiatives have emerged, which emphasize improving the physical care of those with SMI, including taking initiatives to facilitate smoking cessation<sup>12 24</sup>.

### 1.2.2 What works in helping people to quit smoking?

Smokers most commonly cite ‘stress relief and enjoyment’ as their main ‘reason’ for smoking<sup>25</sup>, although the major *cause* is nicotine dependence. Nicotine acts in the midbrain, creating impulses to smoke in the face of stimuli associated with smoking<sup>26</sup>, and producing what may be thought of as a kind of “nicotine hunger” (a feeling of need to smoke) when blood nicotine concentrations are depleted. Smokers also experience nicotine withdrawal symptoms: unpleasant mood swings and physical symptoms that occur on abstinence and are relieved by smoking<sup>27</sup>. Nicotine dependence is the main reason that most unassisted quit attempts fail within a week<sup>28</sup>.

Recent Cochrane systematic reviews<sup>29-38</sup> and evidence-supported guidance from NICE<sup>39 40</sup>, highlight that the following smoking cessation interventions (including medications used as

smoking cessation aids) are helpful in helping smokers reduce their tobacco intake and quit smoking:

**Nicotine replacement therapy (NRT):** There are six different available forms of administering NRT for use as smoking cessation aids. These are the nicotine patch, gum, lozenge, inhaler, nasal spray and sublingual tablet (microtab). These provide a “clean” alternative source of nicotine without the other 4000 toxic chemicals found in cigarette smoke. All deliver a lower dose of nicotine than would be received through smoking with the only difference being differing absorption rates due to different methods of delivery. A meta-analysis of more than 100 randomised controlled trials shows that all forms of nicotine replacement therapy are roughly equally effective in aiding long term cessation (odds ratio 1.77, 95% confidence interval 1.66 to 1.88)<sup>30</sup>. For those not ready to stop smoking, but who are interested in cutting down, NRT prescription has been shown to reduce smoking and to facilitate quit rates later on (Reduce to Stop, or Cut Down to Quit)<sup>41</sup>.

**Anti-depressants & nicotine receptor agonists:** Two non-nicotine pharmacotherapies have been licensed as smoking cessation aids. These are varenicline, a nicotinic acetylcholine receptor partial agonist, (Chantix (USA), Champix (EU and other countries), Pfizer) and bupropion, a noradrenaline and dopamine reuptake inhibitor which was first introduced as an atypical antidepressant (Zyban, GlaxoSmithKline). Varenicline is almost certainly the most effective treatment to date (odds ratio for 12 month continuous abstinence for varenicline vs placebo = 3.22; 95% CI 2.43 to 4.27). It is more efficacious than bupropion (odds ratio for varenicline versus bupropion = 1.66; 95% CI 1.28 to 2.16)<sup>38</sup>. However, its use in people with SMI may be limited by case reports of worsening of depression or mental health in populations with a previous history of mental health difficulties.

FDA guidance on this matter states “some patients have reported changes in behavior, agitation, depressed mood, suicidal thoughts or actions when attempting to quit smoking while taking varenicline or after stopping varenicline.” It states that patients experiencing such changes should stop taking varenicline and contact their physician. A similar recommendation is made for bupropion. General recommendations are that these medications should be used in those whose mental state is stable. The association between varenicline use and exacerbation of mental illness, the frequency of which has yet to be ascertained, must be balanced against the very high risk of continued smoking.<sup>42</sup>

**Behavioural support:** Advice, discussion and encouragement can be delivered via a range of means, from individual to group, open (rolling) or closed group, face-to face or over the telephone or internet. Meta-analyses of trials of multi-session ‘*intensive behavioural support versus brief advice*’ found odds ratios of 1.56 (1.32 to 1.84) for individual support and 2.04 (1.60 to 2.60) for group support<sup>31 32</sup>. Regular support on the telephone is also effective. A meta-analysis of 10 trials of telephone support for people stopping smoking gave an odds ratio of 1.64 (1.41 to 1.92)<sup>36</sup>. There is some evidence to suggest that group support may be more effective in general than one-to one support<sup>4</sup>, and that it should involve multiple sessions<sup>4</sup>. There is also evidence that such sessions can be effective even if conducted over the telephone - odds ratio of 1.64 (1.41 to 1.92)<sup>36</sup>.

The accumulated evidence for the use of current smoking cessation interventions has recently been distilled into clear recommendations for healthcare professionals<sup>43</sup>, and into a manual for those designing, and delivering smoking cessation services<sup>44</sup>. In addition, guidance has been issued by the Royal Colleges of General Practitioners and Psychiatrists to guide the use of smoking cessation interventions for those with SMI<sup>2</sup>.

The most recent work on the effectiveness of smoking cessation strategies in SMI comes from a systematic review of randomized trials by Banham & Gilbody (2010)<sup>45</sup>. This review draws upon the results of ten RCTs of smoking cessation interventions amongst those with SMI, and shows that combinations of behavioral support, and pharmacotherapy (NRT and bupropion) are effective in facilitating smoking cessation. The evidence is strongest from bupropion where the odds of quitting were improved fourfold (three trials; Risk Ratio = 4.18 (95% CI 1.30-13.42). The strongest evidence relates to NRT, where the addition of NRT tripled biochemically-verified quit rates at 4 months (four trials; RR= 2.77 95%CI 1.48 to 5.16). There are however, no trial-based data for varenicline.

Similar results were found following a recent Cochrane review assessing smoking cessation interventions in individuals with schizophrenia<sup>46</sup>. Smoking cessation rates were significantly higher using bupropion compared with placebo (seven trials, RR = 2.78; 95% CI 1.02-7.58) with no report of serious adverse events.

The above evidence and documentation (NICE guidance, guidance from the Royal Colleges of General Practitioners and Psychiatrists, smoking cessation manuals, current Cochrane reviews, and our own reviews of ‘what works in SMI populations’) form the basis of our Bespoke Smoking Cessation (BSC) intervention for people with severe mental illness. Table 1 lists these key documentary sources we have referred to when developing this intervention.

Table 1 – Key references and documents used for developing BSC intervention.

Ref	Document
<sup>1</sup> .	National Institute for Clinical Excellence. <i>Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities</i> . London: NICE, 2008.
<sup>2</sup> .	Royal College of General Practitioners and Royal College of Psychiatrists. <i>Primary Care Guidance On Smoking and Mental Health</i> . London: Forum, 2008.
<sup>43</sup> .	Aveyard P, West R. Managing smoking cessation. <i>British Medical Journal</i> 2007;335:37-41.
<sup>44</sup> .	McEwen A, Hajek P, McRobbie H, West R. <i>Smoking Cessation Manual: A practical guide for health professionals treating smokers</i> : Blackwell Publishing Ltd, London, 2006.
<sup>45</sup> .	Banham L, Gilbody S. Smoking cessation in severe mental illness: what works? <i>Addiction</i> 2010; 105(7)1176-1189.
<sup>46</sup>	Tsoi, D.T., M. Porwal, and A.C. Webster, <i>Interventions for smoking cessation and reduction in individuals with schizophrenia</i> . Cochrane Database of Systematic Reviews, 2010. CD007253(6): p. DOI: 10.1002/14651858.CD007253.pub2.
<sup>47</sup> .	Stead LF, Perera R, Bullen C, Mant D, T. L. Nicotine Replacement Therapy for Smoking Cessation. <i>Cochrane Database of Systematic Reviews</i> 2008;CD000146(1):DOI: 10.1002/14651858.CD000146.pub3.
<sup>29</sup> .	Hughes JR, Stead LF, Lancaster T. Antidepressants for smoking cessation. <i>Cochrane Database of Systematic Reviews</i> 2007;CD000031(1):DOI: 10.1002/14651858.CD000031.pub3.
<sup>31</sup> .	Lancaster T, Stead LF. Individual behavioural counselling for smoking cessation <i>Cochrane Database of Systematic Reviews</i> 2005;CD001292(2):DOI: 10.1002/14651858.CD001292.pub2.

<sup>32</sup> .	Lancaster T, Stead LF. Group behaviour therapy programmes for smoking cessation. <i>Cochrane Database of Systematic Reviews</i> 2005;CD001007(2):DOI: 10.1002/14651858.CD001007.pub2.
<sup>33</sup> .	Cahill K, Stead LF, Lancaster T. Nicotine receptor partial agonists for smoking cessation. <i>Cochrane Database of Systematic Reviews</i> 2007;CD006103(3):DOI: 10.1002/14651858.CD006103.pub3.
<sup>34</sup> .	Lancaster T, Stead LF. Self-help interventions for smoking cessation. <i>Cochrane Database of Systematic Reviews</i> 2005;CD001118(3):DOI: 10.1002/14651858.CD001118.pub2.
<sup>48</sup> .	Lancaster T, Perera R, Stead LF. Telephone counselling for smoking cessation. <i>Cochrane Database of Systematic Reviews</i> 2006;CD002850(3):DOI: 10.1002/14651858.CD002850.pub2.
<sup>49</sup> .	Lancaster T, Stead LF. Physician advice for smoking cessation. <i>Cochrane Database of Systematic Reviews</i> 2008;CD000165(2):DOI: 10.1002/14651858.CD000165.pub3.
<sup>50</sup> .	Hajek P, Stead LF, West R, Jarvis M, Lancaster T. Relapse Prevention Interventions for Smoking Cessation. <i>Cochrane Database of Systematic Reviews</i> 2009;CD003999(1):DOI: 10.1002/14651858.CD003999.pub3.
<sup>51</sup> .	Department of Health. <i>NHS Stop Smoking Services Service and monitoring guide 2009/10</i> . London: HMSO, 2009.

### 1.2.3 Additional considerations relating to smoking in SMI

There are several other important issues associated with smoking which are of particular relevance to the SMI population. Therefore an awareness of these will shape some of the information to be collected during the trial.

#### **Informing the General Practitioner and Psychiatrist of a planned quit attempt.**

Components of cigarette smoke are known induce hepatic cytochrome P450 enzymes which are involved in drug metabolism (including psychotropic drugs<sup>52</sup>), which ultimately increases the required dosage of psychotropic medication for SMI patients who smoke. In the SCIMITAR trial we will have no direct influence over prescribing of psychotropic medications (since this will remain the clinical responsibility of the General Practitioner or Psychiatrist). However in line with recommendations from the Royal College of Psychiatrists and General Practitioners, the person prescribing psychotropic medication will need to consider smoking status (and changes in smoking status) as part of overall care. The MH-SCPs will therefore inform the General Practitioner and Psychiatrist of planned and successful quit attempts, and will ensure that they are given a copy of 'Primary Care guidance on smoking and mental health' – see appendix D

#### **Awareness of known interactions and cautions associated with smoking cessation medications**

There is specific guidance on the prescription of smoking cessation medications in the general population and amongst those with SMI. For example written guidance from the Royal College

of General Practitioners<sup>2</sup> does not preclude the use of Bupropion in those with SMI, and our own reviews<sup>45</sup> show this to be a safe and effective intervention. As a matter of good practice we will ensure that General Practitioners (who will prescribe any smoking cessation medications as is the case in usual care) are made aware of best practice and guidance in this field and are given a copy of the guide 'Primary Care guidance on smoking and mental health' – see appendix D.

