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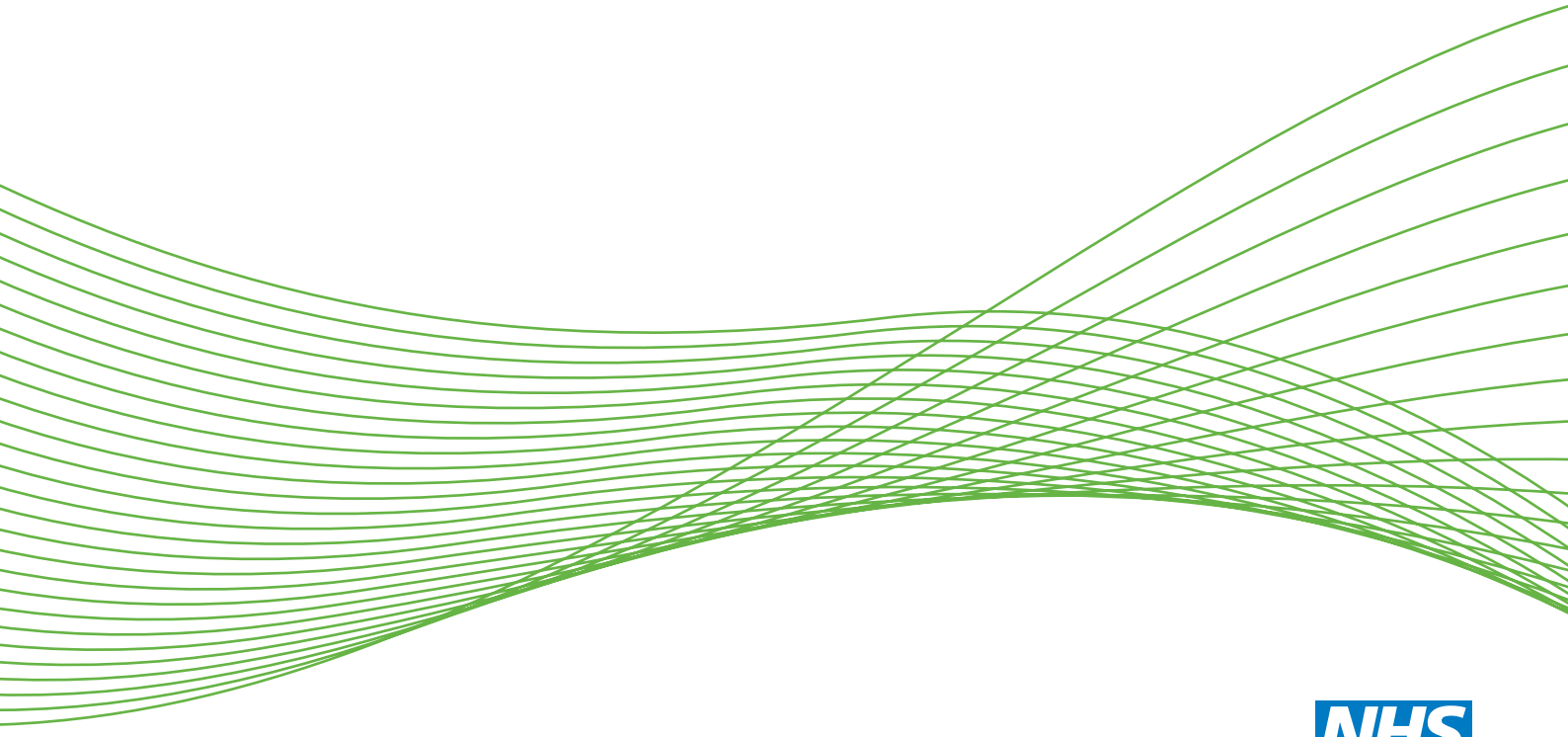

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Smoking Cessation Intervention for severe Mental Ill Health Trial (SCIMITAR): a pilot randomised control trial of the clinical effectiveness and cost-effectiveness of a bespoke smoking cessation service

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Abstract

Smoking Cessation Intervention for severe Mental Ill Health Trial (SCIMITAR): a pilot randomised control trial of the clinical effectiveness and cost-effectiveness of a bespoke smoking cessation service

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Background: There is a high prevalence of smoking among people who experience severe mental ill health (SMI). Helping people with disorders such as bipolar illness and schizophrenia to quit smoking would help improve their health, increase longevity and also reduce health inequalities. Around half of people with SMI who smoke express an interest in cutting down or quitting smoking. There is limited evidence that smoking cessation can be achieved for people with SMI. Those with SMI rarely access routine NHS smoking cessation services. This suggests the need to develop and evaluate a behavioural support and medication package tailored to the needs of people with SMI.

Objective: The objective in this project was to conduct a pilot trial to establish acceptability of the intervention and to ensure the feasibility of recruitment, randomisation and follow-up. We also sought preliminary estimates of effect size in order to design a fully powered trial of clinical effectiveness and cost-effectiveness. The pilot should inform a fully powered trial to compare the clinical effectiveness and cost-effectiveness of a bespoke smoking cessation (BSC) intervention with usual general practitioner (GP) care for people with SMI.

Design: A pilot pragmatic two-arm individually randomised controlled trial (RCT). Simple randomisation was used following a computer-generated random number sequence. Participants and practitioners were not blinded to allocation.

Setting: Primary care and secondary care mental health services in England.

Participants: Smokers aged > 18 years with a severe mental illness who would like to cut down or quit smoking.

Interventions: A BSC intervention delivered by mental health specialists trained to deliver evidence-supported smoking cessation interventions compared with usual GP care.

Main outcome measures: The primary outcome was carbon monoxide-verified smoking cessation at 12 months. Smoking-related secondary outcomes were reduction of number of cigarettes smoked, Fagerstrom test of nicotine dependence and motivation to quit (MTQ). Other secondary outcomes were Patient Health Questionnaire-9 items and Short Form Questionnaire-12 items to assess whether there were improvements or deterioration in mental health and quality of life. We also measured body mass index to assess whether or not smoking cessation was associated with weight gain. These were measured at 1, 6 and 12 months post randomisation.

Results: The trial recruited 97 people aged 19–73 years who smoked between 5 and 60 cigarettes per day (mean 25 cigarettes). Participants were recruited from four mental health trusts and 45 GP surgeries. Forty-six people were randomised to the BSC intervention and 51 people were randomised to usual GP care. The odds of quitting at 12 months was higher in the BSC intervention (36% vs. 23%) but did not reach statistical significance (odds ratio 2.9; 95% confidence interval 0.8% to 10.5%). At 3 and 6 months there was no evidence of difference in self-reported smoking cessation. There was a non-significant reduction in the number of cigarettes smoked and nicotine dependence. MTQ and number of quit attempts all increased in the BSC group compared with usual care. There was no difference in terms of quality of life at any time point, but there was evidence of an increase in depression scores at 12 months for the BSC group. There were no serious adverse events thought likely to be related to the trial interventions. The pilot economic analysis demonstrated that it was feasible to carry out a full economic analysis.

Conclusions: It was possible to recruit people with SMI from primary and secondary care to a trial of a smoking cessation intervention based around behavioural support and medication. The overall direction of effect was a positive trend in relation to biochemically verified smoking cessation and it was feasible to obtain follow-up in a substantial proportion of participants. A definitive trial of a bespoke cessation intervention has been prioritised by the National Institute for Health Research (NIHR) and the SCIMITAR pilot trial forms a template for a fully powered RCT to examine clinical effectiveness and cost-effectiveness.

Trial registration: Current Controlled Trials ISRCTN79497236.

Funding: This project was funded by the NIHR Health Technology Assessment programme and will be published in full in *Health Technology Assessment*, Vol. 19, No. 25. See the NIHR Journals Library website for further project information.

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List of abbreviations

AE	adverse event
BCT	behaviour change technique
BMI	body mass index
BSC	bespoke smoking cessation
CI	confidence interval
CMHT	Community Mental Health Team
CPA	Care Programme Approach
CPN	community psychiatric nurse
CO	carbon monoxide
CONSORT	Consolidated Standards of Reporting Trials
DSM	*Diagnostic and Statistical Manual of Mental Disorders*
EQ-5D	European Quality of Life-5 Dimensions
FTND	Fagerstrom Test for Nicotine Dependence
GCSE	General Certificate of Secondary Education
GMS	General Medical Services
GP	general practitioner
ICD	*International Classification of Diseases*
ICER	incremental cost-effectiveness ratio
MHRN	Mental Health Research Network
MHSCP	mental health smoking cessation practitioner
MTQ	motivation to quit
NICE	National Institute for Health and Care Excellence
NRT	nicotine replacement therapy
OR	odds ratio
PHQ-9	Patient Health Questionnaire-9 items
PI	principal investigator
QALY	quality-adjusted life-year
QOF	Quality and Outcomes Framework
RCT	randomised controlled trial
SAE	serious adverse event
SCIMITAR	Smoking Cessation Intervention for Serious Mental Ill Health Trial
SD	standard deviation
SF-12	Short Form questionnaire-12 items
SMI	severe mental ill health

Plain English summary

Smoking is an important cause of ill health and early death among people who have experienced a severe mental illness such as schizophrenia or bipolar disorder.

To address this problem we developed and tested a bespoke smoking cessation (BSC) service specifically tailored to individual patients with severe mental illness. People with severe mental illness were randomly allocated to one of two interventions: a BSC service or usual general practitioner (GP) care. Those allocated to the BSC service were assigned a mental health nurse or allied health professional who had been trained to deliver evidence-supported smoking cessation interventions. Usual GP care consisted of the care normally given by the patient's GP or practice smoking cessation service without any specific additions for those with mental ill health problems.

People who were allocated to a BSC programme generally engaged well with the intervention. When we tested the clinical effectiveness of the intervention at 12 months we found that the chances of having quit smoking were three times higher in the intervention group. This estimate is in line with previous research, but our trial was relatively small scale. Believable estimates of the clinical effectiveness and costs need to be established in a much larger trial.

This was a pilot study, conducted in preparation of a larger study. Further research is needed to establish the clinical effectiveness of the BSC intervention and whether or not this represents good value for money to the NHS. The Smoking Cessation Intervention for Serious Mental Ill Health Trial (SCIMITAR) pilot study forms a template for a larger-scale study.

Scientific summary

Background

The prevalence of smoking among patients who have experienced severe mental ill health (SMI) is high, despite smoking being a known health hazard associated with numerous diseases such as cancer and heart disease. People with SMI such as bipolar disorder and schizophrenia smoke more heavily and are more likely than the general population to be nicotine dependent. Despite the culture of smoking in mental health services, around 50% of people with SMI express a desire to quit smoking. However, the services currently available to aid quitting may not be suitably responsive or clinically effective for patients with SMI. Therefore, the role of this study is to develop a bespoke smoking cessation (BSC) 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 behavioural support [mental health smoking cessation practitioner (MHSCP)]. This initial pilot study will provide information on the introduction of the BSC intervention and give preliminary estimates of effect size, which can in the future form the basis of a definitive trial of clinical effectiveness and cost-effectiveness.

Objectives

The overarching objective is to eventually establish the clinical effectiveness and cost-effectiveness of a BSC intervention compared with usual general practitioner (GP) care for people with SMI. Prior to this, some preliminary development and research needs to be conducted, and our objective in this project was to deliver a pilot trial prior to conducting a definitive randomised controlled trial (RCT). The pilot trial will ultimately inform the design of a definitive trial.

The specific objectives of the Smoking Cessation Intervention for Serious Mental Ill Health Trial (SCMITAR) pilot trial were:

1. to develop a BSC service, based on evidence-supported treatments, for people with severe mental illness
2. to establish the acceptability and uptake of this BSC service by people with SMI in primary care and specialist mental health services
3. to test the feasibility of recruitment and follow-up in a pilot trial of a BSC service among patients with SMI
4. to obtain preliminary estimates of effect size in relation to smoking cessation at 12 months.

Design

A pragmatic, two-arm, parallel-group, pilot RCT.

Interventions

Participants were randomised to receive either a BSC service or usual care by their GP or mental health specialist. The BSC service was delivered by a mental health professional (MHSCP) trained to deliver smoking cessation behavioural support. The MHSCP provided an individually tailored smoking cessation service based on current guidelines for smoking cessation services but with enhanced levels of contact and

support. Participants randomised to usual GP care were advised to see their GP or to consult with usual NHS quit smoking services with no specific adaptation or enhancement in relation to SMI.

Participants

Potential participants were identified by (1) GP referral, (2) written approach by the GP after identification by GP database screening, (3) primary care referral after an annual health check, (4) referral from Care Programme Approach (CPA) co-ordinators and Community Mental Health Teams (CMHTs) or (5) self-referral by advertisements in outpatient departments, mental health clinics and day centres. To be eligible potential participants needed to be aged 18 years and over, have experienced severe mental illness such as bipolar disorder, schizophrenia or a related psychotic illness, smoke and have expressed a desire to either give up smoking or cut down to quit smoking.

Outcomes

The primary outcome was carbon monoxide (CO)-verified smoking cessation at 12 months. In the absence of a CO measurement, self-reported smoking cessation was used. Secondary smoking-related outcomes were reduction in number of cigarettes smoked, Fagerstrom Test for Nicotine Dependence (FTND) and motivation to quit (MTQ) questionnaire. Other secondary outcomes were a measure of mood [Patient Health Questionnaire-9 items (PHQ-9)], health status [Short Form Questionnaire-12 items (SF-12)], and a measure of health utility [European Quality of Life-5 Dimensions (EQ-5D)]. Secondary outcomes were each measured at 1, 6 and 12 months. Body mass index (BMI) was measured at the end of the trial (12 months) to explore whether or not smoking cessation was associated with weight gain. Aspects of health economics and service utilisation were collected by questionnaire in order to measure cost-effectiveness.

Results

Between May 2011 and May 2012, 97 participants were recruited into the SCIMITAR pilot study. The most common severe mental health problems were schizophrenia and other psychotic illness ($n = 57$; 59%), schizoaffective disorder ($n = 10$, 10%) and bipolar disorder ($n = 30$, 31%). Forty-six participants were randomised to a BSC service and 51 were randomised to usual GP care. Participants were aged between 19 years and 73 years and there were more male ($n = 58$) than female ($n = 39$) participants. At baseline, participants reported smoking between 5 and 60 cigarettes per day (mean 25 cigarettes) and had long smoking histories (mean 27 years).

Out of 46 participants in the intervention group, 41 attended at least one session. The number of sessions per participant ranged from 0 to 25. The average number of sessions per participant was 10. The mainstay of pharmacological treatment chosen by GPs and patients was nicotine replacement therapy. People in receipt of usual care rarely accessed any form of NHS smoking cessation treatment, but often purchased over-the-counter nicotine replacement products.

At 12 months, 36% of participants had stopped smoking in the BSC group, compared with 23% in the usual-care group. The adjusted odds ratio was 2.9 (95% confidence interval 0.8 to 10.5) indicating a greater likelihood of smoking cessation in the BSC group than the usual-care group, but this was not statistically significant.

In terms of secondary smoking-related outcomes at 12 months, the BSC group generally performed better than the usual-care group. At 12 months the MTQ score was higher, number of cigarettes smoked per day was lower, number of cessation attempts was higher and length of cessation was longer in the BSC group,

although these differences were not statistically significant. At 3 and 6 months, there were no differences in any of the smoking-related outcomes.

Mental well-being – as measured by the PHQ-9 and SF-12 – was not different between groups at 1 and 6 months. There was a non-significant difference at 12 months, with lower mood in the BSC group. In terms of physical health outcomes at 12 months, the BSC group fared better than the usual-care group overall, with slightly higher physical component scores and slightly lower BMI, although the differences were not statistically significant.

In the qualitative evaluation of the acceptability of BSC we identified four primary themes. Themes 1 and 2 reflected the lack of support for smoking cessation in current services and, consequently, the perceived benefits of the BSC intervention, which was more tailored to this population. Themes 3 and 4 reflect challenges and barriers reported by patients and professionals, including difficulties sustaining engagement and difficulties liaising with primary care.

The pilot economic analysis demonstrated that it was feasible to carry out a full economic analysis and highlighted ways in which questionnaires designed to capture information needed for the economic analysis could be improved.

Discussion

The main objectives of the pilot trial have been met. A BSC intervention designed for those with SMI has been developed to the point at which this can be delivered in a clinical trial. Sufficient people with SMI have been recruited to a trial and followed up to allow a biologically verified (Russell standard) outcome to be obtained at 12 months. Preliminary estimates of effect based on an underpowered pilot trial show a direction of effect across a range of outcomes that are in favour of a BSC intervention. There was some evidence of lowered mood in the BSC intervention and this issue needs to be explored further in a fully powered trial.

Conclusions

A definitive trial of clinical effectiveness and cost-effectiveness can now be conducted on the basis of the findings of the SCIMITAR pilot trial.

Implications for health care

Although it is important to ensure that there is equitable provision of smoking cessation services for all populations (including those with SMI), it would be premature to invest in BSC services without the results of a definitive clinical trial.

Recommendations for future research

A definitive trial is now needed to establish the clinical effectiveness and cost-effectiveness of BSC services for people with SMI.

Trial registration

This trial is registered as ISRCTN79497236.

Funding

This project was funded by the National Institute for Health Research Health Technology Assessment programme and will be published in full in *Health Technology Assessment*, Vol. 19, No. 25. See the NIHR Journals Library website for further project information.

Chapter 1 Background

Smoking and severe mental illness

People with severe mental ill health (SMI), such as schizophrenia and bipolar disorder, are more likely to smoke[1] and to smoke more heavily[2] than the general population. The point prevalence of smoking among those with SMI has been estimated to be between 58% and 90%.[1,3] The presence of mental ill health is associated with an elevated risk of smoking by a factor of 2.7 [95% confidence interval (CI) 2.4 to 3.2].[4] Smokers with SMI are more nicotine dependent, more likely to become medically ill and less likely to receive help in quitting, than the general population.[5] There are several reasons why people with SMI are more likely to smoke:

- Compared with smokers without SMI, they smoke a greater number of cigarettes per day, and this is evident even before diagnosis.[6]
- They smoke each cigarette more intensely, extracting more nicotine per cigarette.[2,7]
- They are much less likely to receive advice to quit smoking from their general practitioner (GP)[3] or mental health specialist.[8]

People with SMI have a lot of time on their hands, and smoking is part of the 'culture' of mental health services (among both 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.[5] Many people with severe mental illness are also misinformed about the risks and benefits of smoking and those of nicotine dependence treatment.[9,10] They often fear and overestimate the medical risks of nicotine replacement therapy (NRT).[11] Many believe that smoking relieves depression and anxiety[12] (although nicotine actually causes anxiety). Nicotine may also improve some aspects of cognitive dysfunction in schizophrenia, which could be a disincentive for patients to quit smoking.[13]

Smoking contributes to the general poor physical health of those with SMI; in the UK the standardised mortality ratio (SMR) for all causes of death among people with schizophrenia has been reported to be 289 (95% CI 247 to 337), which means that people with schizophrenia have a mortality risk of just under three times that of the general population.[14] 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.[15] Burns and Cohen[16] found that, although the annual general practice consultation rate is significantly higher among people with SMI (13–14 consultations a year) than in the general population (about three consultations per year), their health records are significantly less likely to include data relating to a variety of health promotion areas, including smoking advice. Recent studies show that people with mental health problems are just as likely to want to stop smoking as the general population – and are able to stop when offered evidence-based support.[17,18] However, research also shows that effective stop smoking treatment is not always offered to them.[19]

It is within this context that a number of policy initiatives have emerged, which emphasise improving the physical care of those with SMI, including taking initiatives to facilitate smoking cessation and the promotion of smoke-free environments in secondary care services.[5,20] This has recently been the subject of National Institute for Health and Care Excellence (NICE) recommendations about the provision of smoking cessation services for people with SMI in order to help address this health inequality.[21]

Existing knowledge

Smokers most commonly cite stress relief and enjoyment as their main reasons for smoking,[22] although the major *cause* is nicotine dependence. Nicotine acts in the midbrain, creating impulses to smoke in the face of stimuli associated with smoking,[23] 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.[24] Nicotine dependence is the main reason that most unassisted quit attempts fail within a week.[25] Cochrane systematic reviews[24–34] and evidence-supported guidance from NICE,[35,36] 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

Six different forms of NRT are available for use as smoking cessation aids: 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 as a result of different methods of delivery. A meta-analysis of more than 100 randomised control trials (RCTs) shows that all forms of NRT are roughly equally effective in aiding long-term cessation [odds ratio (OR) 1.77; 95% CI 1.66 to 1.88)].[25] 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).[37]

Antidepressants and 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 noradenaline and dopamine reuptake inhibitor which was first introduced as an atypical antidepressant (Zyban,® GlaxoSmithKline). Varenicline is almost certainly the most effective treatment to date (OR for 12 months' continuous abstinence for varenicline vs. placebo 3.22; 95% CI 2.43 to 4.27). It is more efficacious than bupropion (OR for varenicline vs. bupropion 1.66, 95% CI 1.28 to 2.16).[32] 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.

The US Food and Drug Administration (FDA) guidance on this matter states 'some patients have reported changes in behaviour, agitation, depressed mood, suicidal thoughts or actions when attempting to quit smoking while taking varenicline or after stopping varenicline'.[38] 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.[39]

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 multisession intensive behavioural support compared with brief advice found ORs of 1.56 (95% CI 1.32 to 1.84) for individual support and 2.04 (95% CI 1.60 to 2.60) for group support.[28,29] Regular support on the telephone is also effective. A meta-analysis of 10 trials of telephone support for people stopping smoking gave an OR of 1.64 (95 % CI 1.41 to 1.92).[34] There is some evidence to suggest that group support may be more effective in general than one-to-one support,[40] and that it should involve multiple sessions.[40] There is also evidence that such sessions can be effective even if conducted over the telephone (OR 1.64, 95% CI 1.41 to 1.92).[34]

The accumulated evidence for the use of current smoking cessation interventions has been distilled into clear recommendations for health-care professionals,[41] and into a manual for those designing and delivering smoking cessation services.[42] 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.[43]

Evidence on the effectiveness of smoking cessation strategies in SMI comes from a systematic review of randomised trials by Banham and Gilbody.[44] This review draws on the results of 10 RCTs of smoking cessation interventions among those with SMI and shows that combinations of behavioural 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 (RR) 4.18, 95% CI 1.30 to 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.[45] Smoking cessation rates were significantly higher among those taking bupropion than those taking placebo (seven trials; RR 2.78, 95% CI 1.02 to 7.58) with no report of serious adverse events (SAEs).

Rationale for the Smoking Cessation Intervention for Serious Mental Ill Health 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, 30.5% of smokers with past-month mental illness had a self-reported 'desire to quit' (although this is lower than the rate of 42.5% among smokers without illness).[4] The introduction in 2004 of a new General Medical Services (GMS) contract[46] created a policy impetus to improve the quality of primary care in priority areas. In terms of mental health, the new GMS contract specified that primary care is responsible for the provision of physical health care. Importantly, for smoking cessation initiatives, it 'incentivises' GPs to (1) produce a register of people with severe long-term mental health [Quality and Outcomes framework (QOF) indicator MH8 – the SMI register[47]] 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 health check[48]). This check includes patients seen in primary care, in secondary care and under shared care arrangements.

For those who are admitted to hospital, the introduction of smoke-free polices provides an opportunity to address smoking. This ban includes inpatient psychiatric units, although the complexities of the Mental Health Act[49] have been interpreted by some hospitals as a requirement to provide smoking areas. The admission of an individual to hospital, while 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.

Recent guidance issued by NICE[50] offers clear statements of purpose to make secondary care services (including mental health services) entirely smoke free and to promote a smoke-free culture among staff and users of services. Mental health services are highlighted as areas of priority and unmet need in relation to smoking cessation and there is clear guidance that services should be developed and implemented as a matter of some priority.

Smoking cessation services for people with 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 the Smoking Cessation Intervention for Serious Mental Ill Health Trial (SCIMITAR) is to use enhancements of care to ensure that evidence-supported interventions are offered to (and taken up by) people with SMI and to see if smoking rates can be reduced. This technology represents a 'complex health-care intervention', and this study, therefore, uses the stepwise Medical Research Council complex interventions framework[51] and the updated guidance[52] to evaluate the clinical effectiveness, implementation and content of a bespoke smoking cessation (BSC) service for people with SMI.

Research objectives

1. To develop a BSC service based upon evidence-supported treatments for people with SMI.
2. To establish the acceptability and uptake of this BSC service by people with SMI in primary care and specialist mental health services.
3. To test the feasibility of recruitment and follow-up in a pilot trial of a BSC service among patients with SMI.

Chapter 2 Methods

Details of the methods used for the health economics can be found in *Chapter 5* and details of the methods used in the qualitative substudy can be found in *Chapter 6*.

Study design

This study was a pragmatic, two-arm, parallel-group, pilot RCT. The setting was in primary care and specialist mental health services within three centres: York/Scarborough [principal investigator (PI) Professor Simon Gilbody), Manchester (Investigator Professor Helen Lester) and Hull (PI Professor Simon Gilbody). We recruited from both primary and secondary care settings. Given that this is a hard-to-reach population, several methods were used to try to identify and recruit eligible participants. A two-stage recruitment process was employed to check for eligibility, understanding of the study and to obtain consent. Participants were individually randomised to receive usual care or usual care plus a BSC service. Participants were followed up over the course 12 months, with data collected at 1 month, 6 months and 12 months post randomisation.

Approvals obtained

Ethical approval was sought and granted on 29 October 2010 by Leeds (East) Research Ethic Committee (10/H1306/72). Approval was also obtained from the relevant research and development departments (see *Appendix 1*).

Trial sites

The study was conducted in three sites in England. Sites recruited throughout the duration of the study.

Participant eligibility

Inclusion criteria

To be eligible for inclusion into this study participants needed to meet the following inclusion criteria:

- aged 18 years and above
- have SMI
- are a smoker and express an interest in wanting to cut down smoking (though not necessarily quitting).

There is no agreed definition of SMI so we adopted a pragmatic definition of SMI,[46,53] i.e. a documented diagnosis of schizophrenia or delusional/psychotic illness [*International Classification of Diseases* (ICD) 10 F20.X & F22.X or *Diagnostic and Statistical Manual of Mental disorders* (DSM) equivalent] or bipolar disorder (ICD F31.X or DSM equivalent). This SMI-inclusive diagnosis needed to have been made by specialist psychiatric services and have been documented in either the GP or psychiatric notes.

Exclusion criteria

People who:

- were pregnant or breastfeeding
- had comorbid drug or alcohol problems (as ascertained by the GP or mental health worker)
- were non-English speakers
- lacked capacity to participate in the trial (guided by the 2005 Mental Capacity Act[54]).

Serious mental illness patients who smoke while concurrently abusing substances may require additional medication or specialist advice, which was beyond the brief of the mental health smoking cessation practitioner (MHSCP) and this trial. Similarly, smoking cessation in pregnancy also requires specialist knowledge. It was planned that any participant who became pregnant during the course of the trial would be removed from the study and referred to local smoking cessation services specific to pregnancy.

Identifying participants

We used four methods to recruit participants: direct GP referral or following database screening, primary care referral following annual health check, secondary care recruitment – Care Programme Approach (CPA) and via Community Mental Health Teams (CMHTs) – and patient self-referral.

Direct general practitioner referral or following database screening

General practitioners are encouraged to offer opportunistic advice and information about smoking cessation services to all patients who smoke whenever they consult in primary care. GPs taking part in this study were provided with patient study information packs to give to patients with SMI who were receptive to participating in the trial. GPs then completed and faxed a referral form and patients' consent to be contacted form to the SCIMITAR researchers, who approached the patient for recruitment.

General practitioner surgeries were also asked to consult their patient databases and SMI register, if available, to screen for potentially eligible participants. Patient information packs were sent from the GP practice inviting patients willing to take part in the study to return a completed consent to be contacted form to the SCIMITAR researchers, who then approached the patients to ascertain eligibility and recruitment. Following a database search, GPs were asked to provide details of the number of packs they had sent out to allow a return rate to be calculated.

Primary care referral following annual health check

At the time of the trial, annual primary care health checks for people with SMI[55] (MH9) represented 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 encouraged all primary care staff to make SMI smokers aware of the trial when they received their annual primary care health check. Patient information packs were given to interested and potentially eligible patients during their health check. Similar to GP referrals, practice nurses were instructed to complete referral forms and to fax the patients' completed consent to be contacted form to the SCIMITAR researchers, who then approached the patients for eligibility and recruitment.

Secondary care recruitment – Care Programme Approach and via Community Mental Health Teams

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 health-care needs. Study researchers worked with care co-ordinators and consultants to screen their entire caseloads for potentially eligible participants who matched the inclusion criteria. Participants identified as potentially suitable for the SCIMITAR trial were given a copy of the patient information pack by their care co-ordinator. The patient information pack contained a consent to be contacted form for potential participants to return to the research assistant giving permission for the researcher to contact them by telephone or letter, or in person to discuss the trial further.

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

Patient self-referral

Poster advertisements of the SCIMITAR trial and BSC service were displayed in venues where patients in secondary care often congregated (e.g. clozapine clinics, outpatient departments, day centres, etc.).

The posters invited patients to contact study researchers if they were interested in participating in the study. The introduction of smoking bans in inpatient hospital services raised an ideal opportunity to offer smoking cessation services to patients who were interested in addressing their smoking behaviour. Therefore, we also advertised the BSC service in inpatient mental health settings. Interested participants contacted a SCIMITAR researcher, who sent out a patient information pack, including a consent to be contacted form.

Screening for eligibility

Potential participants identified by database screening or self-referral

Once a potential participant returned their consent to contact form the participant's GP was contacted to check for exclusion criteria (pregnancy or known drug/alcohol problems) and their judgement on the appropriateness of the patient's inclusion into the study. Once the GP had confirmed that it was appropriate for the participant to take part in the trial the participant was contacted by a trial researcher.

Potential participants referred by general practitioner or other health-care professional

If the patient was referred, the health-care professional giving them the information pack (GP, mental health specialist, practice nurse, CPA co-ordinator) explained the trial, assessed the patient for eligibility and screened for the given exclusion criteria. On receipt of a faxed referral form and signed consent to be contacted form, patients were contacted by a trial researcher.

The SCIMITAR researcher first approached the potential participant by telephone. After briefly explaining the trial, the researcher enquired about the patient's smoking habits, specifically: (1) Do you smoke? (2) How much do you smoke? and (3) Would you seriously consider quitting or cutting down with a view to quitting within the next 6 months? These ensured that the patient currently smoked but was seriously contemplating quitting. The researcher also asked screening questions about pregnancy and breastfeeding, drug and alcohol use, which led to exclusion if present. The researcher then arranged a meeting at a mutually convenient time and venue.

Consenting participants

Potential participants who met with the SCIMITAR researcher were given the opportunity to clarify any points they did not understand and ask any questions. A full oral explanation of the trial was given by the SCIMITAR researcher. It was emphasised that the participants may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled. Participants were also informed that, by consenting, they agreed to their GP being informed of their participation in the trial and that their medical records may be inspected by regulatory authorities, but that their name would not be disclosed. Written informed consent was then obtained, with both the participant and the researcher signing and dating the consent forms prior to the patient being randomised.

Baseline assessment

Once participants had consented to take part in the trial, they completed the baseline questionnaires. In addition, height and weight measurements were taken in order to calculate the patient's body mass index (BMI) and an exhaled breath carbon monoxide (CO) reading was taken. These made up the participants' baseline data set. The participant was randomised on completion of this data set.

Randomisation

Simple randomisation was used following a computer-generated random number sequence. The SCIMITAR researcher contacted a secure randomisation line run by the York Trials Unit and, once given the details of the patient's allocation, immediately informed the patient of his or her allocation and set up the first appointment with the MHSCP (if so allocated). A letter was sent to the GP and mental health specialist to be included in the patient's records and to advise them on subsequent smoking cessation management. Owing to the nature of the intervention, it was not possible to blind participants, GPs, researchers or the MHSCPs to the treatment allocation.

Ineligible and non-consenting participants

All ineligible and non-consenting participants were referred back to their GP practice so that any general health-care advice on the importance of stopping smoking could be provided by the patients' GP or community nurses.

Sample size

This pilot trial aimed to recruit 100 patients with SMI to obtain preliminary estimates of the effect size of the BSC service. Using the following assumptions (1) primary care QOF registers were assumed to give prevalence data for SMI of 0.5%; (2) an average of 2.5 whole-time equivalent GPs were assumed to work in each practice each with a list size of 1600 patients (4000 per practice); and (3) at least 80% of people with SMI smoke. If we were to recruit 25% of eligible patients in primary care, around 20 practices would enable us to recruit 100 patients over a 12-month period. This was a conservative assessment which did not allow for recruitment from secondary care, where recruitment is less easy to plan but was in addition to primary care.

