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Effectiveness of a tobacco cessation intervention for individuals with severe mental illness in South Asia

Submission date
24/08/2026

Recruitment status
Recruiting

Registration date
25/08/2026

Overall study status
Ongoing

Last Edited
30/09/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Tobacco use is one of the main preventable causes of illness and death worldwide. Tobacco use is particularly common among people with severe mental illness (SMI), including schizophrenia, schizoaffective disorder, psychosis, bipolar disorder with or without psychosis, and severe depression with or without psychosis. Tobacco use is a major reason why people in this group have shorter lives. It can lead to preventable health problems such as heart disease, breathing problems, and cancer. People with severe mental illness can be motivated to quit and can successfully do so with appropriate support, without worsening mental health outcomes. Behavioural interventions have been shown to help people in this population stop using tobacco. However, most of this evidence comes from high-income countries. There is a lack of suitable and practical tobacco cessation interventions that can be used on a larger scale in low- and middle-income countries.
Tobacco use is particularly common in South Asia. In Bangladesh, India, and Pakistan, people use both smoked and smokeless tobacco, and some people use both. Despite having regular contact with mental health services, many people with severe mental illness do not receive advice from healthcare providers to stop using tobacco
Tobacco Cessation Intervention for Individuals with Severe Mental Illness - South Asia (SCIMITAR-SA) is a tobacco cessation programme designed for people with severe mental illness in Bangladesh, India, and Pakistan. It has been adapted to fit the local culture and needs of these countries. It is based on the Smoking Cessation Intervention for Severe Mental Ill Health, which was first developed and tested in the United Kingdom (SCIMITAR-UK). The programme uses different ways to help people change their tobacco use, is adjusted to each person's needs, and is designed to be part of usual mental health services.
This study aims to evaluate how effective SCIMITAR-SA is in helping people with severe mental illness to stop using tobacco.

Who can participate?
Adults aged 18 years or over who are receiving, or have been referred to, outpatient mental health services at a recruitment facility can take part. Participants must:
1. Have a diagnosis of severe mental illness

2. Use smoked and/or smokeless tobacco
3. Be clinically stable
4. Be able to provide informed consent
5. Be willing to quit all forms of tobacco within the next 30 days
6. Be able to attend at least three face-to-face counselling sessions
7. Be the only participant from their household

What does the study involve?
People who agree to take part will complete the baseline assessments. They will then be randomly allocated to receive either the SCIMITAR-SA tobacco cessation intervention plus Very Brief Advice, or Very Brief Advice alone.
SCIMITAR-SA includes seven behavioural support modules. These are delivered by trained healthcare workers through 7 to 10 individual appointments over 7 to 10 weeks. Participants will be encouraged to set a quit date within 30 days of joining the study.
Participants in the Very Brief Advice group will receive brief advice to stop using tobacco and a self-help leaflet.
Participants will be followed up at 4, 7, and 13 months after randomisation. Information about tobacco use and stopping tobacco will be collected at each follow-up. Biochemical testing to confirm tobacco cessation will be carried out only at the 7-month follow-up.
Any use of other tobacco cessation support or medication during the study will also be recorded.

What are the possible benefits and risks of participating?
Participants may benefit from support to help them stop using tobacco, which could improve their health and quality of life. The counselling will be supportive and tailored to people with mental health conditions. There are minimal risks associated with taking part, although participants may find quitting tobacco difficult or experience withdrawal symptoms. Support will be available throughout the study.