### **Awareness of substance use/drug substitution**

SMI patients are reported to have a higher prevalence of substance abuse disorders, particularly of alcohol and cannabis, compared to the general population<sup>53</sup>. In addition, for patients with schizophrenia and bipolar disorder, a strong relationship exists linking illness severity, substance use and smoking status<sup>54</sup>. 'Self medication' is one of the main reasons given by patients with SMI for substance use and indeed for smoking<sup>55</sup>. The SCIMITAR trial will not recruit patients with co-morbid drug abuse and severe mental illness. However one theoretical unintended consequence of stopping smoking might be the substitution of tobacco for illicit drugs (such as cannabis) or alcohol. We will enquire about drug substitution in the SCIMITAR trial.

### **Weight gain**

There is growing evidence to support the belief that smoking cessation leads to weight gain<sup>56</sup>. Average weight gain after quitting smoking is approximately 3.5 kg but in extreme cases can be more than 11kg, particularly in younger, heavier smokers of a lower socioeconomic class<sup>57</sup>. However studies of longer term abstinence suggest that initial increases in body mass index (BMI) of 1.6 kg/m<sup>2</sup> revert back to mean BMIs equivalent to those who have never smoked<sup>58</sup>. People with SMI are often overweight and there are concerns about the longer term health risks of weight gain (contributing to metabolic syndrome). We will therefore monitor weight (and weight gain) as a matter of course in the SCIMITAR trial. BMI will be assessed at baseline and 12 months in this trial.

### **Other forms of tobacco**

This study is primarily focused on cigarette smoking which along with cigars and pipes, are the most common form of tobacco usage, particularly in the West. A variety of other forms of tobacco exist, which are important to be aware of. There is increasing usage and popularity of the waterpipe (also known as hookah, sheesh, narghile, goza, or hubble bubble) in north Africa and the Middle East. Smokeless tobacco is popular in developing countries and include dry powdered tobacco which is inhaled through the nose (snuff, common in South Africa), oral or chewing tobacco (called snus in Sweden), mixed within a preparation called paan or betel quid (consisting of areca nut, slaked lime and wrapped in a betel leaf which is popular in central and southern Asia)<sup>59</sup>.

Although research into these alternative forms of tobacco are limited, the commonly held misconception is that these are all less harmful than cigarette smoking, yet there is evidence that waterpipe use is associated with equivalent or increased risk of lung cancer, gastroesophageal cancer and infection<sup>60</sup>, whilst oral tobacco is estimated to cause cancer in 100,000 men in Asia per year<sup>59</sup>. In Sweden where the use of snus/snuff in male schizophrenic patients is higher than the national average number of users<sup>61</sup>, there is growing debate on its use as a harm reduction aid for cigarette smoking<sup>62 63</sup>).

Since the prevalence of other tobacco use in SMI populations in the UK are unknown, we will ask participants about alternative forms of tobacco abuse in both control and intervention arms.

### **Motivations and beliefs**

Studies assessing smoking attitudes and beliefs in SMI patients have found that these patients are aware of the harms caused by smoking and that quitting would benefit their health. More formal qualitative studies investigating barriers to quitting have shown that social and environmental reinforcement are particularly important<sup>64</sup> especially if cigarettes are viewed as part of their identity, comforter (when dealing with stress) or an affordable luxury<sup>65</sup>. Of those patients who had tried quitting, NRT was viewed very negatively (believed to be unhealthy or unnecessary)<sup>18</sup>, or reported feeling excluded from mainstream programmes, citing feelings of being judged and misunderstood<sup>65</sup>.

These studies have drawn on SMI patients in long-term care (inpatients<sup>17</sup> and community living patients<sup>65</sup> in USA and Australia. Given these views of current smoking cessation programmes from SMI patients, we will assess these motivations and beliefs amongst SMI patients in the UK, and judge how this changes amongst those who receive our bespoke smoking cessation intervention.

### 1.3 Rationale for SCIMITAR trial

Despite the higher prevalence of smoking, a substantial proportion of people with SMI express a desire to quit. In a large population-based cohort, smokers with past-month mental illness had a self-reported 'desire to quit' rate of 30.5% (although this is lower than smokers without illness - 42.5%)<sup>11</sup>. The introduction in 2004 of a new General Medical Services (GMS) contract<sup>66</sup> created a policy impetus to improve the quality of primary care in priority areas. In terms of mental health, the new general medical services contract specifies that primary care is responsible for the provision of physical healthcare. Importantly, for smoking cessation initiatives, it 'incentivises' GPs to (1) produce a register of people with severe long-term mental health (QOF indicator MH8 - the **SMI register**) and (2) ensure that at least 90% of SMI patients have had a review that includes smoking status recorded within the previous 15 months (the QOF indicator MH9 **SMI healthcheck**). This check includes patients seen in primary care, secondary care and under shared care arrangements.

In addition, for those who are admitted to hospital, the introduction of smoke-free policies provides an opportunity to address smoking. This ban includes inpatient psychiatric units, although the complexities of the mental health act have been interpreted by some hospitals as a requirement to provide smoking areas. The admission of an individual to hospital, whilst being stressful and occurring at a time of personal crisis, also provides a unique opportunity to provide general health advice and to engage individuals in interventions targeted at smoking reduction and cessation.

Smoking cessation services for people with Severe Mental Illness (SMI) are not sufficiently evolved or embedded within the NHS. From the preceding discussion, we know 'what works' for smoking cessation in general; the purpose of SCIMITAR is to use enhancements of care to ensure that evidence-supported interventions are offered (and taken up) by people with SMI and to see if smoking rates can be reduced. This technology represents a 'complex healthcare intervention', and this study therefore uses the stepwise MRC complex interventions framework<sup>67</sup> and the updated guidance<sup>68</sup> to evaluate the effectiveness, implementation and content of a bespoke smoking cessation (BSC) service for people with SMI.

## **2 Study Objectives**

### **2.1 Objectives**

#### **2.1.1 Primary Objective**

- To establish the clinical effectiveness of a bespoke smoking cessation intervention compared with usual GP care, for people with severe mental ill health in facilitating smoking cessation.

#### **2.1.2 Secondary Objective**

- To establish the acceptability of a bespoke smoking cessation intervention for people with severe mental ill health.
- To establish the cost effectiveness of a bespoke smoking cessation intervention for people with severe mental ill health.

## **3 Study Design**

This study will be a pragmatic, randomised controlled trial. See Appendix B for a summary flowchart of participants through the trial.

The setting will be Primary care and specialist mental health services within two centres: York (CI Professor Simon Gilbody) and Manchester (Investigator Professor Helen Lester). We will recruit in both primary and secondary care settings. GPs and specialist mental health centres will be approached to gauge interest in the trial. An information pack will be provided for each site. Clinicians interested in participating in the trial will be fully briefed and trained to search through their practice records of patients or their SMI register to approach potentially eligible participants. Patients identified in such a way will be approached (information packs and consent forms sent by their nurse, psychiatrist or GP) to offer them the opportunity to participate in the SCIMITAR trial.

Patients who have given consent to be contacted will be phoned by a SCIMITAR researcher who will discuss the trial and ask some brief pre-screening questions to assess the subject's eligibility. If eligible, a face-to-face meeting will be arranged with the researcher (either in their own home or in a research or GP setting, depending on patient preference). Eligibility and informed consent will be confirmed in this meeting, and baseline measurements will be taken (including CO and body mass index measurements). They will then be individually randomised to receive either the active bespoke smoking cessation intervention or usual care. If bespoke smoking cessation is allocated, then the first appointment will be made with the Mental Health Smoking Cessation Practitioner (MH-SCP). If usual care is allocated, then they will be encouraged to consult with their general practitioner or practice smoking advisor to discuss their smoking habit. Details of the trial intervention and control are given in section 6.1 and 6.2 respectively.

We will not directly influence the prescription of medications by the GP or mental health specialist for the participants in this trial, but will make GPs aware of NICE guidance for the pharmacological management of smoking cessation<sup>1</sup>, with reference to specific recommendations issued by the Royal College of General Practitioners and Psychiatrists for the use of smoking cessation interventions in those with SMI<sup>2</sup> (see Appendix D for this written guidance in the form that it will be given to GPs and Psychiatrists). We propose no experimental manipulation to directly influence choice or dose of medication, but the MH-SCP will act as a resource and support in the choice of medication in line with NHS-Specified Smoking Cessation services<sup>51</sup>.

## **4 Study Population**

### **4.1 Number of participants**

This is a pilot trial and we aim to recruit a sample size of  $n = 100$  in order to gain preliminary estimates of effect size and to test recruitment and follow up prior to a subsequent larger definitive fully randomised controlled trial.

### **4.2 Inclusion criteria**

Our target population will be adult patients, aged 18 and above with a Severe Mental Illness (SMI), who report smoking and express an interest in wanting to cut down smoking (though not necessarily quitting). There is no agreed definition of Severe Mental Illness so we will adopt a pragmatic definition of SMI stipulated recent in guidance on improving the physical care of people with SMI,<sup>69</sup> and in the GMS contract<sup>66</sup> i.e. a documented diagnosis of schizophrenia or delusional/psychotic illness (ICD 10 F20.X & F22.X or DSM-equivalent) or bipolar disorder (ICD F31.X or DSM-equivalent). This SMI-inclusive diagnosis will need to have been made by specialist psychiatric services – and be documented in the GP or within the psychiatric notes. Participation in the BSC intervention will be offered to all those who might potentially benefit, in line with general policy initiatives that health promotional activity should be targeted at all people with SMI<sup>12 70</sup>.

### **4.3 Exclusion criteria**

Given the pragmatic nature of this trial, there will be few exclusion criteria other than patients who are pregnant or breastfeeding or have co-morbid drug or alcohol problems (as ascertained by the GP or mental health worker). The inclusion of these populations is beyond the remit of the current study. SMI patients who smoke whilst concurrently abusing substances may require additional medication or specialist advice which is beyond the brief of the MH-SCP and this trial. Similarly, smoking cessation in pregnancy also requires specialist knowledge and the needs of this population are subject to specialist services in the NHS. Any participant who becomes pregnant during the course of the trial will be removed from the study and referred to local smoking cessation services specific to pregnancy. It will be necessary to exclude non-English speaking patients due to the potential for communication difficulties which would be incompatible with the intervention. We will also exclude those patients who lack capacity to participate in the trial, guided by the 2005 Mental Capacity Act<sup>71</sup>.

## **5 Participant selection and enrolment**

### **5.1 Identifying participants**

We will recruit by four methods:

#### **5.1.1 Direct GP referral or following database screening**

People with SMI consult with their GPs frequently, largely in connection with physical rather than mental health problems. GPs are encouraged to offer opportunistic advice and information about smoking cessation services to all patients who smoke whenever they consult in primary care. GPs will be given patient information packs which they can give to patients who are receptive to participating in the trial. GPs will then complete and fax a referral form and patients 'consent to be contacted' form to the SCIMITAR researchers who will approach the patient for recruitment.

GP practices will also be encouraged to consult their patient databases and SMI register if available, to screen for potentially eligible participants. Patient information packs will be sent from the GP inviting patients willing to take part in the study to send a completed consent to be contacted form to the SCIMITAR researchers, who will then approach them to ascertain eligibility and recruitment.

### **5.1.2 Primary care referral following annual health check**

For the purposes of the current study, the annual primary care health check for people with SMI<sup>72</sup> (MH9) represents an opportunity to address smoking behaviour, and to offer enhanced smoking cessation services within the context of a trial. Health checks are generally conducted by practice nurses, and we will encourage all primary care staff to make SMI smokers aware of the trial when they receive their annual primary care health check. Patient information packs can be given to interested and potentially eligible patients during their health check. Similar to GP referrals, practice nurses will be instructed to complete referral forms and to fax the patients' completed consent to be contacted form to the SCIMITAR researchers, who will then approach them for eligibility and recruitment.

