STUDY PROTOCOL

Assessing the impact of tobacco control policies on smokeless tobacco uptake and use among secondary school students in South Asia: protocol for a feasibility study of conducting longitudinal surveys [version 1; peer review: 2 approved with reservations]

Masuma Pervin Mishu[1], Kamran Siddiqi[1], Ann McNeill[2], Mona Kanaan[1], Cath Jackson[1], Rumana Huque[3,4], Sushama Kanan[3], S.M. Abdullah[3,4], Fariza Fieroze[3], Suneela Garg[5], M. Meghachandra Singh[5], Amod L. Borle[5], Chetana Deshmukh[5], Zohaib Akhter[6], Laraib Mazhar[6], Zohaib Khan[7], Khalid Rehman[7], Safat Ullah[7], Lu Han[1], Anne Readshaw[1], Romaina Iqbal[6]

[1]Department of Health Sciences, The University of York, Heslington, Yorkshire, YO10 5DD, UK
[2]National Addiction Centre, Institute of Psychiatry, Psychology & Neuroscience (IoPPN), King's College London, London, SE5 8BB, UK
[3]ARK Foundation, Gulshan - 2, Dhaka, 1212, Bangladesh
[4]Department of Economics, University of Dhaka, Dhaka, 1000, Bangladesh
[5]Department of Community Medicine, Maulana Azad Medical College, New Delhi, 110002, India
[6]Departments of Community Health Sciences and Medicine, Aga Khan University, Karachi, 74800, Pakistan
[7]Institute of Public Health & Social Sciences, Khyber Medical University, Peshawar, Khyber Pakhtunkhwa, 25100, Pakistan

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Abstract

Background: Smokeless tobacco (ST) use is common among youth in South Asia where 85% of the world's 300 million ST users live and use the most lethal ST forms. Little is known about the impact of tobacco control policies on the youth ST uptake in those countries. We planned to conduct longitudinal surveys among secondary school students to evaluate existing tobacco control policies on ST uptake and use, and a feasibility study for that prospective, observational cohort study.
Study objectives: (1) To demonstrate the feasibility of selection, recruitment and retention of schools and of study participants; (2) To assess the feasibility and acceptability of the study procedure and study tool (questionnaire); (3) To assess if the questionnaire can assess tobacco uptake and use, and the potential predictors of tobacco uptake and use of the envisaged main study.
Methods and analysis: The feasibility study will be conducted in two administrative areas within each of three South Asian countries:

Open Peer Review

Approval Status ✓ ✓

	1	2
version 2 (revision) 01 Mar 2022	✓ view	✓ view
version 1 11 Sep 2020	? view	? view

1. **Praveen Jodalli**, Yenepoya Dental College, Mangalore, India

2. **Wahyu Septiono**, Universitas Indonesia, Jakarta, Indonesia

Bangladesh, India and Pakistan. We will use both quantitative and qualitative data collection methods. Eight eligible secondary schools will be randomly selected within purposively selected sub-districts from each country. We plan to conduct one baseline and one follow up survey among secondary school students, one year apart. At each time point, data on tobacco uptake and the potential predictors will be collected from students via self-administered questionnaires. The qualitative component will be embedded into the study with each round of data collection to assess the acceptability of the study instrument (questionnaire) and data collection methods, via focus group discussions with students and semi-structured interviews with schoolteachers.
Recruitment and retention rates, completeness of the questionnaires, frequencies and associations of tobacco use and explanatory variables will be reported. Data gathered from the focus group and interviews will be analysed using the framework approach.

Keywords
Smokeless tobacco, secondary school students, adolescents, feasibility, longitudinal study

This article is included in the Health Services gateway.

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Any reports and responses or comments on the article can be found at the end of the article.

