

Comparing different ways to help people stop using smokeless tobacco products in India, Pakistan and Bangladesh

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| Submission date 11/09/2019 | Recruitment status Suspended | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 17/09/2019 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 04/06/2024 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Smokeless tobacco (ST) products are placed in the mouth, chewed or sucked. Unlike cigarettes or pipes, the tobacco is not burned. ST use is linked to a range of harms including cancers, heart disease and poor outcomes in pregnancy. ST use is highly concentrated in South Asia, where about two thirds of the world's ST users live. There are many different tobacco products used in this region, with the tobacco often being mixed with other substances that have their own harmful effects, including betel nuts. These products are often manufactured by shop-keepers and are not regulated in the way that tobacco products in Europe or North America are. There has been little research on what can support ST users to quit. This small-scale study aims to investigate whether it is possible to conduct a larger trial in South Asia, which will explore treatments that can help users of smokeless tobacco to quit.

Who can participate?

Healthy men and women who are daily users of smokeless tobacco products only and not any form of burned tobacco or e-cigarettes. Eligible individuals will be identified at 2-3 selected health facilities each in India, Pakistan and Bangladesh.

What does the study involve?

Once they have agreed to participate, participants will be asked to provide information about themselves, as well as their tobacco use. They will also be asked to provide a spit sample, so that the level of tobacco use can be assessed. They will then be randomly allocated to receive one of the following:

1. Nicotine replacement gum: Participants in this group will receive an 8-week course of nicotine chewing gum, which they will be asked to use from the day they stop using smokeless tobacco.
2. Behavioral support: Participants in this group will receive a series of face-to-face counselling and support sessions with a trained advisor. In the initial sessions, the advisor will work with participants to set a quit date from which they will stop using ST, delivering messages that prepare participants for this attempt. Once they have stopped using ST, participants will meet their advisor on a weekly basis at a scheduled time. Each meeting will last about 15-20 minutes, in which participants will be offered support and encouragement to help them remain tobacco-

free. There will be up to six weekly meetings following the quit date, after which there will be no more contact with the advisor.

3. A combination of face-to-face sessions along with an 8-week course of nicotine-containing gum, meaning that they will receive both of the treatments described in points 1 and 2 above.

4. No treatment: Participants who do not receive either nicotine replacement gum or behavioral support, will receive a brief advice to quit ST from the advisor, along with a leaflet containing information which will help them in planning to quit.

All the enrolled participants will be contacted at 6, 12 and 26 weeks from the date they decide to quit ST use. At each contact, they will be asked to provide information on their tobacco use. At 6 weeks contact, additional questions will be asked about their participation in this trial, which will help in understanding how what worked well, and what can be improved. At 26 weeks, participants will be asked questions about the use of health resources, and their quality of life. If they report no use of tobacco products, participants will also be asked to perform a breath test and provide a spit sample at 12 and 26 weeks contacts, in order to verify that they have remained away from all types of tobacco products. There will be no contact after the 26th week.

What are the possible benefits and risks of participating?

Participants enrolled in this trial are expected to benefit from treatment or support that can help them to quit ST use. There are no particular health risks of participating in this study, as the treatments being tested are safe, and effective measures have been taken to avoid any complications.

Where is the study run from?

The University of York (UK)

When is the study starting and how long is it expected to run for?

Who is funding the study?

The National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Faraz Siddiqui, faraz.siddiqui@york.ac.uk

Study website

<https://www.york.ac.uk/healthsciences/research/public-health/projects/astra/>

Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

RE19/031-000000

Study information

Scientific Title

Addressing Smokeless Tobacco Research and capacity building in South Asia (ASTRA): A randomised, controlled, feasibility trial for smokeless tobacco cessation

Acronym

ASTRA CESSATION

Study objectives

The trial aims to test the feasibility of carrying out a randomized, controlled trial on ST cessation in South Asia. It will answer the following research questions:

1. Delivering the interventions

1.1. What is the feasibility of delivering nicotine replacement therapy (NRT) and behavioral support intervention for smokeless tobacco cessation in adults (BISCA), alone and in combination to ST users?