### **5.1.3 Care Programme Approach (CPA) and via community mental health teams (CMHTs)**

A substantial proportion of people with SMI will be in receipt of the CPA, and will receive an annual review of their psychological, social and healthcare needs. Our research assistants will work with Care Coordinators and Consultants to screen their entire caseloads for potentially eligible participants who match the inclusion criteria. Participants identified as potentially suitable for the SCIMITAR trial will be given a copy of the patient information pack by their Care Coordinator. The patient information pack will contain a 'consent to be contacted' form which potential participants can return to the research assistant to give permission to be contacted by telephone or letter, or in person to discuss the trial further.

Members of the CMHT will also be invited to directly refer eligible patients to the research team, following a similar pathway as GP referrals.

### **5.1.4 Patient self-referral**

We will also advertise the SCIMITAR trial and Bespoke Smoking Cessation service in venues where patients in secondary care often congregate (e.g. Clozapine clinics, out-patient departments, day centres etc.) and invite patients to contact us if they are interested in participating in the study. The introduction of smoking bans in inpatient hospital services raises an ideal opportunity to offer smoking cessation services to patients who are interested in addressing their smoking behaviour. Therefore we will also advertise the Bespoke Smoking Cessation service in inpatient mental health settings. Interested participants will contact a SCIMITAR researcher, who will send out a patient information pack, including 'consent to be contacted' form.

## **5.2 Screening for eligibility**

For potential participants who were selected by database screening or were self referred, and have return their 'assent/consent to be contacted form' by post, the participants GP will be contacted to check for exclusion criteria (pregnancy or known drug/alcohol problems) and their

judgment on the appropriateness of the patients inclusion into the study. This would occur prior to the patient being approached by SCIMITAR researchers.

If the patient has been referred, the person giving them the information pack (GP, mental health specialist, practice nurse, CPA coordinator) will be able to explain most aspects of the trial; assess the patient for eligibility and screen for the given exclusion criteria. On receipt of a faxed referral form and signed 'assent/consent to be contacted form' patients will then be contacted by a trial researcher.

The SCIMITAR researcher will first approach the potential participant by telephone. After briefly explaining the trial the researcher will enquire about the patients' smoking specifically 1) do they smoke? 2) How much they smoke? 3) would they seriously consider quitting or cutting down with a view to quitting within the next 6 months? These ensure that the patient currently smokes but is seriously contemplating quitting. It would not be worthwhile recruiting a patient into the study if they were not prepared to work towards quitting smoking. The researcher will also ask screening questions about pregnancy and breastfeeding, drug and alcohol usage which would lead to exclusion if present. The researcher will then arrange a meeting at a mutually convenient time and venue.

### **5.3 Consenting participants**

Potential participants will initially receive an information pack about the trial. The pack will contain an invitation letter, patient information leaflet(s), consent/assent form(s) and an eligibility questionnaire. The participant information sheet covers all aspects of the trial, what is required of the participant and what are the risks and benefits of participating. It is suggested in the invitation that the patient discusses this trial with their friends and family.

On meeting with the SCIMITAR researcher the patient will have a further opportunity to clarify any points they did not understand and ask any questions. A full oral explanation will be performed by the researcher, covering all the elements specified in the Participant Information Sheet/Informed Consent. It will be emphasised that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled. The participant will also be informed that by consenting, they agree to their GP being informed of their participation in the trial and their medical records may be inspected by regulatory authorities but understand that their name will not be disclosed. Written informed consent will then be obtained with both the participant and the researcher signing and dating the consent forms prior to the patient being randomised.

Participants will have received both oral and written information. The information leaflets will be produced using the current guidelines for researchers on writing information sheets and consent forms, posted on the NRES website.

After consenting, a set of baseline questionnaires will be asked in addition to all the questionnaire outcome measures, BMI and a CO reading taken. These will make up the participants' baseline dataset. The participant will then undergo randomisation.

### **5.4 Ineligible and non-consenting participants**

All ineligible and non-consenting participants will be referred back to their GP where any general healthcare advice on the importance of stopping smoking will be provided by the patients' GP practice or community nurses.

## **5.5 Randomisation**

### **5.5.1 Treatment Allocation**

An eligible patient will be individually randomised to receive either the Bespoke Smoking Cessation service or usual care. The SCIMITAR researcher will contact a secure randomisation line run by the York Trials Unit, in order to determine treatment allocation. Simple randomisation will be used, following a computer generated random number sequence. The researcher will immediately inform the patient of the allocation and set up the first appointment with the MH-SCP (if so allocated). A letter will also be sent to the GP and mental health specialist for the patient's records and to advise them on subsequent smoking cessation management.

### **5.5.2 Premature withdrawal**

A study participant may be withdrawn from the trial by their GP, mental health specialist, smoking cessation practitioner or may choose to do so themselves. If the withdrawal is due to an adverse event, procedures will follow the Standard Operating Procedures (SOPs) for Adverse Events (AEs).

Reasons for withdrawal may include pregnancy, admission to hospital for reasons unrelated to the trial, inability to attend treatment or assessment sessions. Relapse to resuming smoking is not seen as reason to withdraw since participants can resume treatment and make several attempts to quit smoking.

Data will be collected as to the nature of the withdrawal. Participants will be given a choice of (i) withdrawal from treatment only, (where participants are still followed-up at 1, 6 and 12 months) or (ii) complete withdrawal from the study including follow-up. Withdrawal from the study does not affect the patients' treatment or access to NHS services.

Any data collected from the participant prior to withdrawal will still be included in the final analysis of the data.

## **6 Trial Intervention and control**

### **6.1 Trial Intervention**

This is a complex service intervention consisting of a mental health professional trained in smoking cessation interventions (Mental Health Smoking Cessation Practitioner – MH-SCP) who will work in conjunction with the patient and the patient's general practitioner or mental health specialist to provide a smoking cessation service individually tailored to each patient with SMI. The intervention will be delivered according to the Manual of Smoking Cessation (guide for Counsellors and Practitioners)<sup>44</sup> which forms to basis of smoking cessation interventions in the NHS.

This service will be in line with current NICE guidelines for smoking cessation services<sup>1</sup> and will include support sessions specifically adapted for patients with SMI run by the MH-SCP; GP-prescribed pharmacotherapies to aid smoking cessation (nicotine replacement therapies, bupropion or varenicline either separately or in combination as decided by the GP), in addition to regular follow up by the MH-SCP. Examples of specific adaptations to the needs of those with SMI are (1) the need to make several assessment prior to setting a 'quit date'; (2) recognising the purpose of smoking in the context of their mental illness, such as the use of smoking to relieve side effects from antipsychotic medication (and how this will be managed during a cessation attempt); (3) the need to involve other members of the multi-disciplinary team in planning a successful quit attempt for those with complex care needs and multi-agency

programmes of care; (4) a greater need for home visits, rather than planned visits in GP surgeries. For some clients with mental illness, the home environment is the optimum place to work; (5) Providing additional face to face support following an unsuccessful quit attempt or relapse; (6) informing the GP and psychiatrist of a successful quit attempt, such that they can review anti-psychotic medication doses if metabolism changes<sup>73</sup>.

Pharmacotherapies will be provided as long as is deemed necessary in line with NICE guidance and will be determined by the GP without the influence of the SCIMITAR trial team. In line with NICE recommendations, MH-SCP will be able to offer advice on the range of treatments options available to patients under the NHS (including medication, counselling and follow-up). It is not the remit of the trial to assess specific smoking cessation pharmacotherapies or treatments per se, although data will be collected on frequency of their usage.

Participants will be encouraged to: (1) reduce smoking to quit<sup>41</sup>, (2) set their own quit dates and (3) make several attempts to quit if their initial attempt fails. It is generally recommended that patients wait a few months after a failed quit attempt before trying again. This will not be strictly enforced in this population and will be left at the discretion of the MH-SCP. All patients will remain under the care of their GP and will continue to receive their usual NHS treatment, but the MH-SCP will assist in the smoking cessation management of the patient.

Bespoke Smoking Cessation interventions will be in line with best practice guidance relevant to the provision of all NHS Stop Smoking interventions (including for those with mental illness). It sets out fundamental quality principles for the delivery of services and stop smoking support – stipulated in the Department of Health's 'NHS Stop Smoking Services: Service and monitoring guidance' 2009/10<sup>51</sup>.

## 6.2 Control Intervention

This will be a “usual care” control group whereby the patients' GP or mental health specialist will be given advice to follow current NICE guidelines for smoking cessation, without the additional support of a bespoke MH-SCP. Usual care may include pharmacotherapies to aid smoking cessation (nicotine replacement therapies, bupropion or varenicline either separately or in combination), access to self help materials and referral to local NHS stop smoking clinics (which will not be specific tailored for the needs of those with SMI). Patients will also be encouraged to reduce smoking to quit and set their own quit dates, but will be managed solely by their own GP or mental health specialist and crucially, will not receive regular visits from a MH-SCP. Details of smoking cessation management that control participants receive will be gathered by accessing patients' GP notes and requested from participants using the follow-up questionnaires.

## 6.3 Participant compliance with Smoking Cessation interventions

Mental Health Smoking Cessation Practitioners will maintain regular logs per patient to monitor treatment and progress. Patients randomised to usual care will have their GP and/or mental health specialist records scrutinised by researchers to record the details of the interventions for smoking cessation. Smoking status at baseline and follow-up will be ascertained by exhaled carbon monoxide (CO). Readings < 10 ppm is taken that patients have not smoked recently (i.e. within 12 hours). Measurements above 10 ppm will indicate that the patient has not ceased smoking. At least two CO readings will be taken, but if the participant claims to have stopped but their CO readings are above 10ppm, we would probe for when was the last time the participant smoked and whether they had any minor relapses during their quit attempt.

## **7 Trial Assessment**

### **7.1 Quantitative Outcome Measures**

#### **7.1.1 Primary Outcomes**

The primary outcome will be whether patients have stopped or reduced smoking when assessed at 12 months post-recruitment. This will be validated in a secondary analysis using available carbon monoxide measurements and where abstinence is defined as CO < 10 ppm. A logistic regression model will be used to compare the primary outcome from bespoke smoking cessation services with usual care. The analysis will be as proposed in the statistical analysis section 9.2.

#### **7.1.2 Secondary Outcomes**

The following measures will occur at baseline 1, 6 and 12 months post recruitment, unless otherwise stated.

**Measures of smoking status**, including:

- Reduction in the number of cigarettes smoked per day (self-report);
- dependence on smoking as assessed by the Fagerstrom Nicotine Dependence Questionnaire.<sup>3</sup>
- Level of motivation as assessed by the Motivation to quit questionnaire
- If successfully quit smoking, the number of attempts to quit and period of cessation

**General mental health:**

- Patient Health Questionnaire 9 (PHQ9)<sup>74</sup>
- Health Related Quality of Life (SF-12)<sup>75</sup>

**Measures of cost effectiveness**

- EuroQol EQ-5D<sup>7</sup>
- Health Economics/Service utilisation Questionnaire

**Drug substitution** (specifically cannabis use) will be recorded by computerised self report (which has been shown to be non-inferior to urine assay in recent trials)<sup>76</sup>.

**Body Mass Index (BMI):** We will calculate BMI by measuring bodyweight (using portable scales) and height at baseline and 12 months follow-up.