Description of interventions

Trial intervention

This service intervention consisted of a mental health professional trained in smoking cessation interventions (MHSCP) who worked in conjunction with the patient and the patient's GP or mental health specialist to provide a smoking cessation service individually tailored to each patient with SMI. The intervention was delivered in accordance the *Smoking Cessation Manual: A Guide for Counsellors and Practitioners*,[42] which forms the basis of smoking cessation interventions in the NHS via the National Centre for Smoking Cessation Training (www.ncsct.co.uk).

This service was in line with current NICE guidelines for smoking cessation services[56] and included support sessions specifically adapted for patients with SMI run by the MHSCP and GP-prescribed pharmacotherapies to aid smoking cessation (NRTs, bupropion or varenicline either separately or in combination, as decided by the GP), in addition to regular follow-up by the MHSCP. Examples of specific adaptations to the needs of those with SMI are (1) the need to make several assessments 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 multidisciplinary team in planning a successful quit attempt for those with complex care needs and multiagency programmes of care; (4) a greater need for home visits, rather than planned visits in GP surgeries; (5) providing additional face-to-face support following an unsuccessful quit attempt or relapse; and (6) informing the GP and psychiatrist of a successful quit attempt, such that they can review antipsychotic medication doses if metabolism changes.[57]

Pharmacotherapies were provided as long as was deemed necessary, in line with NICE guidance, and were determined by the GP without the influence of the SCIMITAR trial team. In line with NICE

recommendations, the MHSCP offered advice on the range of treatments options available to patients under the NHS (including medication, counselling and follow-up). It was not the remit of the trial to assess specific smoking cessation pharmacotherapies or treatments per se, although data on frequency of their usage were collected.

Participants were encouraged to (1) reduce smoking to quit,[37] (2) set their own quit dates and (3) make several attempts to quit if their initial attempt failed. It is generally recommended that patients wait a few months after a failed quit attempt before trying again. This was not strictly enforced in this population and was left to the discretion of the MHSCP. All patients remained under the care of their GP and continued to receive their usual NHS treatment.

Bespoke smoking cessation interventions were 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 Guide 2009/10*.[3,58]

In training our MHSCPs, we also paid attention to the content of the intervention to ensure that evidence-supported behaviour change techniques (BCTs) were incorporated. We followed contemporary best practice and incorporated evidence-supported BCTs[59,60] in the following way:

1. During the design phase of SCIMITAR we reviewed existing trial data in this area (published in a systematic review by Banham and Gilbody).[44]
2. We contacted the first authors of all existing SMI smoking cessation trials to obtain their smoking cessation manuals (10 manuals were obtained).
3. We classified the behavioural content of all existing mental health smoking cessation manuals using the taxonomy of BCTs developed by Abraham and Michie.[59]

Finally, we identified those BCTs which were associated with a positive trial result (OR > 1.5) and incorporated these into our manualised SCIMITAR intervention.The specific evidence-supported mental health BCTs are summarised in *Box 1*.

BOX 1 Evidence-based BCTs for mental health

Smoking Cessation Intervention for Serious Mental Ill Health Trial: final evidence-based and supported behaviour change techniques for mental health

- Identify reasons for wanting and not wanting to stop smoking.
- Measure CO.
- Facilitate barrier identification and problem solving.
- Facilitate relapse prevention and coping.
- Facilitate action planning/know how to help identify relapse triggers.
- Facilitate goal setting.
- Advise on conserving mental resources.
- Advise on stop-smoking medication.
- Give options for additional and later support.
- Assess current and past smoking behaviour.
- Assess current readiness and ability to quit.
- Assess nicotine dependence.
- Assess physiological and mental functioning.
- Elicit client views.
- Monitor psychiatric medication levels and side effects throughout the quit attempt.

Control intervention

This was a usual-care control group in which participants were encouraged to consult with their GP or local NHS quit smoking services. GPs were given advice to follow current NICE guidelines for smoking cessation, without the additional support of a bespoke MHSCP. Usual care could include pharmacotherapies to aid smoking cessation (NRTs, bupropion or varenicline either separately or in combination), access to self-help materials and referral to local NHS stop smoking clinics (which would not be specifically tailored for the needs of those with SMI). Patients were encouraged to reduce smoking to quit and set their own quit dates, but were managed solely by their own GP or mental health specialist and, crucially, did not receive regular visits from a MHSCP. Details of NRT that control participants received were gathered by accessing patients' GP notes and details of any smoking cessation management were requested from participants in the follow-up questionnaires.

Follow-up

Participants were followed up 1 month, 6 months and 12 months after randomisation.

Baseline assessments and 12-month follow-up were carried out face to face, while 1- and 6-month follow-ups were carried out by telephone interview, using paper questionnaires or via online questionnaires. If it was not possible to meet the participant for a face-to-face 12-month follow-up, a systematic approach was used to explore other avenues to collect data (self-report data only). Follow-up was carried out by researchers who were not blind to treatment allocation; however, the objective nature of the primary outcome eliminated any potential bias.

Outcomes

Primary outcomes

The primary outcome was whether patients had stopped or reduced smoking when assessed at 12 months post recruitment. This was determined by CO measurement, where abstinence is defined as CO < 10 p.p.m. In the absence of a CO measurement, self-reported smoking cessation was used.

Secondary outcomes

- Self-reported number of cigarettes smoked per day.
- Fagerstrom Test for Nicotine Dependence (FTND).[61]
- Motivation to quit (MTQ) questionnaire.
- Self-reported number of attempts to quit and period of cessation.
- Patient Health Questionnaire-9 items (PHQ-9).[62]
- Short Form questionnaire-12 items (SF-12).[63]
- Service utilisation.
- Self-reported drug substitution (specifically cannabis use).

Table 1 gives details of the measures collected and the time points at which they were collected. Copies of the questionnaires can be found in *Appendix 2.*

Participant engagement

Participant engagement was measured using the proportion of intervention participants who engaged with (1) contacts which were offered from a MHSCP; (2) medication when this was offered by their GP (as measured by the number of filled prescriptions issued by the GP); or (3) compliance with CO monitoring by MHSCPs. Smoking status at baseline and (where possible) follow-up were verified by exhaled CO.

TABLE 1 Assessments and time points at which they were carried out

	Timeline (months post randomisation)			
Assessment	**Baseline**	**1**	**6**	**12**
Eligibility and consent				
Eligibility	✓			
Consent	✓			
Background and follow-up				
Personal details	✓			
Body mass index	✓			✓
Mental health details				
Mental health history	✓			
Self-reported current mental health status	✓	✓	✓	✓
Current medications	✓			✓
Referrals to mental health services		✓	✓	✓
Admissions to hospital related to mental health		✓	✓	✓
Smoking details				
Smoking history	✓			
Current smoking status	✓	✓	✓	✓
Use of smoking cessation services	✓	✓	✓	✓
CO measurement	✓			✓
Adverse event reporting	Ongoing collection			
Questionnaires				
FTND questionnaire	✓	✓	✓	✓
MTQ questionnaire	✓	✓	✓	✓
PHQ-9	✓	✓	✓	✓
Health-related quality of Life (SF-12)	✓	✓	✓	✓
Health state utility (EQ-5D)	✓	✓	✓	✓
Health economics/service utilisation questionnaire	✓		✓	✓

EQ-5D, European Quality of Life-5 Dimensions.

Readings < 10 p.p.m. confirmed that participants had not smoked recently (i.e. within 12 hours). Measurements above 10 p.p.m. indicated that the patient has not ceased smoking. At least two CO readings were taken; if participants claimed to have stopped but their CO readings were above 10 p.p.m., they were asked when they had last smoked and whether or not they had any minor relapses during their quit attempt.

Statistical analysis

All analyses were conducted on an intention-to-treat basis, including all randomised patients in the groups to which they were randomised. Analyses were conducted in STATA version 13 (StataCorp, College Station, TX, USA).

Baseline data

The baseline data were summarised by treatment group and described descriptively. No formal statistical comparisons were undertaken. Continuous measures were reported using means and standard deviations (SDs; median and range were also included where appropriate), whereas categorical data were reported using counts and percentages.

Primary analysis

The primary outcome was cessation of smoking at 12 months as measured by the breath CO test and self-reported smoking cessation in the absence of a breath measurement. The two treatment groups were compared using logistic regression with adjustment for prognostic variables: sex, age, number of cigarettes smoked at baseline and alcohol consumption. ORs and corresponding 95% CIs were obtained from this model.

Secondary analyses

The 1-, 6- and 12-month secondary outcomes analysed were self-reported smoking cessation, number of cigarettes smoked per day, dependence on smoking as assessed by the FTND questionnaire, level of motivation as assessed by the MTQ questionnaire, length of cessation of smoking, PHQ-9, BMI, SF-12 physical component score and SF-12 mental component score. Secondary outcomes were summarised descriptively, with no formal statistical comparisons undertaken. Continuous measures were reported using means and SDs (median and range was also included where appropriate), whereas categorical data were reported using counts and percentages.

Missing data

The numbers of patients analysed were reported for the primary and secondary outcomes for each treatment group. For the primary outcome, analysis was performed on complete cases only and cases without a CO measure or a self-reported smoking cessation result at 12 months were excluded from analysis. In a full trial, multiple imputation and mixed modelling would be considered in the presence of missing outcome data.

Qualitative substudy

We explored specific issues of acceptability and adherence of smoking cessation interventions among those with SMI and those who referred to and delivered the intervention. Full details of the qualitative substudy are given in *Chapter 6*.

Cost assessment

A cost assessment was carried out to estimate the cost of the alternative treatment strategies. A costing methodology was carried out in two steps. The first step was to measure resource use by trial patients in physical units. Health-care and community services resource use information was collected using an adapted health economic/service utilisation questionnaire included in the baseline and follow-up questionnaire (see *Appendix 3*). For medication use, the participating GP surgeries were asked to extract prescription information of participants during the trial period from their records at the end of the trial. Owing to the huge variety of medication that could be prescribed to participants, a list of antipsychotic medication was used to reduce the burden of data collection upon the GP surgeries (*Table 2*). Therefore, only the information on antipsychotic medication and prescriptions related to pharmacotherapy for stop smoking was collected from GP surgeries. The pharmacotherapy for stop smoking included NRT products, varenicline and bupropion. While the prescriptions of pharmacotherapy were collected from GP records, the usage of pharmacotherapy was also collected using the trial questionnaire, covering both prescription and over-the-counter purchases. The second step was to calculate the cost of resources used by applying market prices or national average unit costs. Costs were assessed from a NHS and Personal

TABLE 2 The list of antipsychotic medication that was used to collect prescription information

Chemical name
Citalopram hydrobromide
Clozapine
Fluoxetine hydrochloride
Flupentixol decanoate
Fluphenazine decanoate
Haloperidol decanoate
Lithium carbonate
Olanzapine
Paroxetine hydrochloride
Prochlorperazine maleate
Procyclidine hydrochloride
Quetiapine
Risperidone
Trihexyphenidyl hydrochloride
Zuclopenthixol

Social Service perspective. Intervention costs were based on delivery costs within the trial and included staff, equipment, supervision and appropriate annuitised capital costs. Missing data were estimated by using the average value among the same group at the same follow-up point.

A cost-effectiveness analysis was undertaken at 12 months comparing resource use in the BSC group with resource use in the usual-care group using the incremental quit rate for the intervention over and above usual care. This cost-effectiveness analysis is undertaken to demonstrate the analysis that would be undertaken in a full trial. This is a pilot trial and results should be interpreted with extreme caution because of the small sample size. We do not conduct a full cost–utility analysis because of the very small sample size.

Adverse events

Clear guidance on the prescription of antismoking medications in the presence of SMI (including safety considerations) have been published and were made available to all GPs to help inform their prescribing decisions. A key feature of the SCIMITAR trial was to ensure that GPs manage antismoking medications within this framework and with their prior knowledge of the patient and their concomitant use of medication. This was with the aim of replicating real-life practice of the use of antismoking medications in primary care. The medication profile of the individual participants was 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). An important aspect of the design of this study was that the SCIMITAR team had no direct influence over prescribing decisions made by GPs since this was not a drug trial or an investigation of a medicinal product(s).

A standard operating procedure for detecting and reporting adverse events (AEs) was implemented. An AE was defined as any unexpected effect or untoward clinical event affecting the participant. It could be directly related, possibly related or completely unrelated to the intervention. It was also classed according

to severity, either as a non-serious AE (including discomfort or slight worsening of symptoms) or as a SAE (which could be particularly harmful, dangerous or required hospitalisation).

The participant's MHSCP, GP and mental health specialist were requested to inform the research team of any serious or non-serious AEs. In addition, participant responses to questions in the follow-up questionnaire relating to hospital admissions, attendance at accident and emergency, use of the emergency services or if the participant volunteered information which could potentially be classed as an AE or SAE, were followed up by the research team.

All AEs and SAEs were independently reviewed by a clinician and reported to the Data Monitoring and Ethics Committee and Trial Steering Committee. Any SAEs that were deemed to be related to the intervention and unexpected were reported to the Research Ethics Committee and sponsor within 7 days of notification.

Suicide protocol

A protocol for identifying and reporting suicide risk was implemented (see *Appendix 6* for protocol). Question 9 on the PHQ-9, which asks if the patient 'have you had thoughts that you would be better off dead or hurting yourself in some way?', was used to identify any suicide risk.

If the participant indicated a response of 3 for this item, then the suicide protocol was implemented and the patient asked if he or she had talked to a GP, psychiatrist or care co-ordinator/community psychiatric nurse about these feelings. If the patient had not sought help, consent was sought to to inform the patient's GP of the situation. If the patient refused, the relevant designated psychiatrist/health professional was contacted. If the patient agreed, the patient's GP or psychiatrist was contacted immediately. A suicidal intent form was also completed and, where applicable, a 'suicidal intent form: psychiatrist/health professional' was completed. These forms were stored with the patient's trial records.

Chapter 3 Changes to the protocol

Online questionnaires

In the original proposal participants would complete paper questionnaires and the answers would be manually entered into the database by the researcher. However, the possibility of participants completing the questionnaires online became available. As some participants may find this preferable to completing a paper questionnaire, they were given the additional option of completing questionnaires online via a secure website held on the university server.

Extension to end of study date

Owing to recruitment taking longer than anticipated an extension was requested and granted. It was originally planned that the study would end in May 2013. This was extended to November 2013. The extension was to allow sufficient time for the study team to collect all outstanding follow-up data from participants.

Twelve-month follow-up

In the original protocol, all 12-month follow-ups were to be carried out face to face. It became apparent because of the nature of the patient population being studied that this would not always be possible. To collect data from as many participants as possible, we decided that if a participant could not be met face to face, attempts would be made to collect 12-month data via a telephone interview or postal questionnaire. In these cases smoking abstinence or reduction would not be verified by CO measurements; however, self-reported quit rates would still be collected.

Gift vouchers

The SCIMITAR Trial management group offered participants taking part in the qualitative substudy a £10 gift voucher as a goodwill gesture and token of thanks for their time.

Chapter 4 Results

Recruitment

Recruitment started in May 2011 and ended in May 2012. Over the course of the trial, 45 GP surgeries in Manchester, York/Scarborough and Hull mailed out recruitment packs. Recruitment of at least one trial participant occurred in 25 of the 45 GP surgeries which mailed out packs. Twenty-nine CMHTs were enlisted to recruit participants, along with 21 other secondary care organisations and 14 tertiary care organisations. Four participants were recruited through direct referral, having seen a poster advertising the study.

In primary care, 1036 recruitment packs were mailed out by GP surgeries which resulted in 64 consent to contact forms being returned (a response rate of 6.2%). Of these, 51 people were recruited into the study. From secondary care 57 direct referrals were received, of which 42 were recruited and randomised (a rate of 74%); however, it was not possible to determine how many packs were given out by CMHTs and other secondary and tertiary care organisations.

A total of 97 patients were recruited to the trial. The rate of recruitment is shown in *Figure 1*. Recruitment occurred at three sites (York/Scarborough, Manchester and Hull) and was evenly distributed between primary and secondary care (*Table 3*). *Table 4* shows how many people were recruited from each of the different secondary care organisations. Participant flow through the trial is shown in the Consolidated Standards of Reporting Trials (CONSORT) diagram (*Figure 2*). The conversion rates of each stage of the recruitment process in primary care are shown in *Figure 3* and the conversion rate of each stage of the secondary care recruitment process is shown in *Figure 4*. It can be seen that a total GP list size of 466,734 led to 51 randomisations.

Of the 97 participants, 51 were randomised to usual GP care and 46 participants were randomised to BSC (*Table 5*).

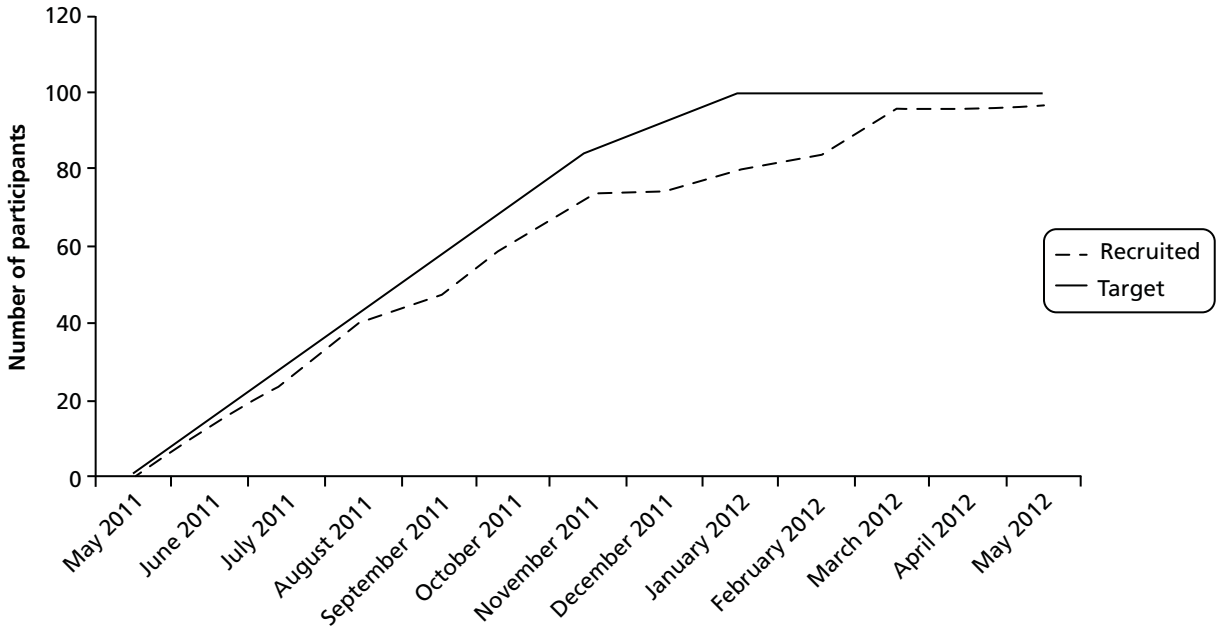

FIGURE 1 Trial recruitment rate.

TABLE 3 Recruitment by site and method

		Recruiting sites			
Recruitment site	**Recruitment method**	**York/Scarborough**	**Hull**	**Manchester**	***Total***
Primary care	Database search	25	9	15	*49*
	Self-referral	1	1	0	*2*
Secondary care	Direct referral	12	2	29	*43*
	Self-referral	0	1	0	*1*
Unknown		0	0	2	*2*
Total		38	13	46	97

TABLE 4 Secondary care recruitment

Centre	CMHT	Clozapine/depot clinic	Assertive outreach	Assisted housing	Other
York/Scarborough	7	0	2	4	3
Manchester	14	4	3	5	10
Hull	8	1	0	3	0
Total	29	5	5	12	13

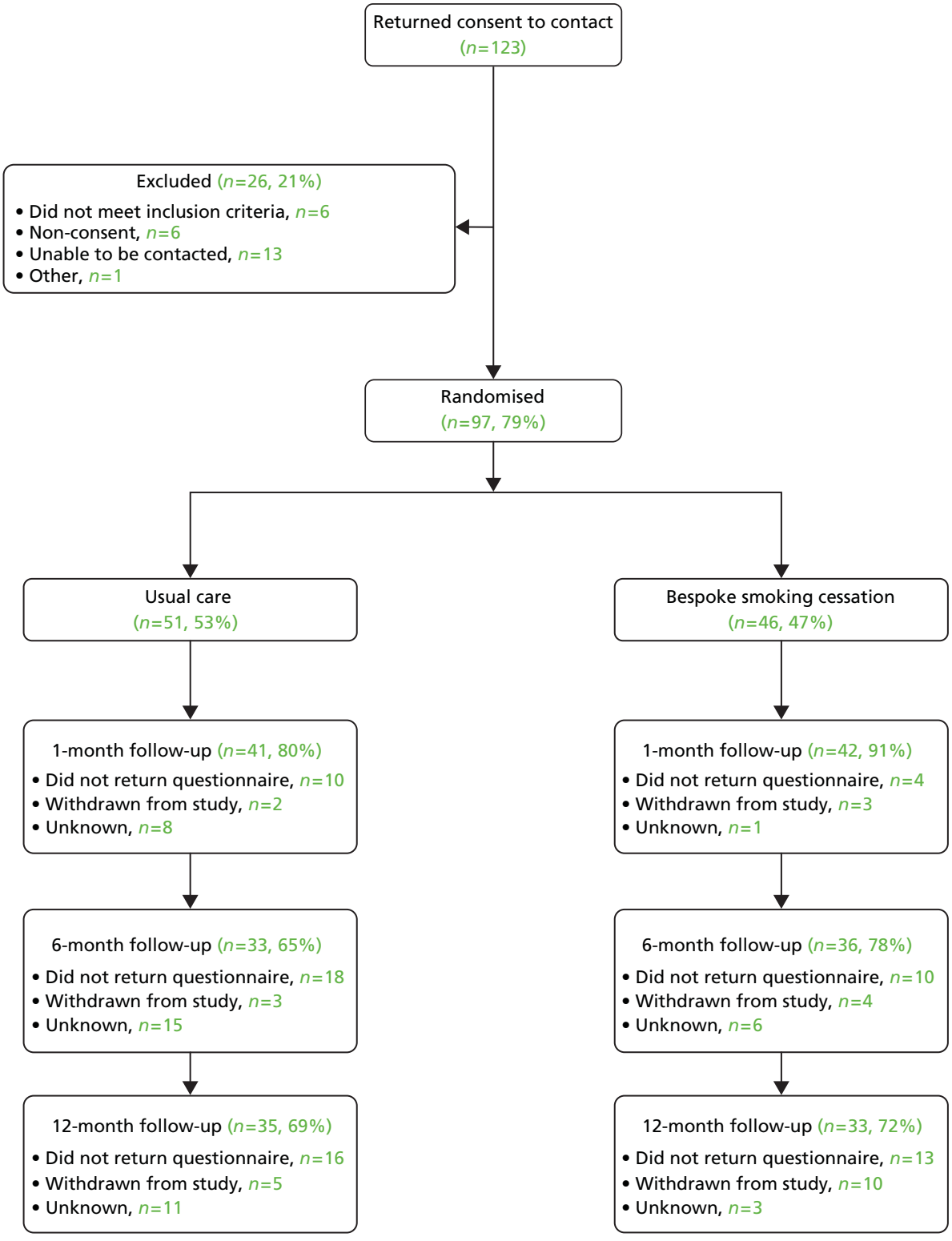

FIGURE 2 A CONSORT diagram showing participant flow through the trial.

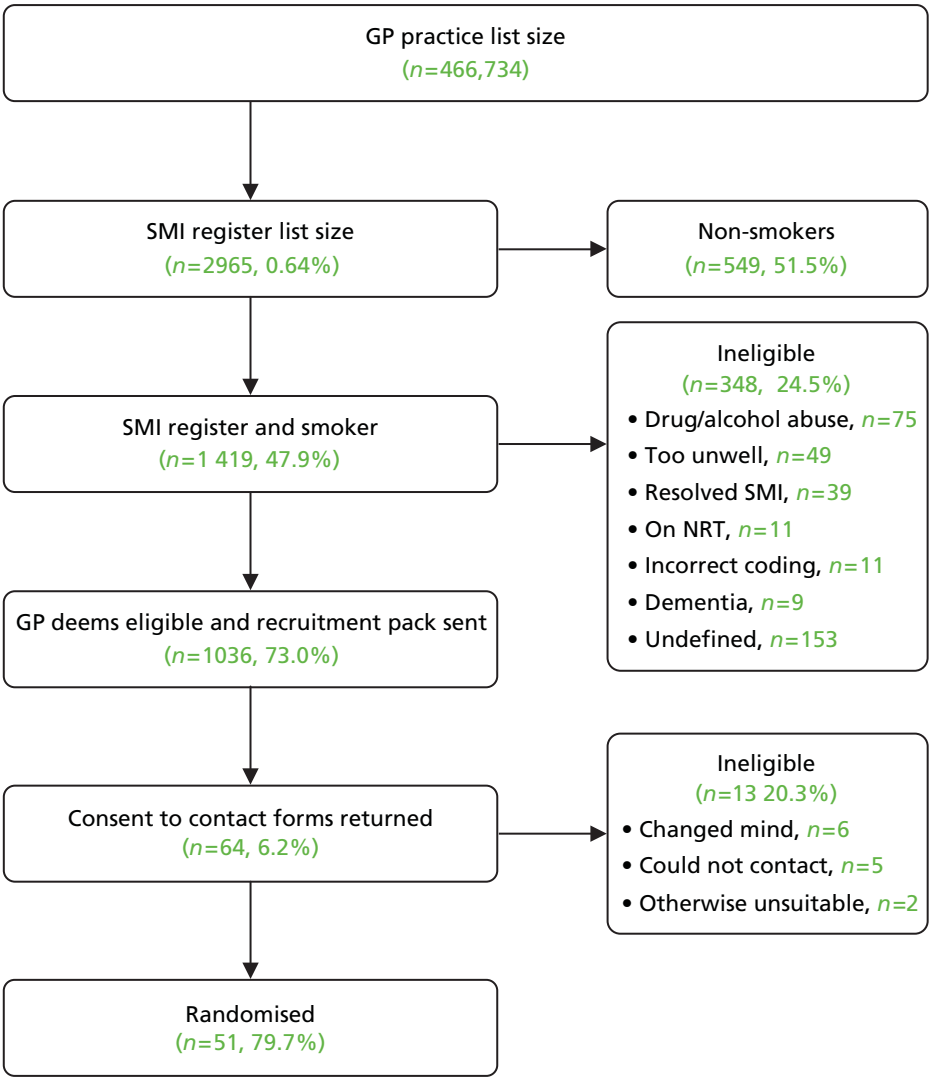

FIGURE 3 Primary care randomisations from GP database searches.

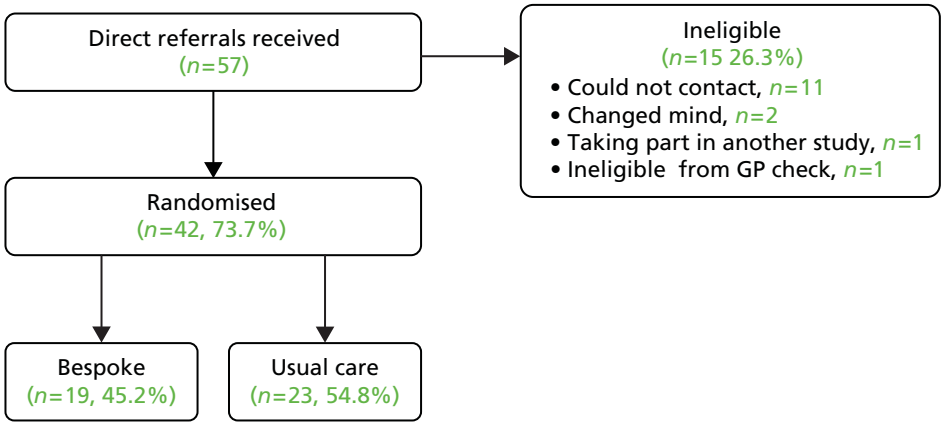

FIGURE 4 Secondary care randomisations.

TABLE 5 Allocation of participants

	Recruiting sites			
Group	York/Scarborough	Hull	Manchester	Total
Usual GP care	18	6	27	51
BSC	20	7	19	46
Total	38	13	46	97

Baseline data

The baseline characteristics of participants are summarised in *Tables 6–10*. *Table 6* summarises participants by the prespecified prognostic factors. There were more male than female participants (59.8% vs. 40.2% respectively) and a greater proportion of men in the BSC group (69.6%) than in the usual GP care group (51.0%). There was some imbalance between the treatment groups with respect to alcohol consumption, with more alcohol consumption in the usual GP care group (62.7%) than in the BSC group (50.0%). The mean age of participants was 47 years, with a range from 19.1 to 73.3 years.

Table 7 summarises the general health of participants. Almost half of participants reported moderate health (48%) over the past year and a mean of 5.5 consultations with a GP in the last 12 months (range 0–40 consultations). The majority of participants (86%) felt that smoking had affected their health, and 63% of participants had been advised to stop smoking by their GP. The mean BMI of participants was 28.6 kg/m^2 (range 17.9–43.1 kg/m^2), which is categorised as overweight (normal weight BMI range is 18.5–25 kg/m^2). Fifteen per cent of participants reported taking recreational drugs.

TABLE 6 Baseline data by prespecified prognostic factors

Characteristic	Usual GP care ($N = 51$)	BSC ($N = 46$)	Overall ($N = 97$)
Sex			
Female, *n* (%)	25 (49.0)	14 (30.4)	39 (40.2)
Male, *n* (%)	26 (51.0)	32 (69.6)	58 (59.8)
Age (years)			
Mean (SD)	45.9 (12.8)	47.8 (12.4)	46.8 (12.6)
Median (range)	46.4 (22.2–71.5)	47.3 (19.1–73.3)	47.2 (19.1–73.3)
Missing, *n* (%)	2 (3.9)	0 (0.0)	2 (2.1)
Alcohol consumption at baseline			
Yes, *n* (%)	32 (62.7)	23 (50.0)	55 (56.7)
No, *n* (%)	19 (37.3)	23 (50.0)	42 (43.3)
Number of cigarettes			
Mean (SD)	22.8 (13.2)	25.8 (11.6)	24.2 (12.5)
Median (range)	20 (5–60)	22.5 (5–60)	20 (5–60)
Missing, *n* (%)	0 (0.0)	2 (4.3)	2 (2.1)

TABLE 7 Baseline general health data

Characteristic	Usual GP care ($N = 51$)	BSC ($N = 46$)	Overall ($N = 97$)
Health over the past year,* n *(%)			
Excellent	4 (8.0)	2 (4.3)	6 (6.3)
Good	11 (22.0)	12 (26.1)	23 (24.0)
Moderate	24 (48.0)	22 (47.8)	46 (47.9)
Poor	9 (18.0)	6 (13.0)	15 (15.6)
Very poor	2 (4.0)	4 (8.7)	6 (6.3)
Number of times consulted GP in the last 12 months			
Mean (SD)	5.4 (7.1)	5.7 (6.2)	5.5 (6.7)
Median (range)	3 (0–40)	3.5 (0–24)	3 (0–40)
Missing, *n* (%)	0 (0.0)	0 (0.0)	0 (0.0)
Smoking has affected the state of your health,* n *(%)			
Yes	43 (84.3)	40 (87.0)	83 (85.6)
No	8 (15.7)	6 (13.0)	14 (14.4)
GP or doctor advised you to quit smoking,* n *(%)			
Yes	30 (58.8)	31 (67.4)	61 (62.9)
No	21 (41.2)	15 (32.6)	36 (37.1)
Recreational drugs at baseline,* n *(%)			
Yes	10 (19.6)	5 (10.9)	15 (15.5)
No	41 (80.4)	41 (89.1)	82 (84.5)
BMI (kg/m²)			
Mean (SD)	29.1 (5.8)	28.1 (5.7)	28.6 (5.7)
Median (range)	29.3 (18.5–43.1)	27.3 (17.9–41.5)	28.6 (17.9–43.1)
Missing, *n* (%)	1 (2.0)	0 (0.0)	1 (1.0)

Table 8 summarises the sociodemographic data of participants and *Table 9* summarises their employment status. The majority of participants (87%) were white British and the next largest ethnic group was black or black British-Caribbean (5%). About 20% of the participants had General Certificates of Secondary Education (GCSEs)/O-levels as their highest educational qualification. Over half of participants (56%) were not employed but not seeking work because of ill health and 75% of those unemployed had not been employed for over 5 years. Over half of participants were single (57%), 20% were married or living with a partner and 19% were divorced or separated.

