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Feasibility of providing support to stop the use of smokeless tobacco through dentists in Pakistan

Submission date 30/10/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/01/2022	**Overall study status** Completed	
Last Edited 22/04/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims

Tobacco use is the single most preventable cause of premature death and disability. The use of smokeless tobacco (ST) alone accounts for 9% of all deaths attributable to tobacco use. The use of ST in Pakistan has deep-rooted cultural and traditional ties. 'Pan'-largely considered as an occasional delicacy -is often a part of the festive celebrations and is consumed by young and old, women and men, alike. Whereas, 'naswar'-the most popular ST product in Pakistan- packed in transparent polyethylene bags without any health warning- is sold to minors openly across Khyber Pakhtunkhwa (KPK), Pakistan.

While many tobacco users wish to quit, majority fail to do so. Dependence on tobacco makes it challenging to quit and support for cessation is often minimal in most countries. Behavioural support for tobacco cessation is a cost effective intervention which typically involves offering advice to quit tobacco use, providing information on how to quit, or a combination of both. Research suggests that behavioural support for tobacco cessation offered by healthcare workers (HCWs)-whether it is in the form of brief advice to stop tobacco use or more intensive behavioural support to quit-is effective in helping users quit. Dentists have a role to play in identifying any changes in the oral cavity caused by the use of smokeless tobacco. Dentists can play a very important role in helping their patients quit the use of tobacco. While dentists help their patients quit the use of ST in some countries, it is not known how this will work for Pakistan. This study aims to find out how feasible it is for dentists to help their patients quit the use of ST by offering a behavior support intervention during their routine clinical practice.

Who can participate?

Dental patients, aged 18 years and above, who use smokeless tobacco and are visiting the two study sites for a periodontal or prosthodontics treatment.

What does the study involve?

This study is looking at dental patients who use smokeless tobacco (ST). The main purpose of the study is to see how feasible it is to provide quit support to smokeless tobacco users via dentists in Pakistan.

The study will involve three steps. In the first step interviews will be conducted with dental

patients and dentists to get their views about the intervention (behavior support to quit tobacco). In light of the findings of these interviews changes will be made to the intervention so that it is suitable to be delivered to dental patients by dentists during routine clinical practice. In Step 2 of this study, the intervention will be delivered via dentists to dental patients who use smokeless tobacco. Participants will be randomly allocated to one of the two groups. The first group will receive the intervention from their dentist. This intervention will involve face to face counselling delivered in three visits. The 2nd group will receive self-help material to quit ST use. All participants will receive the dental treatment for which they are visiting the hospital. All participants will be followed up telepathically at 3 and 6 months to assess quit rates and ST use. Quit rates at 6 months will be validated by cotinine testing of saliva samples at 6 months. Finally interviews will be conducted with some of the trial participants and dentists who delivered the intervention to explore their opinions, views and experiences about the trial and intervention.

What are the possible benefits and risks of participating?
Participants will benefit from the quit support offered to them whether it is face to face counselling or from the self-help material. This will hopefully help reduce ST use which will prove beneficial for general and oral health. There are no known risks involved with participating.

Where is the study from?
University of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
October 2020 to October 2022

Who is funding the study?
Khyber Medical University (Pakistan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
AC21068

Study information

Scientific Title
Behavior change intervention for smokeless tobacco (ST) cessation delivered through dentists within a dental setting: a pilot feasibility study

Study objectives
The aim of this study is to assess the feasibility and acceptability of delivering a behavioral support intervention for smokeless tobacco cessation via dentists within the existing dental settings in Pakistan.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/09/2021, Edinburgh Medical School Research Ethics Committee (EMREC, Queen's Medical Research Institute, University of Edinburgh, 47 Little France Crescent, Edinburgh, EH16 4TJ, UK; no telephone number provided; emrec@ed.ac.uk), ref: 21-EMREC-024

Primary study design
Interventional

Study design
Multi-center randomized controlled pilot study

Study type(s)
Other

Health condition(s) or problem(s) studied
Smokeless tobacco cessation in dental patients

Interventions

Step 1: BISCA- (Behavioral support Intervention for Smokeless Tobacco Cessation in South Asians) is a behavioral support intervention for smokeless tobacco(ST) cessation. This study aims to deliver BISCA via dentist during routine clinical practice in a pilot, randomized controlled trial. Before the trial, interviews will be undertaken with dental patients who are ST users and dentists working at the study sites. The purpose of this qualitative work is to adapt BISCA to meet the needs and cultural context of dental patients in Khyber Pakhtunkhwa, Pakistan, to identify the issues influencing dentist's behavior of offering quit support to their patients and to inform the trial design.