Acceptability, fidelity and adherence to either bespoke smoking cessation programmes or routine NHS services will be examined in qualitative interviews of intervention and control participants, MH-SCPs and GPs.

**Patient compliance with smoking cessation advice**

We will record the proportion of patients who comply with (1) contacts which are offered from a MH-SCP; (2) medication when this is offered by their general practitioner (as measured by the number of 'filled' prescriptions issued by the general practitioner); (3) compliance with CO monitoring by MH-SCPs.

**Fidelity of delivery of Bespoke Smoking Cessation interventions**

We will ask MH-SCPs to complete a treatment log which will record all patient contacts (face-to face meetings, phone calls and joint appointments with MH-SCP and GP), and will judge the

degree to which the intervention as designed on a session by session basis is actually delivered in practice by MH-SCPs.

Participants will be followed up at 1, 6 and 12 months. The following assessments will be taken at the given timepoints as shown on table 2.:

Assessment	Timeline (months post randomisation)			
	Baseline	1	6	12
<b>Eligibility and consent</b>				
-Eligibility	X			
-Consent	X			
<b>Background &amp; Follow-up</b>				
-Personal details	X			
-Body Mass index	X			X
<i>Mental health details</i>				
-Mental health history	X			
-Current mental health status	X	X	X	X
-Current medications	X	X	X	X
-Referrals to mental health services		X	X	X
-Admissions to hospital related to mental health		X	X	X
<i>Smoking details</i>				
-Smoking history	X			
-Current smoking status	X	X	X	X
-Use of smoking cessation services	X	X	X	X
-CO measurement	X			X
-Adverse event reporting	Ongoing collection			
<b>Questionnaires</b>				
-Fagerstrom Nicotine Dependence Questionnaire	X	X	X	X
-Motivation to Quit Questionnaire	X	X	X	X
-Patient Health Questionnaire (PHQ9)	X	X	X	X
-Health related Quality of Life (SF-12)	X	X	X	X
-Health-state utility (EuroQol - EQ5D)	X	X	X	X
-Health Economics/service utilisation questionnaire			X	X

Table 2 – Assessments and timepoints of the trial

Baseline assessments and 12 month follow-up will take place during face-to-face meetings with the participant, whilst 1 and 6 month follow-up assessments will occur either by telephone interview or using paper or online questionnaires. Where it has not been possible to meet with the participant for face-to-face 12 month follow-up data collection (self-report & CO measurement) a systematic approach will be used to explore other avenues to collect any outstanding data (self-report data only). See Appendix C for copies of the questionnaires.

## **7.2 Concurrent qualitative assessment of provision, acceptability and uptake of Smoking Cessation services for those with SMI**

We will explore specific issues of acceptability, fidelity and adherence of smoking cessation interventions amongst those with SMI and those who refer to and deliver the intervention. An in depth appreciation of these issues will be essential in the implementation of a Bespoke Smoking Cessation service, the optimum design in subsequent definitive trials. For the qualitative assessment, in-depth interviews will be performed. For the patient qualitative sample, we will try to recruit a purposive sample including those who successfully quit and those who did not. We will perform a comparison of the interviewed sample to the full trial sample on pre-determined variables (including age, gender, ethnicity, level of education, smoking severity and SMI diagnosis) to determine the representativeness of the interview sample compared to the patient sample as a whole.

We also aim to run in-depth interviews on a subset of health professionals (GPs, practice nurses, mental health professionals) and MH-SCPs to gain their perspectives on acceptability and delivery of Smoking Cessation services for SMI.

In-depth interview topic guides will address the following issues:

- Characteristics of the recipients: what are the specific features of SMI that need to be anticipated and accommodated in delivering BSC?
- Characteristics of the setting: is BSC best delivered in patients' homes, GP surgeries or day hospital settings?
- Mode of delivery: is BSC best delivered face to face, in groups or over the phone?
- Intensity & duration: what is an ideal contact time & number sessions?
- Adherence by MH-SCPs to delivery protocols: Is BSC delivered according to the manualised intervention ('fidelity to treatment protocol')?
- Patients' views of the intervention
- Patients' compliance with the intervention; with specific reference to barriers and facilitators to compliance with smoking cessation interventions.

Qualitative interviews will be held at the end of treatment and will be run throughout the duration of the data collection period. An experienced qualitative researcher will facilitate all interviews and ethical approval will be obtained by the relevant Local NHS Research Ethics Committee. Written consent will be collected from all of the participants. Participants will be asked their consent to the discussions or interviews being recorded and will be informed that all identifiable data will be removed once transcribed. Participants will be informed that they could remove themselves from the group or stop the interview at any time and do not have to answer any questions they were uncomfortable with.

After completion of the interview, the participant will be offered a £10 gift voucher as a goodwill gesture. This is a token of thanks to the participants for their time. Participants will be not

be notified of this voucher until after the interview so as not to be coercive or cause undue influence over the participant's responses.

All interviews will be audio-taped and fully transcribed. These qualitative data will be coded independently by two qualitative researchers to generate emergent themes broken down by categories and issues. Main categories will then be compared across all qualitative data and reintegrated into important themes and issues.

### **7.3 Cost assessment**

Economic evaluation will estimate cost under alternative treatment strategies according to a two-stage process. The first is to measure resource use in physical units as used by trial patients. The second is to 'cost' these resource use data using prices or unit costs. Costs will be assessed from an NHS and Personal Social Service perspective. A separate analysis of costs from a wider perspective will also be undertaken. The wider social costs will be presented separately to avoid double counting with the QALY measure. Resource utilisation will be assessed from case records and patient self-report using an adapted Health Economic/Service Utilisation questionnaire. The study will aim to estimate representative national unit costs. Intervention costs will be based on delivery costs within the trial and include supervision and appropriate capital costs.

We will undertake a cost-effectiveness analysis at twelve months by comparing resource use in the two groups. We will use EQ-5D to measure health-related quality of life and convert into quality adjusted life years (QALYs), then calculate an incremental cost effectiveness ratio (cost per QALY gained), after adjusting for baseline EQ-5D score.

### **7.4 Safety assessment**

Clear guidance on the prescription of anti-smoking medications in the presence of SMI (including safety considerations) have been published and will be made available to all GPs to help inform their prescribing decisions (see appendix D). A key feature of the SCIMITAR trial is to ensure that GPs manage anti-smoking medications within this framework and with their prior knowledge of the patient and their concomitant use of medication. This will replicate 'real life practice' of the use of anti-smoking medications in primary care. The medication profile of the individual participants will be reviewed by their GP or mental health specialist to assess any potential safety issues (in line with the latest practice guidance on the provision of smoking cessation interventions in the NHS). It is an important aspect of the design of this study that the SCIMITAR team will have no direct influence over prescribing decisions by General Practitioners since this is not a drug trial or an investigation of a medicinal product(s).

## **8 Data Management**

Data will be primarily in the form of participant self-report questionnaires, MH-SCP patient logs, logs collated from GP/mental health specialist patient records and case report forms. Qualitative data from face to face interviews will be collected in the form of audio and videotaped interviews which will be independently transcribed.

Questionnaire responses will be collected by telephone interview or face-to-face interviews with patients at 1, 6 and 12 months post recruitment. Postal return of questionnaires may also be offered for 1 and 6 month follow-ups only. Open ended feedback questions will be used to enquire about adverse events which must be recorded on case report forms and reported to the

investigator as necessary. Questions of emergency or planned hospital admissions will also be included and followed up as necessary.

The MH-SCP will fill out a patient log each time the participant is seen to record all smoking related activities and assessments, including breath CO measurements, prescription of smoking cessation medications, and smoking cessation counselling.

At 12 months follow-up, all participants (BSC patients and usual care controls) will be requested to meet with the SCIMITAR researcher for a final assessment. This will include a final outcome assessment of smoking status, expired breath CO, and BMI measurements. Once the participant has completed the study, a researcher will collect their patient logs from the MH-SCP and check GP medical records of intervention and control participants for smoking cessation prescription medications, to collate them for analysis.

Data from questionnaires and case report forms will be entered into tailor-made databases and validated following our standard operating procedures. Briefly this involves that all documents are scanned into a “Download” database, which is second checked by data entry clerks. Second checking involves comparing the scanned record with the hard copy of all questionnaires to ensure for correct scanning of the documents. On completion of second checking, the download database is run through a validation process. This runs a series of database SQL scripts which checks that all the inputted values are within the expected range. Any errors can be flagged for further clarification, so long as an audit trail clearly documents the decisions and any changes made.

This robust data management system ensures an electronic copy of paper questionnaires, conversion to a format which can be analysed and also allows the rapid identification of on-going data issues that can be investigated and resolved.

## **9 Statistics and data analysis**

### **9.1 Sample size**

This initial pilot trial aims to obtain preliminary estimates of the effect size of the Bespoke Smoking Cessation service in order to inform a sample size calculation for a subsequent fully powered definitive RCT. For this study we aim to recruit 100 patients with SMI.

Using the following evidence based assumptions, 1/primary care QOF register prevalence data for SMI of 0.5%, an average of 2.5 WTE GPs in each practice, at least 80% of people with SMI smoke and that we recruit 25% of eligible patients in primary care, 20 practices would enable us to recruit 100 patients over a 12 month period. This is a conservative assessment which does not allow for recruitment from secondary care, where recruitment is less easy to plan but will be in addition to primary care.

### **9.2 Analysis of quantitative data**

We will analyse the data on an intention to treat basis. The primary outcome of smoking cessation at 12 months will be used in a logistic regression model to compare bespoke smoking cessation services with usual care. The analysis will be adjusted for baseline smoking severity (self reported number of cigarettes smoked). Odds ratios and the corresponding 95% confidence intervals will be presented for the primary outcome of smoking cessation. Two-sided 95% confidence intervals for the odds ratio will be calculated.

Secondary outcomes will include reduction in the number of cigarettes smoked, the FTND, changes in motivation to quit, and PHQ9 and SF-12 general mental health measures at 1,6 and 12 months. For each outcome measure the number of non-responders will be calculated for each treatment group and response rates compared. Appropriate sensitivity analyses will be used to examine the effects of missing data on outcomes. All secondary analyses will be conducted using linear or logistic regression, depending on the outcome measure, adjusting for the same covariates as the primary analysis.

Although we will use all possible means of follow up to minimise missing data, it is inevitable that some trial participants will be missed. Conventional approaches to missing data (such as last observation carried forward) tend to make erroneous assumptions, and imputation of missing data based upon this methods tend to underestimate the variance of outcomes of interest. In analysing missing data multiple imputation techniques may be used to assess non-compliance.

### **9.3 Analysis of Qualitative data**

Each in-depth interview will be digitally recorded and transcribed verbatim. Transcripts will be checked and anonymised to remove identifying details and participants will be allocated pseudonyms. Anonymised transcripts will be uploaded to a qualitative data software package. Field notes will also be written by the researcher during each interview to record impressions of participants' responses, thoughts on the functioning of questions, and initial impressions of salient issues arising from the discussion. Data segments will be coded by a qualitative researcher which will then be compared and contrasted with other codes and grouped into more overarching themes to build up an analysis of key emergent themes<sup>77</sup>. The qualitative data analysis will seek to find themes and issues with strong sub-group validation which will be linked and cross referenced to examine potential relationships. Main categories will then be compared across interviews reintegrated into important themes. Finally the frequencies of each theme will be determined to ensure the representativeness of the resulting themes.

