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Tobacco cessation intervention for individuals with severe mental illness in South Asia

Submission date 26/08/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/08/2025	**Overall study status** Ongoing	
Last Edited 18/09/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims

People with severe mental illnesses like schizophrenia, bipolar disorder, and psychosis often use tobacco more than others, which can seriously shorten their lives. In South Asian countries—Bangladesh, India, and Pakistan—tobacco use is very common, including both smoking and smokeless forms like betel-quid and gutkha. Unfortunately, people with mental illness in these regions rarely get help to quit. This study, called SCIMITAR-SA, aims to test a program that helps people with mental illness stop using tobacco. The program is based on a successful UK model and will be adapted to fit the needs and culture of South Asian communities.

Who can participate?

Adults aged 18 and over who are receiving outpatient mental health care in selected clinics in Bangladesh, India, or Pakistan can take part. They must have a diagnosed severe mental illness, use tobacco daily (smoked or smokeless), be stable in their condition, live near the clinic, and be willing to try quitting within 30 days. Only one person per household can join.

What does the study involve?

Participants will be randomly placed into one of two groups.

-One group will receive up to seven one-on-one counselling sessions over 6–7 weeks with trained staff, plus advice on using nicotine replacement products if available.

-The other group will receive brief advice and a leaflet with information on quitting tobacco.

All participants will be encouraged to set a quit date and will be supported through the process. Some sessions may be done remotely if needed.

What are the possible benefits and risks of participating?

Taking part could help participants quit tobacco, which would improve their health and quality of life. The counselling is designed to be supportive and tailored to people with mental health conditions. Risks are minimal, but some people may find quitting tobacco challenging or experience withdrawal symptoms. Support will be available throughout.

Where is the study run from?

The study is coordinated by the University of York in the UK, with research teams working in Bangladesh, India, and Pakistan.

When is the study starting and how long is it expected to run for?
August 2025 to May 2026.

Who is funding the study?
National Institute for Health and Care Research (NIHR) in the UK.

Who is the main contact?
Dr Garima Bhatt, garima.bhatt@york.ac.uk

Study website
https://www.impactsouthasia.com/scimitar-sa/

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Tobacco cessation intervention for individuals with severe mental illness in South Asia (SCIMITAR-SA): a feasibility randomised controlled trial

Acronym
SCIMITAR-SA feasibility trial

Study objectives
We aim to conduct a feasibility randomised controlled trial to inform the design and implementation of a future definitive trial for tobacco cessation in mental health settings in Bangladesh, India and Pakistan. The following research questions will be addressed:
1. Is it feasible to identify individuals with SMI who use tobacco, recruit them to a trial of tobacco cessation and retain them for up to seven months in a trial conducted in mental health facilities?

2. Is it feasible to collect data for the primary (seven months biochemically-verified continuous abstinence) and secondary outcomes of a potential full scale trial and for the economic evaluation?
3. Is it feasible to deliver SCIMITAR-SA in mental health facilities?
4. Is SCIMITAR-SA acceptable to participants, and feasible to deliver by tobacco dependence advisors and mental health facility staff?

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 29/07/2025, Health Sciences Research Governance Committee, University of York (Department of Philosophy, Heslington, York, YO10 5DD, United Kingdom; +44 (0)1904 323253; stephen.holland@york.ac.uk), ref: HSRGC/2024/626/E

2. Approved 25/09/2024, Ethics Committee (Behavioural Science Division) (NIMHANS Hospital, Bengaluru, Karnataka, 560029, India; 080-26995004; deannimhans@yahoo.com), ref: No. /NIMHANS/47thIEC/(BEH.SC.DIV)/2024

3. Approved 26/05/2025, Screening Committee on Research Proposal, Ministry of Health and Family Welfare (Ministry of Health and Family Welfare, New Delhi, 110011, India; 011-23063809; g.latha@nic.in), ref: F.No P-29010/19/2025-DMCell

4. Approved 13/04/2025, National Research Ethics Committee (NREC), Bangladesh Medical Research Council (BMRC) (BMRC Bhaban, Mohakhali, Dhaka, 1212, Bangladesh; +8802-222298396; info@bmrcbd.org), ref: BMRC/NREC/2025-2027/128

5. Approved 10/03/2025, National Bioethics Committee for Research (NBC-R) (Health Research Institute, Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad, 44000, Pakistan; +92519224325; nbcpakistan@nih.org.pk), ref: No.4-87/NBCR-1145/24-25/1422