Table 10 summarises baseline mental health status. The most common severe mental health problems were schizophrenia or other psychotic illness ($n = 57$, 59%), schizoaffective disorder ($n = 10$, 10%) and bipolar disorder ($n = 30$, 31%). Over half of the participants (56%) had a CPA co-ordinator and 60% were under the care of a CMHT. On average, participants had twice (mean) in the last 10 years required psychiatric treatment in hospital, with a range of 1 to 15 periods of hospital treatment. Eighty per cent of participants described their condition as 'stable' and 8% described their condition as 'unstable' (though each participant had been judged to be stable from the point of view of their condition by either their GP or a responsible mental health professional). Almost all participants (99% of those who responded to the question) were taking a medication, the most common being olanzapine (23%) and clozapine (8%).

TABLE 8 Baseline sociodemographic data

Characteristic	Usual GP care (*N* = 51)	BSC (*N* = 46)	Overall (*N* = 97)
Ethnicity,* n *(%)			
White – British	41 (80.4)	42 (93.3)	83 (86.5)
White – Irish	1 (2.0)	0 (0.0)	1 (1.0)
Any other white background	2 (3.9)	1 (2.2)	3 (3.1)
Mixed – white and black Caribbean	1 (2.0)	0 (0.0)	1 (1.0)
Any other mixed background	1 (2.0)	0 (0.0)	1 (1.0)
Asian or Asian British – Pakistani	1 (2.0)	0 (0.0)	1 (1.0)
Black or black British – Caribbean	4 (7.8)	1 (2.2)	5 (5.2)
Black or black British – African	0 (0.0)	1 (2.2)	1 (1.0)
Chinese	0 (0.0)	0 (0.0)	0 (0.0)
Other	0 (0.0)	0 (0.0)	0 (0.0)
Marital status,* n *(%)			
Single	32 (62.7)	24 (52.2)	56 (57.7)
Married	4 (7.8)	7 (15.2)	11 (11.3)
Living with a partner/cohabiting	5 (9.8)	3 (6.5)	8 (8.2)
Divorced/separated	9 (17.6)	9 (19.6)	18 (18.6)
Widowed	1 (2.0)	1 (2.2)	2 (2.1)
Never married	0 (0.0)	1 (2.2)	1 (1.0)
Other	0 (0.0)	1 (2.2)	1 (1.0)
Highest educational qualification			
GCSE/O-level	10 (19.6)	9 (19.6)	19 (19.6)
GCE A/AS-level or Scottish Higher	1 (2.0)	4 (8.7)	5 (5.2)
NVQ/SVQ levels 1–3	6 (11.8)	3 (6.5)	9 (9.3)
BTEC certificate	0 (0.0)	1 (2.2)	1 (1.0)
BTEC diploma	2 (3.9)	1 (2.2)	3 (3.1)
Qualified teacher status	1 (2.0)	2 (4.3)	3 (3.1)
Degree (first degree/ordinary degree)	2 (3.9)	1 (2.2)	3 (3.1)
Postgraduate certificate	7 (13.7)	2 (4.3)	9 (9.3)
Postgraduate diploma	1 (2.0)	0 (0.0)	1 (1.0)
PhD	0 (0.0)	1 (2.2)	1 (1.0)
Other	15 (29.4)	15 (32.6)	30 (30.9)
Don't know/no response	6 (11.8)	7 (15.2)	13 (13.4)

BTEC, Business and Technology Education Council; GCE A, General Certificate of Education – Advanced; NVQ, National Vocational Qualification; PhD, Doctor of Philosophy; SVQ, Scottish Vocational Qualification.

TABLE 9 Baseline employment status

Characteristic	Usual GP care (*N* = 51)	BSC (*N* = 46)	Overall (*N* = 97)
Employment,* n *(%)			
Employed full-time	4 (7.8)	3 (6.5)	7 (7.2)
Employed part-time	2 (3.9)	2 (4.3)	4 (4.1)
Self-employed	2 (3.9)	0 (0.0)	2 (2.1)
Retired	5 (9.8)	7 (15.2)	12 (12.4)
Looking after family or home	2 (3.9)	0 (0.0)	2 (2.1)
Student	3 (5.9)	0 (0.0)	3 (3.1)
Voluntary worker	6 (11.8)	3 (6.5)	9 (9.3)
Not employed but seeking work	1 (2.0)	1 (2.2)	2 (2.1)
Not employed, but not seeking work because of ill health	25 (49.0)	29 (63.0)	54 (55.7)
Not employed, but not seeking work for some other reason	1 (2.0)	1 (2.2)	2 (2.1)
If unemployed, length of unemployment,* n *(%)			
4–12 months	2 (7.4)	0 (0.0)	2 (3.6)
1–2 years	0 (0.0)	1 (3.6)	1 (1.8)
2–5 years	3 (11.1)	5 (17.9)	8 (14.5)
> 5 years	20 (74.1)	21 (75.0)	41 (74.5)
Don't know/no response	2 (7.4)	1 (3.6)	3 (5.5)

Table 11 summarises smoking history of participants. The mean length of smoking was 27 years, with a range from 3 years to 60 years. Most participants smoked packet (66%) or hand-rolled cigarettes (53%) (or both). The median number of attempts to quit was three, with a range of 0 to 150 attempts. The mean duration of reported longest quit attempt was 43 days (median 8.5 days), with a range of 0 to 832 days. The most common self-reported previous strategies used to stop smoking were 'cold turkey' (70%), followed by nicotine skin patches (68%), nicotine chewing gum (52%) and nicotine inhalator (47%).

The reasons for smoking and their importance are summarised in *Table 12*. The most important reason given for smoking was helping to cope with stress (65%), followed by helping to relax (47%).

Table 13 summarises the reasons for giving up smoking. The most important reason cited for trying to give up smoking was that it is bad for health (86%).

Table 14 summarises the smoking behaviour of participants at baseline. Most of the participants smoked more than five cigarettes in the last week (96%). The mean number of cigarettes smoked per day is 25, with a range of 5 to 60. The mean CO reading is 24 p.p.m. with a range of 4 to 58 p.p.m. A CO reading > 20 p.p.m. indicates heavy smoking. The majority of participants (80%) said they smoke the same number of cigarettes every day. *Table 15* summarises recent quit attempts. The median number of quit attempts in the last 6 months was three, with a range of 0 to 150 attempts. The mean length of the most recent quit attempt was 23 days, with a range of 0 to 180 days.

TABLE 10 Baseline mental health status

Characteristic	Usual GP care (*N* = 51), *n* (%)	BSC (*N* = 46), *n* (%)	Overall (*N* = 97), *n* (%)
Do you have a CPA co-ordinator?			
Yes	25 (51.0)	26 (61.9)	51 (56.0)
No	24 (49.0)	16 (38.1)	40 (44.0)
Do you have a CMHT?			
Yes	28 (58.3)	27 (62.8)	55 (60.4)
No	20 (41.7)	16 (37.2)	36 (39.6)
Number of times needed psychiatric treatment in hospital in last 10 years			
Mean (SD)	1.7 (1.6)	2.3 (3.1)	2 (2.4)
Median (range)	1 (0–6)	1 (0–15)	1 (0–15)
Missing	1 (1.9)	0 (0.0)	1 (1.0)
Would you describe your condition as			
Stable	40 (80.0)	37 (80.4)	77 (80.2)
Unstable	4 (8.0)	4 (8.7)	8 (8.3)
Unsure	6 (12.0)	5 (10.9)	11 (11.5)
Do you take any medications?			
Yes	41 (100.0)	34 (97.1)	75 (98.7)
No	0 (0.0)	1 (2.9)	1 (1.3)
Missing	10 (19.6)	11 (23.9)	21 (21.6)
If yes, do you take the following medications			
Haloperidol	2 (3.9)	1 (2.2)	3 (3.1)
Fluphenazine	0 (0.0)	2 (4.3)	2 (2.1)
Clozapine	4 (7.8)	4 (8.7)	8 (8.2)
Olanzapine	11 (21.6)	11 (23.9)	22 (22.7)
Fluvoxamine	0 (0.0)	0 (0.0)	0 (0.0)
Duloxetine	1 (2.0)	0 (0.0)	1 (1.0)
Propranolol	0 (0.0)	0 (0.0)	0 (0.0)
Insulin	0 (0.0)	0 (0.0)	0 (0.0)
Theophylline	0 (0.0)	0 (0.0)	0 (0.0)
Cimetidine	0 (0.0)	0 (0.0)	0 (0.0)
Flecainide	0 (0.0)	0 (0.0)	0 (0.0)

TABLE 11 Baseline smoking history

Characteristic	Usual GP care (*N* = 51)	BSC (*N* = 46)	Overall (*N* = 97)
Length of time smoking (years)			
Mean (SD)	25.8 (12.2)	28.5 (13.5)	27.1 (12.9)
Median (range)	25 (5–55)	26.5 (3–60)	25 (3–60)
Missing, (%)	0 (0.0)	0 (0.0)	0 (0.0)
Type of tobacco used,* n *(%)			
Packet cigarettes	38 (74.5)	26 (56.5)	64 (66.0)
Hand-rolled cigarettes	26 (51.0)	25 (54.3)	51 (52.6)
Cigars	0 (0.0)	2 (4.3)	2 (2.1)
Pipe	0 (0.0)	2 (4.3)	2 (2.1)
Chewing tobacco	0 (0.0)	0 (0.0)	0 (0.0)
Water pipe/Hookah/Sheesha pipe	0 (0.0)	0 (0.0)	0 (0.0)
If using roll-ups or pipe, amount of tobacco used per day (ounces)			
Mean (SD)	7.0 (6.7)	9.1 (11.1)	8.1 (9.2)
Median (range)	7 (0–25)	5.5 (0–50)	7 (0–50)
n	25	28	53
Number of attempts to quit in the past			
Mean (SD)	3.2 (2.5)	9.7 (25.7)	6.3 (18.1)
Median (range)	2 (0–12)	3 (0–150)	3 (0–150)
Missing, *n* (%)	1 (1.9)	0 (0.0)	1 (1.0)
Longest quit attempt (days)			
Mean (SD)	47.5 (139.5)	37.7 (64.2)	42.8 (109.6)
Median (range)	8 (0–832)	9 (0–260)	8.5 (0–832)
Missing, *n* (%)	2 (3.9)	1 (2.2)	3 (3.1)
Previous methods used to stop smoking,* n *(%)			
Nicotine chewing gum	29 (56.9)	21 (45.7)	50 (51.5)
Nicotine skin patches	32 (62.7)	34 (73.9)	66 (68.0)
Nicotine nasal spray	7 (13.7)	3 (6.5)	10 (10.3)
Nicotine inhalator	25 (49.0)	21 (45.7)	46 (47.4)
Nicotine microtab	5 (9.8)	5 (10.9)	10 (10.3)
Nicotine lozenges	5 (9.8)	7 (15.2)	12 (12.4)
Zyban	2 (3.9)	2 (4.3)	4 (4.1)
Champix	3 (5.9)	3 (6.5)	6 (6.2)
'Cold turkey'	37 (72.5)	31 (67.4)	68 (70.1)
Hypnosis	6 (11.8)	6 (13.0)	12 (12.4)
Acupuncture	2 (3.9)	4 (8.7)	6 (6.2)
Other	2 (4.1)	1 (2.2)	3 (3.2)

TABLE 12 Reasons for smoking and their importance

Reasons for smoking	Usual GP care (*N* = 51), *n* (%)	BSC (*N* = 46), *n* (%)	Overall (*N* = 97), *n* (%)
It helps me relax			
Very important	22 (43.1)	24 (52.2)	46 (47.4)
Quite important	26 (51.0)	16 (34.8)	42 (43.3)
Not important	3 (5.9)	6 (13.0)	9 (9.3)
It helps break up my working time			
Very important	11 (21.6)	12 (26.1)	23 (23.7)
Quite important	21 (41.2)	13 (28.3)	34 (35.1)
Not important	19 (37.3)	21 (45.7)	40 (41.2)
It is something to do when I am bored			
Very important	14 (27.5)	18 (39.1)	32 (33.0)
Quite important	28 (54.9)	23 (50.0)	51 (52.6)
Not important	9 (17.6)	5 (10.9)	14 (14.4)
It helps me cope with stress			
Very important	34 (66.7)	29 (63.0)	63 (64.9)
Quite important	14 (27.5)	14 (30.4)	28 (28.9)
Not important	3 (5.9)	3 (6.5)	6 (6.2)
I enjoy it			
Very important	17 (33.3)	18 (39.1)	35 (36.1)
Quite important	19 (37.3)	16 (34.8)	35 (36.1)
Not important	15 (29.4)	12 (26.1)	27 (27.8)
It's something I do with family and friends			
Very important	10 (19.6)	7 (15.2)	17 (17.5)
Quite important	15 (29.4)	17 (37.0)	32 (33.0)
Not important	26 (51.0)	22 (47.8)	48 (49.5)
It stops me putting on weight			
Very important	7 (13.7)	8 (17.4)	15 (15.5)
Quite important	8 (15.7)	6 (13.0)	14 (14.4)
Not important	36 (70.6)	32 (69.6)	68 (70.1)
It stops me getting withdrawal symptoms			
Very important	21 (41.2)	17 (37.0)	38 (39.2)
Quite important	15 (29.4)	19 (41.3)	34 (35.1)
Not important	15 (29.4)	10 (21.7)	25 (25.8)

TABLE 13 Reasons for giving up smoking

Reasons for giving up smoking	Usual GP care (*N* = 51), *n* (%)	BSC (*N* = 46), *n* (%)	Overall (*N* = 97), *n* (%)
It is expensive			
Very important	35 (68.6)	29 (63.0)	64 (66.0)
Quite important	13 (25.5)	9 (19.6)	22 (22.7)
Not important	3 (5.9)	8 (17.4)	11 (11.3)
It is bad for my health			
Very important	44 (86.3)	39 (84.8)	83 (85.6)
Quite important	5 (9.8)	6 (13.0)	11 (11.3)
Not important	2 (3.9)	1 (2.2)	3 (3.1)
I don't like feeling dependent on cigarettes			
Very important	35 (68.6)	31 (67.4)	66 (68.0)
Quite important	13 (25.5)	10 (21.7)	23 (23.7)
Not important	3 (5.9)	5 (10.9)	8 (8.2)
It makes my clothes and breath smell			
Very important	22 (43.1)	17 (37.0)	39 (40.2)
Quite important	18 (35.3)	18 (39.1)	36 (37.1)
Not important	11 (21.6)	11 (23.9)	22 (22.7)
It is a bad example for children			
Very important	25 (49.0)	26 (56.5)	51 (52.6)
Quite important	14 (27.5)	12 (26.1)	26 (26.8)
Not important	12 (23.5)	8 (17.4)	20 (20.6)
It is unpleasant for people near me			
Very important	20 (39.2)	22 (47.8)	42 (43.3)
Quite important	21 (41.2)	14 (30.4)	35 (36.1)
Not important	10 (19.6)	10 (21.7)	20 (20.6)
It makes me less fit			
Very important	33 (64.7)	34 (73.9)	67 (69.1)
Quite important	14 (27.5)	11 (23.9)	25 (25.8)
Not important	4 (7.8)	1 (2.2)	5 (5.2)
People around me disapprove of my smoking			
Very important	17 (34.0)	15 (32.6)	32 (33.3)
Quite important	16 (32.0)	14 (30.4)	30 (31.3)
Not important	17 (34.0)	17 (37.0)	34 (35.4)
It is bad for the health of people near me			
Very important	26 (51.0)	19 (41.3)	45 (46.4)
Quite important	17 (33.3)	18 (39.1)	35 (36.1)
Not important	8 (15.7)	9 (19.6)	17 (17.5)

TABLE 14 Baseline current smoking behaviour

Baseline smoking outcome	Usual GP care (*N* = 51)	BSC (*N* = 46)	Overall (*N* = 97)
Smoked in last week,* n *(%)			
Not even a puff	0 (0.0)	1 (2.2)	1 (1.0)
Yes, just a few puffs	0 (0.0)	0 (0.0)	0 (0.0)
Yes, between one and five cigarettes	2 (3.9)	1 (2.2)	3 (3.1)
Yes, more than five cigarettes	49 (96.1)	44 (95.7)	93 (95.9)
Number of cigarettes per day			
Mean (SD)	23.3 (13.2)	26.5 (12.0)	24.8 (12.7)
Median (range)	20 (5–60)	25 (5–60)	20 (5–60)
Missing, *n* (%)	2 (4)	3 (6.5)	5 (5.2)
Breath CO reading (p.p.m.)			
Mean (SD)	24.7 (14.1)	22.9 (13.2)	23.8 (13.6)
Median (range)	22 (4–57)	21 (6–58)	22 (4–58)
Missing, *n* (%)	1 (2.0)	1 (2.2)	2 (2.1)
Following statement best describes you,* n *(%)			
I smoke the same number of cigarettes every day	37 (72.5)	41 (89.1)	78 (80.4)
I have cut down the number of cigarettes I smoke	13 (25.5)	4 (8.7)	17 (17.5)
I smoke cigarettes but not every day	0 (0.0)	0 (0.0)	0 (0.0)
I have stopped smoking completely	0 (0.0)	1 (2.2)	1 (1.0)

TABLE 15 Motivation to quit and recent quit attempts

Baseline smoking outcome	Usual GP care (*N* = 51)	BSC (*N* = 46)	Overall (*N* = 97)
Number of quit attempts in last 6 months			
Mean (SD)	3.2 (2.5)	9.8 (25.7)	6.3 (18.1)
Median (range)	2 (0–12)	3 (0–150)	3 (0–150)
Missing, *n* (%)	1 (2.0)	1 (2.2)	2 (2.1)
Length of most recent quit attempt (days)			
Mean (SD)	38.1 (70.9)	10.2 (29.9)	23.4 (53.4)
Median (range)	1 (0–180)	0 (0–90)	0 (0–180)
Denominator	8	9	17
FTND questionnaire score			
Mean (SD)	6.1 (2.2)	6.0 (2.6)	6.1 (2.4)
Median (range)	6 (1–10)	7 (0–10)	6.5 (0–10)
Missing, *n* (%)	0 (0.0)	2 (4.3)	2 (2.1)
MTQ questionnaire score			
Mean (SD)	13.4 (2.4)	14.3 (2.3)	13.8 (2.4)
Median (range)	14 (6–18)	14 (10–19)	14 (6–19)
Missing, *n* (%)	0 (0.0)	0 (0.0)	0 (0.0)

Table 16 gives a breakdown of the answers to the FTND questionnaire score at baseline. The mean FTND score at baseline was 6.6, indicating moderate nicotine dependence, with a range of 0 to 10. The mean MTQ questionnaire score at baseline was 13.8, with a range of 6 to 19. *Table 17* summarises the PHQ-9 and SF-12 scores. The mean PHQ-9 score at baseline was 9.2, indicating moderate levels of low mood but below the threshold for case-level depression (indicated by a score ≥ 10). The mean SF-12 physical component score at baseline was 45, with a range of 15 to 67. This is lower than the mean of the general UK population, indicating worse physical health than the general population. The mean SF-12 mental component score was 41, with a range of 13 to 64. This is about one SD lower than the mean of the general UK population, indicating worse mental health than the general population.

Withdrawals

There were 15 participant withdrawals (15%) from the trial: five (10%) from the usual GP care group and 10 (22%) from the BSC group. A total of seven participants (7.2%) withdrew fully from the trial, while five participants (5.1%) withdrew from follow-up and three participants (3.1%) were too unwell to continue (*Table 18*). There are four categories of patient withdrawal:

- Full withdrawal – participant withdrawn from the trial with regards completion of both postal questionnaires and collection of GP data.
- Withdrawal from follow-up – participant has withdrawn from the completion of postal questionnaires, but agrees with the continuing collection of GP data.
- Withdrawal from treatment – participant withdraws from trial intervention treatment, but agrees with continuing completion of postal questionnaires and collection of GP data.
- Too unwell to continue – participant is deemed too unwell by medical staff to complete any questionnaires. This generally only occurs when a participant has been hospitalised.

Follow-up

Participants were given the option of providing data face to face, via the telephone or by postal questionnaire. Of those who returned follow-up data at 12 months only one person declined a face-to-face visit and completed the follow-up by telephone; all the other participants who completed a 12 month follow-up did so face to face. Participants did not use the option of completing questionnaires online.

Primary outcome

Smoking cessation at 12 months was defined as a CO measure of < 10 p.p.m. or self-reported cessation if no CO measure was available. A CO measure of < 10 p.p.m. indicated no smoking in the last 8 hours and self-reported quit indicated no smoking within the last week. At 12 months, 64 participants had a CO measure and four participants had only a self-reported measure. Eight out of thirty-five participants (23%) had stopped smoking in the usual GP care arm and 12 out of 33 participants (36%) had stopped smoking in the BSC arm (*Table 19*).

A logistic regression of smoking cessation at 12 months on randomised group, adjusted for sex, age, number of cigarettes smoked at baseline and alcohol consumption at baseline, gave an OR of 2.9 (95% CI 0.8 to 10.5) for BSC compared with usual care (*Table 20*). This indicates that those randomised to BSC have greater odds of smoking cessation than those randomised to usual care, although this is not statistically significant. However, the analysis has been carried out on a small sample (complete cases, $n = 65$), so results should be interpreted with caution.

TABLE 16 The FTND questionnaire score at baseline

FTND question	Usual GP care ($N = 51$), *n* (%)	BSC ($N = 46$), *n* (%)	Overall ($N = 97$), *n* (%)
How soon after you wake up do you smoke your first cigarette?			
≤ 5 minutes	26 (51.0)	23 (50.0)	49 (50.5)
6–30 minutes	23 (45.1)	17 (37.0)	40 (41.2)
> 30 minutes	2 (3.9)	6 (13.0)	8 (8.2)
Do you find it difficult to stop smoking in no-smoking areas?			
Yes	23 (45.1)	18 (39.1)	41 (42.3)
No	28 (54.9)	28 (60.9)	56 (57.7)
Which cigarette would you hate most to give up?			
The first of the morning	33 (64.7)	35 (76.1)	68 (70.1)
Other	18 (35.3)	11 (23.9)	29 (29.9)
How many cigarettes per day do you usually smoke?			
≤ 10	10 (19.6)	3 (6.7)	13 (13.5)
11–20	21 (41.2)	17 (37.8)	38 (39.6)
21–30	7 (13.7)	15 (33.3)	22 (22.9)
≥ 31	13 (25.5)	10 (22.2)	23 (24.0)
Do you smoke more frequently in the first hours after waking than during the rest of the day?			
Yes	33 (64.7)	24 (52.2)	57 (58.8)
No	18 (35.3)	22 (47.8)	40 (41.2)
Do you smoke even if you are so ill that you are in bed most of the day?			
Yes	22 (43.1)	20 (43.5)	42 (43.3)
No	29 (56.9)	26 (56.5)	55 (56.7)
Do you smoke hand-rolled cigarettes?			
Yes	25 (49.0)	25 (55.6)	50 (52.1)
No	26 (51.0)	20 (44.4)	46 (47.9)
If yes, how many do you usually smoke per day?			
Mean (SD)	16.0 (10.9)	29.1 (14.5)	22.6 (14.3)
Median (range)	15 (2–50)	30 (6–60)	20 (2–60)
Missing, *n* (%)	2 (0.1)	2 (0.1)	4 (0.1)
How much tobacco do you usually use per day (g)?			
Mean (SD)	11.9 (12.5)	14.5 (11.7)	13.1 (12.0)
Median (range)	7 (1–56)	12.5 (1–50)	8.2 (1–56)
Missing (*n*%)	4 (0.2)	6 (0.2)	10 (0.2)

TABLE 17 Scores for PHQ-9 and SF-12 questionnaires

Secondary outcome	Usual GP care (*N* = 51)	BSC (*N* = 46)	Overall (*N* = 97)
PHQ-9 score			
Mean (SD)	8.7 (6.6)	9.8 (7.1)	9.2 (6.8)
Median (range)	9 (0–22)	8 (0–27)	8 (0–27)
Missing, *n* (%)	2 (3.9)	1 (2.2)	3 (3.1)
SF-12 physical component score			
Mean (SD)	45.3 (10.9)	45.0 (10.9)	45.2 (10.8)
Median (range)	46.1 (15.4–67.0)	43.0 (19.1–63.5)	45.1 (15.4–67.0)
Missing, *n* (%)	0 (0.0)	1 (2.2)	1 (1.0)
SF-12 mental component score			
Mean (SD)	40.8 (11.8)	40.8 (13.1)	40.8 (12.4)
Median (range)	43.4 (16.2–62.7)	42.9 (13.1–63.7)	42.9 (13.1–63.7)
Missing, *n* (%)	0 (0.0)	1 (2.2)	1 (1.0)

TABLE 18 Withdrawals by type

Withdrawal type	Usual GP care	BSC	Total
Full withdrawal	2	5	7
Withdrawal from follow-up	2	3	5
Withdrawal from treatment	0	0	0
Too unwell to continue	1	2	3
Total	5	10	15

TABLE 19 Smoking cessation at 12 months by trial arm

Primary outcome	Usual GP care (*N* = 51), *n* (%)		BSC (*N* = 46), *n* (%)		Overall (*N* = 97), *n* (%)	
Number quit (CO verified)	8	24.2[a]	10	32.3[a]	18	28.1[a]
Number with CO measure	33	94.3[a]	31	93.9[a]	64	94.1[a]
Number quit (self-report only)	0	0.0[b]	2	100.0[b]	2	50.0[b]
Number with self-report only	2	5.7[b]	2	6.1[b]	4	5.9[b]
Total number quit	8	22.9[c]	12	36.4[c]	20	29.4[c]
Total number with CO or self-reported measure	35	100.0[c]	33	100.0[c]	68	100.0[c]

a Percentage refers to total number with CO measure.
b Percentage refers to total number with self-reported measure only.
c Percentage refers to total number with CO measure or self-reported measure.

TABLE 20 Adjusted analysis of smoking cessation at 12 months ($n = 65$)

Characteristic	OR	Standard error	95% CI	*p*-value
BSC vs. usual care	2.94	1.91	0.83 to 10.50	0.10
Age	0.97	0.02	0.93 to 1.02	0.30
Male	0.78	0.54	0.20 to 3.04	0.72
Number of cigarettes smoked per day	0.95	0.03	0.89 to 1.01	0.09
Alcohol consumption	1.23	0.80	0.35 to 4.38	0.75

Secondary outcomes

A summary of the smoking-related secondary outcome is given in *Table 21* and a summary of the non-smoking-related secondary outcomes is given in *Table 22*.

TABLE 21 Summary of smoking-related secondary outcomes

Outcome	Usual care			BSC			Overall		
Self-reported quit	**n**[a]	***Frequency***[b]	***%***	**n**[a]	***Frequency***[b]	***%***	**n**[a]	***Frequency***[b]	***%***
1 month	40	2	5.0	42	4	9.5	82	6	7.3
6 months	34	3	8.8	36	4	11.1	70	7	10.0
12 months	35	4	11.4	33	5	15.2	68	9	13.2
Number of cigarettes	**n**	***Mean (SD)***	***Range***	**n**	***Mean (SD)***	***Range***	**n**	***Mean (SD)***	***Range***
1 month	37	19.4 (12.3)	0–50	38	18.4 (9.6)	4–60	75	18.9 (11.0)	0–60
6 months	30	17.1 (11.6)	1–50	31	16.8 (9.6)	1–40	61	16.9 (10.5)	1–50
12 months	30	18.4 (11.6)	5–50	26	20.1 (10.6)	2–40	56	19.2 (11.1)	2–50
Number quit attempts	**n**	***Mean (SD)***	***Range***	**n**	***Mean (SD)***	***Range***	**n**	***Mean (SD)***	***Range***
1 month	40	1.1 (1.8)	0–10	41	1.4 (2.8)	0–15	81	1.2 (2.3)	0–15
6 months	33	0.9 (1.1)	0–4	34	1.1 (1.1)	0–4	67	1.0 (1.1)	0–4
12 months	35	0.7 (1.2)	0–6	32	3.1 (7.5)	0–32	67	1.9 (5.3)	0–32
Length of cessation	**n**	***Mean (SD)***	***Range***	**n**	***Mean (SD)***	***Range***	**n**	***Mean (SD)***	***Range***
1 month	12	0.3 (0.9)	0–3	10	1.0 (1.8)	0–5	22	0.59 (1.4)	0–5
6 months	11	1.3 (2.8)	0–7	10	46.5 (72.9)	0–180	21	22.8 (54.2)	0–180
12 months	8	1.8 (2.4)	0–7	8	21.1 (42.5)	0–120	16	11.4 (30.7)	0–120
FTND score	**n**	***Mean (SD)***	***Range***	**n**	***Mean (SD)***	***Range***	**n**	***Mean (SD)***	***Range***
1 month	40	5.5 (2.4)	0–10	38	5.2 (2.1)	0–9	78	5.3 (2.3)	0–10
6 months	32	4.8 (2.1)	0–9	30	5.2 (2.3)	1–9	62	5.0 (2.2)	0–9
12 months	29	4.9 (2.2)	0–9	27	5.3 (2.0)	1–9	56	5.1 (2.1)	0–9
MTQ score	**n**	***Mean (SD)***	***Range***	**n**	***Mean (SD)***	***Range***	**n**	***Mean (SD)***	***Range***
1 month	40	11.8 (2.4)	7–17	41	14.2 (2.5)	9–19	81	13.0 (2.7)	7–19
6 months	34	12.3 (3.1)	4–19	33	12.6 (3.2)	6–18	67	12.5 (3.1)	4–19
12 months	32	11.1 (3.1)	4–18	33	12.1 (4.0)	5–19	65	11.6 (3.6)	4–19

a n = number who completed the questionnaire.
b Frequency is the total number who self-reported having quit smoking.

TABLE 22 Summary of non-smoking-related secondary outcomes

Secondary outcome	Usual care			BSC			Total		
	n	Mean (SD)	Range	*n*	Mean (SD)	Range	*n*	Mean (SD)	Range
PHQ-9 score									
1 month	39	8.3 (6.5)	0–27	41	9.2 (7.1)	0–26	80	8.8 (6.8)	0–27
6 months	32	8.7 (7.0)	0–23	33	9.6 (6.5)	0–27	65	9.2 (6.7)	0–27
12 months	34	7.7 (7.3)	0–23	33	11.2 (7.0)	0–23	67	9.4 (7.3)	0–23
SF-12 physical component score									
1 month	40	45.4 (10.1)	20.2–61.8	42	45.4 (11.2)	18.8–64.4	82	45.4 (10.6)	18.8–64.4
6 months	34	46.9 (11.4)	20.2–65.9	35	47.8 (11.1)	23.1–72.4	69	47.43 (11.2)	20.2–72.4
12 months	33	45.8 (9.1)	25.0–63.0	33	46.2 (11.1)	22.0–61.6	66	46.0 (10.1)	22.0–63.0
SF-12 mental component score									
1 month	40	42.6 (10.2)	21.8–61.7	42	39.9 (13.3)	9.1–62.4	82	41.2 (11.9)	9.1–62.4
6 months	34	41.6 (10.7)	22.2–59.5	35	37.1 (12.9)	8.2–58.2	69	39.3 (12.0)	8.2–59.5
12 months	33	41.8 (11.0)	16.2–61.3	33	39.1 (11.2)	20.0–61.7	66	40.4 (11.1)	16.2–61.7
BMI (kg/m²)									
12 months	34	29.6 (6.5)	17.4–46.7	33	27.8 (6.5)	10.7–42.2	67	28.7 (6.5)	10.7–46.7

The FTND questionnaire produces a score between 0 and 10, where a score of 1–2 indicates low dependence, 3–4 indicates low to moderate dependence, 5–7 indicates moderate dependence and 8–10 indicates high dependence. The FTND score slightly decreased over time for both randomised groups (*Table 21*). The usual-care group has a lower FTND score than the BSC group at 12 months, but the CIs overlap (*Figure 5*).

The MTQ questionnaire produces a score between 4 and 19, where a higher score indicates greater motivation to stop smoking. The MTQ score decreases over time in both randomised groups (*Figure 6*). The MTQ score is higher in the BSC group than in the usual-care group at all three time points and the CIs are not overlapping at 1 month.