## **10 Adverse Events**

### **10.1 Definitions**

An **adverse event** is any unexpected effect or untoward clinical event affecting the participant. It can be directly related, possibly related or completely unrelated to the intervention. It can also be classed according to severity, such that non-serious Adverse Event (AE) includes discomfort or slight worsening of symptoms, or Serious Adverse Event (SAE), which may be particularly harmful, dangerous or require hospitalisation.

Note: Hospitalisations for treatment planned prior to randomisation and hospitalisation for elective treatment of a pre-existing condition will not be considered as an AE. Complications occurring during such hospitalisation will be AEs.

### **10.2 Detecting and recording AEs and SAEs**

Any adverse events will be recorded at each visit by the MH-SCP or GP/mental health specialist. All events related and unrelated to the smoking cessation intervention will be recorded on adverse events forms. Any SAEs will be reported to the trial co-ordinator within 24 hours who will inform the trial sponsor and the research ethics committee. Further information may be requested for follow up of these events. Detailed records will be kept of all adverse events.

### 10.3 Evaluation of AEs and SAEs

All adverse events will be evaluated for seriousness, causality, severity and expectedness by the investigator and reviewed by an independent clinician/mental health specialist.

#### 10.3.1 Assessment of Causality and relatedness

The Investigator must make an assessment of whether the AE/SAE is likely to be related to treatment according to the following definitions:

**Unrelated:** where an event is not considered to be related to the study intervention.

**Possibly:** although a relationship to the study intervention cannot be completely ruled out, the nature of the event, the underlying disease, concomitant medication or temporal relationship make other explanations possible.

**Probably:** the temporal relationship and absence of a more likely explanation suggest the event could be related to the study intervention.

**Definitely:** The known effects of the study intervention, or based on challenge testing, suggest that study intervention is the most likely cause.

All AEs/SAEs judged as having a reasonable suspected causal relationship (e.g. possibly, probably, definitely) to the study intervention will be considered as an adverse reaction or serious adverse reaction (SAR).

Alternative causes such as natural history of the underlying disease, concomitant therapy, other risk factors and the temporal relationship of the event to the treatment should be considered.

#### 10.3.2 Assessment of Severity

The Investigator should make an assessment of severity for each AE/SAE and record this on the CRF according to one of the following categories:

**Mild:** an event that is easily tolerated by the participant, causing minimal discomfort and not interfering with every day activities.

**Moderate:** an event that is sufficiently discomforting to interfere with normal everyday activities.

**Severe:** an event that prevents normal everyday activities.

Note: the term 'severe', used to describe the intensity, should not be confused with 'serious' which is a regulatory definition based on participant/event outcome or action criteria. For example, a headache may be severe but not serious, while a minor stroke is serious but may not be severe.

#### 10.3.3 Assessment of Expectedness

If an event is judged to be an adverse reaction, the evaluation of expectedness should be made based on knowledge of the reaction and any relevant product information used in the intervention documented in Investigator's Brochure.

### 10.4 Reporting SAEs/SARs

All reporting of adverse events or reactions of a serious nature will follow regulatory reporting requirements as set out in article 17 of the EU directive 2001. These will be reported

immediately to the sponsor and within 7 days to the MREC/IEC. Any relevant further information will be subsequently communicated within 8 days. In addition, all associated investigators will be notified.

The numbers and details of all AEs and SAEs will be reported to the trial management committee and data monitoring and ethics committees.

## **10.5 Follow-up procedures**

If possible, the patient and the person reporting the serious adverse event will be contacted for detailed information regarding the timescale and course of events leading up to the adverse event. Copies of hospital records, laboratory or diagnostic results or coroners reports where appropriate, may be requested.

One month following notification of an AE or SAE, the event will be reviewed. If the patient makes a full recovery, they will be assessed by their GP or mental health specialist and a decision made as to their continued treatment or participation in the study.

## **11 Trial Management and Overseer Arrangements**

### **11.1 Trial Management Group (TMG)**

The Trial Management Group will be established to oversee the conduct of the trial including the qualitative part of the study. This committee will consist of trial co-ordinators from the two main centres, data management staff, principle investigators and the trial statistician. The committee will meet every 2 months to discuss recruitment, targets, general progress and adverse events. The committee will produce progress reports for the TSC and when necessary for the local ethics committee.

### **11.2 Independent Trial Steering Committee (TSC)**

This committee will comprise the principle investigators of the study, an independent chair and at least two other independent members. The steering committee will meet on at least annually to discuss progress of the trial. The DMEC, trial co-ordinators and statisticians will report to the TSC as necessary.

### **11.3 Data Monitoring and Ethics Committee (DMEC)**

This committee will consist of experts (including independent statistician and mental health professional) independent of the principle investigator and host institutions. Its remit will be to monitor the trial data, in particular quality control and quality assurance of data collected, and progress of the trial, including adherence to the trial protocol. This committee will also examine and ensure that the dignity, rights, safety and well-being of all the study participants are maintained at all stages of the trial. Data reports will be provided, including any adverse events, and the committee can have direct access to source data and documentation.

### **11.4 Risk Assessment**

A risk assessment will be carried out by members of the trial management team prior to the start of the study. During the trial, ongoing assessments of all aspects of the study will be made by the TMG, TSC and DMEC committees. All participants will receive usual GP and/or mental health specialist care, and therefore no treatment will be withheld by participating in this trial. By participating in this trial, patients will receive a more intensive level of monitoring than that normally received in primary care.

## **12 Good Clinical Practice**

### **12.1 Ethical conduct**

We are aware that people with SMI represent a vulnerable group. However, we do not anticipate any major ethical issues since we will only offer interventions recommended in recent guidance issued by the NICE<sup>39 40</sup>. Where participation in the trial is felt to be detrimental to health and wellbeing (as decided by a clinician who has fore-knowledge of the patient), we will not make an approach to participate.

Patients will not be denied any form of care that is currently available in the NHS by participating in the SCIMITAR trial, since patients allocated to usual care will still have full access to NICE-recommended treatments, subject to local provision of services. Our key research question relates to the optimum design and delivery of these services, and our intervention will be offered in addition to ‘usual NHS care’.

Therefore this study will be conducted in accordance with the principles of the good clinical practice (GCP) and a favourable ethical opinion from the appropriate REC and local NHS R&D approval will be obtained prior to commencement of the study.

### **12.2 Research Governance**

The trial will be conducted to protect the human rights and dignity of the participant as reflected in the 1996 version of the Helsinki Declaration. Patients will not receive any financial inducement to participate. In order to protect the trial participants the following provisions will be made/upheld; the trial has been designed to minimise pain, discomfort and fear and any foreseeable risk in relation to the treatments involved, the explicit wishes of the participant will be respected including the right to withdraw from the trial at any time, the interest of the patient will prevail over those of science and society, provision will be made for indemnity by the investigator and sponsor and a contact name for further information will be provided.

Steps outlined in section 12.3.5 will ensure that patient confidentiality will be maintained.

### **12.3 Investigator responsibilities**

The Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of GCP, the following areas listed in this section are also the responsibility of the Investigator.

Responsibilities may be delegated to an appropriate member of study site staff such as trial managers or trial coordinators.

#### **12.3.1 Informed consent**

The Investigator is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in clinical research is voluntary and should be based on a clear understanding of what is involved.

The trial will use a 2-stage consent process. Firstly patients will be given or sent an information pack and it is requested that they complete and send the “consent to be contacted form” back to researchers. The Investigator or delegated researcher from the SCIMITAR team will then arrange a meeting with the patient to explain and discuss the trial. If the patient consents, both the researcher and the participant will sign and date the Informed Consent Form to confirm that

consent has been obtained. The participant will receive a copy of this document and a copy will be filed in the Investigator Site File (ISF).

### **12.3.2 Study site staff**

It is the Investigator's responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their trial related duties.

The York-based trial manager will be responsible for the day-to-day running of the trial, obtaining ethical and research and development approval, designing trial documentation, recruitment of GPs and participants, trial centre co-ordination, collection of data, assisting the statistician to clean and analyse the data, write the initial draft of the research papers and disseminate the study's findings

The Manchester trial site will also have a full time research fellow/trial coordinator to facilitate recruitment and co-ordinate data collection.

A qualitative researcher will be dedicated to the qualitative part of the study. Responsibilities will involve organizing the recruitment of participants for the qualitative study, conducting the individual interviews, assisting transcription, analyzing and reporting on the qualitative data.

The trial secretary will assist the trial coordinators with the tasks of running the trial.

The data manager will validate and manage the data prior to analysis.

The trial statistician will be responsible for cleaning the data, conducting the statistical analyses and sending the data to the DMEC.

The economic analysis will require the specialist input of Steve Parrott.

Clinical supervision and GP liaison will be undertaken by research active clinicians with full GMC registration (York – Gilbody, Manchester – Lester).

Research fellows will ensure patient follow-up, liaise with MH-SCPs, collate GP/mental health specialist records to establish service utilisation, smoking cessation prescriptions and conduct post-intervention qualitative interviews and focus groups.

### **12.3.3 Data recording**

The Investigators (or delegated researchers) are responsible for the quality of the data recorded in that the information is complete, accurate, reliable, relevant and in the correct format. Data management will then be undertaken by the York Trials Unit.

### **12.3.4 Investigator documentation**

Prior to beginning the study, each Investigator will be asked to provide particular essential documents to the Sponsor, including an original signed Investigator's Declaration (as part of the Clinical Trial Agreement documents); Curriculum vitae (CV), signed and dated by the Investigator indicating that it is accurate and current.

The Chief Investigator, with the agreement of the Sponsor, will ensure all other documents required for compliance with the principles of GCP are retained in a Trial Master File and that appropriate documentation is available in local ISFs.

### **12.3.5 Confidentiality**

At randomisation each participant will be allocated a unique trial identification number. This number will be used to identify patients through-out the study. The master register linking patients personal and contact details with the identifier will be maintained by the York Trials Unit data manager. Only the trial co-ordinator, trial administrator and trial data manager will have access to this information via a password protected database within secure offices.

Clinical information will not be released without the written permission of the participant, except as necessary for monitoring and auditing by the Sponsor, its designee, Regulatory Authorities, or the REC. The Investigator and study site staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

### **12.3.6 Data Protection**

All collection, storage, processing and disclosure of personal information will be performed in compliance with the Data Protection Act 1998. All investigators and study site staff will uphold the Act's core principles. Any communications, reports or published results will not contain any personal data that could allow identification of individual participants.

All computers used to collate data will have limited access measures via user names and passwords. Databases are stored in right-restricted areas with limited access. All data are stored in locked facilities within card-accessed secure offices.

## **13 Study Conduct Responsibilities**

### **13.1 Protocol amendment**

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant, will be reviewed and approved by the Chief Investigator. Amendments to the protocol will be submitted in writing to the REC and local R&D for approval. Only once approval has been granted will the amended protocol be implemented.

### **13.2 Protocol violations and deviations**

The Investigator should not implement any deviation from the protocol without agreement from the Chief Investigator and REC and R&D approval except where necessary to eliminate an immediate hazard to trial participants.

In the event that an Investigator needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the CRF. If this necessitates a subsequent protocol amendment, this will be submitted to the REC and local R&D for review and approval if appropriate.

### **13.3 Study record retention**

All study documentation and data will be kept for a minimum of 5 years after the end of the final analysis of the study. All paper records will be stored in secure storage facilities. Personal identifiable paper records will be stored separate from anonymised paper records. All electronic records will be stored on password protected servers within the York Trials Unit and the

University of Manchester. All contact information will be destroyed securely immediately at the end of the trial.