Study design
Two arm parallel group individually randomized multi-country multicentre external pilot trial with an embedded qualitative process evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied

Users of smoked and/or smokeless tobacco with a confirmed diagnosis of one or more Severe mental illness

Interventions

Intervention Group: Participants in the intervention arm will also receive the SCIMITAR-SA intervention. The behavioural support offered in the SCIMITAR-SA intervention will comprise up to seven one-to-one counselling sessions which will range between 20 and 30 minutes each, delivered over a period of 6-7 weeks alongside encouragement/guidance to use Nicotine Replacement Therapy (NRT) where available/ affordable.
The SCIMITAR-SA intervention will allow for two pre-quit sessions, a quit day session and weekly follow up to the 4 week post-quit point (feasibility of the number of sessions and mode of delivery will be informed by the feasibility trial) with trained tobacco dependence advisors (TDA). In line with the findings of (UK) SCIMITAR the sessions may need to be split into shorter, more frequent interventions if needed to meet the needs of the patients, and delivery could extend beyond the 6-7 weeks if the patient takes a prolonged period of time to set the quit date. (allowing for the 30 day window from first interaction to quit day). The splitting of sessions will most likely be relevant to the 2 x pre quit session. Therefore, we could have a provision of 4 x pre quit sessions of a shorter duration.
The SCIMITAR-SA intervention will be delivered by the TDAs, who are healthcare workers experienced in caring for mental health patients (specialist or non-specialist) and who receive the SCIMITAR-SA training. There will be supervisors to oversee intervention delivery, and to provide the necessary ongoing support for those who deliver SCIMITAR-SA. This will be built in by training of trainers. There will be catch up meetings between the TDAs and the behaviour change experts (who will be delivering the training on SCIMITAR-SA intervention to respective country research teams as well) to discuss any challenges and iron out teething problems.
The participant will be prompted to set a quit date within 30 days of enrollment. Each session is designed to be delivered face-to-face until the quit day session, beyond which the participants would be encouraged to meet face-to-face by the advisor but there would be a fallback option of remote counselling (via platforms such as Call/WhatsApp and/or Zoom) for those patients who are unable to attend face-to-face. Participants in the group will also receive very brief intervention (VBA).

Control Group: Participants in the control group will only receive very brief intervention (VBA). We will provide Very Brief Advice (VBA), along with a self-help educational information leaflet on tobacco cessation as usual care. VBA is an evidence-based intervention designed to increase quit attempts among people who smoke. VBA was developed by the National Centre for Smoking Cessation Training (NCSCT) in the United Kingdom (UK) (www.ncsct.co.uk/VBA) and involves three steps:
“Ask” patients about their tobacco use,
“Advise” them about quitting, and
“Act” by supporting them with making a quit attempt using available cessation support.

Random allocation will be managed using consecutively-numbered sealed opaque envelopes. A statistician at York Trials Unit (YTU) will generate a random allocation schedule (using Stata v18 or later) using stratified (by site and smoker type [smoked only, smokeless only & dual]) block randomisation with varying block sizes of 2 and 4. Each allocation will be copied onto an individual card and sealed in opaque envelopes (prepared by YTU) labelled sequentially in accordance with the schedule. The envelopes will be transported to the trial sites in advance, where they will be securely stored in a locked cabinet accessible only to authorized staff at a central research office in each country. After completing the baseline data collection at

respective trial sites, the Research Assistant (RA) will telephone a trial coordinator based at the country's central research office. The coordinator will open the next envelope and will inform the RA of the allocation. The RA will record the allocation at the end of the baseline e-CRF.

Intervention Type
Behavioural

Primary outcome measure
1. Recruitment, retention, acceptability
1.1. Recruitment rates, assessed as the number of participants eligible, consenting and randomised, out of those screened.
1.2. Reasons for ineligibility/non-participation/non-consent of participants where provided.
1.3. Retention in the study, assessed as the number of participants randomised who are successfully followed up at four and seven months 4 post randomisation with details of withdrawals and loss to follow-up where available.
2. Intervention Delivery
2.1. Retention in intervention reported as the total number of sessions attended out of the total number of sessions offered.
2.2. Qualitative feedback from research staff, health facility staff and trial participants on trial processes.
2.3. Qualitative feedback from tobacco dependence advisors, mental health facility staff and trial participants on delivery, implementation and receipt of the SCIMITAR-SA intervention.
3. Data completion
3.1. Completeness of data for baseline assessments, outcome measures for the definitive trial and data on health resource use at 4 and 7 months.
3.2. Data completeness of self-reported and biochemically verified continuous abstinence from all tobacco products at 7 months.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
27/08/2025