Corresponding author: Romaina Iqbal (romaina.iqbal@aku.edu)

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Introduction

Use of different types of tobacco products, both smoking and smokeless tobacco (ST), is a complex public health challenge for many countries (United States National Cancer Institute, 2016). ST use poses complex problems, because its characteristics, patterns of use, health effects, production practices, and policy responses vary widely between countries and regions. In total, 85% of the world's 300 million ST users live in South Asia and use the most lethal ST forms, which contain high levels of carcinogens, notably tobacco-specific nitrosamines (Stanfill *et al.,* 2011). The use of these forms of ST leads to head and neck cancers and increases the risk of cardiovascular deaths (Sinha *et al.,* 2016; Vidyasagaran *et al.,* 2016). Over 650,000 deaths per year, due to all causes, could be attributed to ST use worldwide; with 88% of this burden borne in South-Asia alone (Sinha *et al.,* 2018). Despite the huge burden on health and the economy, ST remains largely neglected by policy makers and researchers, particularly in low and middle-income countries (LMICs). ST control has received less attention than smoking control and ST policies are poorly developed and have not been supported by high-quality research (Siddiqi *et al.,* 2017). Compared to smoking, there is a huge policy implementation gap for ST (Mehrotra *et al.,* 2019). The evidence for Framework Convention on Tobacco Control (FCTC) measures is mostly derived from cigarettes and the experiences in high-income countries. Little is known about their transferability to ST use in LMICs. Furthermore, most South Asian institutions do not have enough researchers or funds to carry out high-quality research in this area. Bangladesh, India, and Pakistan are three LMICs in South Asia where smoking and ST use have become an increasingly prevalent problem (Islam *et al.,* 2014). Despite being signatories of the World Health Organisation (WHO) FCTC, these countries have made little progress towards tobacco control policies, in particular for ST (Mamudu *et al.,* 2016; U.S. National Cancer Institute, 2016). For youth, the issue is even more complex as policies that work for the adult population might not be effective (Crawford *et al.*, 2002). There is a need to develop a wider evidence-based response to FCTC for ST, particularly for youth in these countries.

A study assessing tobacco use among adolescents aged 12–15 years in 68 LMICs showed that mean prevalence of current tobacco use was 13.6%. About 10% of adolescents were cigarette smokers, while 8.1% were users of non-cigarette products that included ST (Xi *et al.,* 2016). According to the recent Global Youth Tobacco Survey (GYTS), 4.5%, 9.0% and 5.3% of students were current ST users in Bangladesh (GYTS Bangladesh, 2013), India (GYTS India, 2009) and in Pakistan (GYTS Pakistan, 2013), respectively. Since most adult tobacco users start ST use in adolescence, young people are targeted by the tobacco industry (Wen *et al.,* 2005) and ST manufacturers (Connolly, 1995; Tobacco Free Initiative & WHO, 2002). Thus, it is important to prevent the initiation of ST in adolescents, which would protect against the health risks of ST use in adult life. The WHO FCTC provides specific legislative measures to inhibit tobacco access and use by youth, increase awareness of the harm caused by tobacco and prevent the promotion of tobacco through sponsorship and advertisements (WHO, 2003). Nonetheless, little is known about the impact of such tobacco policies on tobacco uptake and use among youth, due to lack of testing of effectiveness of policies in these countries. Within the current surveillance system, due to the cross-sectional design of the GYTS survey, it was only possible to look at the prevalence and associations but not a true evaluation of impact of the tobacco control policy. Moreover, questionnaires used in the GYTS ask specific questions for smoking but do not include similar questions on ST (sale, ST exposure outside the home and/or public places, health warnings on ST pack). Therefore, there is a gap of comprehensive assessment of ST.

We plan to conduct longitudinal surveys among secondary school students (year 6, 7 and 8 students), to test the impact of existing tobacco control policies. We will focus specifically on price and taxation policies, packaging and labelling policies for ST products, raising public awareness of tobacco-related harms, banning tobacco advertisement, promotion and sponsorship of tobacco, and policies banning tobacco sales to minors. The main aim of the study will be to test awareness of and exposure to policies and to assess their impact on ST use among adolescents over time compared to smoking. We have developed a comprehensive questionnaire that will cover both cigarette and ST use, and awareness and exposure to various tobacco control policies.

