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

Submission date
11/09/2019

Recruitment status
Suspended

Registration date
17/09/2019

Overall study status
Completed

Last Edited
04/06/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Multi-country factorial-design feasibility trial

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
Point abstinence to all forms of tobacco (smoked and smokeless) at 6 and 12 weeks following quit date. Participants will be asked about the 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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
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Bangladesh
Dhaka-1212

Study participating centre
Aga Khan University
Stadium Road
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Study participating centre
National Institute of Cancer Prevention and Research
I–7, Sector 39
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Sponsor information

Organisation
University of York

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

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?
Results article		20/05/2024	04/06/2024	Yes	No
Protocol article		22/08/2022	23/08/2022	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes