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 UNIVERSITY of York

The Department of Health Sciences

H·Y·M·S THE HULL YORK MEDICAL SCHOOL

MANCHESTER 1824 The University of Manchester

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.

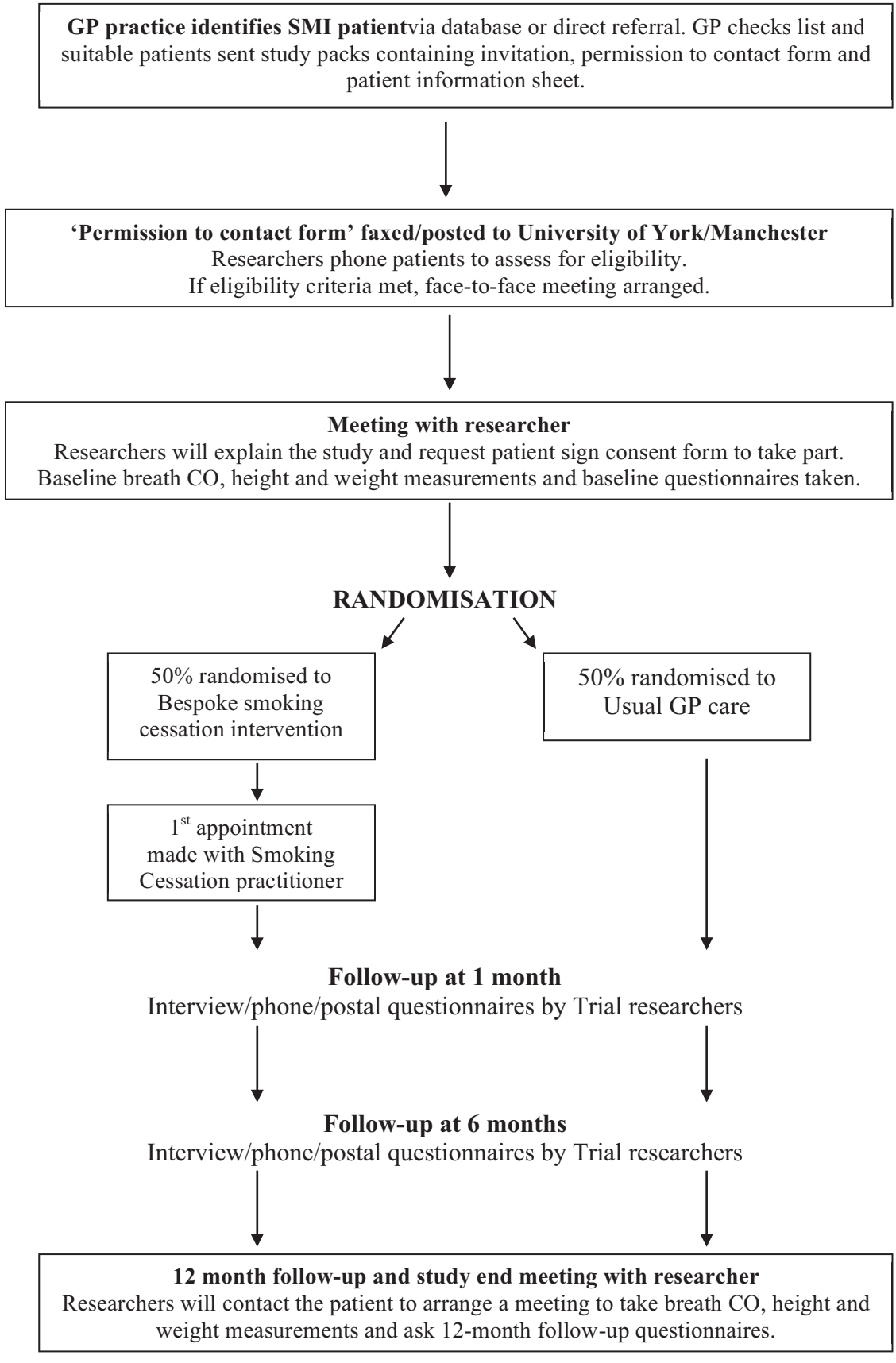
The number of patients eligible will depend on prevalence of SMI patients on your database. **We will provide all stationery, documentation, and postage.**

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>.