1.2. How acceptable are NRT and BISCA when delivered alone and in combination to ST users?

1.3. What is the fidelity of delivering NRT and BISCA, alone and in combination?

1.4. Which mechanisms (ST users' cognitions) and contextual factors (social, economic, environmental and political) are likely to influence the impact of BISCA, alone and when combined with NRT?

2. Recruitment, Randomisation and Retention

2.1. What is the feasibility of recruitment and retention of participants in a trial on ST cessation?

2.2. What is the feasibility of retaining/proportion of participants retained in their original study arms following randomisation?

3. Identification of measures for data collection

3.1. What are the characteristics of proposed baseline and follow-up variables?

3.2. What are the characteristics of proposed outcome measures (self-reported and validated abstinence measures for ST) at 6, 12 and 26 weeks?

3.3. What are the logistics of obtaining and analysing samples for biochemical validation (salivary cotinine) in trial participants?

3.4. What are the appropriate measures to collect information on health resource use and quality of life for an economic evaluation?

3.5. What are the appropriate implementation variables to conduct a process evaluation in a ST cessation trial?

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Trial protocol (v1.1) approved 05/10/2018, Health Sciences Research Governance Committee, University of York (Department of Health Sciences, c/o Department of Philosophy, Heslington, York, YO10 5DD; +44 (0)1904 323253; smh12@york.ac.uk), no reference number

2. Protocol amendment (v1.2) approved 22/08/2019, Health Sciences Research Governance Committee, University of York (Department of Health Sciences, c/o Department of Philosophy, Heslington, York, YO10 5DD; +44 (0)1904 323253; smh12@york.ac.uk), no reference number
3. Approved 26/04/2019, Aga Khan University Ethics Review Committee (Stadium Road, P. O. Box 3500 Karachi 74800, Pakistan; Rehana.Siddiqui@aku.edu), ref: 2019-1114-3494
4. Approved 26/10/2018, Institutional Ethics Committee, National Institute of Cancer Prevention and Research (I-7, Sector-39, Noida 201301, Uttar Pradesh, India; +91 0120 2446900; ravi.mehrotra.gov.in), ref: NICPR/116/DIR/Ethical/2018/02
5. Approved 03/01/2019, National Research Ethics Committee, Bangladesh Medical Research Council (BMRC Bhaban, Mohakhali, Dhaka-1212, Bangladesh; +88 02 9848396; info@bmrcbd.org), ref: BMRC/NREC/2016-2019/961
6. Approved 13/03/2019, Health Ministry's Screening Committee, Indian Council of Medical Research (V. Ramalingaswami Bhawan, P.O. Box No. 4911, Ansari Nagar, New Delhi - 110029, India; +91-11-26588895; icmr@cdac.in), ref: 2018-2675
7. Approved 28/02/2019, National Bioethics Committee Pakistan, Pakistan Health Research Council, Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad, Pakistan; +92-51/9224325; nbcpakistan.org@gmail.com), ref: 4-87/NBC-355/19/1695

Study design

Multi-country factorial-design feasibility trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Smokeless tobacco use

Interventions

This is a multi-country, factorial design, feasibility trial of nicotine replacement and behavioral support. Once they have agreed to participate, participants will be asked to provide information about themselves, as well as their tobacco use. They will also be asked to provide a saliva sample, so that the level of nicotine by-products in their body can be assessed. They will then be randomly allocated to receive one of four interventions. Participants in intervention arms 2, 3 and 4 will receive either or both of the interventions; those who do not receive an active intervention (arm 1) will receive very brief advice (VBA) along with a self-help leaflet for stopping smokeless tobacco use. The trial will be unblinded, and assignment to intervention arms will be through random allocation using an equal allocation.