Step 2: Pilot Randomized controlled trial.
Following assessment of eligibility, completion of informed consent, and collection of baseline data, the participants (dental patients) will be randomized to one of two groups. Participants will be randomly assigned to the control or intervention arm in a 1:1 allocation ratio according to the randomization schedule generated by STATA using permuted blocks of random sizes. The randomization code will be contained in a sealed opaque envelope, each bearing on the outside the name of the study site and a unique number for each participant.

Control group: Participants will receive self-help quit material from their dentist.

Intervention group: Participants in the intervention group will receive the behavioral support intervention for smokeless tobacco cessation. This will be delivered by their dentist in three sessions.
For all participants, follow up will involve routine dental treatment delivered over several appointments as deemed appropriate by the dentist treating the participant. Additionally all participants will be followed up at 3 and 6 months telepathically to ascertain ST use/quit status.

Step 3: A sample of the participants will be asked to attend 1 additional visit for qualitative interviews about their experiences in the study. Additionally the dentists involved in delivering the intervention will also be interviewed to share their opinion about the intervention.

Intervention Type

Behavioural

Primary outcome(s)

1. Eligibility rate: will be assessed from the screening record at the end of recruitment.
2. Patients willingness to participate in the trial: Will be assessed from the screening record at the end of the trial.
3. Dentists' willingness to participate in the trial: Will be measured by counting the number of dentists consenting to participate versus the number of eligible dentists working in the selected wards at the study sites.
4. Recruitment rate: Will measured by counting the number of participants who have consented to participate in the study out of the total eligible participants.
5. Retention rate: Will be measured by counting the number of participants who remained in the study at end of 6 month follow up after the trial.
6. Randomized group contamination rates (i.e. the extent of cross-over between the two arms of the trial) will be established by audio recording the sessions delivered by the dentists (both of the arms)
7. Self-reported ST use (Use of ST and frequency of ST use per day), will be assessed for all patients.
8. Tobacco dependence scores(mean +/- SD) will be estimated using Fagerström test for

nicotine dependence for smokeless tobacco(FTND-ST)& Oklahoma Scale for Smokeless Tobacco Dependence (OSSTD)
9. Participants adherence to the intervention will be measured by estimating the completion rates of the self-help calendars.
10. Fidelity to the intervention: Will be assessed by audio recording of the sessions. Fidelity index for the intervention already exists which consists of 29-items. Of these 22 items (representing the intervention components) are included in the 'adherence index' whereas seven items (assessing the competence with which the intervention is delivered)- are included in the 'quality index'.
11. Self-reported quit rates will be measured at 3 and 6 month telephonic follow up after the trial.
12. Biochemical verification of quit rates will be done at 6 months following trial completion.
13. Acceptability of the dentists and issues with delivering the intervention will be assessed through qualitative interviews after trial completion.
14. Acceptability and experiences of the dental patients regarding the intervention and trial will be assessed through qualitative interviews.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
01/10/2022

Eligibility

Key inclusion criteria
1. Aged 18 years and above.
2. Regular smokeless tobacco users (regular use=at least once in 7 days for 6 months or more).
3. Those residing in the catchment area of the study sites.
4. Willingness to visit the study site multiple times.
5. Willing and able to provide written informed consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Currently accessing cessation support.
2. Less than 18 years old.
3. Those residing out of the catchment area of the study sites.
4. Unwilling or unable to provide written informed consent.

Date of first enrolment
25/01/2022

Date of final enrolment
02/03/2022

Locations

Countries of recruitment
Pakistan

Study participating centre
Khyber College of Dentistry
near IRNUM Hospital
University of Peshawar
University Rd
Peshawar
Pakistan
25000

Study participating centre
Sardar Begum Dental College
Canal Road
Academy Town
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Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
University/education

Funder Name
Khyber Medical University, Pakistan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/12/2023	16/02/2024	Yes	No
Protocol article		21/04/2022	22/04/2026	Yes	No
Other publications		16/05/2024	22/04/2026	Yes	No