Feasibility studies are carried out before the main studies in order to test the processes involved (such as recruitment and retention of study participants and procedures for data collection) and estimate important parameters that are needed to design the main study (Arain *et al.,* 2010). Most longitudinal studies have been carried out on smoking and very few of those included ST use. As very limited longitudinal studies have been conducted on high school students in Bangladesh, India and Pakistan to evaluate tobacco control policies particularly focusing on ST uptake, therefore, it is important to conduct a feasibility study before the envisaged longitudinal study.

Study aim and objectives

Aim

To assess the feasibility of conducting longitudinal surveys among secondary school students in Bangladesh, India and Pakistan to evaluate existing tobacco control policies on ST uptake and use among this group.

Objectives

1. To demonstrate the feasibility of selection, recruitment and retention of schools and of study participants.

2. To assess the feasibility and acceptability of the study procedure and study tool (questionnaire).

3. To assess if the questionnaire can assess tobacco uptake and use, and the potential predictors of tobacco uptake and use to be assessed in the envisaged main study.

Methods

We aimed to conduct a feasibility study of a longitudinal survey in secondary schools in three South Asian countries, Bangladesh, India and Pakistan, involving both quantitative and qualitative

data collection. In this section the processes that have already been conducted are described in past tense, and those still to do are described in the future tense. The schools and students have been recruited and baseline data were collected between October 2019 and February 2020 and the data entry is still going on. We will revise the data collection tools in the light of feedback from the baseline data collection before carrying out follow-up data collection one year after the baseline data collection. We will revise the follow-up questionnaire if needed, based on the follow-up data collection experience.

Sampling strategy

We used a multi-stage stratified random sampling strategy to recruit eight schools within each country. We purposively selected two administrative areas in each country, and from each administrative area, we selected one urban and one rural sub-district. From each selected sub-district, we selected schools that met the inclusion/exclusion criteria (Table 1) and then stratified the schools by whether they were public or private and randomly selected one public and one private school from each sub district.

An invitation letter including brief information about the study was sent to the head teacher of each selected school taking part in the study. Interested schools were provided with a detailed information sheet and consent form. Those schools that provided written informed consent were recruited.

Selecting the sample and recruitment

There are two groups of study participants: secondary school students and school staff – headteacher or a representative of the school and class teachers.

In each selected school, three classes (class 6th, 7th and 8th) were selected. We aimed to recruit at least 25 students per class (at least 75 students from each school). As this was a feasibility study, we did not conduct a sample size calculation because we did not want to test any hypothesis. The steps taken to recruit eligible students are shown in Figure 1. First, we prepared a list of eligible students who met the inclusion criteria (Table 1) and excluded those that fell into the exclusion criteria list. Once an eligibility list was prepared by the field investigators with the help of the class teachers, we gave the schools the required number of information packs containing an information sheet, and a parent/carer consent form to proceed with the recruitment. All students participating in this study were under 16 years old and therefore parental/carer consent was required for them to take part. The participating schools sent out the study information packs to the parents of all eligible students.

We asked parents/carers to discuss the study with their child and to indicate whether they were willing to let their child participate by sending back the signed consent form through the class teacher within one week. At the time of recruitment, children whose parents had provided consent were provided with an information sheet and an assent form so they could make an informed decision whether or not to participate. If students were unwilling, they could inform their class teacher. They were not coerced to consent. Students were asked to sign the assent form if they were willing to participate in the study. All participating students were given an enrolment number (including a code for school), which were recorded on the final list of eligible students and entered in the database.

For the qualitative student component, we used purposive and random sampling to select four schools (two urban, two rural). The intention was to conduct three focus group discussions (FGDs) per school, one per class (6th, 7th and 8th), with a mix of boys and girls. Students were randomly selected, having previously secured parental consent. Verbal assent was obtained from the selected students before the FGD commenced.

The headteacher or another nominated representative and the class teachers in all eight schools were approached to participate in a semi-structured interview. They were provided with an information sheet and asked to sign a consent form before the interview commenced. Where possible the class teachers were interviewed together to prompt discussion.

Outcomes to be measured

To address the objectives of the feasibility study, we will assess the following outcomes that have quantitative and qualitative components (Table 2).