The interventions include:

Treatment A: Nicotine replacement therapy (NRT) in the form of Nicorette nicotine chewing gum. Participants will receive either a 4-mg or 6-mg dose of nicotine gum, depending on the heaviness of their smokeless tobacco (ST) use (i.e time to first use, number of times ST is used in a day). The nicotine gum will be used from the participant's quit date over a period of 8 weeks. Participants will be instructed to use nicotine replacement on an hourly basis, using no more than 15 gums per day. The first dose will be taken in the morning, within 1 hour of waking up. Participants will be given written instructions on how to use the gum.

Treatment B: Behavioral support Intervention for Smokeless tobacco Cessation in Adults (BISCA): this will be delivered face to face by trained cessation advisors, and will include prequit, quit and post-quit sessions. The first session will be delivered at the health facility, where participants will be recruited, with further sessions to be delivered at participants' homes. Participants in this group will receive a series of face-to-face counselling and support sessions with a trained advisor. In the initial sessions, the advisor will work with participants to set a quit date from which they will stop using ST, delivering messages that prepare participants for this attempt. Once they have stopped using ST, participants will meet their advisor on a weekly basis at a scheduled time. Each meeting will last about 15-20 min, in which participants will be offered support and encouragement to help them remain quit. There will be up to six weekly meetings following the quit date, after which there will be no more contact with the advisor.

The above treatments will be provided either alone (Trial arm 2 - NRT, Trial arm 3 - BISCA) or in combination (Trial arm 4 - BISCA + NRT). In Trial arm 1 (no active intervention), participants will receive a 1-min very brief advice on smokeless tobacco cessation from the advisors, along with a one-page self-help leaflet on quit planning.

All the enrolled participants will be contacted at 6, 12 and 26 weeks from the date they decide to quit ST use. At each contact, they will be asked to provide information on their tobacco use. At 6 weeks contact, additional questions will be asked about their participation in this trial, which will help in understanding how what worked well, and what can be improved. At 26 weeks, participants will be asked questions about the use of health resources, and their quality of life. If they report no use of tobacco products, participants will also be asked to perform a breath test and provide a saliva sample at 12 and 26 weeks contacts, in order to verify that they have remained away from all types of tobacco products. There will be no contact after the 26th week.

Intervention Type

Mixed

Primary outcome measure

1. Self-reported continuous abstinence to all forms of tobacco (smoked and smokeless) at 26 weeks after the quit date, verified by carbon monoxide breath test and salivary cotinine assessment. Participants will be asked a set of questions (one for each type of tobacco product) asking: "have you used this product at all since your quit date?" The possible responses are: no, not even once; yes, 1- 5 times; yes, >5 times. Participants who report consuming tobacco <5 times since quit date, as well as having CO levels that are consistent with abstinence, will be considered as abstinent.

2. Feasibility of conducting a full trial on smokeless tobacco cessation, particularly the feasibility of delivering the intervention, recruitment, randomisation and retention, as well as measures for data collection in a full trial, will be demonstrated through analysis of trial data, as well as preliminary process evaluation and economic assessments

Secondary outcome measures

Point abstinence to all forms of tobacco (smoked and smokeless) at 6 and 12 weeks following quit date. Participants will be asked about their tobacco use (all forms) in the past 7 days. Those who report not to have used any tobacco product in the past 7 days will be labelled as abstinent, while those who have used any tobacco product >5 times will be labelled as non-abstinent.

Overall study start date

01/10/2017

Completion date

31/12/2021

Eligibility

Key inclusion criteria

1. Self-reported daily user of ST products at least for the last 6 months or ST use on >25 days in the past month
2. Aged >18 years at the time of recruitment
3. Able to provide informed consent
4. Motivated and willing to quit ST use within the next 30 days.

Participant type(s)

All

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

A total of 264 participants (88 per country) will be enrolled in the trial.