Where is the study run from?
The study is coordinated by the University of York (UK), with research teams working in Bangladesh, India, and Pakistan

When is the study starting and how long is it expected to run for?
September 2026 to April 2028

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

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

Contact information

Type(s)
Principal investigator, Scientific

Contact name
Prof Simon Gilbody

ORCID ID
https://orcid.org/0000-0002-8236-6983

Contact details
Department of Health Sciences, University of York, Heslington
York
United Kingdom
YO10 5DD
+44 (0)1904323052
simon.gilbody@york.ac.uk

Type(s)
Principal investigator, Scientific

Contact name
Dr Krishna Prasad Muliyala

Contact details
Dept. of Psychiatry, National Institute of Mental Health and Neurosciences
Bengaluru
India
560029
+91 (0)8026995864
krishnadoc2004@gmail.com

Type(s)
Scientific

Contact name
Prof Kamran Siddiqi

ORCID ID
https://orcid.org/0000-0003-1529-7778

Contact details
Department of Health Sciences, University of York, Heslington
York
United Kingdom
YO10 5DD
+44 (0)1904323052
kamran.siddiqi@york.ac.uk

Type(s)
Scientific

Contact name
Prof Najma Siddiqi

ORCID ID
https://orcid.org/0000-0003-1794-2152

Contact details

Department of Health Sciences, University of York, Heslington
York
United Kingdom
YO10 5DD
+44 (0)1904323052
najma.siddiqi@york.ac.uk

Type(s)
Scientific

Contact name
Prof Catherine Hewitt

ORCID ID
https://orcid.org/0000-0002-0415-3536

Contact details
Department of Health Sciences, University of York, Heslington
York
United Kingdom
YO10 5DD
+44 (0)1904323052
catherine.hewitt@york.ac.uk

Type(s)
Public, Scientific

Contact name
Dr Garima Bhatt

ORCID ID
https://orcid.org/0000-0002-5258-7339

Contact details
Department of Health Sciences, University of York, Heslington
York
United Kingdom
YO10 5DD
+44 (0)1904323052
garima.bhatt@york.ac.uk

Type(s)
Scientific

Contact name
Prof Imran Bashir Chaudhry

Contact details
Suite 201, 2nd Floor, Doctors Plaza, Khayaban-e-Iqbal, Block 9 Clifton
Karachi
Pakistan

75600
+92 (0)2135371084
imran.chaudhry@pill.org.pk

Type(s)
Scientific, Principal investigator

Contact name
Prof Asad Nizami

Contact details
Institute of Psychiatry, Rawalpindi Medical University Institute of Psychiatry, Rawalpindi Medical University Murree Road, Near Chandani Chawk
Rawalpindi
Pakistan
46000
+92 (0)51 5702225
ioprmu@gmail.com

Type(s)
Scientific, Principal investigator

Contact name
Prof Rumana Huque

Contact details
House # 06, Road # 109, Gulshan-2
Dhaka
Bangladesh
1212
+880 (0)255069866
rumanah14@yahoo.com

Type(s)
Scientific

Contact name
Dr Pratima Murthy

ORCID ID
https://orcid.org/0000-0002-7738-9670

Contact details
NIMHANS Hospital
Bengalruru
India
560029
+91 (0)8026995001
pratimamurthy@gmail.com

Additional identifiers

Study information

Scientific Title
Effectiveness of SCIMITAR-SA compared with very brief advice for tobacco cessation among individuals with severe mental illness in South Asia: a multicountry randomised controlled trial

Acronym
SCIMITAR-SA

Study objectives
Among people with Severe Mental Illness (SMI):
1. Is tobacco cessation intervention (SCIMITAR-SA) + Very Brief Advice (VBA) more effective than VBA alone in achieving biochemically-verified continuous abstinence from tobacco at 7 months post-randomisation?
2. Is SCIMITAR-SA + VBA more effective than VBA alone in achieving self-reported continuous abstinence from tobacco at 13 months post-randomisation?
3. Does SCIMITAR-SA +VBA lead to more improvement in physical health, mental health and quality of life than VBA alone at 4, 7 and 13 months post-randomisation?
4. What are the barriers and drivers to the delivery, implementation and potential future scale-up of SCIMITAR-SA?
5. Is SCIMITAR-SA +VBA more cost-effective than VBA alone , and what is its impact on health inequalities?
6. What are the mechanisms of action in achieving tobacco cessation?