### **13.4 End Study**

The Investigators and/or the trial steering committee have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants and ensure that the appropriate follow up is arranged for all involved.

A summary report of the study will be provided to the REC within 1 year of the end of the study.

## **14 Reporting, Publications and notification of results**

We will publish papers relating to this trial that will include (as a minimum), the results of the clinical and cost effectiveness comparisons, and qualitative analysis. We aim to publish in peer reviewed, professional journals to ensure that clinicians and academics have prompt access to our findings.

We will produce a short newsletter summary of the results that can be distributed to all trial participants, including patients, GPs and mental health specialists as well as relevant patient and other interested groups.

Finally we will aim to disseminate our findings in the wider media by issuing a press release. This will serve to bring the public and clinicians' attention to our findings.

## **15 Statement of Indemnity**

Normal NHS Indemnity procedures will apply. The University of York will also provide relevant cover.

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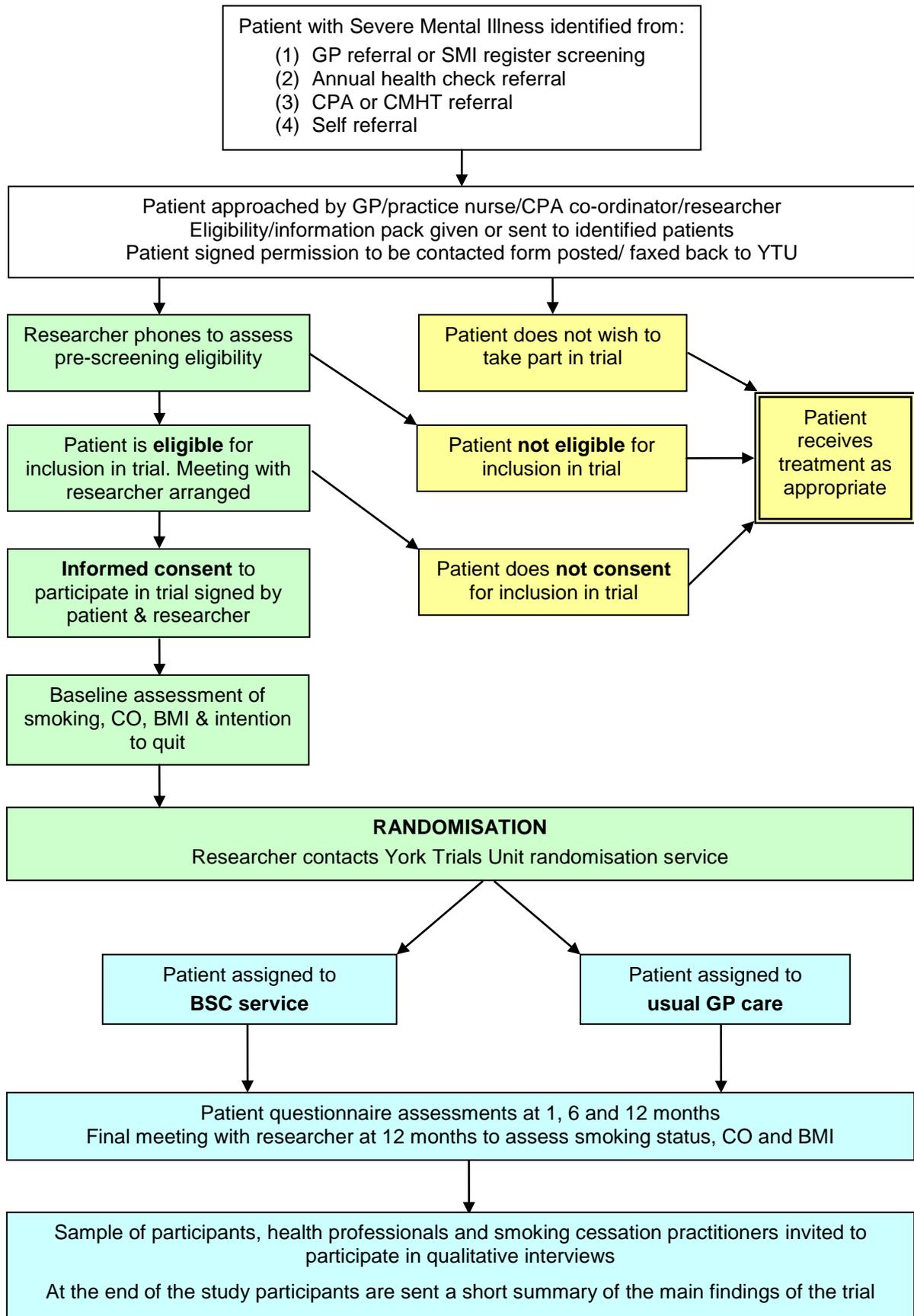
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## **Appendix B – Flowchart of participant through the SCIMITAR trial**



## **Appendix C – Questionnaires and Assessments**

### **Baseline Questionnaire**

#### **Section A – General Health**

1. What is your date of birth?

		/			/				
--	--	---	--	--	---	--	--	--	--

*(please write your date of birth)*

day

month

year

2. Are you

Male  Female

3. How would you describe your health over the past year? *(circle one number)*

Excellent	1
Good	2
Moderate	3
Poor	4
Very poor	5

4. How many times have you consulted your GP in the last 12 months?

\_\_\_\_\_times

5. Do you feel that smoking has affected the state of your health?

Yes  No

6. Has your GP or any other doctor advised you to quit smoking?

Yes  No

7. Are you pregnant or breastfeeding?

Yes  No

8. Have you ever suffered from any of the following health problems?

Heart disease

Yes  No

Cancer

Yes  No

Stroke

Yes  No

Bronchitis/emphysema

Yes  No

Asthma

Yes  No

Stomach or duodenal ulcer

Yes  No

Epilepsy, seizures or fits

Yes  No

Head injury

Yes  No

Brain tumour

Yes  No

Eating disorder

Yes  No

Liver disease

Yes  No

Kidney disease

Yes  No

9. Do you drink alcohol?

Yes  No

*If yes, please specify what you drink:*

*how much you drink  
\_\_\_\_\_per week*

10. Do you take recreational drugs?

Yes  No

*If yes, please specify what you take:*

*how much you take  
\_\_\_\_\_per week*

**Section B – Sociodemographic Details**1. Are you? *(please cross one box)*

- |                                      |                          |    |
|--------------------------------------|--------------------------|----|
| White – British                      | <input type="checkbox"/> | 1  |
| White – Irish                        | <input type="checkbox"/> | 2  |
| Any other White background           | <input type="checkbox"/> | 3  |
| Mixed – White and Black Caribbean    | <input type="checkbox"/> | 4  |
| Mixed – White and Black African      | <input type="checkbox"/> | 5  |
| Mixed – White and Asian              | <input type="checkbox"/> | 6  |
| Any other mixed background           | <input type="checkbox"/> | 7  |
| Asian or Asian British – Indian      | <input type="checkbox"/> | 8  |
| Asian or Asian British – Pakistani   | <input type="checkbox"/> | 9  |
| Asian or Asian British – Bangladeshi | <input type="checkbox"/> | 10 |
| Any other Asian background           | <input type="checkbox"/> | 11 |
| Black or Black British - Caribbean   | <input type="checkbox"/> | 12 |
| Black or Black British - African     | <input type="checkbox"/> | 13 |
| Chinese                              | <input type="checkbox"/> | 14 |
| Other, please specify here _____     | <input type="checkbox"/> | 15 |

## 2. What is your highest educational qualification?

GCSE/ O level	<input type="checkbox"/>	1
GCE A/AS level or Scottish Higher	<input type="checkbox"/>	2
NVQ/SVQ levels 1-3	<input type="checkbox"/>	3
GNVQ (Advanced)	<input type="checkbox"/>	4
B Tec Certificate	<input type="checkbox"/>	5
B Tec Diploma	<input type="checkbox"/>	7
National Certificate or Diploma (ONC/ OND/ HNC/HND)	<input type="checkbox"/>	8
Qualified Teacher Status	<input type="checkbox"/>	9
Higher Education Diploma	<input type="checkbox"/>	10
Degree (First Degree/ Ordinary Degree)	<input type="checkbox"/>	11
Post Graduate Certificate	<input type="checkbox"/>	12
Post Graduate Diploma	<input type="checkbox"/>	13
Masters Degree	<input type="checkbox"/>	14
PhD	<input type="checkbox"/>	15
Other	<input type="checkbox"/>	16
Don't know/no response	<input type="checkbox"/>	17

5. Are you? (please cross the box that describes you best)

- |   |                          |    |
|---|--------------------------|----|
| Employed full-time (30+ hours per week)                         | <input type="checkbox"/> | 1  |
| Employed part-time (<30 hours per week)                         | <input type="checkbox"/> | 2  |
| Self-employed   | <input type="checkbox"/> | 3  |
| Retired   | <input type="checkbox"/> | 4  |
| Looking after family or home                                    | <input type="checkbox"/> | 5  |
| Student (full or part-time)                                     | <input type="checkbox"/> | 6  |
| Voluntary worker  | <input type="checkbox"/> | 7  |
| Not employed but seeking work                                   | <input type="checkbox"/> | 8  |
| Not employed but <b>not</b> seeking work because of ill health  | <input type="checkbox"/> | 9  |
| Not employed, but <b>not</b> seeking work for some other reason | <input type="checkbox"/> | 10 |
| Other, please specify here _____                                | <input type="checkbox"/> | 11 |

5a. What is your job title: \_\_\_\_\_

5b. In the last six months, how many weeks have you been working  1

5c. On average, how many hours do you work per week  2

5d. What is your current weekly wage before tax? £  3

5e. If unemployed, how long have you been unemployed?

