SCIMITAR +

Participant Information Sheet

- We would like you to take part in a research study. Before you decide, you need to understand why this study is being done and what it will involve for you.
- Please take time to read the following information carefully.
- Talk to others about the study if you wish.
- Ask us if there is anything that is not clear or if you would like more information.
- Take time to decide whether or not you wish to take part.

Thank you for taking the time to read this.

What is the purpose of the research?

Smoking is a major cause of poor physical health, but stopping smoking is not easy. There are no quit smoking support services especially for people with mental health problems. So we have created a support service designed specifically for people who have had problems with their mental health. The aim of this service is to help people to cut down smoking until they are ready to quit. We need to know if this service is any better than current NHS services for smoking. We will also compare the costs of the support service with current NHS services for smoking to see if the support service represent a good investment.

Why have I been chosen?

You have been chosen because you are a smoker and you have received care from mental health services either recently or in the past.

Do I have to take part?

No, it is up to you whether or not you decide to take part. If you do decide to be included you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you decide to withdraw you will not be followed up and you will have no further part in the study. A decision not to take part will not affect any of the care you receive now or in the future.

What will be involved if I decide to take part?

Once we receive your permission 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 to take part in the study we will invite you to meet with a researcher where you will have an opportunity to ask any questions about the study. This meeting will last about one hour.

At this meeting the researcher will ask you to complete some questionnaires 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).

You will be asked to attend to further meetings with the researcher 6 and 12 months after joining the study. At these meetings you will be asked to complete some questionnaires about your smoking habits, your general health and we will measure your height, weight and breath carbon monoxide levels. We will ask you to give us the names of up to three family members/friends/carers who we can contact to ask if you have given up smoking if we are unable to contact you for the 6 months and 12 months follow up meetings. At the 6 and 12 month meetings we will give you a £10 voucher as a gesture of thanks.

After your first meeting with the researcher you will be allocated to one of two groups, you will have an equal chance of being allocated to either:

Group 1 - Participants receive visits from a smoking cessation practitioner plus continue with usual GP care.

Group 2 - Participants 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.

Group 1 - Smoking Cessation Practitioner group

If you are allocated to this group you will be assigned a smoking cessation practitioner who will advise on the best way to cut down or give up smoking. They will tailor the advice they give you to your individual needs. The smoking cessation practitioner is someone with a background in mental health care and is an accredited level 2 Quit smoking officer.

We will arrange your first appointment with your smoking cessation practitioner at your convenience either at your home, local GP clinic or hospital. 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.

We may ask you for permission to record some of your sessions with the smoking cessation practitioner; you do not have to give permission for your sessions to be recorded. Any recordings made will only be used for analysis as part of the research. If you do not wish to be recorded you can still take part in the study and meet with the smoking cessation practitioner.

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 and encouraged to make an appointment with your GP. You will receive the care that is usually offered to all people in your practice or community.

What do I have to do now?

If you would like to take part in this study you need to complete and return the enclosed permission to contact form in the pre-paid envelope provided.

What are the possible benefits of taking part?

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. Stopping smoking also has the added benefit of saving you a lot of money that you would have spent on cigarettes.

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.

What are the disadvantages of taking part?

When you stop smoking you may experience withdrawal symptoms. These symptoms may include feeling depressed, anxious or irritable, having difficulty concentrating or feeling 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. 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.

What happens when the study ends?

The study will last for 12 months, once you have had your 12 month follow up 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. This will not affect your rights or your future care in any way.

Will my taking part in this study be kept confidential?

All information that you give us will be kept strictly confidential. Your name will not be mentioned in any reports. Only members of the research team and your GP will know that you have agreed to take part in the study. As we will be sending you further questionnaires we need your name and contact details. These personal details will be stored in locked filing cabinets and all electronic copies will be stored on a secure server accessed by password protected computers.

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. 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.

Results of the research study

The results of this research study will be available after we have analysed the data and we will send you a copy of the results if you would like us to.

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

This study has been reviewed by Leeds East Research Ethics Committee.

Who is organising and funding this research?

This study is being funded by the Health Technology Assessment Programme. The trial is sponsored by the University of York and managed by researchers at the York Trials Unit, University of York.

Who can I contact for more information?

If you have any queries or wish to obtain further information about this study, please contact Emily Peckham, phone: [redacted], email: [redacted].

For independent information about participating in this study, contact your local <insert local Patient Advisory Liaison Service (PALS) details or equivalent (if not known locally as PALS) here>, <local contact details entered here>, <local contact detail entered here>.

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: [redacted] or free phone: [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 taking this the time to read this information sheet.

Please keep this copy.

What to do now

If you **do not** want to take part – do nothing

If you **do** want to take part - complete:

- The permission to contact form

Then post it in the prepaid envelope provided.

Participant consent form

Patient Consent Form

Participant Identification number:

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

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

1. 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. ☐

2. I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving any reason, if I chose to withdraw I will not be followed up and will have no further part in the study, and that my medical care and legal rights will not be affected. ☐

3. 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. ☐

4. I agree to complete the relevant questionnaires at the start, 6 and 12 months follow-up, and also have my weight, height and breath carbon monoxide measured during the study. ☐

5. 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. ☐

6. 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. ☐

7. I agree to up to three family members/friends/carers being contacted to ask whether I have quit smoking in the event that the researcher has been unable to contact me. ☐

8. I understand that I may be asked for permission to record treatment sessions and that I am free to refuse, and that I can still take part in the study if I refuse to be recorded and that any recordings made will only be used for analysis as part of the research. ☐

9. I agree to take part in the SCIMITAR study.

……. …/…/……

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Name of participant (BLOCK CAPITALS) Date Signature

……. …/…/……

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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 like to be sent information related to other studies, please tick this box ☐