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 06/08/2026, Health Sciences Research Governance Committee, University of York (Department of Philosophy Heslington, York, YO10 5DD, United Kingdom; +44 (0)1904 323253 /1; stephen.holland@york.ac.uk), ref: HSRGC/2024/626/E: SCIMITAR-SA

2. Approved 24/08/2026, Ethics Committee (Behavioural Science Division) (NIMHANS Hospital, Bengaluru, 560029, India; +91 (0)80 26995004; deannimhans@yahoo.com), ref: NIMHANS /47thIEC/(BEH.SC.DIV)/2024

3. Approved 13/04/2025, National Research Ethics Committee (NREC), Bangladesh Medical Research Council (BMRC) (BMRC Bhaban, Mohakhali, Dhaka, 1212, Bangladesh; +880 (0)2-222298396; info@bmrcbd.org), ref: BMRC/NREC/2025-2027/128

4. Approved 29/09/2026, National Bioethics Committee for Research (NBC-R) (Health Research Institute, Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad, 44000, Pakistan; +92 (0)519224325; nbcpakistan@nih.org.pk), ref: 4-87/NBCR-1145/24-25/1422

Primary study design
Interventional

Allocation

Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Adult users of tobacco (smoked and/or smokeless) with a confirmed diagnosis of one or more Severe Mental Illness(SMI) including (schizophrenia, schizoaffective disorder, psychosis, bipolar disorder with out without psychosis, or severe depression with/without psychotic features), who are willing to quit all forms of tobacco use within the next 30 days.

Interventions
Randomisation will be conducted on a 1:1 basis using a block stratified sequence, generated by an independent statistician at York Trials Unit (using STATA v19 or later). Stratification will be based on study location and type of tobacco use (smoked tobacco products only, smokeless tobacco products only, or dual use). The randomisation sequence will be implemented using a secure, centralised Google Form–based system developed by the software developers at York Trials Unit. Following completion of baseline assessments, the research assistant (based at trial facility) will submit a randomisation request via a google form where the participant's unique study ID and stratification factors will be specified. Upon submission, the study arm will be allocated to the participant's ID and the RA will be informed of this via an automated email. The underlying allocation sequence will be managed by the software developers at York Trials Unit and not made accessible to any participant facing research staff in order to maintain concealment.

Very Brief Advice (VBA):
All trial participants will receive VBA, delivered by health professionals during outpatient visits in interactions lasting up to 1 minute. It will include a brief conversation on tobacco use status (smoked and/or smokeless), advice to quit and providing a self-help educational leaflet that has been adapted from our previous research.

SCIMITAR-SA intervention:
Participants allocated to the intervention arm will receive SCIMITAR-SA intervention in addition to the VBA. The SCIMITAR-SA intervention is a culturally adapted, patient-centred behavioural tobacco cessation programme designed for individuals with severe mental illness (SMI) in South Asian contexts (Bangladesh, India, and Pakistan). Adapted from SCIMITAR-UK and the NCSCT Standard Treatment Programme, it addresses both smoked and smokeless tobacco use, dual-use patterns, and local cultural norms.

It consists of seven tailored behavioural modules delivered using corresponding patient-facing flipbooks, spanning pre-quit, quit, and post-quit stages. Initial appointments for pre-quit modules are conducted face-to-face, with subsequent sessions offering flexible remote options. Participants target a quit date within 30 days of enrolment, supported by core techniques such as goal setting, relapse prevention, and guidance on accessible Nicotine Replacement Therapy.