- |                        |                          |   |
|------------------------|--------------------------|---|
| < 3 months             | <input type="checkbox"/> | 1 |
| 4-12 months            | <input type="checkbox"/> | 2 |
| 1-2 years              | <input type="checkbox"/> | 3 |
| 2-5 years              | <input type="checkbox"/> | 4 |
| >5 years               | <input type="checkbox"/> | 5 |
| Don't know/no response | <input type="checkbox"/> | 6 |

6. What is your marital status?  
(please cross one box)

- Single  1
- Married  2
- Living with a partner/co-habiting  3
- Divorced/separated  4
- Widowed  5
- Never married  6
- Other (please specify)  7
- Don't know/no response  8

7. Do you have any children  
(please cross one box)

- Yes  1
- No  2

7a. If yes, how old are your children

- 1  Years 1
- 2  Years 2
- 3  Years 3

8. What is your current accommodation type  
(please cross one box)

- Detached house  1
- Semi-detached house  2
- Terraced house  3
- Flat  4
- Bedsit/studio  5
- Communal establishment  6
- Caravan/other mobile shelter  7
- No fixed abode  8

8. What type of accommodation have you lived in within the last six months	Number of days
Domestic accommodation (owned or rented)	1
Living with friends or relatives	2
Bed & breakfast, boarding house or hotel	3
Homeless, living on the streets	4
Staffed accommodation (staffed during the day only)*	5
Staffed accommodation (staffed day and night)*	6
Other please specify _____	7

\*may include hostel, shelter, refuge, half-way house, NHS residential accommodation

9. Do you have other people living with you?	
Yes	1
No	2
Don't know/no response	3

9a. If yes to question 9, how many?	
1	1
2	2
3	3
4	4
5	5
6	6
7 or more	7
Don't know/no response	8

**Section C - Mental health status**

1. What is the term used to describe your mental health problem? \_\_\_\_\_
2. When were you diagnosed with your mental health problem \_\_\_\_\_
3. What is the name of your current psychiatrist? \_\_\_\_\_
4. Do you have a Care Programme Approach (CPA) coordinator? Yes  No   
*If yes, what is their name?* \_\_\_\_\_
5. Are you seen by a Community Mental Health Team? Yes  No   
*If yes, who is your case manager/key worker?* \_\_\_\_\_
6. What was the date of your most recent annual health check? \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_
7. In the last 10 years, how many times have you needed psychiatric treatment in hospital? \_\_\_\_\_ times
8. Would you describe your condition as: Stable   
 Unstable   
 Unsure
9. Do you take any medications: Yes  No   
*If yes, then please list **ALL** medications below:*

## Section D - Smoking History

1. How long have you been a smoker? \_\_\_\_\_years\_\_\_\_\_months
2. What type of tobacco do you use?
  - Packet cigarettes
  - Hand-rolled cigarettes
  - Cigars
  - Pipe
  - Chewing tobacco
  - Water pipe/hookah/sheesha pipe
3. How many cigarettes do you usually smoke per day? \_\_\_\_\_cigarettes/packets
4. If you use roll-ups or a pipe, how much tobacco do you usually use per day? \_\_\_\_\_ounces
5. How many times have you tried to give smoking in the past? \_\_\_\_\_attempts
6. What is the longest period of time that a quit attempt has lasted? \_\_\_\_\_days/weeks
7. Have you ever tried nicotine chewing gum? Yes  No   
 If yes, how many pieces did you use altogether? \_\_\_\_\_pieces
8. Have you ever tried nicotine skin patches? Yes  No   
 If yes, how many patches did you use altogether? \_\_\_\_\_patches
9. Have you ever tried nicotine nasal spray? Yes  No   
 If yes, how many bottles did you use altogether? \_\_\_\_\_bottles
10. Have you ever tried nicotine inhalator? Yes  No   
 If yes, how many cartridges did you use altogether? \_\_\_\_\_cartridges
11. Have you ever tried nicotine microtab? Yes  No   
 If yes, how many tablets did you use altogether? \_\_\_\_\_tablets
12. Have you ever tried nicotine lozenges? Yes  No   
 If yes, how many lozenges did you use altogether? \_\_\_\_\_lozenges

13. Have you tried any other methods to stop smoking?

Zyban (Bupropion) Yes  No

Champix (Varenicline) Yes  No

Cold Turkey Yes  No

Hypnosis Yes  No

Acupuncture Yes  No

Other (Please state \_\_\_\_\_) Yes  No

14 How important are these reasons for smoking?

Very important      Quite important      Not important

It helps me relax

It helps to break up my working time

It is something to do when I am bored

It helps me cope with stress

I enjoy it

It's something I do with my family & friends

It stops me putting on weight

It stops me getting withdrawal symptoms

15 What are your reasons for trying to give up smoking?

Very important      Quite important      Not important

It is expensive

It is bad for my health

I don't like feeling dependent on cigarettes

It makes my clothes and breath smell

It is a bad example for children

It is unpleasant for people near me

It makes me less fit

People around me disapprove of my smoking

It is bad for the health of people near me

## Outcome Measures

### Smoking status

This section is about your smoking now and your attempts to quit smoking.

1. Have you smoked at all in the last week? (*cross one box*)
- No not even a puff
- Yes just a few puffs
- Yes between 1 and 5 cigarettes
- Yes more than 5 cigarettes

If yes, please answer 1a and 1b:

1a. what time of day did you have that first puff? (*Please write the time in the box and circle a.m. or p.m.*)

a.m./p.m.

1b. How many cigarettes are you normally smoking per day

\_\_\_\_\_cigarettes/packets

\*Baseline and 12 month follow-up only

Breath carbon monoxide reading = \_\_\_\_\_ppm  
 \_\_\_\_\_COHb

2. Which of the following statements best describes you at the moment?

I smoke the same amount of cigarettes (including hand-rolled) every day

I have cut down the number of cigarettes (including hand-rolled) I smoke

I smoke cigarettes (including hand-rolled) but not every day

I have stopped smoking completely

3. How many serious quit attempts to stop smoking have you made in the last 6 months? \_\_\_\_\_attempts

4. How long did your most recent quit attempt last before you went back to smoking? \_\_\_\_\_ Days  
 \_\_\_\_\_ Weeks  
 \_\_\_\_\_ Months

## Fagerstrom Test of Nicotine Dependence (FTND)

This set of questions will enable us to see how dependent you are on your cigarettes.

- 
1. How soon after you wake up do you smoke your first cigarette? *(Cross one box)*
- |  |                   |                          |   |
|--|-------------------|--------------------------|---|
|  | Within 5 minutes  | <input type="checkbox"/> | 3 |
|  | 6-30 minutes      | <input type="checkbox"/> | 2 |
|  | More than 30 mins | <input type="checkbox"/> | 0 |
2. Do you find it difficult to stop smoking in no-smoking areas? *(Cross one box)*
- |  |     |                          |   |
|--|-----|--------------------------|---|
|  | Yes | <input type="checkbox"/> | 1 |
|  | No  | <input type="checkbox"/> | 0 |
3. Which cigarette would you hate most to give up? *(Cross one box)*
- |  |                          |                          |   |
|--|--------------------------|--------------------------|---|
|  | The first of the morning | <input type="checkbox"/> | 1 |
|  | Other                    | <input type="checkbox"/> | 0 |
4. How many cigarettes per day do you usually smoke? *(Write the number on the line **and** cross one box)*
- |  |               |                          |   |
|--|---------------|--------------------------|---|
|  | _____ per day |                          |   |
|  | 10 or less    | <input type="checkbox"/> | 0 |
|  | 11 to 20      | <input type="checkbox"/> | 1 |
|  | 21 to 30      | <input type="checkbox"/> | 2 |
|  | 31 or more    | <input type="checkbox"/> | 3 |
5. Do you smoke more frequently in the first hours after waking than during the rest of the day? *(Cross one box)*
- |  |     |                          |   |
|--|-----|--------------------------|---|
|  | No  | <input type="checkbox"/> | 0 |
|  | Yes | <input type="checkbox"/> | 1 |
6. Do you smoke if you are so ill that you are in bed most of the day? *(cross one box)*
- |  |     |                          |   |
|--|-----|--------------------------|---|
|  | No  | <input type="checkbox"/> | 0 |
|  | Yes | <input type="checkbox"/> | 1 |
7. Do you smoke hand-rolled cigarettes?
- |                                  |     |                          |   |
|----------------------------------|-----|--------------------------|---|
|                                  | No  | <input type="checkbox"/> | 0 |
| If Yes, please answer 7a and 7b: | Yes | <input type="checkbox"/> | 1 |
- 7a. How many do you usually smoke per day?
- |  |               |  |  |
|--|---------------|--|--|
|  | _____ per day |  |  |
|--|---------------|--|--|
- 7b. How much tobacco do you usually use per week?
- |  |              |  |  |
|--|--------------|--|--|
|  | _____ ounces |  |  |
|--|--------------|--|--|
-

## Motivation to Quit questionnaire

This next set of questions tells us about your motivation to stop smoking.

- 
- |   |                        |                          |   |
|---|------------------------|--------------------------|---|
| 1. How important is it to you to give up smoking altogether at this point in time? <i>(Cross one box)</i> | Desperately important  | <input type="checkbox"/> | 4 |
|   | Very important         | <input type="checkbox"/> | 3 |
|   | Quite important        | <input type="checkbox"/> | 2 |
|   | Not all that important | <input type="checkbox"/> | 1 |
- 

- |  |                         |                          |   |
|--|-------------------------|--------------------------|---|
| 2. How determined are you to give up smoking at this point in time? <i>(Cross one box)</i> | Extremely determined    | <input type="checkbox"/> | 4 |
|  | Very determined         | <input type="checkbox"/> | 3 |
|  | Quite determined        | <input type="checkbox"/> | 2 |
|  | Not all that determined | <input type="checkbox"/> | 1 |
- 

- |   |   |                          |   |
|---|---|--------------------------|---|
| 3. Why do you want to give up smoking? <i>(Cross the most important reason)</i> | Because my health is already suffering      | <input type="checkbox"/> | 5 |
|   | Because I am worried about my future health | <input type="checkbox"/> | 4 |
|   | Because smoking costs too much              | <input type="checkbox"/> | 3 |
|   | Because other people are pressurising me to | <input type="checkbox"/> | 2 |
|   | For my family's health                      | <input type="checkbox"/> | 1 |
- 

- |   |                |                          |   |
|---|----------------|--------------------------|---|
| 4. How high would you rate your chances of giving up smoking for good at this point in time? <i>(Cross one box)</i> | Extremely high | <input type="checkbox"/> | 6 |
|   | Very high      | <input type="checkbox"/> | 5 |
|   | Quite high     | <input type="checkbox"/> | 4 |
|   | Not very high  | <input type="checkbox"/> | 3 |
|   | Low            | <input type="checkbox"/> | 2 |
|   | Very low       | <input type="checkbox"/> | 1 |
-

**PHQ9**

This section is about how you have been feeling in the last 2 weeks.

Answer each question by placing a cross in the box that best describes your answer.

	Over the past 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several Days	More than half the days	Nearly every day
1	Little interest or pleasure in doing things	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Feeling down, depressed or hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Trouble falling asleep, staying asleep or sleeping too much	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Feeling tired or having little energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Poor appetite or overeating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Feeling bad about yourself – or that you are a failure or have let yourself or your family down	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Trouble concentrating on things, such as reading the newspaper or watching TV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Moving or speaking so slowly that other people have noticed? Or the opposite – being so fidgety or restless that you have been moving around more than usual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Thoughts that you would be better off dead or of hurting yourself in some way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**EQ-5D**

Please indicate which statements best describe your own health today?  
Place a cross in one box in each group that best describes your answer

**Mobility**

I have no problems in walking about

I have some problems in walking about

I am confined to bed

**Self-Care**

I have no problems with self-care

I have some problems washing or dressing myself

I am unable to wash or dress myself

**Usual Activities** (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities

I have some problems with performing my usual activities

I am unable to perform my usual activities

**Pain/Discomfort**

I have no pain or discomfort

I have moderate pain or discomfort

I have extreme pain and discomfort

**Anxiety/Depression**

I am not anxious or depressed

I am moderately anxious or depressed

I am extremely anxious or depressed

**SF-12**

The following questions ask about your views about your health. This section will help us understand more about how patients feel and how well they are able to do their usual activities. **Please answer every question.** If you are unsure how to answer a question, please give the best answer that you can.

