The SCIMITAR-SA programme to address tobacco-related multiple long-term conditions in Severe Mental Illness (SMI) in South Asia

Participant information sheet - Main Trial

You are being invited to take part in a research study called SCIMITAR-SA. Before you decide whether to take part, it is important to understand what the study is about and what it will involve. Please read this information sheet carefully, or have someone read it out for you. If you have any questions, please contact the person named at the end of this document. Your participation is important to us but is entirely voluntary.

Background and rationale for the study:

Tobacco use in any form is a key cause of illness and premature death among people with severe mental illnesses. Treatments that involve counselling have been shown to help people with severe mental illnesses quit tobacco use. However, most of what we know about these treatments comes from Western countries. There is limited knowledge of how effective such treatments are for tobacco users in South Asia.

We have designed a counselling-based treatment for tobacco use (SCIMITAR-SA) specifically for people with severe mental illnesses in South Asia. There is a need to test whether this treatment can help people quit tobacco use (smoked and smokeless forms) when delivered in mental health facilities.

What is the purpose of this trial?

The main objective of this study is to test whether SCIMITAR-SA, delivered by a trained advisor in mental health facilities can help people with severe mental illnesses who use different types of tobacco products (including smokeless tobacco) to quit, and if it offers good value for money. We are conducting this study in three South Asian countries: Bangladesh, India and Pakistan. We aim to recruit 1450 participants in total from across the three countries.

Who can participate in this trial?

We are inviting Individuals (aged 18 years or above) who have a diagnosis of severe mental illness (i.e. schizophrenia, schizoaffective disorder, bipolar affective disorder, psychosis, severe depression with psychosis) and are current smokers, or users of smokeless tobacco to take part.

Participants must be willing to quit using tobacco and be able to provide consent. They should be willing to attend up to 10 face-to-face or remote counselling appointments and should not already be on treatment for quitting tobacco use.

Do I have to take part?

It is up to you to decide whether you would like to participate in this trial. If you do not want to take part, your rights, and the care that you are already receiving from your mental health care team will not be affected in any way. If you do not wish to participate in the trial but still want to get help to stop tobacco use, please talk to your mental health team.

What will be involved if I take part in this trial?

Once you have read the information sheet and have had any questions answered, and are willing to participate, you will be asked to write your name and signature (or) provide a thumb impression (in the presence of an impartial witness) on two copies of the informed consent form. You will give one

copy to the researcher and keep the other one for your records. These forms indicate your willingness to participate in the trial.

After that, you will be allocated by chance (like flipping a coin) to receive very brief advice for tobacco cessation (roughly 1 minute advice from your clinician) along with an information leaflet, or the SCIMITAR-SA treatment. The SCIMITAR-SA treatment will involve 7 modules delivered in up to 10 one-to-one counselling appointments with a trained healthcare worker over three months. Each appointment will last 15-40 minutes and will be delivered either face-to-face or remotely using telephone or video calls. The first appointment of each of the first three modules (two pre-quit and quit day) will be delivered face-to-face. Any additional appointments and post quit modules could be delivered remotely where necessary.

A researcher will also invite you to complete a questionnaire, where they will ask you a series of questions covering different topics such as your tobacco use behaviour, as well as other information related to your physical and mental health, quality of life, and use of healthcare facilities. You will also have your height and weight measured. We expect completing this questionnaire to take about 30 minutes. We will collect information on tobacco use again at four, seven and thirteen months; if at seven months you tell us that you have not used tobacco at all, we will ask you to provide a sample of your saliva for verification.

We will also conduct 1:1 interviews with some trial participants at four months follow up to learn more about their experience of receiving SCIMITAR-SA. Individuals who are invited to these interviews will receive separate information about this in due course and will be asked to fill out an additional consent form as well.

What is the estimated duration of participation in this trial?

The total duration of your participation in the trial, from the time of enrollment, will be thirteen months.

What are the advantages or benefits of taking part?

We cannot guarantee any direct benefits to you from participating in this trial. However, you might find tobacco cessation counselling helpful. Your participation is, however, likely to benefit people with severe mental illnesses who use tobacco in the long term. If the SCIMITAR-SA is effective and offers good value for money, it could be extended to the wider population of people with severe mental illnesses in Bangladesh, India and Pakistan.

What are the disadvantages or risks of taking part?

SCIMITAR-SA and Very Brief Advice are both relatively safe and unlikely to cause harm.

We have taken great care to ensure participant anonymity and confidentiality. All trial procedures will be conducted by experienced and appropriately qualified researchers who have completed pre-requisite training. The safety of trial participants and the research team has been taken into consideration at all points of the study.