Total final enrolment

264

Key exclusion criteria

1. Self-reported users of any combustible tobacco product (cigarettes, bidis, hookah) or e-cigarettes in the past 30 days or those having carbon monoxide (CO) levels >10 ppm, identified by breath test
2. Pregnant or breastfeeding women
3. Individuals with health conditions that warrant caution in using NRT and have previously been excluded in trials of nicotine replacement in smoking. These will be assessed by participant self-report at the pre-trial screening by asking participants whether they have suffered angina pectoris, myocardial infarction or stroke in the past 3 weeks.
4. Individuals who are already on an existing treatment, either pharmacological or behavioral, for tobacco cessation

5. ST-using individuals with diagnosis of oral cancer. Due to the nature of care required, any such individuals identified during the recruitment process will receive a direct referral to specialist care for treatment.

Date of first enrolment

01/10/2019

Date of final enrolment

30/09/2020

Locations

Countries of recruitment

Bangladesh

India

Pakistan

Study participating centre

ARK foundation

Suite C-3 & C-4

House #06

Road #109

Gulshan-2

Dhaka

Bangladesh

Dhaka-1212

Study participating centre

Aga Khan University

Stadium Road

P. O. Box 3500

Karachi

Pakistan

74800

Study participating centre

National Institute of Cancer Prevention and Research

I-7, Sector 39

NOIDA

Distt. Gautam Buddha Nagar

Uttar Pradesh

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Uttar Pradesh – 201 301

Sponsor information

Organisation

University of York

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Sponsor type

University/education

Website

<https://www.york.ac.uk/>

ROR

<https://ror.org/04m01e293>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health 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 proposed trial will report the overall feasibility and acceptability of conducting a cessation trial for ST users in South Asia and will lay the groundwork for a definitive trial in the future. The feasibility trial will not generate evidence on the effectiveness or cost-effectiveness of proposed interventions, however we anticipate that dissemination of information will still benefit both academic and non-academic audiences. To effectively disseminate our results, we will use the following strategies:

1. Academic audiences

These will include members of the scientific community including:

1.1. Behavioral researchers working in tobacco control and addiction, particularly in relevant LMICs.

1.2. Clinician and public health researchers with an interest in tobacco cessation

1.3. Health economists working in tobacco control and LMICs.

1.4. Graduate and post-graduate researchers and academics interested in behaviour change, tobacco control and public health, particularly in LMICs.

We will engage with the above listed academic audience through scientific presentations at national and international conferences and seminars on tobacco, oral health, cancer and non-communicable diseases (NCDs), publication of the trial protocol and feasibility trial findings in an open access, peer-reviewed scientific journal and highlighting our work on the electronic platforms, including websites and social media platforms, associated with the University of York and partner institutions.

2. Non-academic audiences

A wider stakeholder group comprising national and regional level policy makers, tobacco control advocates, non-governmental organisations (NGOs) and physicians will be established at the trial development stage. In addition, non-academic audiences will also include: Research participants, their family members and community stakeholders (community residents, local administrative figures, health workers working in primary care or tobacco control in the respective communities) that constitute a broader stakeholder group (which also includes national and regional level policy makers, tobacco control advocates, non-governmental organisations and physicians) for whom the following dissemination plans have been outlined:

2.1. Research participants, their family members and members of the community will be invited to a dissemination workshop at the end of the study, which will highlight and share key findings and results.

2.2. Wider dissemination to audiences beyond our study sites will be aimed through: Electronic, print and social media, dissemination through charitable groups and on annual activities such as the World No Tobacco day and World Cancer Day, seminars and lecture sessions for undergraduate and graduate students, and technical reports and policy briefs for stakeholders which include governmental and non-governmental bodies.

Intention to publish date

31/03/2022

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|---------|--------------|------------|----------------|-----------------|
| Protocol article | | 22/08/2022 | 23/08/2022 | Yes | No |
| Results article | | 20/05/2024 | 04/06/2024 | Yes | No |