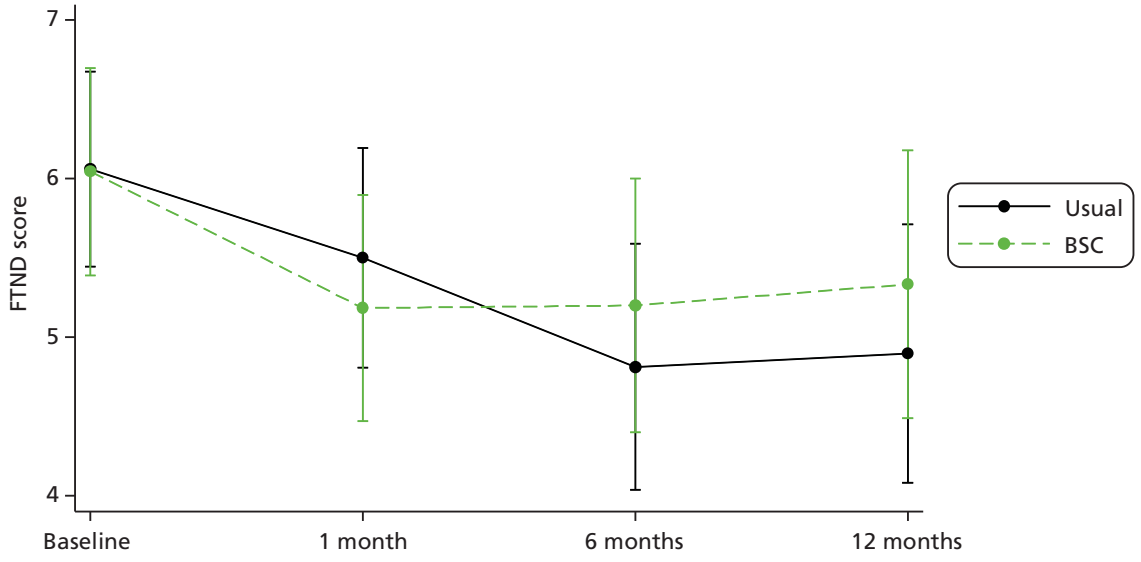

FIGURE 5 Mean FTND questionnaire score and 95% CI by randomised group.

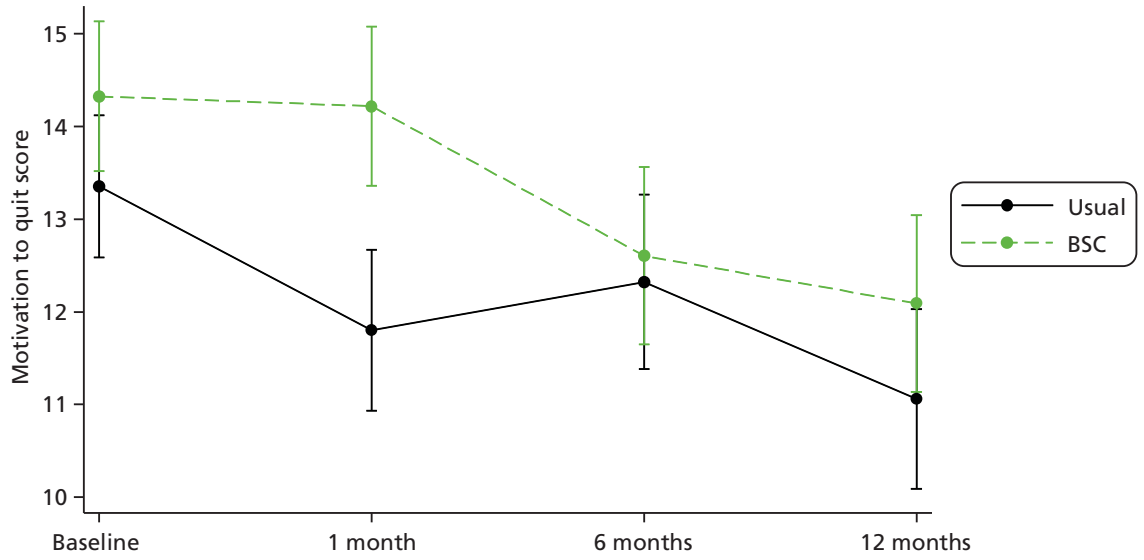

FIGURE 6 Mean MTQ questionnaire score and 95% CI by randomised group.

The PHQ-9 produces a score between 0 and 27, where scores of 5, 10, 15 and 20 are used as cut-off points for mild, moderate, moderately severe and severe depression respectively. The PHQ-9 score is fairly stable over the first 6 months and then increases at 12 months for the BSC group and decreases for the usual-care group (*Figure 7*). The PHQ-9 score is higher (indicating lowering of mood) in the BSC group than in the usual-care group, but the CIs are overlapping.

The SF-12 physical component score ranges from 0 to 100, where 0 indicates the lowest level of health and 100 indicates the highest level of health measured by the scale. The physical component score appears to be fairly stable over time, increasing slightly at 6 months and then decreasing at 12 months (*Figure 8*). The physical component score is slightly higher in the BSC group than in the usual-care group at 6 and 12 months, indicating better physical health, but there is very little difference between the two groups.

The SF-12 mental component score ranges from 0 to 100, where 0 indicates the lowest level of health and 100 indicates the highest level of health measured by the scale. The mental component score appears to be fairly stable over time for the usual-care group and decreases in the BSC group (*Figure 9*). The mental

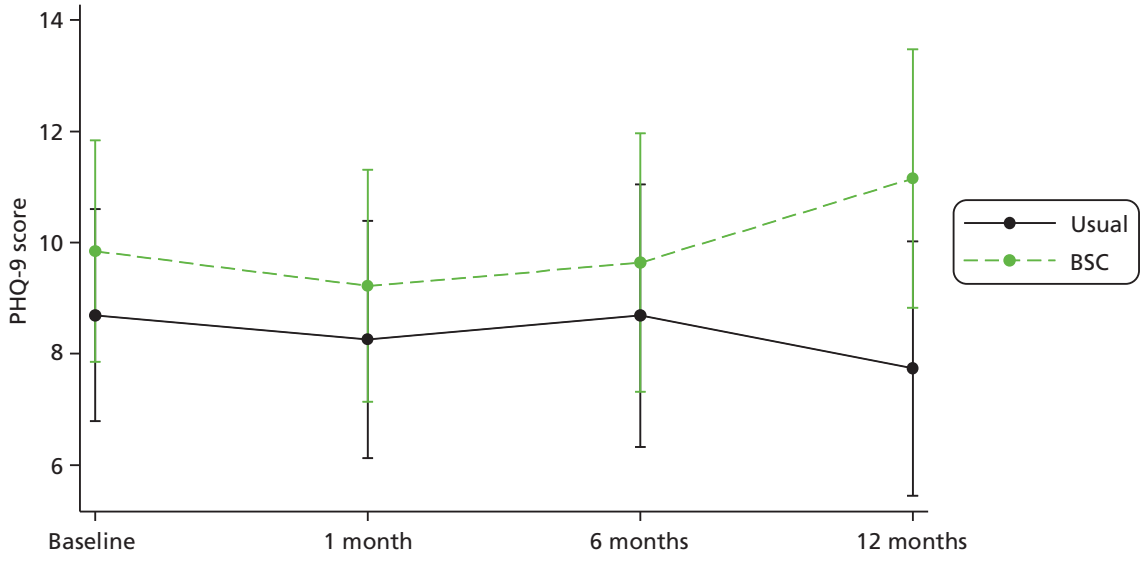

FIGURE 7 Mean PHQ-9 score and 95% CI by randomised group.

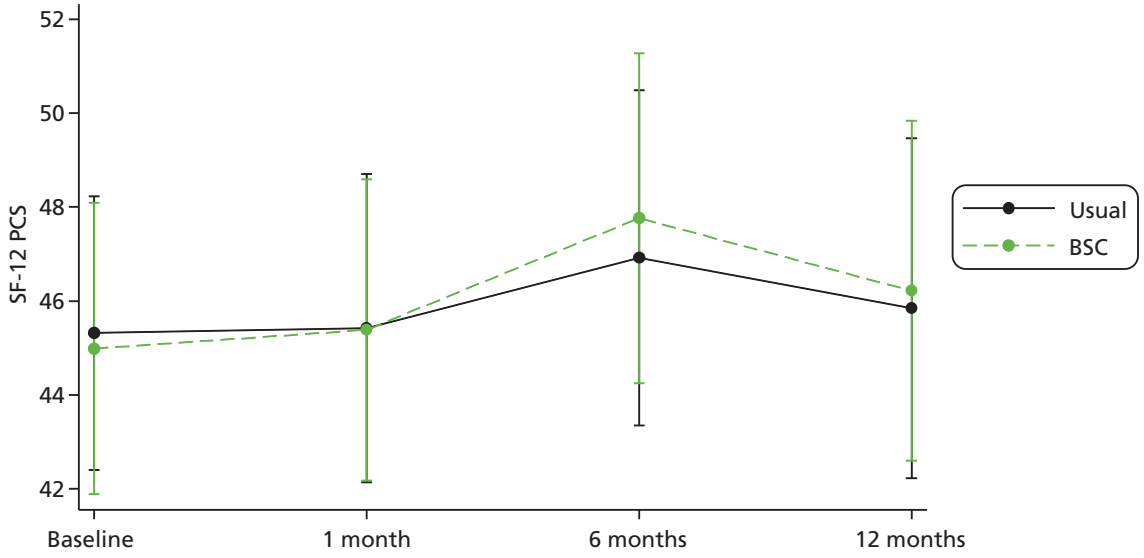

FIGURE 8 Mean SF-12 physical component score and 95% CI by randomised group. PCS, physical component score.

component score is lower in the BSC group than in the usual-care group, indicating lower composite mental health, but the CIs overlap at all time points.

The number of cigarettes smoked per day appears to be fairly stable over time (*Figure 10*). At 12 months, fewer cigarettes were smoked in the BSC arm than in the usual-care group.

The number of attempts to quit in the last 6 months appears to decrease at 6 months and increase at 12 months. The number of attempts to quit is greater in the BSC arm than in the usual-care arm at all time-points, including at 12 months (*Figure 11*).

The length of the most recent quit attempt has a large range in the BSC group at 6 and 12 months (*Table 22*). The length is shorter at 1 month in the BSC group than in the usual-care group, but longer at 6 and 12 months. *Figure 12* give details of the percentage of self-reported smoking cessation by randomised group.

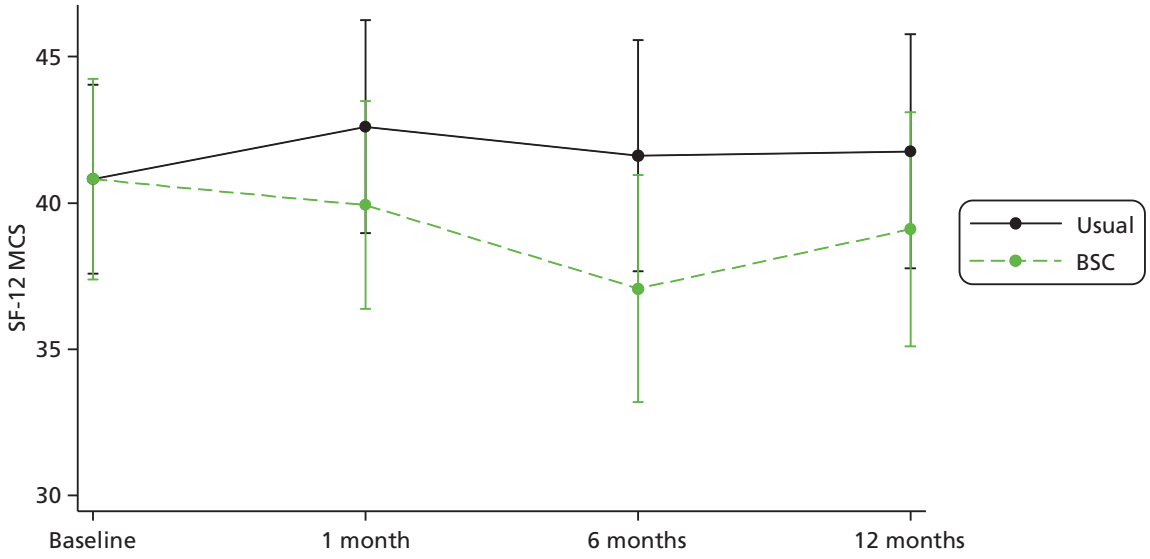

FIGURE 9 Mean SF-12 mental component score and 95% CI by randomised group. MCS, mental component score.

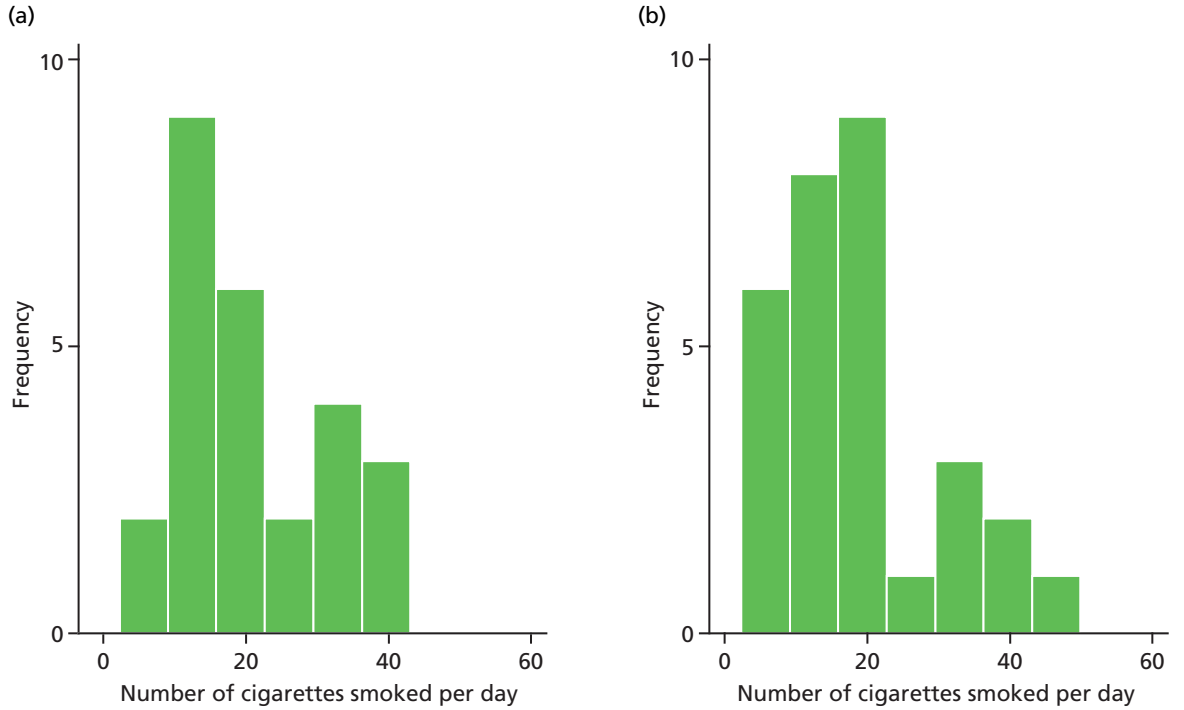

FIGURE 10 Histograms of number of cigarettes smoked per day by randomised group at 12 months. (a) BSC; and (b) usual GP care.

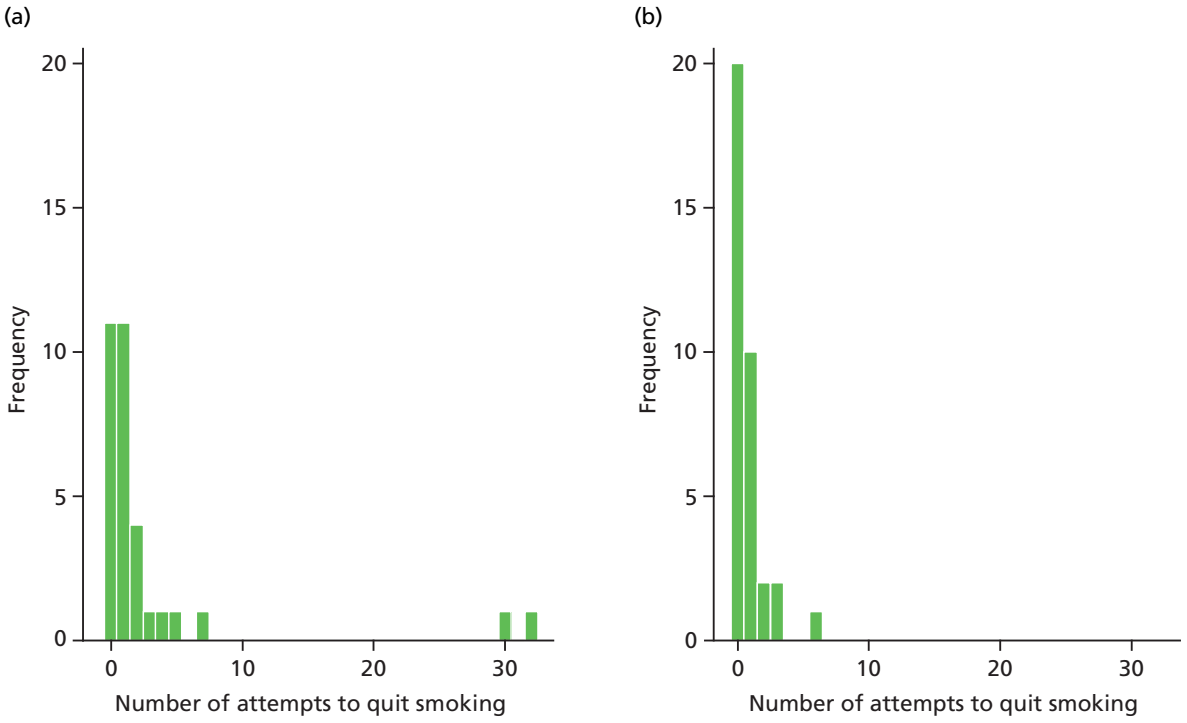

FIGURE 11 Histograms of number of attempts to quit by randomised group at 12 months. (a) BSC; and (b) usual GP care.

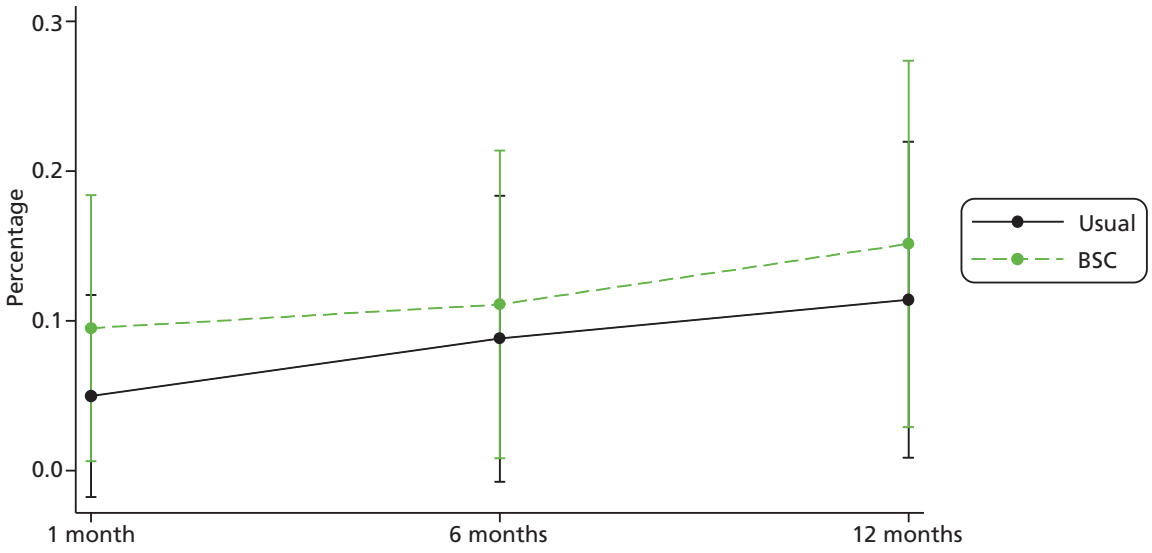

FIGURE 12 Percentage of self-reported smoking cessation and 95% CI by randomised group.

The number of participants self-reporting cessation increased slightly over time (*Table 22*). The self-reported quit rate was higher in the BSC group than in the usual-care group at all time-points, but the CIs overlap. A cross-tabulation of self-reported quit with CO-measured quit showed moderate agreement between the two measures ($\kappa = 0.48$). There were no participants who had quit according to the self-report measure and not quit according to the CO measure, but there were 11 participants who had quit according to the CO measure but did not self-report quitting (*Table 23*). However, note that a CO measure of < 10 p.p.m. indicates no smoking in the last 8 hours and self-reported quit indicates no smoking within the last week.

At 12 months, there were two participants who reported drug use in the BSC arm (6%) and four in the usual-care arm (12%).

Adverse events

There were 21 AEs among 17 participants during the course of the trial. Of these, 11 were classed as serious. More participants in the BSC group (23.9%) than in the usual GP care group (11.8%) experienced one or more AEs. The six AEs that were definitely or probably related to the intervention were all non-serious AEs (*Table 24*).

Of the participants who experienced SAEs, eight were hospitalised as a result of deterioration in their mental health; one participant had surgery for an existing problem, two participants were hospitalised for illnesses unlikely to be related to the study and one participant died as a result of lung cancer.

TABLE 23 Cross-tabulation of self-reported quit and CO-measured quit

Outcome	CO-measured smoking	CO-measured cessation	Total
Self-reported smoking	46	11	57
Self-reported cessation	0	7	7
Total	46	18	64

TABLE 24 Relationship of AEs

Event type	Relationship to study	Usual GP care	BSC	Total
SAE	Definitely related	0	0	0
	Probably related	0	0	0
	Unlikely to be related	1	4	5
	Unrelated	0	6	6
Non-serious AE	Definitely related	1	0	1
	Probably related	2	3	5
	Unlikely to be related	0	0	0
	Unrelated	1	2	3
Total		5[a]	15	20

a One serious adverse event in usual-care arm unclassified.

Of the participants reporting AEs, one experienced a deterioration in their mental health that did not require hospitalisation, four participants experienced side effects of NRT products (burning mouth, feeling sleepy, headaches), two participants experienced side effects of smoking cessation medication (headaches, nightmares) and one participant had an unrelated complaint (ear infection).

Summary of findings

At 12 months, 36% of participants had stopped smoking in the BSC group, compared with 23% in the usual-care group. The adjusted OR was 2.9 (95% CI 0.8 to 10.5), indicating a greater likelihood of smoking cessation in the BSC group than the usual-care group, but the difference is not statistically significant.

In terms of smoking-related outcomes at 12 months, the BSC group generally performed better than the usual-care group. At 12 months the FTND questionnaire score, MTQ score, number of cigarettes smoked per day and number of cessation attempts were higher in the BSC group than in the usual-care group. In addition, the duration of cessation was longer in the BSC group.

In terms of mental health outcomes at 12 months, the BSC group had a slightly lower mean mental component score (a measure of psychological well-being incorporating anxiety and depression) and a slightly higher PHQ-9 score (a measure of depression). Mental health outcome – as measured by these metrics – was not different between groups at either 1 or 6 months. In terms of physical health outcomes at 12 months, the BSC group fared better than the usual-care group overall, with slightly higher mean physical component scores and slightly lower mean BMI.

Chapter 5 Health economic analysis

The health economic analysis for the SCIMITAR pilot trial examined the feasibility of a cost-effectiveness analysis in a full trial of supplementing usual care with BSC compared with usual care alone. The costs of both BSC and usual care were identified, measured and valued. The intervention stage consisted of recruitment, follow-up and assessment. Costs were recorded for both intervention and control groups at baseline, 6-month follow-up and 12-month follow-up. European Quality of Life-5 Dimensions (EQ-5D) data were collected at baseline, and at 6- and 12-month follow-up.

Costs

Intervention costs were calculated based on training costs and the costs of delivering the intervention.

Training costs

At the pre-intervention stage, the cost of training MHSCPs was recorded. Training was provided by a NHS Stop Smoking Services trainer and a pharmacist and lasted for 1 day at a cost of £650. Five MHSCPs participating in the trial received training. Based on their wage bands, the cost of 1 day's training was calculated as £745, in total. The total training cost during this period was estimated to be £1395.

Intervention costs

For the intervention group, the costs of BSC included staff cost of MHSCPs and other relevant expenses (e.g. telephone, travel, CO monitor, etc.).

The individual cost for contacts with MHSCPs was calculated according to the contact and non-contact time recorded on the treatment log. The working time of all MHSCPs was 290 hours in total, including contact and non-contact time. The wage rates for the five MHSCPs were also recorded. The total staff cost was, therefore, estimated to be £5810.

The cost of CO monitors was calculated for 1 year of its 3 life-years. The price of a CO monitor was £196. In the trial, five CO monitors were used by MHSCPs for 12 months. The allocated 1-year cost for five CO monitors was, therefore, £327. The mean recorded expenses including travel and telephone were £55.86 per participant.

The total cost of providing the incremental cost of BSC over and above usual care was £221 (SD £160).

Medication costs (prescriptions)

The details of antipsychosis medication and pharmacotherapy for prescriptions for smoking cessation products during the trial period were extracted from GP records through participating GP surgeries. The corresponding prices were taken from the *British National Formulary* and prescription cost analysis 2012, where applicable.[64,65] The proportion of participants who had taken antipsychotic medication was similar in each group (50% in the BSC group; 47% in the usual-care group). The mean cost of antipsychotic medication prescription in BSC group was £474, compared with £428 in the usual-care group. During the trial period, GP records showed that 22 participants (48%) in the BSC group had used pharmacotherapy for smoking cessation, whereas only 10 participants (19%) in the usual-care group did so. The mean cost of pharmacotherapy per participant was £62 in the BSC group and £17 in the usual-care group.

Health-care and community services costs

Items on the health-care service use questionnaire were analysed for completeness in order to assess the feasibility of collecting wider service use data from patients in a full trial. Other than data missing because of loss of follow-up, the number of missing data with regard to health-care resources and social service section was relatively low in the pilot trial. *Table 25* presents the number of missing data items by question

TABLE 25 Number of missing data by group and follow-up time

Health-care and social service item	Baseline	6 months		12 months	
		BSC	Usual care	BSC	Usual care
A&E	0	2	0	0	1
Hospital admission	0	2	1	0	1
Outpatient appointment	0	3	2	0	1
Day case/procedure	0	2	1	0	3
999 emergency ambulance	0	2	0	0	1
Patient transport service	0	1	0	0	1
GP – home	0	3	1	0	1
GP – surgery	0	3	1	0	1
GP – telephone	0	4	1	0	1
Practice nurse	0	3	1	0	1
District nurse, health visitor	0	4	1	0	1
Care co-ordinator, case manager, key worker	0	4	1	0	1
Psychiatrist	0	3	1	0	1
Clinical psychologist	0	4	1	0	1
CPN	0	2	1	0	1
CAMHS worker	0	4	1	0	1
Counsellor	0	4	1	0	2
Family therapist	0	4	1	0	1
Art/drama/music/occupational therapist	0	4	1	1	1
Social worker	0	3	1	1	1
Family support worker	0	4	1	1	1
Accommodation key worker	0	4	1	1	1
Drug/alcohol support worker	0	4	1	1	1
NHS Direct telephone helpline	0	4	1	1	1
Day centre/drop-in centre	0	5	1	1	1

A&E, accident and emergency; CAMHS, Child and Adolescent Mental Health Services; CPN, community psychiatric nurse.

at baseline and follow-ups for each group. Most of the missing data were a consequence of participants not responding to the whole section of the questionnaire.

Health-care resources and community services used by patients were self-reported using a health economic/service utilisation questionnaire (see *Appendix 3*). The total volume of usage was calculated by summing the total number of episodes that occurred or the total number of contacts in each group. National average unit costs of corresponding services were applied to quantities recorded to derive the total cost of health-care resources and community services for each trial participant. National average unit costs were extracted from published sources where applicable (*Table 26*). The quantities of resources used during the trial period are reported in *Table 27*.

TABLE 26 Unit costs of health and community services

Resource	Unit cost	Sources
A&E (admitted)	£147/episode	Department of Health 2012[66]
A&E (not admitted)	£95/episode	Department of Health 2012[66]
Hospital admission	£1236/episode	Department of Health 2012[66]
Outpatient appointment	£131/episode	Department of Health 2012[66]
Day case/procedure	£681/episode	Department of Health 2012[66]
Emergency ambulance	£98/episode	Department of Health 2012[66]
Patient transport service	£34/episode	Department of Health 2011,[67] inflated with HCHS Index to 2011–12 prices[66]
GP – home visit	£4.7/minute × 11.4 minutes/visit = £54/visit	Curtis 2012[68]
GP – surgery	£3.7/minute × 11.7 minutes/visit = £43/visit	Curtis 2012[68]
GP – telephone	£3.7/minute × 7.1 minutes/telephone call = £26/telephone call	Curtis 2012[68]
GP – practice nurse	£45/hour × 15.5 minutes/contact = £12/contact	Curtis 2012[68]
District nurse/health visitor	£39/contact	Department of Health 2012.[66] (There was a different unit cost for health visitor: £44/visit. Since we were unable to distinguish the utilisation between the two, we opted for the unit cost for the more specific role)
Care co-ordinator/case manager/key worker	£67/hour of face-to-face contact × 1 hour/contact = £67/contact	Curtis 2012.[68] (Data were not available on these specific roles. As we learned during the trial, these roles could be held by CPN or other personnel. It was not possible to determine the individuals held these roles. We used unit cost for CPN to estimate the costs. No data available on the average duration per contact, we assumed a 1-hour contact)
Community psychiatrist	£319/face-to-face contact	Curtis 2012[68]
Clinical psychologist	£141/contact	Department of Health 2012[66]
CPN	£67/hour of face-to-face contact × 1 hour/contact = £67/contact	Curtis 2012.[68] (No data available on the average duration per contact, we assumed a 1-hour contact)
CAMHS worker/STAR worker or advocate	£244/contact	Department of Health 2012.[66] (Data were only available for CAMHS worker. As we were unable to distinguish the utilisation between the two, we used the unit cost for CAMHS worker to estimate both)
Counsellor (NHS, school/college or private)	£59/consultation	Curtis 2012.[68] (We were unable to distinguish the utilisation of counsellor from public or private sectors. We estimated the costs using the unit cost in public sector)
Family therapist	£66/contact	Department of Health 2012.[66] (No data available specifically on family therapist. The unit cost here was estimated based on all community therapy provided by NHS)

continued

TABLE 26 Unit costs of health and community services (*continued*)

Resource	Unit cost	Sources
Art/drama/music/ occupational therapist	£71/contact	Department of Health 2012.[66] (No data available on art/drama/music therapy but occupational therapy. We used the unit cost for occupational therapy to estimate the costs in the other area)
Social worker	£156/hour of face-to-face contact × 1 hour/face-to-face contact = £156/face-to-face contact	Curtis 2012.[68] (No data available on the average duration per face-to-face contact. We assumed a 1-hour contact)
Family support worker	£49/hour of client-related work × 1 hour of client-related work/contact = £49/contact	Curtis 2012.[68] (No data available on the average duration of client-related work for one contact. We assumed a 1-hour workload)
Accommodation key worker	£156/hour of face-to-face contact × 1 hour/face-to-face contact = £156/face-to-face contact	Curtis 2012.[68] (No data available on accommodation key worker. We used the unit cost for social worker to estimate the cost. No data available on the average duration per face-to-face contact. We assumed a 1-hour contact)
Drug and alcohol support worker	£113/contact	Department of Health 2012[66]
Day centre/ drop-in centre	£30/session	Curtis 2012[68]
Community pharmacist	£125/hour of direct clinical activities × 5 minutes = £10/contact	Curtis 2012,[68] Wu *et al.* 2009[69]
NHS Stop Smoking Services helpline	£6/telephone call	Wu *et al.* 2009,[69] £5.93/telephone call in 2009, inflated with HCHS Index to 2011–12 prices[66]
Podiatrist	£40/appointment	Department of Health 2012[66]
Crisis team	£184/contact	Curtis 2012[68]
Dentist	£96/appointment	Department of Health 2012[66]
Therapy centre	£66/contact	Department of Health 2012.[66] (Based on the responses, we were not able to determine what therapy this participant went to. The unit cost here was estimated based on all community therapy provided by NHS)
Social care support for mental health	£169/week for 10 people	Curtis 2012[68]
Physiotherapist	£46/contact	Department of Health 2012[66]
Daily care	£67/week for 20 people	Curtis 2012[68]

A&E, accident and emergency; CAMHS, Child and Adolescent Mental Health Services; CPN, community psychiatric nurse; HCHS, Hospital and Community Health Services; STAR, Support Time and Recovery.