You will be asked a set of questions after enrollment in the trial, and at four, seven and thirteen months. The questions will take some time, and you may find some of them uncomfortable to answer. We have made efforts to minimise this and would appreciate it if you could answer all questions to the extent possible. If however, you still feel uncomfortable, please let the researcher know so that they do not continue to ask you those specific questions. If you feel distressed, you can ask the researcher to take a break or stop the interview altogether. The researcher will also seek help from clinic staff (e.g. counsellors) on your behalf if you feel the need.

Will taking part in this trial cost me anything?

Participating in the trial is not expected to cost you anything, except taking time out of your normal schedule to attend the counselling session(s) and complete the questionnaire. We are not offering any personal incentive to you for taking part in the trial. However, we will reimburse the travel expenses for your visits to the healthcare facility.

Will the information I provide be kept confidential?

If you decide to participate in the trial, the counselling sessions and questionnaire completion will be conducted in a private room. You will be assigned a unique study ID number that will be used on all your study data. No identifying information will be stored alongside your study data. We will protect all study data on a secure server by using passwords so that it can only be accessed by the project staff working on the study and representatives from regulatory authorities (e.g. if the research is audited). Any paper copies (e.g. informed consent forms) will be stored in locked cabinets in locked offices at the study sites.

You will find that some of the questions asked when completing the questionnaires are about your age, gender, marital status, and occupation. These data will only be used to produce summary characteristics of those who have participated in the trial. These summaries will not contain your name or any other information that can be used to identify you individually.

You will be asked to write your name and sign (or) provide a thumb impression on an informed consent form. The informed consent form or any other document that may contain information that can be used to identify you, and will be stored securely and separately from the study data. All data collected will be kept confidential and in line with the respective countries' Data Protection Act (Bangladesh, India, Pakistan, and the UK).

Access to participants' personal details will be restricted to research staff only. Monitors and auditors might also need to access the data. At the end of the study, data will be securely archived at the study site or the University of York, as appropriate, for 25 years.

Can I withdraw from the trial at any time?

You can withdraw from the trial at any time without it having any consequences. You do not have to provide a reason. If you decide to do so, you can inform the researchers. Once you withdraw, no further data will be collected from you, however, we will retain and use the data collected from you up until the day of your withdrawal. If you do not wish for these data to be kept and used for the research, please explicitly inform the researchers before the end of your original follow-up period, before data analysis takes place.

What will happen to the results of the study?

The results from this study will be presented as a report,published in journals and presented at conferences. Individual participants will not be identified in any reports, publications, or presentations. We may store data from the study and make this available to third parties (other researchers and institutions) for future studies. If we do this, it will not be possible to identify you.

If you wish to get feedback on the findings and progress of the study, please contact the country lead at the contact details provided below and they will give you this information. Any new information that affects the study or data that has clinical relevance to you (including incidental findings) will be made available to you. We will also inform your healthcare providers if you give us consent to do so.

Who is organising and funding the research?

The study is sponsored by the University of York, UK, and funded by the National Institute of Health Research (NIHR) in the UK. The study is a collaboration of researchers from:

- ARK Foundation, Bangladesh
- Centre for Health Innovation and Policy (CHIP) Foundation, India
- Ishrat Husain Pakistan Institute of Living and Learning (PILL), Pakistan
- National Heart Foundation Hospital and Research Institute (NHFH&RI), Bangladesh
- National Institute of Mental Health (NIMH), Bangladesh
- National Institute of Mental Health and Neurosciences (NIMHANS), India
- Rawalpindi Medical University, Pakistan
- University of York, United Kingdom

The research team is jointly led by Professor Simon Gilbody (University of York) and Professor Pratima Murthy (NIMHANS, India). The country lead for Bangladesh is Professor Rumana Huque, ARK Foundation, Bangladesh. The country lead for Pakistan is Dr Faiza Aslam, Rawalpindi Medical University, Pakistan.

Who has reviewed and approved this study?

The study has been reviewed and approved by:

- Health Sciences Research Governance Committee, University of York, UK
- Bangladesh Medical Research Council
- Indian Council of Medical Research (ICMR), India
- Ethics Committee (Behavioural Sciences Division), NIMHANS, Bengaluru, India
- National Bioethics Committee (NBC), Pakistan
- Institutional Research and Ethics Forum, Rawalpindi Medical University, Pakistan

Who do I contact for more information about the study?

If you want to know more about the study or if you have concerns or complaints about any aspect of this study, you may ask the researcher now. You can also contact the country lead of this study at any point during the study using the following contact details:

Country	**Name of researcher**	**Contact details**
Bangladesh		
India		
Pakistan		

Who do I contact in the event of a complaint?

If you have any questions about your rights as a research participant, wish to complain, or have any concerns about how the study is being carried out, you may contact the following**:**

Name of In-Country Ethics Committee Representative	*Contact Details:*

Thank you for taking the time to read this information sheet.