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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]



Participant Information Sheet for Interview Study



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]

[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>

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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

A handwritten signature in black ink, appearing to read "Mei-See Man".

Mei-See Man
SCIMITAR Trial Coordinator
York Trials Unit





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.

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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]



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:
any)	Mon/Tues/Wed/Thurs/Fri/Sat (circle any)
Address: _____ _____ _____	Telephone number: (with dialing code)
_____	Mobile number:
Email: _____ @ _____	

Post Code:

Date:

_____/_____/_____

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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.