TABLE 27 Health-care and community services use during trial period, by group

	Number of patients (%)		Total use (number of contacts)	
Resources	BSC	Usual care	BSC	Usual care
A&E (admitted)	6 (13)	1 (2)	6	1
A&E (not admitted)	9 (20)	7 (14)	12	8
Hospital admission	4 (9)	2 (4)	7	2
Outpatient appointment	23 (50)	20 (39)	116	53
Day case/procedure	6 (13)	6 (12)	8	12
Emergency ambulance	7 (15)	4 (8)	9	6
Patient Transport Service	4 (9)	2 (4)	111	22
GP home visit	5 (11)	3 (6)	9	6
GP surgery	35 (76)	33 (65)	233	182
GP telephone	11 (24)	13 (25)	31	32
GP practice nurse	28 (61)	29 (57)	122	131
District nurse/health visitor	3 (7)	4 (8)	10	19
Care co-ordinator/case manager/ key worker	19 (41)	21 (41)	961	243
Community psychiatrist	26 (57)	25 (49)	73	87
Clinical psychologist	7 (15)	7 (14)	79	205
CPN	18 (39)	13 (25)	278	140
CAMHS worker/STAR worker or advocate	10 (22)	8 (16)	745	228
Counsellor (NHS, school/college or private)	3 (7)	4 (8)	30	78
Family therapist	2 (4)	0 (0)	10	0
Art/drama/music/occupational therapist	3 (7)	8 (16)	244	222
Social worker	7 (15)	4 (8)	134	32
Family support worker	1 (2)	0 (0)	2	0
Accommodation key worker	3 (7)	1 (2)	19	24
Drug and alcohol support worker	3 (7)	4 (8)	17	37
Day centre/drop-in centre	8 (17)	8 (16)	223	221
Community pharmacist	7 (15)	9 (18)	17	23
NHS Stop Smoking Services helpline	1 (2)	3 (6)	1	8
Podiatrist	1 (2)	0 (0)	1	0
Crisis team	1 (2)	0 (0)	14	0
Dentist	19 (41)	19 (37)	54	46
Therapy centre	0 (0)	1 (2)	0	108
Social care support for mental health	1 (2)	0 (0)	12	0
Physiotherapist	1 (2)	1 (2)	10	12
Daily care	0 (0)	1 (2)	0	182

A&E, accident and emergency; CAMHS, Child and Adolescent Mental Health Services; CPN, community psychiatric nurse; STAR, Support Time and Recovery.

Total costs

Mean total health-care costs are presented in *Table 28* for BSC and usual care. Mean total cost per participant in the BSC group was £12,674, compared with £6867 in the usual-care group. The health-care resources/community services were the main cost driver in both groups, representing the majority (94%) of the costs incurred.

Mean costs and their SDs were calculated. The SDs demonstrated a high variance among costs, especially the cost of health-care resources/community services. The exact range of each cost component is shown in *Table 29*. Because of the small sample size in both groups, low-frequency, high-tariff costs can have a significant impact upon the mean cost. One participant in the BSC group stayed in rehabilitation for 6 months immediately prior to the trial and subsequently received multiple services on a daily basis for at least another 6 months. No patients in the usual-care group were observed to have similar episodes; hence, in the small sample, the average in the BSC group may be inflated by this case. This is a common problem in the analysis of pilot trials with small populations, where small sample size, even under random allocation, can result in some baseline imbalances.

It should also be noted that the greatest proportion of cost was accounted for by the utilisation of wider health care and social services outside the trial, which was considerably higher in the intervention group (*Figure 13*). The highest utilisation of health care and social services occurred in the intervention group, and the utilisation level remained higher in the intervention group when the outliers were excluded (as shown by the BSC* line in *Figure 13*). Although there was a consistent difference in health-care and social services usage between two groups, the limited sample size prevented us from concluding a statistically significant difference.

European Quality of Life-5 Dimensions

Quality-adjusted life-years (QALYs) were derived from EQ-5D data by calculating the area under the curve derived from EQ-5D at each time point.[70] EQ-5D data were collected at baseline and at the 1 month, 6 months and 12 months time points. Missing data at each point were replaced with the mean value in

TABLE 28 Cost per participant during 12-month trial period

Cost item	BSC ($n = 46$) (SD)	Usual care ($n = 51$) (SD)
BSC intervention	£221 (£160)	£0 (£0)
Antipsychosis medicine prescription	£474 (£913)	£428 (£782)
Pharmacotherapy for stop smoking prescription	£62 (£132)	£17 (£60)
Health-care resources/community services	£11,917 (£16,601)	£6421 (£6089)
Total	£12,674 (£16,595)	£6867 (£6026)

TABLE 29 Cost range (per participant) for 12-month trial period

Cost item	BSC ($n = 46$)	Usual care ($n = 51$)
BSC intervention	£37–£824	–
Antipsychosis medicine prescription	£0–£3712	£0–£3247
Pharmacotherapy for stop smoking prescription	£0–£706	£0–£300
Health-care resources/community services	£352–£96,896	£86–£33,217
Total cost	£716–£97,232	£343–£33,217

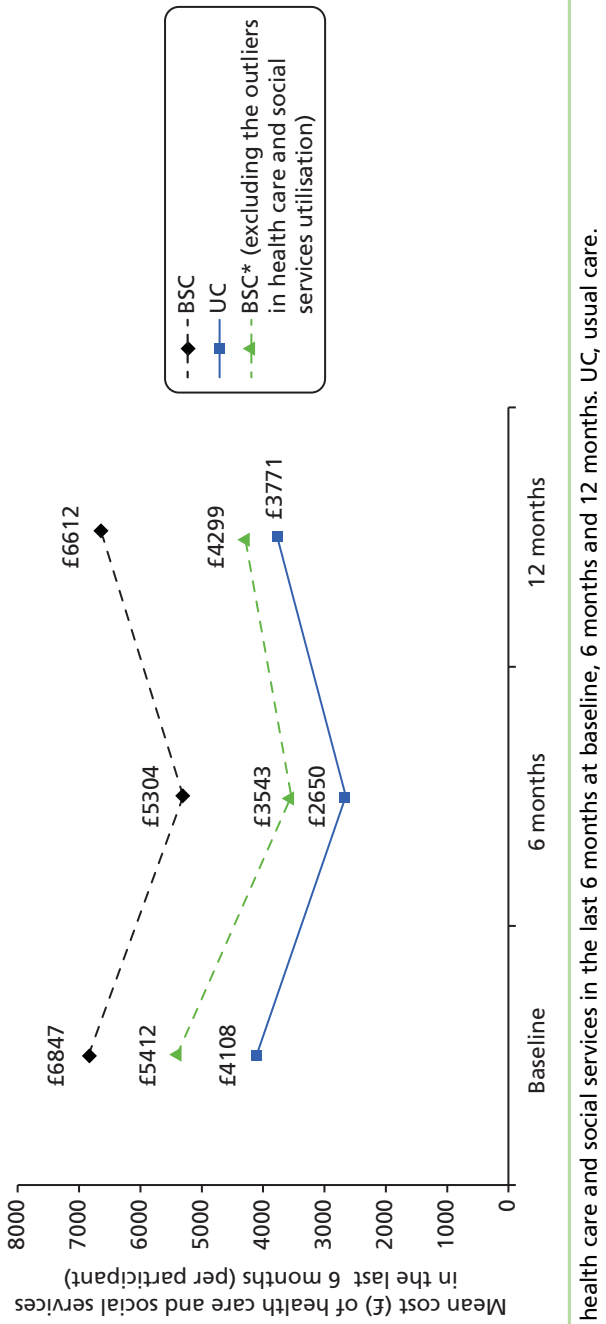

FIGURE 13 Mean cost of health care and social services in the last 6 months at baseline, 6 months and 12 months. UC, usual care.

the relevant group. *Figures 14–16* show the proportion of participants who reported a problem in each individual domain of EQ-5D (i.e. domain score of 2 or 3) over the trial period in each group. Similar patterns in mobility and usual activities were evident in both groups. However, the patterns in other domains were almost opposite between the two groups. During the 12-month trial period, participants in the BSC group gained a mean of 0.65 QALYs (95% CI 0.58 to 0.72 QALYs), while participants in the usual-care group gained, on average, 0.69 QALYs (95% CI 0.63 to 0.75 QALYs).

We have not undertaken a full incremental cost-effectiveness analysis, as this is a pilot trial and was not powered to detect significant differences in cost-effectiveness. The aim of this pilot is to assess the feasibility of conducting a full economic evaluation and to investigate the completeness of data. We should also note that a 12-month trial may not demonstrate the potential long-term impact on health as well as health-care and social services utilisation. It is likely that cost savings and quality-of-life gains as a result of smoking cessation would extend beyond the 12-month follow-up in this study.[71] Hence, a full-trial analysis would use longer-term modelling to project costs and outcomes beyond 12 months.

Cost-effectiveness

Total health-care and social care costs were combined with the primary outcome of the trial to estimate the cost per quitter at 12 months. As this is a pilot trial, which is not powered to estimate cost-effectiveness, we report a simple incremental cost-effectiveness ratio (ICER) by combining the costs with the number of successful quitters at 12 months; the incremental cost was £58,197 per quitter. This ICER should be treated with caution because of the small sample size and large variance of total cost. In a pilot trial, high-tariff, low-frequency costs can have a large impact on the overall ICER if these high-cost cases fall into a treatment arm by chance. Therefore, the main aim of the economic analysis of this trial has been to pilot questionnaires and assess the feasibility of collecting such data in a larger trial.

Smoking cessation help beyond the trial

Beyond our analysis perspective, 19 participants in the BSC group and 14 participants in the usual-care group used resources other than NHS-funded resources regarding smoking cessation, including other helplines, the internet and self-help booklets. Among these participants, eight in the BSC group used other helplines, ranging from one to nine times during the trial period, while six participants in the usual-care group used other helplines between 1 and 24 times. Similar numbers of participants used the internet in both groups (seven in the BSC group vs. eight in the usual-care group), but the participants in the usual group appeared to use the internet more frequently (one or two times in 12 months in BSC group vs. 2–10 times in 12 months in usual-care group). Nine participants in each group used self-help booklet for

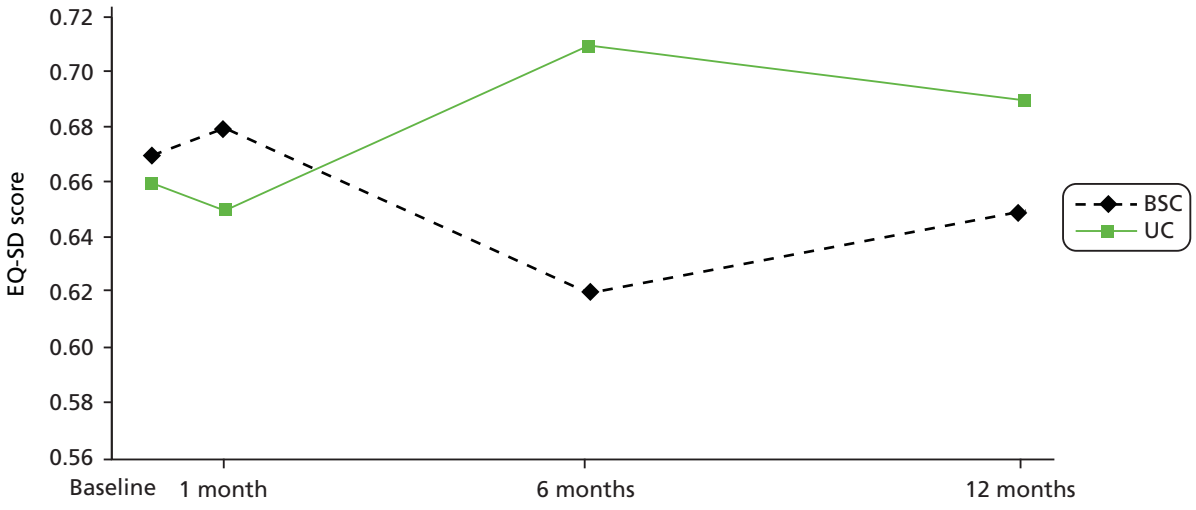

FIGURE 14 Mean EQ-5D score at baseline and at 1 month, 6 months and 12 months. UC, usual care.

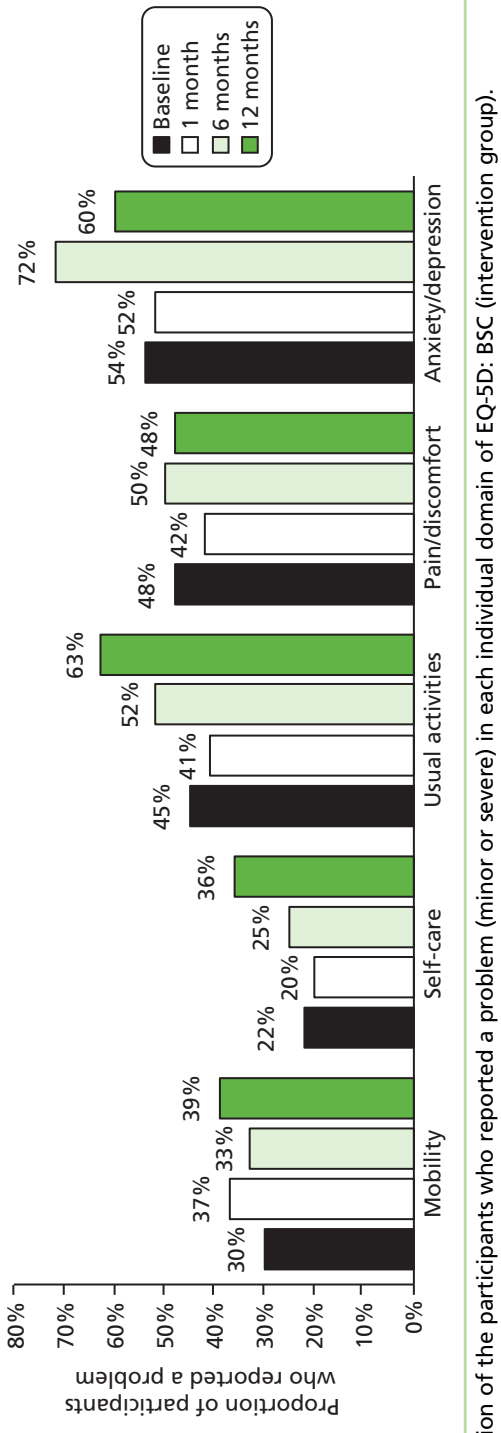

FIGURE 15 Proportion of the participants who reported a problem (minor or severe) in each individual domain of EQ-5D: BSC (intervention group).

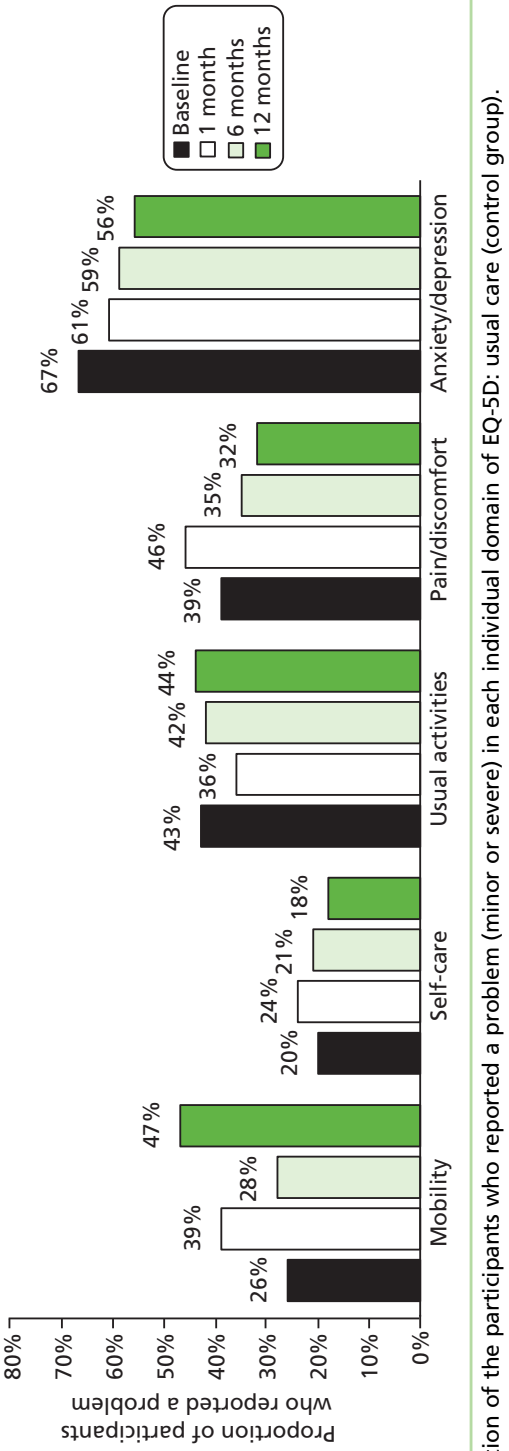

FIGURE 16 Proportion of the participants who reported a problem (minor or severe) in each individual domain of EQ-5D: usual care (control group).

advice to stop smoking. Except for one participant in the BSC group who reported using the booklet 40 times during the trial period, the remainder of participants used the self-help booklet fewer than ten times in the same period. These results could indicate an unmet need for smoking cessation support in this population.

The results from self-report in the follow-up questionnaire indicated that in both groups more participants were using smoking cessation products at 12 months than at baseline (36 in the BSC group vs. 21 in the usual-care group), but the proportion in the BSC group remained higher than in the usual-care group (78% vs. 41%). Comparing data extracted from GP records and participants' self-report demonstrated that, while participants in the BSC group remained more likely to use pharmacotherapy than those in the usual-care group, participants in both groups tended to use pharmacotherapy obtained from other sources in addition to, or instead of, that obtained through GP prescription (*Table 30*). Considering that the participants in this sample rarely seek help through NHS Stop Smoking Services, it was reasonable to assume that products not covered by GP prescription were purchased over the counter. This also suggests that participants in the usual-care group tended to obtain their products over the counter. Overall, 42% of the pharmacotherapy cost was spent over the counter in the BSC group, whereas 66% was spent over the counter in the usual-care group. Furthermore, the results also indicated that participants in the BSC group were more likely to receive other NRT products (*Figure 17*). However, this observation was not evident when using self-report information. Although participants in the BSC group appeared to be more likely to receive multiple pharmacotherapies, the range of products used was similar in both groups (*Figure 18*).

TABLE 30 Mean cost of pharmacotherapy during 12-month trial period

Trial arm	Pharmacotherapy cost per participant	
	By prescription (SD), recorded by GP surgeries	By prescription and over the counter (SD), reported by participants
BSC	£62 (£132)	£106 (£138)
Usual care	£17 (£60)	£50 (£56)

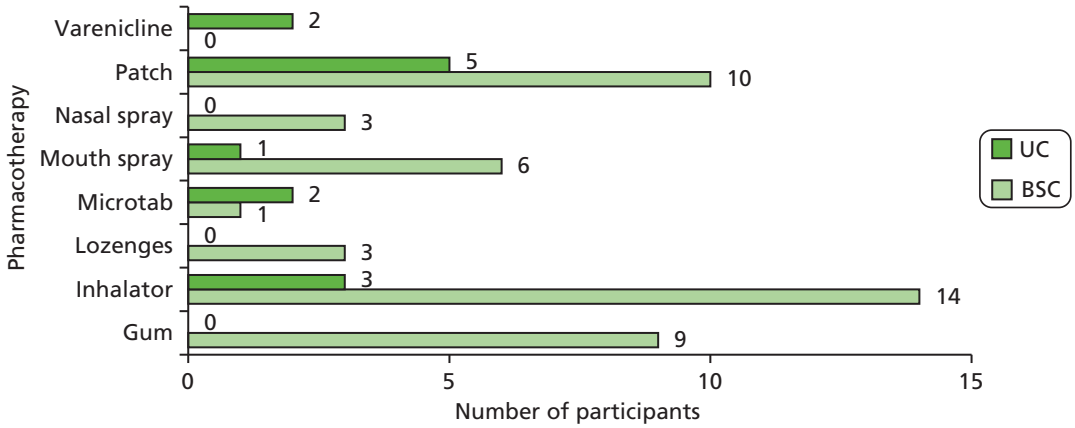

FIGURE 17 Number of participants using pharmacotherapy during trial period by GP records, by group and pharmacotherapy. UC, usual care.

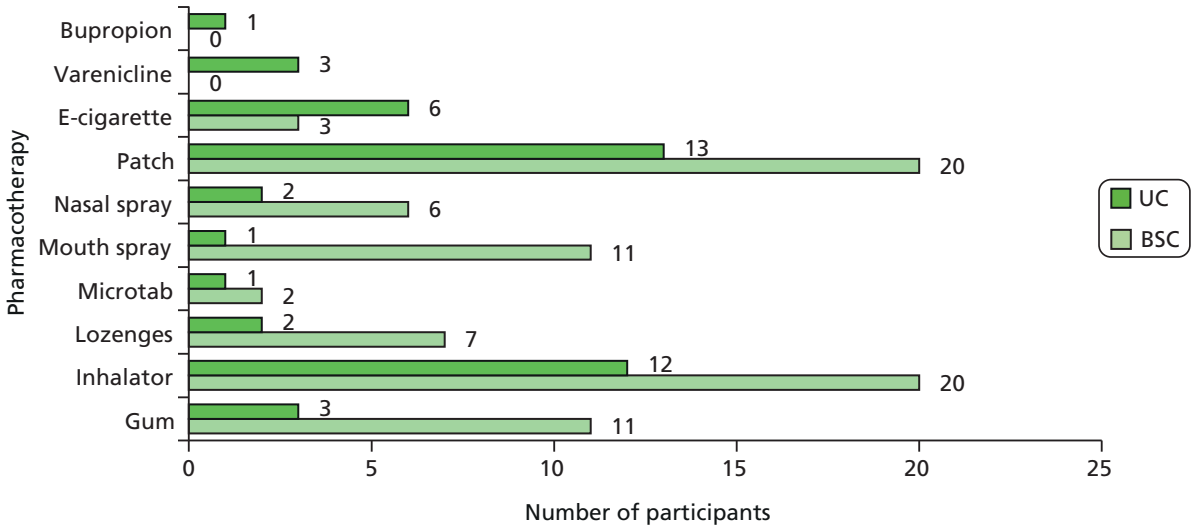

FIGURE 18 Number of participants using pharmacotherapy during trial period by self-report, by group and pharmacotherapy. UC, usual care.

Piloting the health-care and social care service use questionnaire

In order to explore the feasibility and scope of analysis full of a economic evaluation, a questionnaire was used to collect data on health-care resources and community services utilisation. While a comprehensive list of services available was essential to the analysis, the pilot identified several issues when using this questionnaire with this population.

Firstly, by compiling a complete service list, some of the community services were potentially overlapping. For example, the duties of a care co-ordinator, case manager and key worker could be carried out by a community psychiatric nurse (CPN) or a district nurse, since these positions are in some cases interchangeable between different staff members. Listing roles separately appeared to result in confusion and possible double counting. However, a lack of conclusive evidence means that we cannot determine if double counting occurred. Consequently, although we are aware of it, the results reported here were not adjusted for this possibility. It is something which would be addressed in a full trial.

Secondly, the groupings of services highlighted potential issues regarding costs. For instance, a health visitor could be a district nurse or other personnel, depending on the situation. The average cost per health visitor visit is higher than for a district nurse, so further distinctions need to be made. Although it might not cause problems on the participants' side, the cost cannot be valued properly when the two are listed as one service.

In addition, some of the services are available from both public and private sectors. Without supervision, the nature of the self-report questionnaire might lead to a result that included the private sector, regardless of the intention. As the final two open questions regarding usage of other services indicated, although the questions were clearly listed under community service, some participants' responses indicated that they might not have a clear idea of the nature of service providers. Some of the services mentioned were apparently not provided by the NHS or social care service, while others were provided by both private and public sector. Without further information, we were unable to determine what proportion of the services, if any, which were provided by public sector.

It should also be noted that, while we attempted to determine pharmacotherapy use from GP records in order to derive more accurate estimates, there were discrepancies between GP records and self-report which could not be fully explained by out-of-pocket purchase. This could result from recall error or participants failing to follow instructions. However, although prescription information collected from GP

surgeries is believed to be more reliable, it is unlikely to be replicated in a full trial with a larger sample size. The workload could be too high for GP surgeries to respond.

Because of the nature of this population, any information collected through personal recall could be less reliable than under normal circumstances. Therefore, cost assessment regarding this population should be interpreted with caution.

Summary of findings

The incremental cost of providing the BSC intervention over and above usual care was estimated at £221 (SD £160) per participant. When the wider use of health-care and social care and prescriptions is included, the total cost in the BSC group was £12,674 (SD £16,596) per participant, compared with £6867 (SD £6026) per participant in the usual-care group. However, because of the small sample size, we recommend that these results should be treated with caution as the means are influenced by extreme values. Combining costs with the number of successful quitters at 12 months, the incremental cost was £58,197 per quitter. However, these results are from a pilot trial which is not powered to detect a significant difference from an economic perspective. It is also likely that in the longer term, beyond the 12-month follow-up, cost savings may accrue as a result of successful quits. Furthermore, improvements in health-related quality of life would be expected beyond the trial follow-up, which would be modelled in a full trial.

The pilot trial demonstrates the feasibility of conducting a full economic evaluation in a sufficiently powered trial of BSC over and above usual care. Several issues with regard to questionnaire design have been identified which would improve the accuracy and completeness in the collection of service use data.

Chapter 6 Engagement with the bespoke smoking cessation intervention to patients and professionals

Background/introduction

We explored specific issues of acceptability and engagement with the BSC interventions among patients with SMI and with professionals who delivered the intervention. An understanding of these issues is essential for improving the implementation of a BSC service and informing the design of the intervention in subsequent definitive trials. The aim of the substudy was to qualitatively explore, from both patient and therapist perspectives, perceptions of the need for smoking cessation services for this population and their experience of delivering or receiving the bespoke intervention. In particular, we aimed to explore how the bespoke intervention differed to any previous experiences of smoking cessation in usual care, and to identify barriers and facilitators of implementing or engaging with the intervention in practice.

Methods

In-depth semistructured interviews were conducted with a purposive sample including participants who completed the intervention and those who struggled to engage, and to compare those who sustained engagement with those who struggled or withdrew from treatment, and to identify barriers and facilitators to patient engagement. All participants in the intervention arm who had completed their treatment with the MHSCP or withdrawn from treatment were invited to take part. We did not preselect participants based on any other specific criteria, such as sex or smoking history. Participants who responded by post with an expression of interest or who verbally informed either their MHSCP or the research team that they were interested were contacted by telephone to discuss participation. We performed a comparison of the interviewed sample to the full trial sample on predetermined variables (including age, sex, ethnicity, number of previous quit attempts, smoking history and SMI diagnosis) to determine the representativeness of the interview sample compared with the patient sample as a whole.

We also conducted semistructured interviews with the MHSCPs to gain their perspectives on acceptability and delivery of smoking cessation services for SMI.

In-depth interview topic guides addressed the following issues:

- Characteristics of the recipients: what are the specific features of SMI that need to be anticipated and accommodated in delivering BSC?
- Mode and setting of delivery: is BSC best delivered in patients' homes, GP surgeries or day-hospital settings? Is BSC best delivered face to face, in groups or over the telephone? What is an ideal contact time and number of sessions?
- Prior experience of smoking cessation, including support received from other primary care or mental health professionals.
- Acceptability of the intervention to patients, and satisfaction with the BSC, particularly in comparison with previous smoking cessation interventions received.
- Patients' engagement with the intervention, with specific reference to barriers and facilitators to working with the MHSCPs.
- Implementation in routine care, including perceptions of who is best to deliver the BSC and any anticipated barriers to implementation.

Qualitative interviews were held at the end of treatment and ran throughout the duration of the data collection period. An experienced qualitative researcher facilitated all interviews and ethical approval was obtained by the relevant local NHS research ethics committee. Written consent was collected from all of the participants. Participants were asked to consent to the discussions or interviews being recorded and were informed that all identifiable data would be removed once transcribed. Participants were informed that they could remove themselves from the group or stop the interview at any time and did not have to answer any questions they were uncomfortable with.

After completion of the interview, as a token of thanks for their time, the participant was offered a £10 gift voucher as a good-will gesture.

Changes to the original protocol

In the original protocol we intended to interview practice staff who had been involved in the delivery of the intervention (GPs, practice nurses). However, during the study it became apparent that such staff had minimal involvement in the intervention itself and, therefore, we did not interview GPs directly. We did, however, modify the topic guides for both patients and MHSCPs to ask specifically about their interactions with GPs to ensure any relevant issues were captured (and to reconsider the need for interviewing GPs if it became apparent that their involvement was greater than expected, although the interviews confirmed our perceptions that GPs had minimal involvement in delivering or referring to the intervention). The following results are, therefore, from the patient and MHSCP interviews.

Participant characteristics

Interviews took place between August 2012 and January 2013. Thirteen patients were recruited from across the three recruitment sites (five from Manchester, six from York and two from Hull) and three MHSCPs, one from each site, were interviewed.

Comparison of the qualitative subsample to the trial population

Of the 13 patients, two were female (although the trial sample as a whole was 60% male, which suggests that women were under-represented in the qualitative sample.) The average age was 50 years (range 32–68 years). The trial population had smoked for a mean of 27 years and the median number of quit attempts was three; in the qualitative sample, the participants had smoked an average of 32 years and had tried to quit five times, indicating that the smoking history of the qualitative sample is fairly representative of that of the trial population as a whole. All of the participants in the study were white British. Although this group made up the majority of the trial population (85%) this does suggest that further qualitative work may be needed with black and minority ethnic participants to determine if the results are representative. Consistent with the trial population as a whole, the majority of the qualitative sample were unemployed and not seeking work due to ill health. Regarding diagnosis, five of the patients had bipolar disorder, six had schizophrenia (three reported paranoid schizophrenia) and two had experienced depression with psychotic symptoms.

All three MHSCPs were female and white British.

Analysis

Each in-depth interview was digitally recorded and transcribed verbatim. Transcripts were checked and anonymised to remove identifying details.

Transcripts were read independently by two researchers and analysed using the constant comparison (CC) method. The CC method aims to inductively develop themes through categorising and coding data and exploring connections between them, repeating the cycle across the data set until theoretical saturation is achieved. Emergent themes were discussed and verified with a third researcher. Analysis was completed prior to the quantitative analysis being complete, and was therefore blind to study outcome.

The MHSCP transcripts were initially analysed independently from the patient transcripts, but the analysis was combined when preliminary readings suggested consensus in core themes across both the patient and professional data sets and also indicated that novel insights could be synthesised across the two samples to provide a holistic picture of the intervention. Similarly, we did not analyse the data of engaged and disengaged patients separately, partly because only two of the participants were formally considered to have 'disengaged' (having been discharged because of a lack of contact with the MHSCP), but also because analysis suggested this separation did not reflect differences in experienced barriers and facilitators as we has assumed it would. Both the disengaged patients reported positive experiences with the intervention itself, suggesting other circumstances may have contributed to their disengagement, and even patients considered to have engaged with treatment reported difficulties maintaining motivation and planning future sessions. This suggests that engagement was less reflective of the acceptability of the intervention and more indicative of the chaotic nature of this population, which was a recurrent theme in the data (theme 3 below).

Main findings

We identified four primary themes. Themes 1 and 2 reflected the lack of support for smoking cessation in current services and, consequently, the perceived benefits of the BSC intervention which was more tailored to this population. Themes 3 and 4 reflect challenges and barriers reported by patients and professionals, including difficulties sustaining engagement and difficulties liaising with primary care.

Theme 1: NHS smoking cessation services were not responsive to the needs of people with severe mental ill health

Interviews revealed the perceived unsuitability of generic stop smoking services for patients with SMI, emphasising the need for sensitised intervention, which was reported by both patients and professionals. This included issues around the lack of support for smoking cessation (both implicit and explicit) from other health professionals in primary care and mental health services, and concerns about stigma when accessing generic services

> *I've actually had a doctor turn round and say, after quite an episode, which was quite a lengthy episode, and I talked about giving up, he said, oh no, you don't want to be giving up at the moment. So it was kind of like a medical permission to carry on smoking . . . The doctor might say, as he said, terrible thing smoking. But never actually say, you should give up, and I'll refer you. I've had to ask for that. The last thing you want to think about is giving up, that sort of comment comes across.*
>
> *Y1085*

> *I did have one chap that came, which was … and he'd been to normal standard NHS services, and he'd been to a group, and he had a diagnosis of bipolar, and . . . she'd given them all a prescription request sheet for Champix. And he went to see his GP and his GP said, 'I'm not giving you Champix, you've got bipolar.' So he came back next week, and he was the only one in the room that hadn't been given the Champix. And he said he felt really awkward. 'How do I explain why I couldn't have the Champix?' He said, 'I didn't want to tell them it's because I had a mental health problem.'*
>
> *MHSCP1*

Theme 2: participants valued the mental health background of smoking cessation practitioners and the flexibility of the bespoke intervention

Perceived benefits included the mental health background of the MHSCP and the greater flexibility of the intervention. The mental health background of the MHSCP was considered essential, especially when contrasted with the generic smoking cessation services available. Patients reported that MHSCPs had a of better understanding of their condition and also adopted a more supportive, collaborative relationship with them.