Intervention Type
Behavioural

Primary outcome(s)
1. Continuous abstinence from all tobacco products measured using self-reported tobacco abstinence and biochemical verification through salivary cotinine and anabasine levels at 7 month follow up

Key secondary outcome(s)
1. Continuous abstinence from all tobacco products will be measured using self-report, with the relevant information collected by administering a questionnaire to participants at 4, 7 and 13 months post-randomisation. Changes in physical and mental health will be assessed using the SF-12 questionnaire, psychiatric symptom severity using the Brief Psychiatric Rating Scale (BPRS), quality of life using the EQ-5D-5L questionnaire, and anthropometric measures in accordance with the WHO STEPwise approach to Surveillance (STEPS) protocol. These outcome measures will be measured at 4, 7, and 13 months post-randomisation

2. Barriers and drivers to the delivery, implementation and potential future scale-up of SCIMITAR-SA, as well as the mechanisms of action in achieving tobacco cessation, measured using qualitative interviews and focus group discussion (FGDs) at 4 months post-randomisation

3. Cost-effectiveness and impact on health inequalities measured using self-reported health resource use, with the relevant information collected by administering a questionnaire to participants at 4, 7, and 13 months post-randomisation

Completion date
30/04/2028

Eligibility

Key inclusion criteria
Adults aged ≥18 years receiving or referred for outpatient mental health services who:
1. Have a psychiatrist-diagnosed severe mental illness (schizophrenia, schizoaffective disorder, psychosis, bipolar disorder with out without psychosis, or severe depression with/without psychotic features)
2. Have used smoked and/or smokeless tobacco for ≥6 months and on ≥25 of the past 30 days
3. Are clinically stable, able to provide informed consent, and have had no more than a 25% medication dose change or ECT/neuromodulation in the past 3 months
4. Is the only participant from their household
5. Are willing to quit all tobacco within 30 days and can attend at least three counselling sessions. The first sessions of the first three modules must be face-to-face; other sessions may be remote if needed

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
1450

Key exclusion criteria
Individuals who:
1. Have used e-cigarettes, heated tobacco products, or oral nicotine pouches in the past 30 days alongside smoked or smokeless tobacco
2. Have a comorbid substance use disorder (drug or alcohol), personality disorder, eating disorder, autism spectrum disorder, intellectual developmental disorder, or Post-Traumatic Stress Disorder (PTSD)
3. Have received tobacco cessation medication (e.g., bupropion, varenicline), nicotine replacement therapy, or behavioural cessation support other than brief advice in the past 30 days, or are currently taking bupropion for any indication (eg., depression)

Date of first enrolment
01/09/2026

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
Bangladesh

India

Pakistan

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
Bogura
Bangladesh
5800

Study participating centre
Shaheed Ziaur Rahman Medical College Hospital (SZRMCH)
Silimpur
Bogura
Bangladesh
5800

Study participating centre
National Institute of Mental Health and Neurosciences (NIMHANS)
NIMHANS Hospital
Bengaluru
India
560029

Study participating centre
Institute of Psychiatry, Benazir Bhutto Hospital, Rawalpindi Medical University
Institute of Psychiatry, Rawalpindi Medical University Institute of Psychiatry, Rawalpindi Medical University Murree Road, Near Chandani Chowk
Rawalpindi
Pakistan
46000

Study participating centre
Department of Psychiatry, Civil Hospital Karachi, Dow University of Health Sciences
Mission Rd, near Civil Hospital Masjid, New Labour Colony Nanakwara
Karachi
Pakistan
74400

Study participating centre

Karwan-e- Hayat
Near Karachi Port Trust Hospital, East Wharf
Karachi
Pakistan
75620

Study participating centre
Jinnah Postgraduate Medical Centre (JPMC)
Rafiqui, Sarwar Shaheed Rd, Karachi Cantonment
Karachi
Pakistan
75510

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type

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

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the study will be available on request. To protect the scientific integrity of the study, the data will not be shared before the end of the trial for publication or presentation without approval from the Project Management Team and Chief Investigator. A detailed data-sharing plan will be provided at a later stage.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	05/08/2026	24/08/2026	No	Yes
Protocol file	version 1.1	06/08/2026	24/08/2026	No	No
Study website			24/08/2026	No	No