1. **In general**, would you say your health is:  
(please circle one number only)

Excellent	Very Good	Good	Fair	Poor
1	2	3	4	5

2. During a typical day, does **your health** limit you in **moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf? If so how much?:  
(please circle one number only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
1	2	3

3. During a typical day, does **your health** limit you in climbing **several** flights of stairs? If so by how much?  
(please circle one number only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
1	2	3

4. During the **past 4 weeks**, how much time have you accomplished less than you would like in regular activities **as a result of your physical health**?  
(please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

5. During the **past 4 weeks**, how much time have you been limited in performing any kind of work?  
(please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

6. During the **past 4 weeks**, how much time have you accomplished less than you would have liked in your work or any other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious) ?  
(please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

7. During the **past 4 weeks**, how much time have you done work or other activities less carefully than usual **as a result of any emotional problems** (such as feeling depressed or anxious) ?  
(please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

8. During the **past 4 weeks**, how much did pain interfere with your normal work (both outside the home and housework)? (please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

9. This question is about how you feel and how things have been with you **during the last month**. Please give the one answer that comes closest to the way you have been feeling. How much during the last month have you felt calm and peaceful?  
(please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

10. This question is about how you feel and how things have been with you **during the last month**. Please give the one answer that comes closest to the way you have been feeling. How much during the **last month** did you have a lot of energy?  
(please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

11. This question is about how you feel and how things have been with you **during the last month**. Please give the one answer that comes closest to the way you have been feeling. How much during the **last month** have you felt downhearted and low?  
(please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

12. During the **past 4 weeks**, how much of the time has your **physical health** or emotional problems interfered with your social activities (like visiting friends, relatives etc.)  
(please circle one number only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
1	2	3	4	5

## Health Economics/Service Utilisation Questionnaire

The next section is about any health care you have received as a patient for any reason.

1. Have you attended an accident and emergency department (A&E) in the last **six months**?

Yes

No

Don't know

If yes, please record details below:

Reason	Admitted Yes/No	Number of nights stayed

2. In the **last six months**, have you had a planned hospital admission where you have stayed in hospital overnight?

Yes

No

Don't know

If yes, please record details below:

Reason	Number of nights

3. Have you been to hospital for an outpatient appointment in the **last six months**?

Yes

No

Don't know

If yes, please record details below:

Details of appointment	Number of appointments

4. Have you been in hospital as a day case/procedure patient in the **last six months**?

Yes

No

Don't know

If yes, please record details below:

Details of day case/procedure	Number of appointments

5. Have you used a '999' emergency ambulance in the **last six months**?

Yes

No

Don't know

If yes, how many times in the last six months? \_\_\_\_\_

6. Have you used the Patient Transport Service in the **last six months**?

Yes

No

Don't know

If yes, how many times in the last six months? \_\_\_\_\_

## Community Services

7. Have you had contact with any of the following community based professionals or services in the last **six months**:

	Service	Number of contacts
01	General Practitioner – home	
02	General Practitioner – surgery (including NHS walk-in clinic)	
03	General Practitioner – telephone	
04	Practice Nurse (nurse in GP surgery)	
05	District nurse, health visitor	
06	Care co-ordinator, case manager, key worker	
07	Psychiatrist	
08	Clinical psychologist	
09	Community psychiatric nurse	
10	CAMHS worker, STAR worker or advocate	
11	Counsellor (NHS, school/college or private)	
12	Family therapist	
13	Art/drama/music/occupational therapist	
14	Social worker	
15	Family support worker	
16	Social services youth worker	
17	Accommodation key worker	
18	Connexions	
19	Mentor	
20	Drug/alcohol support worker	
21	Advice service e.g. citizen's advice bureau, housing association	
22	NHS Direct telephone helpline	
23	Other helplines e.g. Samaritans, MIND	
24	Day centre/drop-in centre	
25	Complementary therapist e.g. homeopath, osteopath, reflexologist	
26	Any other health services eg Dentist – give details:	
27	Other – give details:	

## Other smoking cessation services

8. In the **last six months**, how many times have you asked for help or advice from:

	Number of contacts
A pharmacist	
Your Mental Health Smoking Cessation Practitioner	

9. In the **last six months** have you used these other services:

	Number of contacts
Phoned the NHS stop smoking helpline service	
Phoned other smoking helplines e.g. QuitLine	
Used the internet for help and support on stopping smoking	
Used self help books for advice to stop smoking	

10. In the **last six months** have you used any **nicotine replacement therapy (NRT)** products to help you quit smoking:

Yes

No

Don't know

If yes, please complete the following:

a. Did you use Nicotine **Patches**?

Yes

No

Don't know

If yes:

How many patches did you use? \_\_\_\_\_ patches

How long did you use them for? \_\_\_\_\_ Days/weeks/months

Did you get them on GP prescription

Yes

No

Don't know

b. Did you use Nicotine **gum**?

Yes

No

Don't know

If yes:

How many pieces of gum did you use? \_\_\_\_\_ pieces

How long did you use them for? \_\_\_\_\_ Days/weeks/months

Did you get them on GP prescription

Yes No Don't know c. Did you use Nicotine **Lozenges**?Yes No Don't know 

If yes:

How many lozenges did you use? \_\_\_\_\_ lozenges

How long did you use them for? \_\_\_\_\_ Days/weeks/months

Did you get them on GP prescription

Yes No Don't know d. Did you use Nicotine **microtabs**?Yes No Don't know 

If yes:

How many tablets did you use? \_\_\_\_\_ tablets

How long did you use them for? \_\_\_\_\_ Days/weeks/months

Did you get them on GP prescription

Yes No Don't know e. Did you use Nicotine **Inhalator**?Yes No Don't know 

If yes:

How many cartridges did you use? \_\_\_\_\_ cartridges

How long did you use them for? \_\_\_\_\_ Days/weeks/months

Did you get them on GP prescription

Yes No Don't know f. Did you use Nicotine **Nasal Spray**?Yes No Don't know 

If yes:

How many bottles did you use? \_\_\_\_\_ bottles

How long did you use them for? \_\_\_\_\_ Days/weeks/months

Did you get them on GP prescription

Yes No Don't know 

11. In the **last six months**, have you used **Zyban (Bupropion)** to help you quit smoking?

Yes No Don't know 

If yes, how many quit attempts did you try using Zyban (Bupropion)? \_\_\_\_\_ attempts

For each quit attempt, please state how long you used Zyban for?

	Most recent quit attempt	Next most recent quit attempt	Third most recent quit attempt
Less than 24 hours			
24 hours			
1 to 6 days			
7 to 14 days			
2 to 4 weeks			
Longer than 4 weeks			
Cannot remember			

12. In the **last six months**, have you used **Champix (Varenicline)** to help you quit smoking?

Yes No Don't know 

If yes, how many quit attempts did you try using Champix (Varenicline)? \_\_\_\_\_ attempts

For each quit attempt, please state how long you used Champix for?

	Most recent quit attempt	Next most recent quit attempt	Third most recent quit attempt
Less than 24 hours			
24 hours			
1 to 6 days			
7 to 14 days			
2 to 4 weeks			
Longer than 4 weeks			
Cannot remember			

13. How much have you spend on buying additional products to help you stop smoking over the previous six months (not including NRT and drugs on prescription)

Nothing	
£1 - £10	
£11 - £20	
£21 - £30	
£31 - £40	
£41 - £50	
£50 - £100	
Over £100	

**Appendix D: Primary care guidance on smoking in mental health by the Royal College of General Practitioners and the Royal College of Psychiatrists**



## Primary Care Guidance On Smoking and Mental Health

December 2008

### Smoking the biggest killer

Smoking is the largest cause of preventable illness in the UK with smokers dying on average 10 years earlier than non-smokers.<sup>1</sup> Smokers who smoke at least 20 cigarettes a day also have a 61% increased risk of type 2 diabetes compared with non-smokers.<sup>2</sup>

People with mental health problems smoke significantly more than others<sup>3</sup> and therefore experience proportionally even greater smoke-related harm.

### Smoking and mental illness

Smoking is associated with an increased prevalence of all major psychiatric disorders<sup>4</sup> as well as higher suicide rates.<sup>5</sup> Smoking also increases the lifetime risk of developing a mental health problem.<sup>6</sup>

Life expectancy for people with schizophrenia is 20% shorter compared to the general population.<sup>7</sup> Since smoking is responsible for most of this increased mortality<sup>8</sup>, many premature deaths are preventable with appropriate smoking cessation support.

Furthermore, the amount of tobacco smoked is related to the number of depressive or anxiety symptoms and, after cessation, such symptoms reduce.<sup>4,9</sup>

### Effective interventions exist

Pharmacotherapy and other support such as counseling can increase abstinence rates in those with mental health problems to similar rates as for the general population.<sup>10, 11</sup>

However, people with mental illness have previously been less likely to receive smoking cessation interventions in primary care.<sup>12</sup>

### Smoking and medication

Smoking increases metabolism of different medications including some antidepressants (tricyclics and mirtazapine), anti-psychotics (clozapine, olanzapine and haloperidol), benzodiazepines and opiates. This can result in significantly lower plasma levels<sup>11</sup> and therefore, larger doses are required for a similar therapeutic effect.

However, following smoking cessation, doses of these medications can be reduced.

### Key learning points

**Smoking is a major determinant of health inequality for those with mental illness**

**With appropriate support, those with mental illness are able to stop smoking.**

**Smoking cessation for those with mental illness significantly improves mental and physical health while reducing the risk of premature death.**

**Doses of medication can be significantly reduced following cessation**

### Cessation and medication

Stopping smoking can reduce metabolism of some medication resulting in higher, sometimes toxic blood levels over a few days.<sup>11,13</sup> Therefore, it is recommended that:

- 1. Blood levels of clozapine (and olanzapine if assays available) should be measured before smoking cessation.<sup>13</sup> With clozapine and olanzapine, 25% dose reduction should occur during first week of cessation and then further blood levels taken on a weekly basis until levels have stabilised.<sup>13</sup>**
- 2. Doses of fluphenazine and benzodiazepine should be reduced by up to 25% in first week of cessation.<sup>13</sup>**

**3. Tricyclic antidepressants may need to be reduced by 10-25% in first week.<sup>13</sup> Further dose reductions within British National Formulary levels may be required with continued cessation.**

### The key role of primary care

Explain how smoking cessation can improve both physical and mental health and also reduce doses of medication.

Initially offer Nicotine Replacement Therapy (NRT) to all, including those who continue to smoke which supports smoking reduction as a first step to cessation.

Encourage engagement in group or individual smoking cessation counseling.

Coordinate with psychiatric secondary care services and NHS Stop Smoking Services to offer ongoing smoking cessation support as part of a more joined up health promoting service.

Following cessation, monitor mental state especially of those with depression since a minority who stop smoking experience an increase in depressive symptoms.<sup>14</sup>

### Smoking cessation prescribing

**Nicotine** replacement is available in a variety of forms and strengths to encourage patient preference and acceptability. Combining patch and faster-acting oral NRT improves efficacy. Side effects include mild local irritation of mouth, throat or nose.

**Bupropion** has been shown to be effective for those with depression and schizophrenia<sup>11</sup> although it has been associated with increased anxiety and depression. It is associated with seizures and is contraindicated in bipolar affective disorder and epilepsy. It should not be prescribed with drugs which increase risk of seizures such as tricyclic antidepressants and some anti-psychotics. Bupropion can also alter blood levels of medication such as anti-psychotics and antidepressants.

**Varenicline** has been reported to be more effective and have fewer side effects than bupropion.<sup>15</sup> However, since reports of exacerbation of depression and suicidal ideation are currently being reviewed, further data is required for those with mental illness.



## Useful Resources

- RCGP News Article Dec 2008
- Faculty of Public Health position statement about smoking and mental health

Download these resources from:  
<http://www.iris-initiative.org.uk/provide-practitioner-learning/smoking-and-mental-health.html>

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## The Forum

The Forum for Mental Health in Primary Care is jointly hosted by the Royal College of Psychiatrists and the Royal College of General Practitioners. It aims to encourage communication, collaboration and creativity between individuals and organisations who work to enable day-to-day mental health in everyone.

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