> *It wasn't just a stop smoking clinic for Tom, Dick and Harry, she understood the mental health side, which is obviously a big concern . . . Because I wouldn't go to a normal – because I'm frightened . . . Well [the MHSCP] knows what I've got. Whereas if you go to a normal stop smoking thing and they know you've got mental health problems then it's stigma isn't it? . . . you've got to trust the person who you're talking to and be comfortable with them, especially on mental health issues, because if you're talking to somebody who doesn't understand then you think well, you're not on the same wavelength as me, you don't understand me.*
>
> *H1098*

Second, the flexibility and personalisation of the intervention were valued, in terms of where and when sessions were held, allowing for both cutting down and quit targets, and tailoring the intervention depending on the patients' condition and circumstances.

> *It was individual to the person really, flexible to their needs, like seeing them when they wanted within reason and then not putting too much pressure on them . . . just tailored to the person see what works for each person . . . It was interesting how each person was completely different what they wanted to do and what they wanted from me and how motivated they were and everything . . . you can't just say 'I've got to read this script.'*
>
> *MHSCP2*

Theme 3: there were additional challenges for people with severe mental ill health with regard to smoking cessation

Both patients and professionals acknowledged the challenges of smoking cessation in this population; patients reported that motivation could waver and that having help available at the right time was important. MHSCPs noted that this patient group struggles with planning and organisation. Proactive follow-up was necessary to try to sustain patient engagement, although this could be problematic, particularly if patients suffered an acute episode.

> *It [starting the intervention] was over Christmas, and before Christmas I really, really wanted to quit, and I was ready to quit. But when I saw [the MHSCP], I don't think I was ready to quit . . . When things get a bit rough, I start smoking. And that really [happened] actually about a couple of months before I started seeing [the MHSCP]. If I'd have started seeing her in the first place, it would have been a different tale. I would have quit, and I know I would. Timing, timing. Getting the timing right.*
>
> *Y1084*

> *She disengaged and was texting me saying, 'Oh I've not done too well this week so can you come next week?' And I'd go and she wouldn't be there . . even if I could say only one of my clients attended every appointment [but] none of them did . . . I think it's reflective of the patient group really . . . they're just so chaotic.*
>
> *MHSCP2*

Theme 4: the need for integration of smoking cessation services between primary and secondary care

Potential barriers to implementation were also evident. MHSCPs reported that it would be better if the smoking cessation could be integrated with existing mental health support but questioned whether or not

resources in terms of time and cost would be available to support this and also if the workers would prioritise smoking cessation given other demands.

> *You could put this work into main stream, you know, into CPNs work, but I don't know that everybody would do it, that's the thing, and how much time and attention they would give, because you need to be quite focused.*
>
> *MHSCP3*

> *Whether if they said to people in CMHTs just get somebody who does a specific smoking cessation speciality I don't know if it would work because say at [Community Residential Unit] they had a smoking cessation worker there who I met and I'm like 'Well why am I here like?' And it's because her role just was eclipsed and she was just doing the general support work. So you'd have to have a specific . . . you'd have to be quite regimented in doing your work.*
>
> *MHSCP2*

Both patients and professionals referred to difficulties encountered by MHSCPs when liaising with primary care services, specifically when trying to organise NRT for patients.

> *If the GP wouldn't prescribe . . . then you're chasing it up and then when the client goes it's not there and they get annoyed that they've wasted a visit to the doctors. Some GP surgeries refused to do it on my recommendation and had to see the client. So then the client had to make an appointment with the GP which just didn't happen. So then I'd say well I'll give you a letter to take with the doc . . . and then they lose the letter.*
>
> *MHSCP2*

> *I would have said, if anything, my own doctor's let [the MHSCP] down because she would put things in to request for things that I needed, but they weren't coming through quick enough . . . I think we used to sometimes do texts, can I just check, have you spoken to my doctor? And she'd say, I've written the letter. And I'd go across and try and pick up my prescription, and it just wouldn't be ready.*
>
> *H1066*

Summary of themes

Overall, the findings of the qualitative substudy support the need for a sensitised and BSC intervention for this population. Providing this through mental health trained workers was perceived to be most appropriate by both patients and professionals. Challenges to be addressed include difficulties in helping patients to manage their cessation plans, and better communication or integration with primary care to organise prescribing. Implementation in routine care settings, particularly considering who would take on the MHSCP role and cost implications of this, should also be explored.

Limitations

Only three MHSCPs could be interviewed given that this was a pilot study. Future work should explore whether or not larger cohorts of MHSCPs report similar experiences. Although the patient sample is fairly small, the participants interviewed included patients with both bipolar disorder and schizophrenia and were largely representative of the overall trial population. The consistency in emergent themes across the patients also supports the representativeness of the results. However, women and black and minority ethnic participants were under-represented and further research is necessary to explore the acceptability of the BSC intervention to this population.

Chapter 7 Discussion

This report presents the results of the first UK trial of a BSC intervention designed specifically for people with severe mental ill health. The SCIMITAR trial was commissioned by the National Institute for Health Research Health Technology Assessment programme in view of the clinical need of this population and the widening health inequalities which exist in relation to smoking and smoking-related illness. The SCIMITAR trial is a pilot study, which now paves the way for a fully powered trial to assess clinical effectiveness and cost-effectiveness. The SCIMITAR programme has followed a developmental pathway to produce a feasible intervention to the point at which this can now be evaluated within the context of a definitive trial. We have first drawn upon existing evidence (taken from high-quality systematic reviews) of 'what works' in helping people to cut down or quit smoking.[25] We have also conducted a systematic review of 'what works' in relation to people with SMI, and have shown that the same pharmacological and behavioural approaches to smoking cessation are effective amongst people with SMI as with the rest of the population.[44] Despite this evidence, it is clear that people with SMI do not access conventional NHS quit smoking services, and a coherent response is to design a service and intervention that ensures that evidence-supported pharmacotherapies and BCTs are applied with specific reference to the needs of people with SMI.

The BSC intervention at the centre of the SCIMITAR pilot trial was designed to address the unmet needs and barriers to accessing smoking cessation interventions for this population. We will now review the main findings and address the main objectives of the SCIMITAR pilot trial in turn before considering whether or not the SCIMITAR trial can now be scaled up as a fully powered RCT.

Main findings

The main finding of the SCIMITAR trial is that smoking cessation can be achieved among people with SMI and that the use of a BSC intervention increased the chances of sustained quitting, as estimated by a biochemically verified outcome measure (exhaled CO).[72] The observed odds of successful quitting at 12 months were almost three times higher among those who received BSC (OR 2.9, 95% CI 0.8 to 10.5), although this value was calculated using a small sample and, therefore, requires cautious interpretation.

A range of secondary outcomes were also measured and there was a general direction of effect in favour of BSC in relation to the (1) number of cigarettes smoked, (2) number of quit attempts, (3) reported nicotine dependence and (4) reported MTQ. Taken together, the positive overall primary outcome and consistency of direction of effect among primary and secondary outcomes (reduced number of cigarettes smoked, increased number of quit attempts, increased MTQ) add weight to the hypothesis that BSC is effective for this group. The consistency of findings from the pilot trial, alongside systematic review evidence[44] represents an accumulation of evidence. Ultimately the clinical effectiveness of a BSC intervention can really be tested only within a fully powered RCT. The pilot trial also found some evidence of deterioration in mental health in the intervention group compared with the usual-care group. This finding is not consistent with other evidence, where smoking cessation tends to improve mental health.[73] However, this does indicate that mood should be monitored in clinical practice and the safety of smoking cessation should be tested in a fully powered trial. The various findings and experience from conducting a pilot trial will now be considered in turn in order to inform the design of a fully powered definitive RCT.

Is it possible to recruit people with severe mental ill health to a trial of a smoking cessation intervention?

At the outset of the SCIMITAR pilot trial there was genuine uncertainty as to whether or not sufficient people with SMI would express an interest in a smoking cessation intervention and agree to undergo randomisation. An important finding from the SCIMITAR pilot trial is that it was possible to recruit a mixed

population of people with SMI and successfully randomise almost 100 participants to the trial. This finding is in line with research evidence that shows that the proportion of smokers with SMI who express a desire to cut down or quit smoking is now broadly in line with expressions of desire to cut down/quit within the general population.

The participants recruited to the SCIMITAR pilot trial were largely middle-aged people of both sexes with heavy tobacco addiction and long smoking histories (mean duration of smoking 27 years). The participants were recruited from both primary and secondary care settings. A successful fully powered trial would, therefore, be able to recruit participants from both of these settings. The availability of primary care computer records allowed GPs to write to their patients directly and offer them the opportunity to participate in a trial. The experience of recruiting in secondary care was more mixed and the geographical areas which were the most successful in recruiting participants were those where there were well-integrated teams of research workers and good engagement between the Mental Health Research Network (MHRN) and local NHS services. The resources required to populate a fully powered trial can be estimated from the current study. We anticipate that more than 100 general practices would need to be enlisted, with direct GP approaches to potentially eligible patients. With respect to secondary care, we judge that four mental health trusts would need to be enlisted, with preference given to those trusts where there is an embedded model of research support offered by a research network such as that currently offered by the MHRN.

Is the treatment acceptable to participants and health professionals from primary and secondary care?

The SCIMITAR trial found that participants who underwent randomisation generally engaged with BSC services. In the qualitative evaluation of the bespoke intervention it was found that participants valued the fact that smoking cessation therapists were drawn from staff working within mental health services. Smoking cessation practitioners had a familiarity with SMI and the specific needs of that group, and this was seen as a positive aspect of the intervention by participants. There was a coherent theme within the qualitative interviews that people with SMI felt excluded from conventional smoking cessation services and that the less-flexible and time-limited nature of NHS Stop Smoking Services were seen as barriers to successful treatment. By addressing these factors, the SMI participants felt that their smoking was more readily addressed and they felt less stigmatised than might have been the case in conventional services. Participants were attracted to a service which offered the prospect of cutting down prior to quitting, and they appreciated the opportunity to receive NRT prior to setting a quit date. In the control group, there was a lack of engagement with conventional NHS quit smoking services despite control participants being given smoking cessation literature and encouraged to visit their GP or NHS quit smoking service.

Engagement with the bespoke intervention was good: 41 out of 46 participants attended at least one session and the mean number of sessions was 10. The intervention was clearly more intensive than that which would be offered in conventional NHS services and the overall cost of BSC was £283 (£221 practitioner costs and £62 medication costs).

Within the SCIMITAR pilot trial participants were encouraged to choose an appropriate form of smoking cessation medication in collaboration with their GP. The mainstay of treatment was NRT and only two participants were prescribed varenicline. None was prescribed bupropion. Qualitative interview data showed that GPs were very reluctant to prescribe smoking cessation products other than NRT. It was also noted that participants experienced difficulties in obtaining supplies of NRT from their GPs, and in a future trial it might be more acceptable for participants to be prescribed NRT medication by their secondary care provider. This recommendation is in line with 2013 NICE guidance on smoking cessation provisions for people with mental ill health, which recommends that mental health services make this provision for smokers who use their services.[50]

In a definitive trial we would propose that the mainstay of treatment should be NRT and that this be provided within mental health services rather than from the GP (when participants are in receipt of secondary mental health care).

Is it possible to achieve follow-up of people with severe mental ill health within a trial?

The SCIMITAR pilot trial sought to establish the feasibility of follow-up in both the short and longer term (12 months). Smoking cessation trials conventionally focus on short-term quit rates and it is important to also judge the longer-term impact of programmes. The SCIMITAR pilot trial showed that biologically verified long-term outcomes could be achieved and it was shown that 70% of participants then agreed to giving a CO measurement. The importance of using a biologically verified smoking cessation outcome was also underlined when biologically verified and self-report data were compared. There was moderate concordance between gold standard CO smoking status and self-report with a kappa value of 0.48.

In addition, several participants who reported being smokers were found not to have smoked when their CO was tested. This point prevalence non-smoking status is a potentially less rigorous measure of abstinence, and a future trial should consider a higher level of evidence such that non-smoking participants must be self-reported non-smokers and must be abstinent on CO testing. This is in line with the Russell standards of reporting.

In moving forward to a definitive trial it will be important to record a Russell-standard outcome at all follow-up points, in line with evidence-supported recommendation on the standards of smoking cessation trials.[72] An additional recommendation might be that a small financial payment may improve follow-up rates at all time points and that 90% follow-up could be achieved by this means.

How large would a definitive trial need to be?

The SCMITAR pilot trial has established the important parameters to allow the sample size to be calculated for a definitive trial. A fully definitive trial with sufficient power to detect a 15% reduction in smoking would require a sample size of 296 participants (baseline quit rate 23%, two-sided, $\alpha = 0.05$, $\beta = 80\%$). Firstly, we have established the baseline 12-month quit rate for smokers with SMI. This quit rate lies within the range of quit rates expected in non-SMI populations, and allows a reasonable control quit rate to be set for a power calculation. Secondly, the SCIMITAR trial provides a range of plausible effect sizes which are broadly in line with the quit rates seen in a review of smoking cessation interventions in SMI[44] (pooled relative risk estimates 2.74, 95% CI 1.10 to 6.81), and are also in line with effect sizes observed in non-SMI populations for a NRT-based intervention.[41]

A full trial with sufficient power to detect a relative increase in quitting of 1.7-fold would require a sample size of 260 participants (baseline quit rate 23%, two-sided, $\alpha = 0.05$, $\beta = 80\%$). However, a control group quit rate of 23% may be considered high, so we instead consider a more plausible value of 20%. In this case, we would require a sample size of 314 participants (again with RR = 1.7, $\alpha = 0.05$, $\beta = 0.8$). All sample sizes would need to be inflated to allow for 15–30% loss to follow-up.

Limitations of the Smoking Cessation Intervention for Serious Mental Ill Health Trial pilot study

The SCIMITAR pilot study had insufficient power to detect a plausible effect size, but as a pilot trial was not designed to detect a difference.

We found that there was a withdrawal rate of 15% from the trial, making the trial potentially open to biases of unrepresentative participants in the follow-up and differential attrition between arms. The dropout rate was higher in the intervention than in the control arm, and a future trial will have to ensure that follow-up and retention are maximised. Nevertheless, the withdrawal rate was lower than that seen in comparable trials in SMI populations[44] and is, in part, a feature of the nature of the population within the trial, who are prone to periods of illness that in turn might impact on motivation and ability to remain in longer-term follow-up studies. A further 15% of participants did not complete a 12-month follow-up, meaning that 70% of participants completed their 12-month follow-up. Initial follow-up at 12 months was lower than we had hoped for; therefore, we initiated a more robust method of following people up at 12 months. This involved telephoning participants at different times of the day and in some cases

working with the participant's care co-ordinator to arrange times for follow-up visits to be completed. The implementation of this more robust method led to an increase in our 12-follow-up rate; hence, we would use these strategies in a future trial to ensure a higher level of follow-up.

A third limitation is the absence of a biologically verified quit outcome at 1 and 6 months, and a future trial should seek to capture short- and medium-term quit with a CO-verified measure. The methods to collect this outcome and to maximise follow-up could replicate those used at 12 months.

Finally, this was a pragmatic evaluation of a complex intervention: combining case management, pharmacological treatment, behavioural support and evidence-supported behaviour change techniques. We have described the developmental phase of this complex intervention. However, it is not possible within the context of a pragmatic health technology assessment trial (either pilot or fully powered) to disaggregate the relative contributions of these elements. This remains a topic for future research if the clinical effectiveness of bespoke cessation is ultimately demonstrated in a fully powered trial.

Conclusions

The SCIMITAR pilot trial has shown that it is possible to recruit to a trial of a BSC intervention for people with SMI. Follow-up in 70% of participants has been achieved using a biologically verified measure smoking status at 12 months. The preliminary estimates of clinical effectiveness are supportive of BSC across a range of primary and secondary outcomes. The clinical effectiveness and cost-effectiveness of bespoke smoking can now be established in a fully powered trial. A recruitment strategy for a fully powered trial should enlist participants from primary and secondary care and the SCIMITAR pilot trial has delineated the relative strengths and practical limitations of approaches in both of these settings. Both approaches should be used in a definitive trial.

Implications for health care

Although it is important to ensure that there is equitable provision of smoking cessation services for all populations, it would be premature to invest in BSC services without the results of a definitive clinical trial.

Recommendations for future research

A definitive trial is now needed to establish the clinical effectiveness and cost-effectiveness of BSC services for people with SMI. The SCMITAR trial forms a template for this trial, with some modification which follow from the experience of conducting this pilot trial.

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This trial is dedicated to the memory of Professor Helen Lester (1961–2013), and is a celebration of her work and contribution to the care and well-being of people with SMI. This was her abiding passion and will be her lasting contribution.

Contribution of authors

Simon Gilbody and **Mei-See Man** wrote the original protocol.

Simon Gilbody, **Jinshou Li**, **Susan Michie** and **Tim Bradshaw** were co-applicants on the Health Technology Assessment application and refined the protocol.

Simon Gilbody was the chief investigator and oversaw the study.

Mei-See Man, **Natasha Mitchell** and **Emily Peckham** were trial mangers.

Taeko Becque designed and conducted the clinical analysis.

Jinshou Li and **Steve Parrott** designed and undertook the economic analysis.

The writing team consisted of **Taeko Becque**, **Simon Gilbody**, **Sarah Knowles**, **Mei-See Man**, **Emily Peckham**, **Claire Planner** and **Charles Shepherd** who drafted the report.

Collaborations

The SCIMITAR collaborators (current and past) are:

Katie Atherton, Taeko Becque, Tim J Bradshaw, Helen Cox, Ben Cross, Jane Dallender, Emma Davies, Rhian Gabe, Linda Gask, Simon Gilbody, Edward Greenward, Kerin Hannon, Laura Hermann, Catherine Hewitt, Hayley Jackson, Sarah Knowles, Helen Lester, Jinshou Li, Andy McEwen, Mei-See Man, Sarah Mercer, Susan Michie, Natasha Mitchell, Ann Mortimer, Emily Peckham, Claire Planner, David Richards, Kath Richardson, Charles Shepherd, Maggie Stronach, David Torgerson, Muhammad Usman, Ian Watt and Robert West.

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Catherine Hewitt, **David Richards**, **David Torgerson** and **Ian Watt** were co-applicants on the Health Technology Assessment application and refined the protocol.

Rhian Gabe and **Catherine Hewitt** designed the clinical analysis.

Catherine Hewitt oversaw the conduct of the analysis.

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Patient and public involvement in research

The SCIMITAR trial benefited from involvement of users of mental health services and carers of people with SMI throughout the research period. Our Trial Steering Committee included representation from a carer. Our protocol and study materials were scrutinised and supported by users and carers in the north-west of England and by the user and carer groups of our local MHRN.

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Appendix 1 Regulatory approvals

Trust	Research and development approval granted
NHS East Riding of Yorkshire	31 January 2011
NHS Hull	10 February 2011
Humber NHS Foundation Trust	12 January 2011
NHS North Yorkshire and York	20 January 2011
Greater Manchester West Mental Health NHS Foundation Trust	7 January 2011
Manchester Primary Care Trust	6 December 2010
Manchester Mental Health and Social Care Trust	17 January 2011
Salford Primary Care Trust	19 January 2011
Stockport Primary Care Trust	8 December 2010
NHS Lincolnshire and North East Lincolnshire Care Trust Plus	21 March 2012
Tees Esk and Wear Valleys NHS Foundation Trust	23 December 2011
NAViGO Health and Social Care Community Interest Company	10 January 2012

Appendix 2 Patient information sheets and consent form

Patient name and address GP Practice Name

SCIMITAR
Smoking Cessation in Mental Ill health Trial

Dear <Title>.<Patient surname>,

Our surgery, in collaboration with the University of York and the University of Manchester, is taking part in a research study exploring how we can help people with mental health problems improve their well-being by helping them reduce and quit smoking. The aim of this study is to see how well a mental health care worker trained as a smoking cessation practitioner will help support and manage smoking in mentally ill patients. The information collected during the research will be used to help medical professionals make decisions about treating smoking in mental health in the future.

According to our records you have received care for mental health problems in the past, and you are also a smoker. The University researchers and this practice would like to request your help by participating in this study **if you are interested in cutting down your smoking**. There is an information sheet enclosed which describes the research and what to expect if you decide to become involved. Please take time to read it carefully and discuss it with others if you wish.

If after reading the information sheet you are interested in taking part in the study, please complete the 'Permission to Contact' forms and send **one** to the research team in the enclosed stamped addressed envelope. The other form is for you to keep. A study researcher will contact you within a few days and will arrange a meeting at your convenience, where you will have an opportunity to ask questions about the study.If you agree to take part in the study, the researcher will assess your eligibility for the study and you will be allocated into a study group. If you are not interested, you do not need to do anything – your normal care with us will continue.

If you would like to discuss the study in more detail, before returning the forms, please do not hesitate to get in touch with the study researcher, <Researcher Name> on <Telephone> or email <email address> who would be happy to answer your questions.

While your help in this project would be greatly appreciated, it is completely voluntary. If you decide not to take part, it will not affect the care you receive at your doctor's surgery. **Your GP surgery has not given your name, personal or medical information to the University researchers**, and the only information the researcher will receive will come from you if you decide to participate. All smoking cessation sessions are free of charge and will be provided in your area.
Yours sincerely,
<GP Practice Name>

THE UNIVERSITY of York
The Department of Health Sciences

H·Y·M·S
THE HULL YORK MEDICAL SCHOOL

SCIMITAR
Smoking Cessation in Mental Ill health Trial

Participant Information Sheet

MANCHESTER 1824
The University of Manchester

This information leaflet invites you to take part in a research study exploring whether a Smoking Cessation practitioner can help you reduce and eventually quit smoking. Your decision to participate is important, so we would like to take this opportunity to explain why the research is being done and what it will involve. We encourage you to read the following information carefully and to discuss it with your family and friends if you find it helpful. We appreciate you taking the time to decide whether or not to participate. Thank-you for reading this information sheet.

Why you have been chosen?

You have been invited to take part in this research because you are a smoker and you have received care from mental health services either recently or in the past. Your GP believes that you can improve your health and your finances by reducing or by quitting smoking.

What is the purpose of this research?

Many people with mental health problems are smokers. Smoking is a major cause of poor physical health, but stopping smoking is not easy. There are no quit smoking support services specially for people with mental health problems. So we have created a support service designed specifically for people who have suffered problems with their mental health. If you are interested in cutting down the number of cigarettes that you smoke or in quitting smoking, then having the right support services may help you. Smoking cessation practitioners with a background in mental health care will work with your GP to offer support and advice with smoking. The aim of this service would be to help you cut down smoking until you are ready to quit; and to do this in a way that works for you. We need to know if this service is any better than current NHS services for smoking or whether people with mental health problems will use this service. We will also look at how the costs of the two treatments compare to each other to judge whether specialist services represent a good investment compared to other investments that can be made in NHS smoking and mental health services.

This study may be of interest to you if you are only thinking of doing something about your smoking, but may not necessarily give up smoking at this time.

If you decide to take part

If you agree to take part in this research project please complete and sign the enclosed permission to contact forms. This is a consent form, and in signing this you are giving us

permission to get in touch with you to tell you more about the study. Return one form using the pre-paid envelope provided and you keep the other form. Once we receive your consent to contact form, a study researcher will telephone you to tell you about the study and ask a few questions to see if you are eligible to participate. Unfortunately, we cannot include people who are or become pregnant or are breast-feeding because they would require some additional support which we cannot provide as part of this study. We also need to check that your GP is happy for you to take part in the study. If you are eligible, we will invite you to meet with a researcher where you will have an opportunity to ask any questions you have about the study. This meeting will last about one hour.

If you consent to take part in the study, the researcher will ask you some more detailed questions about your smoking habits, your general health and ask to measure your height, weight and breath carbon monoxide levels (this is a commonly used method to find out how much you smoke). These will also be measured at the end of the study. The level of carbon monoxide in your breath gives us a good measure of how much you have been smoking. After completing these measures, you will have an equal chance (50/50 chance) of being allocated to one of two groups:

Group one - Participants receive visits from a smoking cessation practitioner plus continue with usual GP care.

Group two - Participants continue to receive usual GP care.

Our aim is to recruit about 100 people in total, out of which around 50 will have visits from a smoking cessation practitioner in addition to continuing with usual GP care, while the other 50 will continue to receive usual GP care. We cannot say which of these treatments you will receive as this will be randomly selected, and completely down to chance. None of the researchers, clinicians, or participants will have any influence over this process. Each individual has a one in two (or 50/50) chance of being selected for either group.

Group 1 - Smoking Cessation Practitioner group

If you are allocated to this group, you will have access to a smoking cessation practitioner who will advise you about the best way to cut down or give up smoking. They will tailor the smoking advice they give you according to your individual needs depending on how ready you are to give up smoking, how your mental health is and what medication you are on.

About the smoking cessation practitioner

The smoking cessation practitioner is someone with a background in mental health care, has been trained at the Centre for Smoking Cessation and Training and is an accredited level 2 Quit smoking officer. They observe the NHS codes of practice and ethics.

Your first appointment

We will arrange the first appointment with your smoking cessation practitioner at your convenience. This may be at your home, local GP clinic or hospital. The practitioner will take a full and detailed history of your smoking habits and your mental wellbeing. They will then be able to advise you on how to manage your smoking with a view to cutting down and eventually quit smoking. There are many things that they could suggest, for example, they might go along with you to see your GP and who will then advise on nicotine replacement therapies or drugs to help you quit. They may take you along to a group quit smoking session, or may run sessions for people like you. Do feel free to ask them questions. The smoking cessation practitioner will try to arrange regular meetings with you and/or visits to the GP to see how things are working and whether you need to change your treatment as necessary. It is important that you tell the practitioner if you have any side effects from cutting down your smoking or if you change your medication. This will affect how your treatment is managed by your GP.

Group 2 - Usual GP care treatment group

If you are allocated to this group you will be provided with some advice produced by the NHS about what to do if you are interested in stopping smoking. You will be encouraged to make an appointment with your GP. Your GP and the staff working in the GP practice will be very experienced in helping all people to quit smoking irrespective of whether they have had mental health problems or not. You will receive the care that is usually offered to all people in your practice or community. Your GP may offer you advice to stop smoking, prescribe nicotine replacement therapies or drugs to help you quit or suggest you visit a local stop smoking service, but you will not receive visits from a mental health smoking cessation practitioner. Your smoking habits will be monitored at regular intervals throughout the trial.

What we need from you

In addition to completing the consent forms included with this letter, you will be asked to meet with a study researcher at least twice. At these meetings, the researcher will ask you questions about your general health, your smoking habits and will also measure your height, weight and take your breath carbon monoxide levels. These meetings will take place once at the beginning of the study and again after being in the study for 12 months. We also will ask you some similar follow-up questions at 1 and 6 months where you will have the option of a face-to-face meeting, a telephone interview or postal questionnaires. The questionnaires are designed to enable us to determine your general well-being and how useful the treatment was for you. It should take about half an hour to fill in these questionnaires. This information is important to us and we may have to send reminder letters to people who do not return these follow-up questionnaires.

A small number of you will be invited to take part in an in-depth interview about your experience of being in the study and trying to stop smoking. These interviews are optional and will take place towards the end of the study. The interview will be conducted by a University researcher and be scheduled for a convenient time and place for you. The interviews will last about one hour. If you agree to participate in the study you are under no obligation to participate in the interview.

What are the alternatives to taking part?

If you choose not to take part, then your GP or mental health worker will discuss with you the options available for your treatment. Whatever you decide will not affect the standard of care that you receive.

The possible disadvantages

When you stop smoking, there are known craving effects and withdrawal symptoms. You may feel depressed, anxious or irritable. You may have difficulty concentrating or feel restless. You may also feel hungry and put on weight. These are normal symptoms which may be particularly strong when you first quit, but should lessen over time. Generally these reactions are a sign that your body is having to adapt to not having cigarettes. The smoking cessation practitioner will help and support you so that when you are ready to quit smoking, you will be motivated and able to cope.

There may be other risks from mixing smoking cessation drugs with medication used to manage your mental illness. The risk of side effects are low, but if you get headaches or worsening of your mental health symptoms, you should tell your GP or smoking cessation practitioner immediately.

The possible benefits

Stopping smoking is the single most helpful thing you can do to improve your own health. Smoking causes serious illnesses such as lung cancer and heart disease. Cutting down the total number of cigarettes you smoke is a step in the right direction. Giving up smoking completely will not only improve your own well being, it will help protect the health of your friends and family around you. It may also mean that you could reduce the dose of your

medication that you take for your mental health problem, although this must be assessed by your GP. Stopping smoking also has the added benefit of saving you a lot of money that you would have spent on cigarettes.

It is not easy to give up smoking, which is why we are looking at whether the extra support of the smoking cessation practitioner may be helpful. We cannot promise that the study will directly help you, but the information we get from this study will help health professionals decide the best way to help people with mental health problems to quit smoking in the future.

When the study ends

When you have had your 12 months follow-up appointment and completed your 12 month questionnaire, you will be at the end of the study. The smoking cessation practitioner will no longer be funded to help manage your smoking. Your GP will continue managing any smoking cessation drugs you may be taking and you will still be able to access your local Quit smoking clinics and services. You will still be entitled to your usual GP care including prescription medication.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw from the study at any time without giving any reason. If you withdraw from the study, we will delete your contact details from our records, but we will need to use the data collected up to your withdrawal. You may also choose to withdraw from treatment but continue being followed up. It is up to you to tell us. However, if you let us know of your decision, then we will know not to contact you in future. This will not affect your rights or your future care in any way.

Expenses and payments

This trial is funded by the NHS. Your GP will be given compensation for their time in helping recruit and manage smoking cessation of study participants. However, we cannot offer any patient expenses including travel expenses. We anticipate that in most cases the researcher and/or smoking cessation practitioner will be able to visit you in your own home. If you receive free prescriptions, you will not have to pay for any prescribed smoking cessation medication.

Confidentiality

All information collected about you during the course of the study will be kept in strict confidence. The information, including your questionnaires, is subject to legal requirements and the Data Protection Act of 1998. Therefore, only your GP and the principal researchers will know which patients have agreed to be included in the study. Some parts of your medical records may need to be looked at by authorised persons from the research team to check medication and medical history. Your information will not be disclosed to any unauthorised person. Any information about you which is used in reports of the study will be made completely anonymous and used in such a way that you cannot be identified. Your GP and mental health team will be informed of your participation in this study and they may be approached if circumstances occur where we may be concerned for your health and safety.

What will happen to the data that are collected about me?

Your data will be held in a secure place in the coordinating centre at the University of York. All study data will be held for a minimum of 5 years. We will remove all names and other identifying information before data analysis and results are presented to the medical community.

Results of the research study

The results of this research study will be available after we have analysed the data. We will publish the results in healthcare journals to provide GPs and other healthcare practitioner's with information. You will be able to access the results of this study via the York Trials Unit's webpage: www.york.ac.uk/healthsciences/research/trials.htm

What happens if something goes wrong?

This research only includes treatments that you would normally receive. The clinicians and health care professionals will take every opportunity to reduce risk. If something were to go wrong, they would offer you the best possible solution to resolve it. If you believe that you have been harmed by taking part in the study, you have the right to pursue a complaint through the usual NHS procedures.

Who reviewed the study

All research in the NHS is looked at by an independent group called a Research Ethics Committee. They make sure that the research is fair. The study has been reviewed by the National Research Ethics Service.

Who is organising and funding this research?

This study is being funded by the Health Technology Assessment Programme, which is part of the NHS National Institute for Health Research. The trial is sponsored by the University of York and managed by researchers at the York Trials Unit, University of York and University of Manchester.

Who can I contact for more information

If you have any queries or wish to obtain further information about this study, please contact one of the researchers at the York Trials Unit, University of York: [redacted]

Or study researchers at the University of Manchester: [redacted]

For independent information about participating in this study, contact your local Patient Advisory Liaison Service (PALS), [redacted]

If you are unhappy with any aspect of this study, you can speak with any study researcher (contact details above) or your care coordinator who can relay your dissatisfaction to the lead investigator, Prof Simon Gilbody. You can also file a formal complaint with the NHS complaints procedure (Tel: 0121 449 5725 or free phone: 0800 389 8391). Taking part in this study in no way affects your right to complain about any aspect of the way in which you have been treated during the course of this study.