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. Adults (≥18 years) receiving outpatient mental healthcare at any of the aforementioned trial facilities.
2. Confirmed diagnosis of one or more SMI (i.e. schizophrenia, schizoaffective disorder, bipolar affective disorder, psychosis, severe depression with or without psychosis) by healthcare staff.
3. Self-reported daily users of smoked products (including cigarettes, bidis, waterpipe) and/or users of smokeless forms of tobacco (such as betel-quid, naswar, gutkha, khaini, zarda, paan, pan-masala, gul, shada pata) for the last six months (daily or non-daily) and >=25 days in the last month.
4. Confirmed to be clinically stable* by the healthcare staff at the time of recruitment and able to provide informed consent.
5. One member per household is eligible for trial participation (to avoid contamination).

6. Willing to quit all forms of tobacco use in the next 30 days and able to attend up to seven face-to-face counselling sessions with trained mental healthcare staff.
7. Living within the catchment area for the study facility that is defined by the district /administrative jurisdiction** in respective countries.

*Patients will be considered clinically stable based on the assessment conducted by the treating clinician (Psychiatrist), with less than 25% change in the dosage of the medication and no administration of Electroconvulsive Therapy (ECT) or other neurostimulation treatments within the preceding three months.
**The trial facilities will maintain a record of patients with their consent, including their addresses and contact information, who will be excluded from the feasibility trial due to residing outside the district or administrative jurisdiction in which the trial facilities are located. This record will be reviewed prior to initiating the main effectiveness trial and will serve as a reference for reassessing and refining the eligibility criteria for inclusion/exclusion moving forward.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
100 (10 each from two facilities based in Karachi and 20 each from remaining four facilities)

Key exclusion criteria
1. Self reported use of Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS), Heated Tobacco 2. Products (also known as Heat-Not-Burn products) (HTP/HNBs), noncombustible nicotine products, known as Oral Nicotine Pouches (ONPs) and/or in combination with either smoking and/or smokeless forms of tobacco in the past 30 days.
3. Individuals with comorbid drug or alcohol use disorder (as ascertained by the SCIMITAR-SA research team), personality disorders, eating disorders, autism spectrum disorders, disorders of intellectual development, Post Traumatic Stress Disorder (PTSD) as ascertained clinically by the treating psychiatrist.
4. Individuals who have received any pharmacotherapy (including nicotine replacement therapy) or psychosocial intervention except brief advice for tobacco cessation in the past 30 days.
5. Dual users who are willing to quit only one form of tobacco use/ product.

Date of first enrolment
01/09/2025

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
Bangladesh

India

Pakistan

Study participating centre
NIMHANS
NIMHANS Hospital, Bengaluru
Karnataka
India
560029

Study participating centre
National Institute of Mental Health (NIMH)
Sher-E-Bangla Nagar
Dhaka
Bangladesh
1207

Study participating centre
TMSS Medical College & Rafatullah Community Hospital
Rangpur Hwy, Thengamara
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Study participating centre
Karwan-e- Hayat
Near Karachi Port Trust Hospital, East Wharf
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Study participating centre

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Study participating centre
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Organisation
University of York

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Sponsor type
University/education

Website
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ROR
https://ror.org/04m01e293

Funder(s)

Funder type

Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trial results will be disseminated through multiple channels to ensure its findings reach diverse audiences. The trial results will be published in peer-reviewed journals (journal TBC) to contribute to the scientific literature and inform future research. In addition, we will use social media platforms, professional networks, and established contacts with key stakeholders to share updates and outcomes in accessible formats. Dissemination will also extend to the wider community, employing appropriate and culturally sensitive methods to ensure that people directly affected can engage with and benefit from the findings. This multi-pronged approach will maximize reach, impact, and relevance across academic, policy, clinical, and community contexts.

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. To maintain the scientific integrity of the study, data will not be released before the end of the trial, either for publication or oral presentation purposes, without the permission of the Project Management Team and the Chief Investigator. The full data-sharing plan will be made available at a later date.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.3	16/07/2025	27/08/2025	No	Yes

Protocol file	version 3	20/08/2025	27/08/2025	No	No