Thank-you for reading this information sheet and for considering whether to take part in this study.

SCIMITAR
Smoking Cessation in Mental Ill health Trial

Permission for release of Personal details

I agree that my personal details be given to researchers carrying out the SCIMITAR study. I have filled in my contact details and I understand that a researcher will now contact me. This will enable them to explain the study in more detail so that I can then decide whether or not to take part.

(BLOCK CAPITALS PLEASE)

Name:	……. Mr/Mrs/Miss	…….. Forename	……. Surname
Address:	…….		
	…….		
	…….		
Postcode:	……		
Tel No:	……		
Mobile No:	……		
Email:	……@……		
How would you prefer to be contacted (please circle)?			Telephone/ Mobile/ Email
At what time of day would you prefer to be contacted (please circle)?			Morning/Afternoon/ Evening/ Don't Mind

……. ……/……../20…..
Signature of patient Date

Please post one copy of this form using the enclosed stamped addressed envelope to the SCIMITAR research team.

If completed with GP/practice nurse/CPA/CMTH member please fax to: 01904 321387.

If you have any questions, please contact [redacted]

Office use only	ID:		
GP code:	GP practice code:	DOB:	NHS no:

Patient Consent Form

Participant Identification number: ☐☐☐☐

Title of Study: The SCIMITAR trial - Smoking Cessation In Mental Ill health Trial.

Name of researcher taking consent: _____

Please read carefully. If you agree with each point please **initial each box** below:

- I confirm that I have read the information sheet version <no> dated <date> for the above study and have had the opportunity to consider the information, to ask questions and to have these answered satisfactorily. ☐
- I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving any reason, and my medical care and legal rights will not be affected. ☐
- I give permission to members of the research team, regulatory authorities and NHS trust where relevant to access my medical records and data collected from the study. Information held at the General Register Office may be used to keep in touch with me and follow up my health status for the duration of the study. ☐
- I agree to complete the relevant questionnaires at the start, 1, 6 and 12 months follow-up, and also have my weight, height and breath carbon monoxide measured during the study. ☐
- I agree to my GP and mental health care professionals being informed of my participation in the study. They may also be approached during the study if information or advice is required for my health and safety. ☐
- I agree to this consent form and other data collected as part of this study being kept by researchers at the University of <York/Manchester>. I understand that my participation in this study is confidential and that no materials which could identify me will be used in any reports of this study. ☐
- **I agree to take part in the SCIMITAR study.** ☐

…….	…/…/……	
…….		
Name of participant (BLOCK CAPITALS)	Date	Signature

…….	…/…/……	
…….		
Name of researcher (BLOCK CAPITALS)	Date	Signature

Other research studies

Researchers from the SCIMITAR team would like to contact people who agree to take part in the main SCIMITAR study to see if they are interested in helping with other related studies – these are entirely optional. If you would not like to be sent information related to other studies, please tick this box ☐

When completed, 1 for patient; 1 (original) kept in GP notes; 1 for research centre.

THE UNIVERSITY of York
The Department of Health Sciences

H·Y·M·S THE HULL YORK MEDICAL SCHOOL
MANCHESTER 1824 The University of Manchester

UNIVERSITY OF YORK/MANCHESTER
Insert address

SCIMITAR
Smoking Cessation in Mental Ill health Trial

Dear <Doctor/practice manager>,

The Universities of York and Manchester are jointly running a study aimed at helping people with severe mental ill health to stop smoking. This trial is funded by the Health Technology Assessment Programme, an initiative of the NHS National Institute for Health Research. We would like to invite your practice to take part in this study.

The trial aims to assess whether the addition of a bespoke smoking cessation intervention to usual GP care is more clinically effective, cost effective and acceptable to patients with severe mental health problems compared to usual care. Eligible patients randomised to this group will have regular visits from a smoking cessation practitioner who has a background in mental health care. The smoking cessation practitioner will advise the patient and work with the patient's GP in order to help the patient cut down and eventually quit smoking. This would not be as rigorous a regime as some Quit smoking clinics.

Enclosed in this pack is an information sheet giving details of what we would require of you, your practice and what would happen to any patients approached and recruited into the study. I would appreciate it if you could read through this leaflet carefully.

You will be compensated for your time for every patient recruited into the study.

If you would like to discuss the study in more detail, please do not hesitate to get in touch with the study researcher, <researcher name> on <phone number> or email <email address> [redacted] would be happy to answer your questions.

Yours sincerely

Mei-See Man
SCIMITAR trial coordinator, YTU

The majority of people with severe mental illness (SMI) smoke. Patients with SMI smoke more heavily and are more likely to be nicotine dependent compared to the general population. Despite this, a significant proportion of patients with SMI express a desire to quit smoking or to reduce their tobacco consumption. Research has shown that the usual treatments for smoking cessation (such as Nicotine replacement) are just as effective for people with SMI. However, existing NHS stop smoking services may not be accessible or effective in patients with SMI.

The role of this study is to develop a bespoke smoking cessation intervention specifically targeted at people with SMI with an emphasis on support provided by a mental health professional trained in smoking cessation therapy (Mental Health-Smoking Cessation Practitioner, MH-SCP). The practitioner will work with you and your practice staff, and you will retain responsibility for providing smoking cessation medication in the same way as you would for all your patients

The Universities of York and Manchester has obtained funding from the NHS National Institute for Health Research's initiative, the Health Technology Assessment Programme, to carry out a multicentre randomised controlled trial to evaluate the clinical effectiveness and cost effectiveness of a bespoke smoking cessation intervention for people with SMI. Patients will be randomised to one of two treatments:

- **Bespoke Smoking Cessation Intervention + usual care** – Patients allocated to this group will be put in touch with a Mental Health-Smoking Cessation Practitioner, who is a mental health care professional/nurse and who has had special training in smoking cessation with people with SMI. Their job is to advise and manage the smoking habits of the patient in order to help them cut down and eventually quit smoking. Depending on the patients' condition and motivation, the practitioner may request additional appointments with the GP to discuss possible smoking cessation aids or medication. They may suggest attending smoking cessation clinics, either at your practice if you have one, or a local smoking cessation service. The smoking cessation practitioner will provide one-to-one or group behavioural support quit smoking sessions.
- **Usual care only** - Patients allocated to this group will continue to receive treatment based on the usual level of care that you provide as a GP. This may well include any smoking cessation services you run at your practice, brief interventions for smoking cessation, or advice on smoking cessation aids. For patients allocated to 'usual care' we simply ask that you and your team provide your usual high standard of care to patients in this group and not do anything different from normal.

What would the study involve from you?

We have designed the trial to make minimal demands on the workload of busy general practices, and we will work alongside the current Quality and Outcomes Framework (QOF) guidelines in ensuring the best physical care is offered to people with severe mental ill health. We would ask that all patients are offered the opportunity to participate in this trial at their annual health check (where smoking will be routinely asked about and smoking

reduction/cessation may be discussed). We would also ask that you and members of your team make patients aware of this study when you see them at times other than their physical health check. We will also help you to identify patients who might be potentially eligible according to procedures outlined below. Your time in recruiting patients to this trial will be compensated in line with recommendations made under current NHS R&D agreements. You will receive this re-imbursement for each patient who is recruited to the trial.

The following **Screening criteria** are used to identify patients for the trial:

- Over 18 years of age
- Has a documented diagnosis of schizophrenia or delusional/psychotic illness or bipolar disorder as diagnosed by specialist psychiatric services
- Smokes at least 10 cigarettes per day
- Not pregnant or breast-feeding
- No co-morbid drug or alcohol abuse
- Are not currently on nicotine replacement therapy or other smoking cessation medication (Champix/Varenicline or Zyban/Bupropion).

We request that all patients who are on your SMI register (if you have a separate register), or have a current diagnosis of SMI to be identified from your records using agreed codes, and screened according to the criteria above. This should identify a list of potential patients to approach. We ask that the GP checks this list to ensure that the patient is suitable for participation in the trial. Once this patient approach list is agreed, a study pack, provided by the Universities, will be posted to the patient's address by a member of staff from your surgery. The patient study pack will contain a cover letter, a patient information sheet, and a permission to contact form. If a patient decides he/she is interested in participating he/she will complete the permission to contact form, and return it in the pre-paid envelope to the University of York/Manchester.

Alternatively, GPs and practice nurses can directly refer patients into the study. In which case we request that the permission to contact form be faxed to the coordinating study centre.

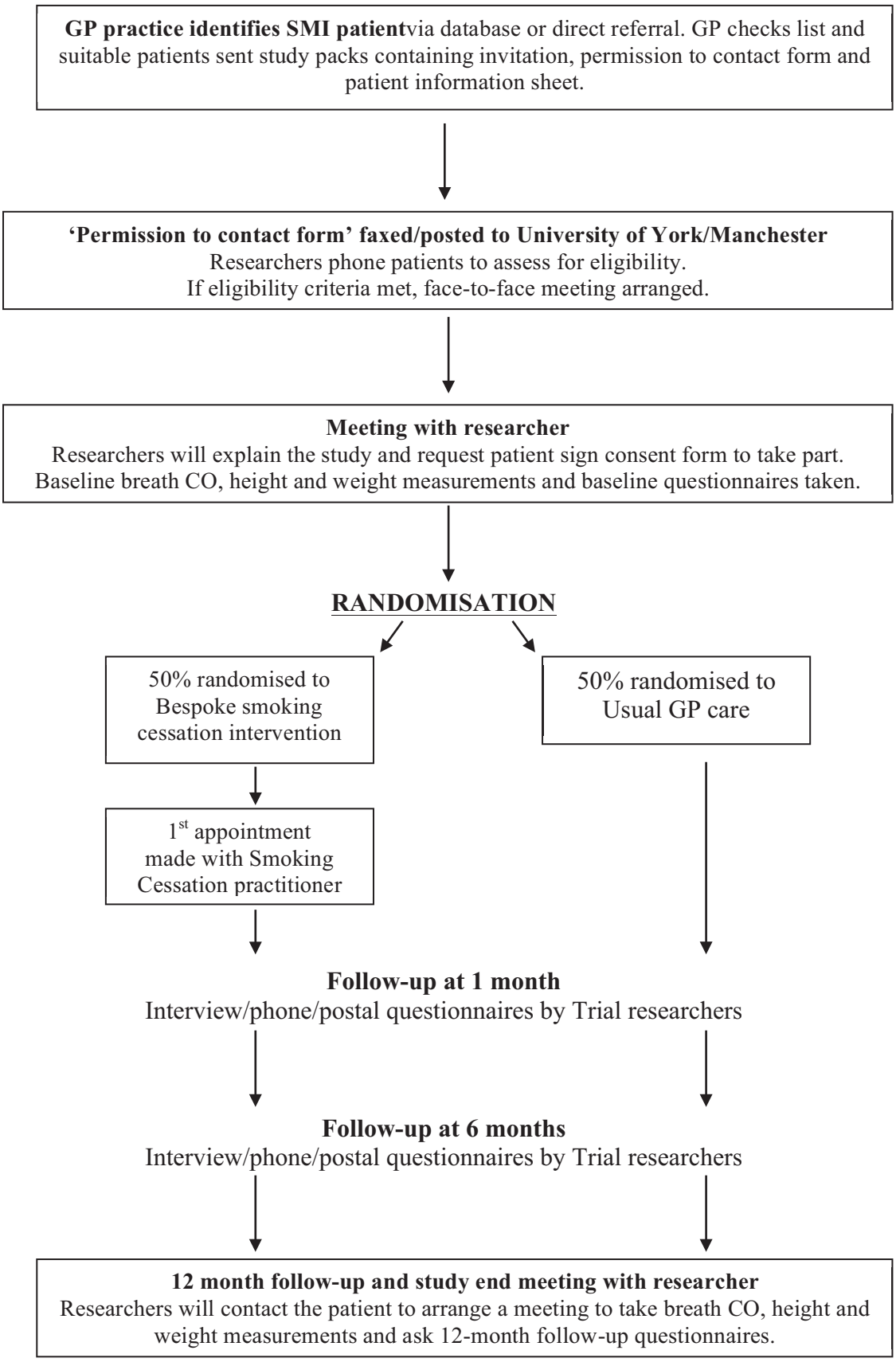
The number of patients eligible will depend on prevalence of SMI patients on your database. **We will provide all stationery, documentation, and postage.**

The Comprehensive Local Research Network (CLRN) will be providing support to your practice during the recrutiment phase of this trial. For each of your patients **randomised** to the trial your practice will receive compensation for your time.

Your responsibilities in the trial would include:

- **providing us with a single sheet of practice letter head which will be used and duplicated by us for the letter of invitation to patients.**
- **identification of SMI patients who smoke and checking patient's suitability.**
- **labelling the study packs provided by us and posting the study packs to patients.**
- **Working with the Smoking cessation practitioner to help manage smoking cessation medications for patients randomised to the active intervention.**
- **Flagging patients recruited to the trial on your practice database and providing prescription and number of contacts information per trial participant.**

Flow chart of Trial procedures.



What would the study involve for your patients?

We will contact your patient to set up a meeting at their convenience, where we will discuss the study and answer any queries they may have. If they are happy to participate in the study, we will ask them to sign a letter of consent. They will then be asked to fill out a set of baseline questionnaires and have their breath carbon monoxide, height and weight measured. On completion, the researcher will then phone through to the York Trials Unit to randomly allocate the subject to one of the two arms of the trial: bespoke smoking cessation intervention or usual care. Once a patient has been randomised, we will notify you by letter which patients from your practice have been recruited into the study. Patients will be followed up for 1 year and will be asked to complete questionnaires about their smoking and wellbeing at 1, 6 and 12 months.

Contacts for further information

If you have any questions about any aspect of this study, please contact trial coordinators at the York Trials Unit, University of York:

[redacted]

Or trial researchers at the University of Manchester:

[redacted]

If you would like more information on smoking cessation services and medication use within SMI populations, please contact the chief investigator and consultant psychiatrist on the study:

[redacted]

The University of York is the sponsor and is providing indemnity for the research.

[redacted]

SCIMITAR
Smoking Cessation in Mental Ill health Trial

GP PRACTICE AGREEMENT TO PARTICIPATE

GP Research Lead:

GP Practice:

		Please tick
1.	I have read the information sheet regarding practical requirements and funding arrangements, and can confirm that this practice wishes to participate in the SCIMITAR study.	☐
2.	The practice agrees to identify patients eligible for the SCIMITAR study (SMI patients who smoke, over the age of 18 and not pregnant, breast-feeding or have serious co-morbid drug or alcohol abuse), and send them an invitation and information pack.	☐
3.	The practice gives consent to allow registered patients to be contacted by the research team at the [study centre name] after patients have returned signed consent forms to the study centre.	☐
4.	The practice will provide follow-up data to the study centre at 12 months post recruitment. Follow-up data will consist of number of contacts/appointments, prescribing records, plus other information to confirm participants' current contact details.	☐

Representative from GP practice signing agreement:

Print name: _____ **Position:** _____

Signature: _____ **Date:** _____

Please return this form to: <Local researcher><local site address>.

Appendix 3 Data collection forms

SCIMITAR
Smoking Cessation in Mental Ill health Trial

Biographical Questionnaire

For office use only

Trial ID ☐☐☐☐

Date ☐☐/☐☐/☐☐☐☐

Funded by:
NIHR HTA code 07/41/05
ISRCTN 79497236
Biographical Questionnaire v2.0

Organised by:

THE UNIVERSITY of York MANCHESTER 1824

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*

Any comments about General Health?

Section B – Sociodemographic Details

1. How would you describe your ethnic background?*(please cross one box)*

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

2. What is your highest educational qualification?

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

5. How would you describe your employment status?
(please cross the box that describes you best)

Employed full-time (30+ hours per week)	☐ 1
Employed part-time (<30 hours per week)	☐ 2
Self-employed	☐ 3
Retired	☐ 4
Looking after family or home	☐ 5
Student (full or part-time)	☐ 6
Voluntary worker (paid or unpaid)	☐ 7
Not employed but seeking work	☐ 8
Not employed but **not** seeking work because of ill health	☐ 9
Not employed, but **not** seeking work for some other reason	☐ 10
Other, please specify here _____	☐ 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	☐ 1
4-12 months	☐ 2
1-2 years	☐ 3
2-5 years	☐ 4
>5 years	☐ 5
Don't know/no response	☐ 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

8a. 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? _____ people

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 psychiatrist? _____

   Contact Details: _____

   Phone number: _____
4. Are you seen by:

   Care Programme Approach (CPA) coordinator? Yes ☐ No☐

   Community Psychiatric Nurse (CPN) ? Yes ☐ No☐

   Community Mental Health Team? Yes ☐ No☐
5. Name of key mental health care worker? _____

   Contact Details: _____

   Phone number: _____
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, please list **ALL** medications below:*

Any comments about Mental Health?

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/grams
5. How many times have you tried to give up 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

Any comments about past quit attempts?

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	☐	☐	☐

SCIMITAR
Smoking Cessation in Mental Ill health Trial

Questionnaire

For office use only

Trial ID ☐☐☐☐

Date ☐☐/☐☐/☐☐☐☐

Funded by:
NIHR HTA code 07/41/05
ISRCTN 79497236
Biographical Questionnaire v2.0

Organised by:

THE UNIVERSITY of York MANCHESTER 1824

PLEASE READ ALL THE INSTRCUTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for taking part in this study and agreeing to compete this questionnaire.

The responses you give to this questionnaire will provide information to help health professional manage smoking cessation in people with mental health problems.

The information you provide will be kept strictly confidential. You will not be personally identified in any report resulting from this study.

Please answer ALL the questions. Although some of the questions may appear similar, repetitive or seem irrelevant, it is important to the study that you answer every one. Please answer all questions honestly and to be nest of your ability.

Follow the instructions for each question carefully.

When answering the questions, use a cross rather than a tick, as if you are filling out a ballot paper. For example in the following question, if your answer is yes, you should place the cross firmly in the box next to yes.

Example:

Do you smoke? Yes ☒

No ☐

If you are asked to write an answer, please print clearly.

Example:

What is your age? | 3 | 8 |

Where were you born? DISTRICT Hospital

Please use a black or blue pen. Please do not use a pencil or coloured pen.

If you have any queries or problems completing this questionnaire, please contact your local study centre:

<Local study centre trial coordinator>
Trial coordinator name
Address
Phone number
Email

Smoking Status
This section is about your smoking now and your attempt to quit smoking.

1. Have you smoked in the last week?
(*please put a cross in one box only*)

Not even a puff ☐
Yes just a few puffs ☐
Yes between 1 and 5 cigarettes ☐
Yes more than 5 cigarettes ☐

If 'yes', please answer questions 1a and 1b:

1a. What time of day did you have the first puff? ☐☐:☐☐ am/pm

(*Please write the time of day in the box and* ***circle a.m. or p.m.***)

1b. How many cigarettes are you normally smoking per day? ☐☐ Cigaretters /packets
(*Please* ***circle cigarettes or 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 on 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 quit attempts to stop smoking ☐☐☐ attempts
Have you made in the last 6 months?

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?
(*Please cross one box only*)

Within 5 minutes ☐
6-30 minutes ☐
More than 30 minutes ☐

2. Do you find it difficult to stop smoking in no-smoking areas?
(*Please cross one box only*)

Yes ☐
No ☐

3. Which cigarettes would you most hate to give up?
(*Please cross one box only*)

The first of the morning ☐
Other ☐

4. How many cigarettes per day do you usually smoke?
(*Please write the number on the line and cross one box only*) ☐ per day

10 or less ☐
11 to 20 ☐
21 to 30 ☐
31 or more ☐

5. Do you smoke more frequently in the first hours after waking than during the rest of the day?
(*Please cross one box only*)

Yes ☐
No ☐

6. Do you smoke if you are so ill that you are in bed most of the day?
(*Please cross one box only*)

Yes ☐
No ☐

7. Do you smoke hand rolled cigarettes?
(*Please cross one box only*)

Yes ☐
No ☐

If 'yes', please answer questions 7a and 7b

7a. How many do you usually smoke per day? ☐ per day

7b. How much tobacco do you usually use per day? ☐ ounces

Motivation to Quit questionnaire

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

1. How important is it for you to give up Smoking altogether at this point in time? (*Please cross in one box only*)

- ☐ Desperately important
- ☐ Very important
- ☐ Quite important
- ☐ Not all that important

2. How determined are you to give up Smoking at this point in time? (*Please cross one box only*)

- ☐ Extremely determined
- ☐ Very determined
- ☐ Quite determined
- ☐ Not all that determined

3. Why do you want to give up smoking? (*Please cross the most important box*)

- ☐ Because my health is already suffering
- ☐ Because I am worried about my future health
- ☐ Because smoking costs too much
- ☐ Because other people are pressurising me to
- ☐ For my family's health

4. How high would you rate your chances of giving up smoking for good at this point in time? (*Please cross one box only*)

- ☐ Extremely high
- ☐ Very high
- ☐ Quite high
- ☐ Not very high
- ☐ Low
- ☐ Very low

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 last 2 weeks, how often have you been bothered by any of the following problems?
(*Please cross one box per row only*)

	Not at All	Several days	More than half the days	Nearly every day
1. Little interest or please in doing things	☐	☐	☐	☐
2. Feeling, down, depressed or hopeless	☐	☐	☐	☐
3. Trouble falling or staying asleep, or sleeping too much	☐	☐	☐	☐
4. Feeling tired or having little energy	☐	☐	☐	☐
5. Poor appetite or overeating	☐	☐	☐	☐
6. Feeling bad about yourself- or that you are a failure or have let yourself or your family down	☐	☐	☐	☐
8. Trouble concentrating on things, such as reading the newspaper or watching TV	☐	☐	☐	☐
7. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	☐	☐	☐	☐
9. Thoughts that you would be better off dead, or of hurting yourself in some way	☐	☐	☐	☐

EQ5D

By placing a cross in one box in each group below, please indicate which statement best describes your own health state today.

Mobility

I have no problems waking 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 some pain or discomfort ☐

I have extreme pain or discomfort ☐

Anxiety/Depression

I am not anxious or depressed ☐

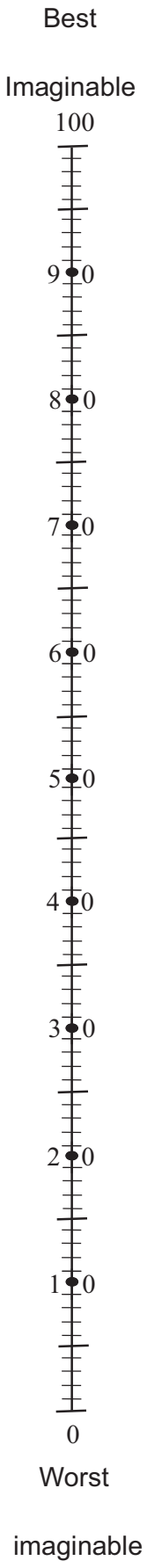
I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



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SF12

These questions ask for your views about your health. This section will help us to keep track of how you feel and how well you are able to do your usual activities.

Answer each question by marking a cross in the appropriate box. If you are unsure on how to answer a question, please give the best answer you can.

1. In general, would you say your health is:
(P*lease cross one box only*)

Excellent	Very good	Good	Fair	Poor
☐	☐	☐	☐	☐

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

Yes, limited a lot	Yes, limited a little	No, not at all limited
☐	☐	☐

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

Yes, limited a lot	Yes, limited a little	No, not at all limited
☐	☐	☐

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

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

5. During the **past 4 weeks**, how much of the time have you been limited in performing any kind of work or other regular daily activities **as a result of your physical health**?
(*Please cross one box only*)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

6. During the **past 4 weeks**, how much of the time have you been limited in performing any kind of work or other regular daily activities **as a result of any emotional problems (**such as feeling depressed or anxious**)**?
(*Please cross one box only*)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

7. During the **past 4 weeks**, how much of the 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 cross one box only*)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

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

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

9. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes the closest to the way you have been feeling. How much during the **past four weeks** have you felt calm and peaceful?
(*Please cross one box only*)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

10. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes the closest to the way you have been feeling. How much during the **past four weeks** did you have a lot of energy?
(*Please cross one box only*)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

11. This question is about how you feel and how things have been with you during the **past 4 weeks**. Please give the one answer that comes the closest to the way you have been feeling. How much during the **past four weeks** did you feel downhearted and depressed?
(*Please cross one box only*)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

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 cross one box only*)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

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 any contact with any of the following community based professionals or services in the **last six months**:

Services	Number of Contacts
1. General practitioner – home	
2. General practitioner – surgery (including NHS walk-in clinic)	
3. General practitioner – telephone	
4. Practice nurse (nurse in GP surgery)	
5. District nurse, health visitor	
6. Care co-ordinator, case manager, key worker	
7. Psychiatrist	
8. Clinical psychologist	
9. 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, Mental Health	
24. Day centre/drop-in centre	
25. Complementary therapist e.g. homeopath, osteopath, reflexologist	
26. Any other health service e.g. 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:

Phoned the NHS stop smoking helpline service	☐☐☐
Phoned other smoking helplines e.g. QuitLine	☐☐☐
Used the internet to look 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:

Did you use Nicotine <u>patches</u>? *Yes ☐ No ☐ Don't know ☐

*If '**Yes**':

How many pieces of patches did you use? ☐☐☐ Patches

How long did you use them for? Days ☐☐ Weeks ☐☐ Months ☐☐

Did you get them on a GP prescription? Yes ☐ No ☐ Don't know ☐

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 a GP prescription? Yes ☐ No ☐ Don't know ☐

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 a GP prescription? Yes ☐ No ☐ Don't know ☐

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

*If '**Yes**':

How many pieces tablets did you use? ☐☐☐ Tablets

How long did you use them for? Days ☐☐ Weeks ☐☐ Months ☐☐

Did you get them on a GP prescription? Yes ☐ No ☐ Don't know ☐

Did you use Nicotine Inhaler? *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 a GP prescription? Yes ☐ No ☐ Don't know ☐

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 a GP prescription? Yes ☐ No ☐ Don't know ☐

Did you get them on a GP prescription? Yes No Don't know

Did you use any Other Nicotine Replacement Product?

e.g. mouth spay, e-cigarette *Yes ☐ No ☐ Don't know ☐

*If '**Yes**', please state the product used: ☐

How much did you use? ☐

How long did you use them for? Days ☐☐ Weeks ☐☐ Months ☐☐

Did you get them on a 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 most recent attempt, please state how long you used Zyban for?

	Less than 24 hours	24 hours	1 to 6 days	7 to 14 days	2 to 4 weeks	Longer than 4 weeks	Cannot remember
Most recent Quit attempt	☐	☐	☐	☐	☐	☐	☐

*If more than 1 attempt was made using Zyban, please put details in the comment box.

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 most recent attempt, please state how long you used Champix for?

	Less than 24 hours	24 hours	1 to 6 days	7 to 14 days	2 to 4 weeks	Longer than 4 weeks	Cannot remember
Most recent Quit attempt	☐	☐	☐	☐	☐	☐	☐

*If more than 1 attempt was made using Champix, please put details in the comment box.

13. How much have you spent 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	£51 - £100	Over £100
☐	☐	☐	☐	☐	☐	☐	☐

14. How do you travel to your GP surgery/stop smoking clinic? ☐

15. How much have you spent on travel to your GP surgery/stop smoking clinic to help you stop smoking in the last six months? **£** ☐☐☐

16. Do you currently take Recreational Drugs? *Yes ☐ No ☐

☐

*If 'Yes' please specify what you take:

how much do you take per week:

If you have any general comments about the study, or this questionnaire, please write them below:

Thank you for taking time to complete this questionnaire

Patient ID number : ☐☐☐

Date: _____/_____/_____

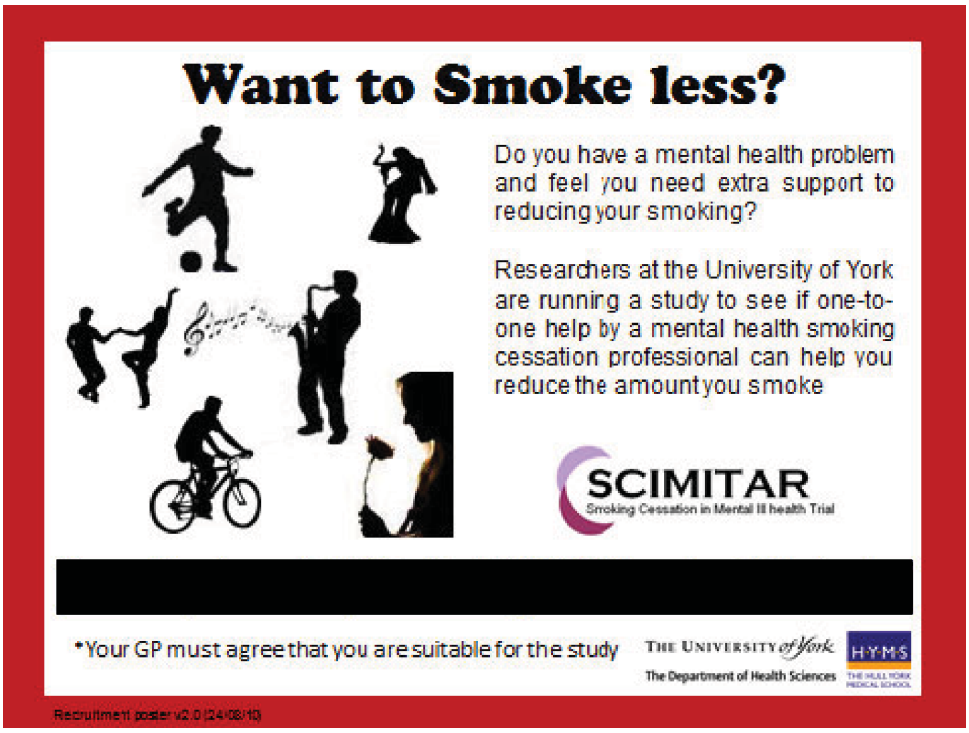
Body Mass Index (BMI) Measurement

Patient's weight (kg) = _____

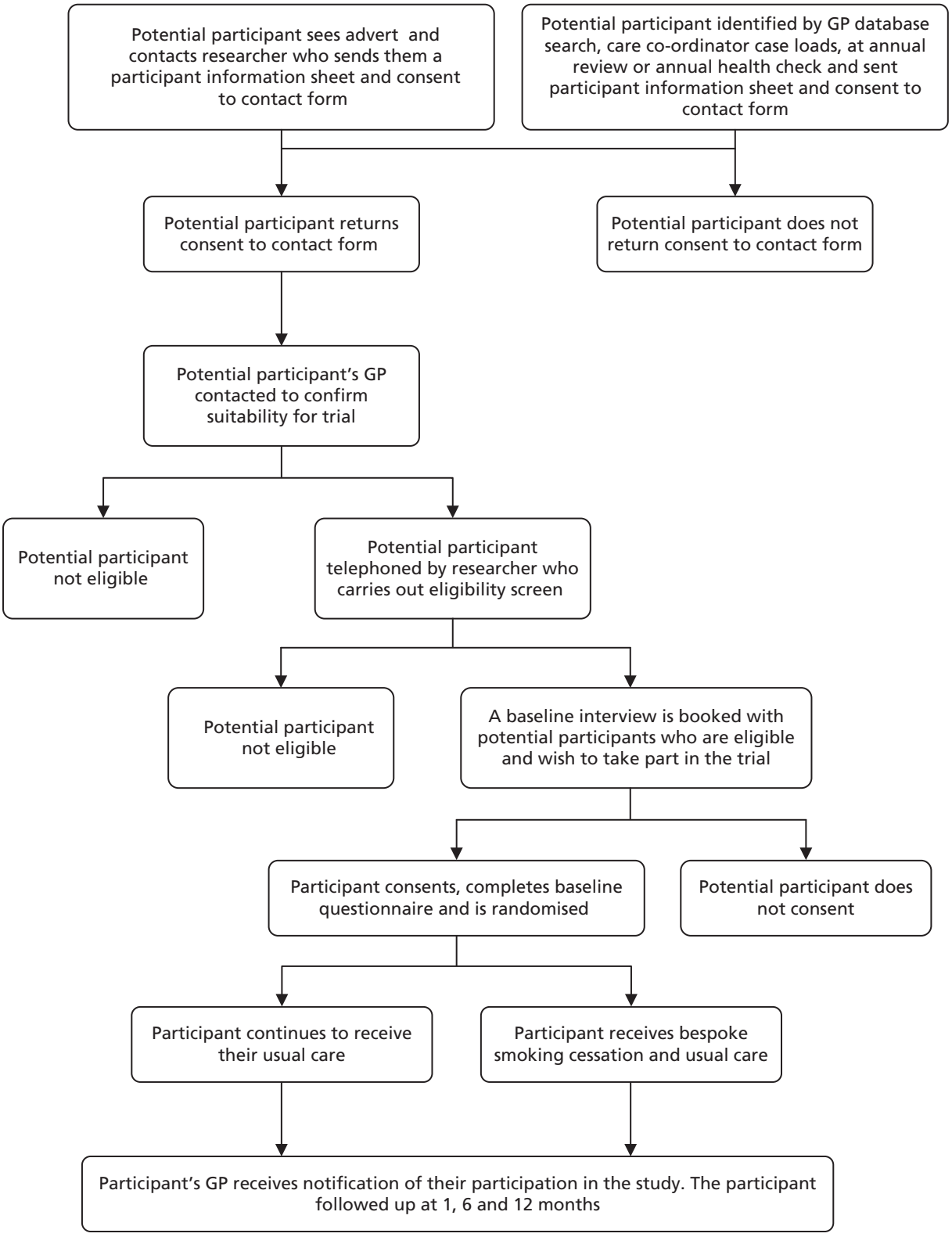
Patient's height (m) = _____

$$\text{BMI} = \frac{\text{weight}}{\text{Height}} = \frac{\text{_____}}{\text{_____}} = \text{_____}$$

Appendix 4 Advertising materials



Appendix 5 Flow chart for Smoking Cessation Intervention for Serious Mental Ill Health Trial



Appendix 6 Protocols

Suicide protocol

If at any time you believe that there is significant suicide risk with a patient who is participating in the study that has not been recently communicated to their GP, psychiatrist or care coordinator/CPN, you must contact Prof Simon Gilbody (Consultant psychiatrist) or the relevant designated centre psychiatrist or health professional, if Prof Gilbody is unavailable.

Prof Gilbody, or the designated psychiatrist/ health professional, will then assess the patient and if it believed necessary, and if there is a significant risk, they will notify the patient's GP and/.or psychiatrist with or without their patient's consent.

Suicide risk identified during face-to-face or telephone interview

The PHQ-9 questionnaire asks if the patient has had "**Thoughts that you would be better off dead or hurting yourself in some way" (Question 9).**

If the participant indicates a response of 3 for this item, then you should ask whether the patient has talked to their GP, psychiatrist or care coordinator/CPN about these feelings. **If the patient has spoken of these thoughts to their GP or psychiatrist, then no action is required.**

If not, you should ask the patient whether it is OK for you to contact their GP and inform them of the situation. If the patient refuses, contact Prof Gilbody or the relevant designated psychiatrist/health professional. If the patient agrees, you should immediately get in touch with the patients GP or psychiatrist.

If unable to contact Prof Gilbody or any of the designated centre psychiatrists/health professionals, contact the Trial manager, Mei-See Man or any other of the co-investigators who will advise further

Please also complete the attached Suicidal Intent Form, if the patient agrees to you contacting their GP/psychiatrist and inform the Trial Manager. If relevant, Professor Gilbody or the relevant designated centre psychiatrist/health professional should also complete the Suicidal Intent Form: Psychiatrist/ Health Professional. These forms should be stored with the patient's trial records.

Suicide risk identified on a postal or online questionnaire

At 1 month and 6 month follow up points, some patients can choose to receive and return questionnaires by post or online. If you receive a PHQ-9 in which the patient has indicated a score of 3 for question 9, you will need to follow the suicide protocol.

Contact the patient by phone and say that you are concerned with their response to this question. Ask if they have discussed these feelings with their GP or psychiatrist. **If the patient has spoken of these thoughts to their GP or psychiatrist, then no action is required.**

If not, you should ask the patient whether it is OK for you to contact their GP and/or psychiatrist and inform them of the situation. If the patient refuses, contact Prof Gilbody, or the relevant designated psychiatrist/health professional. If the patient agrees, you should immediately get in touch with the appropriate GP and/or health professional.

If unable to contact Prof Gilbody or any of the designated centre psychiatrists/health professionals, contact the Trial Manager, Mei-See Man or any other of the co-investigators who will advise further.

If any other written responses on the questionnaires give you cause for concern, raise this with Prof Gilbody, or the relevant designated psychiatrist/health professional.

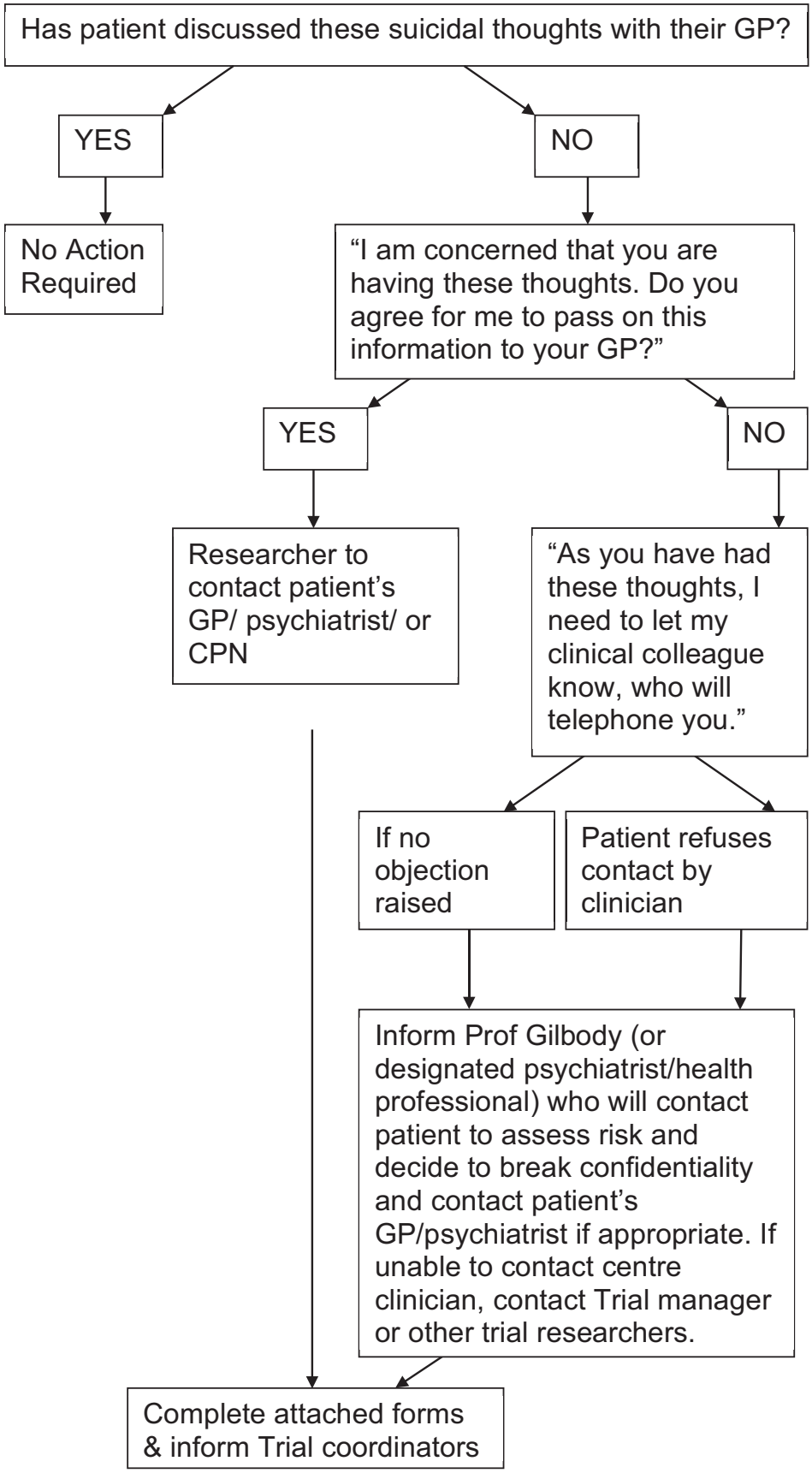
If you are unable to contact the patient within 24 hours, contact the patient's GP or psychiatrist. Inform them of the patient's questionnaire response and that you have been unable to contact the patient to assess the situation further.

At this point also check the patient's contact telephone number is correct. It may be that the telephone number on the database is out of date. If an alternative number is provided and the GP/ health professional agrees, attempt to contact the patient again.

If still unable to contact the patient and if no alternative contact details are available, confirm with the GP/ health professional that they will follow up with the patient as they feel appropriate based on their clinical knowledge of the patient.

Inform Prof Gilbody or the relevant designated psychiatrist/health professional of the patient's questionnaire response and details of resultant contacts with the patients GP/psychiatrist.

Complete the appropriate Suicidal Intent Forms.



Contacts

	Telephone	Mobile
Prof Simon Gilbody		
Mei-See Man		
Helen Cox		
For Manchester		
Tim Bradshaw		
Prof Linda Gask		
For Hull		
Dr Renato Merolli		
For York		
Prof Ian Watt		
Prof David Torgerson		

Suicidal Intent Form

The patient below has shown thoughts of suicidal intent on the PHQ-9 Questionnaire and has agreed for their GP and/or psychiatrist to be contacted by the researcher.

Date of birth: _____/_____/_____

SCIMITAR Participant ID: __ __ __ __

Action taken

Name of GP/Psychiatrist contacted: _____

Date of contact: _____/_____/_____ Time: ___:___ am/pm

Outcome of contact/Action/Comments:

Suicidal Intent Form: Psychiatrist/Health Professional

Name of Participant: _____

Date of birth: ____/____/_____

Name of Psychiatrist/trial health professional notified: _____

Date notified: ____/____/_____

Action taken

Patient contacted: Yes ☐ No ☐

GP/Psychiatrist contacted Yes ☐ No ☐

If yes, GP/psychiatrist contacted with Patient's consent?

Yes ☐ No ☐

Name of GP contacted:_____

Date: __/__/___

Name of Psychiatrist contacted: _____

Date: __/__/___

Outcome of contact/Action/Comments:

Adverse event protocol

THE UNIVERSITY of York
The Department of Health Sciences
H·Y·M·S THE HULL YORK MEDICAL SCHOOL

MANCHESTER 1824
The University of Manchester

SCIMITAR
Smoking Cessation in Mental Ill health Trial

Serious Adverse Event Reporting Standard Operating Procedure

TITLE: Serious Adverse Events Reporting	
Version number: 1.2 **Date:** 04/08/2011	
Prepared by: Helen Cox Date: 04/08/2011	
Purpose: To describe the process of adverse event reporting and follow-up of adverse events for all of the care team involved in the SCIMITAR study.	

1. BACKGROUND

This SOP highlights how Adverse Events and Serious Adverse Events should be reported and conforms to ICH GCP guidance (1996). Researchers must ensure they are aware of the following definitions.

The definition of an adverse event is: *"Any untoward medical occurrence in a patient which does not necessarily have a causal relationship with this treatment". This includes "any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with any research procedure.* This may include, for example, a cold, or an accident.

The definition of a **serious adverse event** (SAE) is one that fulfils at least one of the following criteria:

- Is fatal – results in death (NOTE: death is an outcome, not an event)
- Is life-threatening
- Requires inpatient hospitalisation or prolongation of existing
- Hospitalisation
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect

If the medical occurrence does not fulfil at least one of the above criteria, it is classified as a **non-serious adverse event**.

An adverse reaction is 'unexpected' if its nature and severity are not consistent with the information about the medicinal product (NRT/pharmacotherapy) or illness in question.

All serious adverse events should be reported to the trial coordinating centre **within 24 hours** of the investigator becoming aware of the event. Adverse event definitions and procedures will be detailed in the study protocol. If any trial staff is in doubt whether to report an occurrence as a SAE, contact the trial centre for further advice.

2. PURPOSE

To describe the procedure for identifying, recording and reporting adverse events and serious adverse events in the SCIMITAR study.

3. PROCEDURE

3.1 Who?

All trials researchers that are in contact with patients are responsible for noting adverse events that are reported by the patient and making them known to York Trials Unit. Patients entered into clinical trials must be encouraged from the outset of any study to contact their researcher at the time of an event occurring.

It is important that if patients are admitted to ward areas that the research team are informed of the hospital admission as soon as possible. The researchers should conduct study assessments, and ensure that all adverse events are identified for each patient as far as possible.

3.2 When?

At each visit, or study assessment, adverse events that might have occurred since the previous visit or assessment should be elicited from the patient. In many cases this will be captured at the point of data collection. Where a patient indicates particularly a hospital visit/admission or any other health related event at the point of data collection, this will need to be elaborated on and where necessary an adverse events form completing. These events need to be detailed in the patients adverse events form including the start dates (if known) of the onset of the event as well as the date the event stopped or changed, if applicable. Adverse events ongoing on completion of the study should be followed up as required by the protocol and as clinically indicated. The clock starts from the time the study team were made aware of the event.

The ICH GCP Guidelines state that: *"All serious adverse events should be reported immediately to the sponsor"* (trial organisers), and that *"immediate reports should be followed promptly by detailed written reports"*.

3.3 How?

1. Document event in a clear way as far as possible using the using the SCIMITAR adverse events data collection form (Appendix B).

2. Ask patient the date and start and stop time of event; If the patient cannot remember, then as near as possible.

3. Document the action taken regarding study drug – if any. For example was the treatment dose reduced, or was study drug/treatment delayed etc. Please document any medication the patient is receiving.

4. Document any treatment/medication given for the event, including the dates the treatment/medication was commenced and the date it was stopped/changed, if applicable.

5. Document and date the event outcome. (ie ongoing/resolved)

6. Events ongoing at study completion should be followed up as detailed in the protocol and as clinically indicated.

7. Adverse events should be recorded on a CRF and reported to the study centre as required by the protocol.

<u>Serious Adverse Events</u>

8. All adverse events/adverse drug reactions must be documented as above. For definitions of a serious adverse event, see section 1.

9. Inform York Trials Unit as soon as possible **within 24 hours** of knowledge of the event. This can be done by faxingthe Adverse Event form to York Trials Unit (01904 321387). It is important that the timeline for reporting (i.e. when theresearcher became aware of the event, and when the trial centre wasnotified) are documented.

10. Should the event be initially reported orally (e.g. by telephone), a written report should follow within 24 hours.

11. Note that for specific trials, certain kinds of event may be exempted from immediate reporting – this will be documented in the protocol.

12. Respond promptly to requests for additional information from the Sponsor, and send follow-up reports as required to document the progress of the event.

14. Copies of all correspondence (including emails) relating to the SAE should be retained in the patients individual patients research records or master site file including summaries of telephone conversations. All conversations with the study centre must be documented on the communications log. Reasons for late reporting must be documented on the SAE form and in the patients research records or the master site file.

15. Pregnancy in a patient or in the trial should always be reported to York Trials Unit.

York Trials Unit is responsible for:

7a. Promptly notifying any investigators, RECs and Competent Authorities (CAs) (e.g. Medicines and Healthcare Products Regulatory Agency/ Funder) of any findings that may affect the health of the subjects.

7b. Keeping detailed reports of all AEs reported and performing an evaluation with respect to seriousness, causality and expectedness.

7c. Reporting all unexpected and related AEs to CAs and RECs within given timelines.

7d. Breaking treatment codes before submitting expedited reports to CAs and RECs for specific subjects, even if the PI has not broken the code.

7e. Setting up of an independent Data Monitoring Ethics Committee (DMEC) with the role to monitor data and make recommendations to the Trial Steering Committee (TSC) on whether there are any ethical or safety reasons why the trial should not continue.

7f. Reporting to the TSC and DMEC on a regular basis the occurrence of all AEs and the immediate reporting of any unexpected or related SAEs.

Data Monitoring Ethics Committee (DMEC) and the Trial Steering Committee (TSC).

The occurrence of adverse events during the trial will be monitored by an independent Data Monitoring Ethics Committee (DMEC) and the Trial Steering Committee (TSC). The DMEC/TSC will immediately see all SERIOUS adverse events thought to be treatment related. They will see the following events at the next scheduled meeting:-

- Serious adverse events not thought to be treatment related by the Trial Management Group
- Non-serious adverse events thought to be related to the treatment
- Non-serious adverse events thought to be unrelated to the treatment

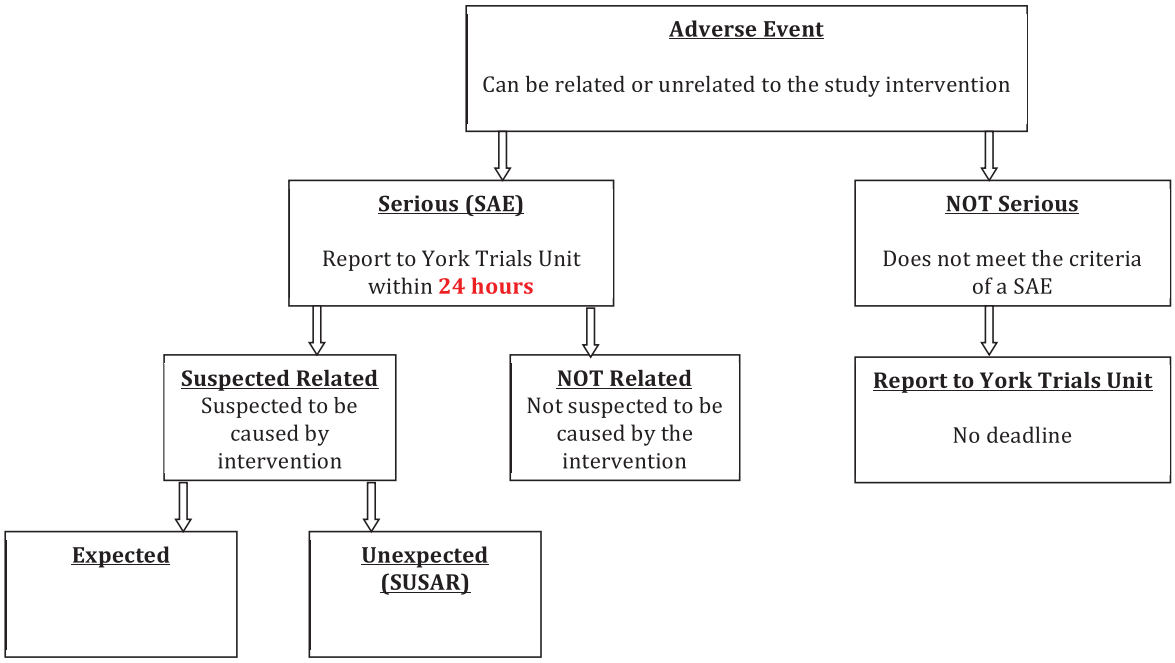
4. REFERENCES AND FURTHER READING

ICH Harmonised Tripartite Guideline for Good Clinical Practice (1996)
The Medicines for Human Use (Clinical Trials) Regulations 2004 Statutory Instrument 2006/1031, implemented 1st May 2004, as amended.
Some of the text of this SOP adapted from:
National Cancer Research Network SOP, Study files and filing, 2004.

5. APPENDICES

Appendix A - Classification of Adverse Event
Appendix B - SCIMITAR Adverse Events Collection Form

APPENDIX A



THE UNIVERSITY of York

Appendix B: SCIMITAR Adverse Event Reporting

SCIMITAR
Smoking Cessation in Mental Ill health Trial

Patient Trial Number

Date of birth (day / month / year)

Date of onset of event (day / month / year)

How were you notified of the event? **Date notified:**

Full description of the event:
(including any current medication)

The local research team deem this event to be: **SERIOUS** ☐ **Non-Serious** ☐

Classification if SERIOUS:

- Death ☐
- Persistent or significant disability/incapacity ☐
- Hospitalisation required/prolonged ☐
- Is a congenital anomaly or birth defect ☐
- Is life threatening ☐
- Other medically important condition ☐

Please state outcome of event at time of this report (tick one box only)

- Recovered fully ☐
- Recovered partially ☐
- Died ☐
- Ongoing ☐

Date recovered / died (Day / Month / Year)

Researcher Name

Signature

Date

Patient Trial Number | | | | |

Appendix B: SCIMITAR Adverse Event Reporting

SCIMITAR
Smoking Cessation in Mental Ill health Trial

Relationship of the event to any of the research procedures ***(to be completed by reviewer)***

Unrelated	Unlikely to be related	Possibly related	Probably related	Definitely related	Not able to assess if related
☐	☐	☐	☐	☐	☐

Any further important information:

Is this event expected

(Is the adverse event an expected or common occurrence in this patient group)

☐ *Yes* ☐ *No*

Ongoing Notes if Applicable ***(to be completed by York Trials Unit if patient is followed up)***

Date

Reviewed by

Reviewer's signature

Appendix 7 Qualitative interviews: participant information sheets

<DATE>
<NAME>
<ADDRESS>
<ADDRESS>
<ADDRESS>
<POST CODE>

SCIMITAR
Smoking Cessation in Mental Ill health Trial

Qualitative interview sub-study

Dear <Participant's title and surname>, Participant ID

Thank-you for your continued support with this study. This research will help your doctor and other health professionals decide the best way to help people who experience mental health problems to quit smoking. As an extra part of the research, we would like to ask about your views and opinions about smoking, trying to quit and whether you found being part of the study useful.

The information you provide is extremely helpful, even if you have not quit smoking, the answers you give and the information we receive are still very important and relevant.

Please find enclosed an information sheet giving details on what this interview study will involve, and a consent form. One of our researchers will contact you by phone in one weeks time to find out if you are interesting in taking part in these interviews. If you are, they will arrange to visit you at a place and time of your choosing to collect the signed consent form and conduct the interview with you. If you are not interested, just tell the researcher this when they call – your participation in the study will be unchanged and your normal care from your GP will continue.

If you have any questions about this interview study or any part of the SCIMITAR study, please contact <Qual Researcher name>, on <phone number> or <name local trial coordinator><phone number>.

Yours sincerely

Mei-See Man
SCIMITAR Trial Coordinator
York Trials Unit
[redacted]

THE UNIVERSITY of York
The Department of Health Sciences

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SCIMITAR
Smoking Cessation in Mental Ill health Trial

Participant Information Sheet for Interview Study

MANCHESTER 1824
The University of Manchester

We appreciate your participation in the trial of Smoking Cessation and would like to invite you to take part in an in-depth interview exploring your experience with smoking cessation. We hope to gain a broader understanding of what influences smoking and health in patients receiving mental health care. We are seeking the views of patients, smoking cessation practitioners, and other health professionals involved in the trial to answer this question. Please feel free to discuss this information sheet with your family, friends or people involved in your care.

Why you have been chosen?

You have been invited to take part in this interview study because you have been involved in the main trial of smoking cessation in people with mental health problems and we are interested in your experience and what you thought of the service.

If you decide to take part

One of our researchers will contact you by phone in one weeks time to find out if you want to participate in this part of the study. If you are, they will arrange to visit you at a place and time of your choosing to collect the signed consent form and conduct the interview with you. If you are not interested, just tell the researcher this when they call – your participation in the study will be unchanged.

What happens at the interview?

In the interview, we will ask about your experience with the SCIMITAR study, how you found working with the smoking cessation practitioner, your experience of smoking cessation, and the broader impact this experience has had on your mental and physical health and wellbeing. The interview will be audio recorded. This will allow the researcher to concentrate on what is being said, rather than spending his or her time writing everything down. The interview will last approximately one hour.

Your participation in the interview is entirely voluntary. If you decide to take part, you may withdraw from the study at anytime without giving a reason. The decision to withdraw or the decision to not take part will not affect your participation in the main trial.

Possible risks and disadvantages

We do not anticipate that being interviewed by our researcher will have any side effects. However, talking about past events and emotions can be uncomfortable, so if you find the interview stressful in anyway, you are free to not answer or stop without having to explain your reasons why. The only disadvantage of taking part in the study is giving up your time to meet with the researcher.

Possible benefits

The information you give may help us improve smoking cessation services for people with mental health problems.

Confidentiality

All information collected about you during the course of the study will be kept in strict confidence. The interview tape will be transcribed to protect your identity and all names will be changed to maintain anonymity. Once the tapes are transcribed, they will be destroyed. The only people who will have access to your identity will be the researchers who will ensure that steps are taken to maintain security and confidentiality. Your information will not be disclosed to any unauthorised person. Any information about you which is used in reports of the study will be made completely anonymous and used in such a way that you cannot be identified.

What will happen to the data that are collected about me?

Your data will be held in a secure place in the research centre at the University of <York/Manchester>. All study data will be held for a minimum of 5 years. We will remove all names and other identifying information before data analysis and results are presented to the medical community.

Results of the research study

The results of this research study will be available after we have analysed the data. We will publish the results in healthcare journals to provide GPs and other healthcare practitioner's with information.

Who reviewed the study

All research in the NHS is looked at by an independent group called a Research Ethics Committee. They make sure that the research is fair. The study has been reviewed by the National Research Ethics Service.

Who is organising and funding this research?

This study is being funded by the Health Technology Assessment Programme, which is part of the NHS National Institute for Health Research. The trial is sponsored by the University of York and managed by researchers at the York Trials Unit, University of York and University of Manchester.

Who can I contact for more information

If you have any questions about this interview study or any part of the SCIMITAR study, [redacted], or study researchers at the University of Manchester: <Researcher name>, phone <phone number>, email: <email address>

If you are unhappy with any aspect of this study, you can speak with any study researcher (contact details above) or your care coordinator who can relay your

dissatisfaction to the lead investigator, Prof Simon Gilbody. [redacted] Taking part in this study in no way affects your right to complain about any aspect of the way in which you have been treated during the course of this study.

Thank-you for reading this information sheet and for considering whether to take part in this study.

Office use only	ID:		
GP code:	GP practice code:	DOB:	NHS no:

Participant Consent Form

Smoking Cessation in Mental Ill Health Trial – Interview Study

Please read carefully. If you agree with each point, please **initial each box**:

- I confirm that I have read and understand the information sheet dated (Date, Version X) for the above study. I have had the opportunity to consider the information, to ask questions and to have these answered satisfactorily. ☐

- I understand that my participation is voluntary and that I am free to decline the offer to participate without giving any reason, and my medical care and legal rights will not be affected. ☐

- I understand that the interview will be audio recorded and transcribed, that the tapes will be destroyed when transcription is complete and that no material which could identify me will be used in any reports of this study ☐

- I agree to take part in the SCIMITAR interview study ☐

One of our researchers will contact you by phone in one weeks time to find out if you want to participate in this part of the study. If you are, they will arrange to visit you at a place and time of your choosing. Please have this form with you for your arranged appointment.

If you have any questions, please contact <Name Qual researcher><phone number> or <name local trial coordinator> on <phone number>.

Thank you for your interest in participating in this interview study for the SCIMITAR trial.

<DATE>

<NAME>
<ADDRESS>
<ADDRESS>
<ADDRESS>
<POST CODE>

SCIMITAR
Smoking Cessation in Mental Ill health Trial

Qualitative interview sub-study

Dear <MH-SCPs title and surname>,

Thank-you for your participation in delivering the intervention for this study. This research will help doctors and other health professionals decide on the best way to manage people with severe mental illness to quit smoking. As an additional part of the research, we would like to invite you to take part in an interview study to ask about your views and experiences of managing smoking cessation in patients with SMI.

Please find enclosed an information sheet giving details on what this interview study will involve, and a consent form. If you are interesting in taking part in these interviews, please complete and sign the consent form, and let us know when you would be available to take part in an interview. Please send this consent form back to us in the pre-paid envelope provided. If you are not interested, you do not need to do anything – your involvement in the study will be unchanged.

If you have any questions about this interview study or any part of the SCIMITAR study, please contact <Qual Researcher name>, on <phone number> or <name local trial coordinator><phone number>.

Yours sincerely

Mei-See Man
SCIMITAR Trial Coordinator
York Trials Unit
[redacted]

THE UNIVERSITY of York
The Department of Health Sciences

MANCHESTER 1824
The University of Manchester

H·Y·M·S
THE HULL YORK MEDICAL SCHOOL

SCIMITAR
Smoking Cessation in Mental Ill health Trial

Smoking Cessation Practitioner Information for Interview Study

As part of the trial for Smoking Cessation in people with severe mental ill health, we would like to invite you to take part in an in-depth interview exploring your involvement in the trial and your experience with managing smoking cessation. We hope to gain a broader understanding of what influences smoking and health in patients receiving mental health care. We are seeking the views of patients, smoking cessation practitioners, and GPs involved in the trial to answer this question.

Why you have been chosen?
You have been invited to take part in this interview study because you have been involved in delivering the smoking cessation service in the main SCIMITAR trial and we are interested in your experience and what you thought of the delivering the service.

If you decide to take part
If you agree to participate, please keep this information sheet, complete and sign the consent forms. Please return one of the consent forms in the pre-paid envelope. The other is for you to keep. One of our researchers will contact you by phone in about one weeks time to arrange to visit you at a place and time of your choosing. If you are not interested, please let us know and your participation in the study will remain unchanged.

What happens at the interview?
In the interview, we will ask about your experience with the SCIMITAR study, how you found working with SMI patients, their GPs, your experience of managing smoking cessation in patients with SMI, and the broader impact this experience has had on general management of mental and physical health of SMI patients. The interview will be audio recorded. This will allow the researcher to concentrate on what is being said, rather than spending his or her time writing everything down. The interview will last approximately one hour.

Your participation in the interview is entirely voluntary. If you decide to take part, you may withdraw from the study at anytime without giving a reason. The decision to

withdraw or the decision to not take part will not affect your participation in the main trial.

Possible risks and disadvantages

We do not anticipate that being interviewed by our researcher will have any side effects. However, talking about past events and emotions can be uncomfortable, so if you find the interview stressful in anyway, you are free to not answer or stop without having to explain your reasons why. The only disadvantage of taking part in the study is giving up your time to meet with the researcher.

Possible benefits

The information you give may help us improve smoking cessation services for people with mental health problems.

Confidentiality

All information collected about you during the course of the study will be kept in strict confidence. The interview tape will be transcribed to protect your identity and all names will be changed to maintain anonymity. Once the tapes are transcribed, they will be destroyed. The only people who will have access to your identity will be the researchers who will ensure that steps are taken to maintain security and confidentiality. Your information will not be disclosed to any unauthorised person. Any information about you which is used in reports of the study will be made completely anonymous and used in such a way that you cannot be identified.

What will happen to the data that are collected about me?

Your data will be held in a secure place in the research centre at the Universities of York/Manchester. All study data will be held for a minimum of 5 years. We will remove all names and other identifying information before data analysis and results are presented to the medical community.

Results of the research study

The results of this research study will be available after we have analysed the data. We will publish the results in healthcare journals to provide GPs and other healthcare practitioner's with information.

Who reviewed the study

All research in the NHS is looked at by an independent group called a Research Ethics Committee. They make sure that the research is fair. The study has been reviewed by the National Research Ethics Service.

Who is organising and funding this research?

This study is being funded by the Health Technology Assessment Programme, which is part of the NHS National Institute for Health Research. The trial is sponsored by the University of York and managed by researchers at the York Trials Unit, University of York and University of Manchester.

Who can I contact for more information

If you have any questions about this interview study or any part of the SCIMITAR study, please [redacted]

[redacted]

If you are unhappy with any aspect of this study, you can speak with any study researcher (contact details above) or your care coordinator who can relay your dissatisfaction to the lead investigator, Prof Simon Gilbody. You can also file a formal complaint with the NHS complaints procedure (Tel: 0121 449 5725 or free phone: 0800 389 8391). Taking part in this study in no way affects your right to complain about any aspect of the way in which you have been treated during the course of this study.

Thank-you for reading this information sheet and for considering whether to take part in this study.

Office use only	ID number:
	Practice code:

Participant Consent Form – MH-SCP

Smoking Cessation in Mental Ill Health Trial – Interview Study

Please read carefully. If you agree with each point, please **initial each box** and complete the information below:

- I confirm that I have read and understand the information sheet dated (Date, Version X) for the above study. I have had the opportunity to consider the information, to ask questions and to have these answered satisfactorily. ☐
- I understand that my participation is voluntary and that I am free to decline the offer to participate without giving any reason, and my medical care and legal rights will not be affected. ☐
- I understand that the interview will be audio recorded and transcribed, that the tapes will be destroyed when transcription is complete and that no material which could identify me will be used in any reports of this study ☐
- I agree to take part in the SCIMITAR interview study ☐

Please complete the information below and return this form in the pre-paid envelope. Your contact information will be kept confidential and will only be used to contact you regarding the interview trial

Printed name:_____

Time it is better to reach you: am/pm (circle one)

Signature:_____

Day of the week most convenient for you:

Mon/Tues/Wed/Thurs/Fri/Sat (circle any)

Address:

_____

_____

_____

_____

_____

Telephone number:

(with dialing code)

Mobile number:

Email:_____@_____

Post Code:

_____/_____/_____

Date:

If you have any questions, please contact <Name Qual researcher><phone number> or <name local trial coordinator> on <phone number>.

Thank you for your interest in participating in this interview trial.

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