Table 1. Inclusion and exclusion criteria of selection of schools and students.

	Schools	Students
Inclusion criteria	• Follow mainstream curricula approved by the educational authorities. • Secondary schools that have year-six, seven, eight, nine and ten classes.	• Students of year 6-8 from the selected schools, who have the ability to give assent.
Exclusion criteria	• Have only primary school classes. • Teach in English medium only rather than national language. • Have already received training on a smoke-free intervention (or any other tobacco control intervention) from any previous project. • Religious or faith-based schools not following the prescribed curricula.	• Physical or mental disabilities • Learning difficulties and/or special learning-needs • Behavioral problems and/or conduct disorder • Serious medical condition which is either life-threatening or requires regular hospitalization

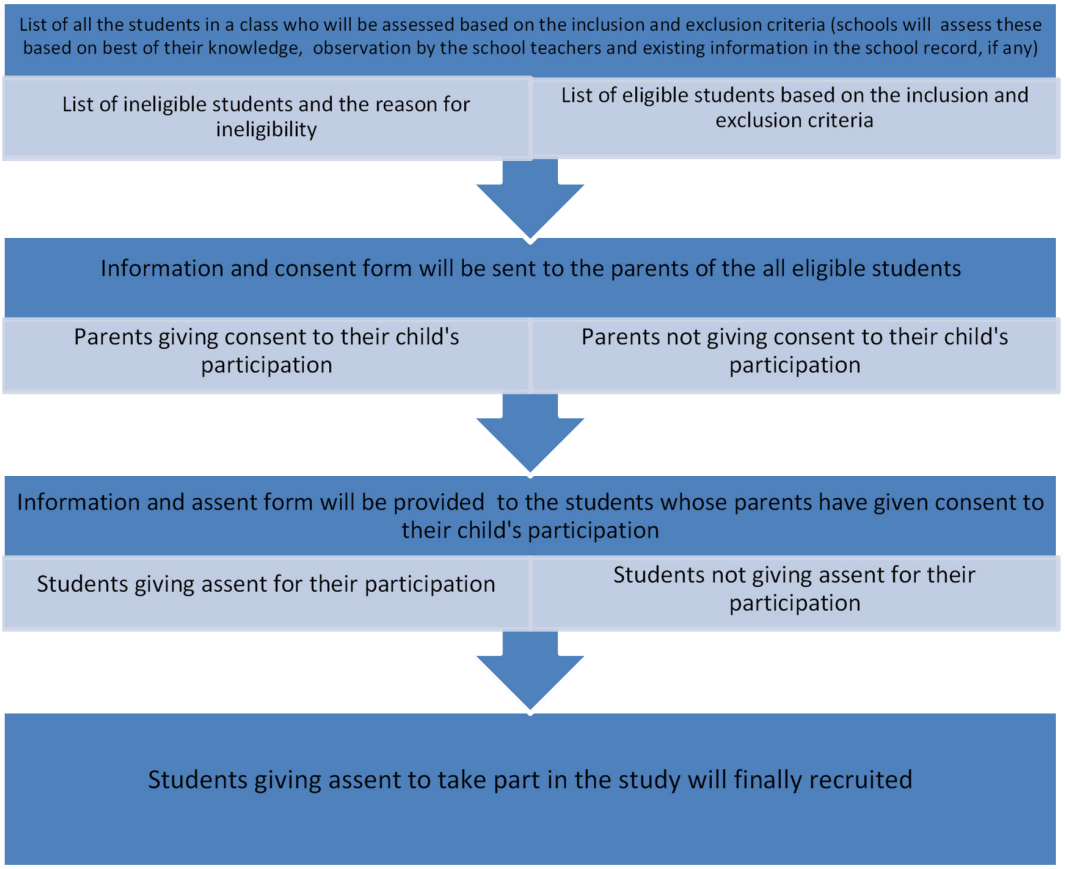

Figure 1. Stages of recruitment of the students.

Table 2. Objective and outcomes.

Study objectives	Study outcomes (quantitative)	Study outcomes (qualitative)
Demonstrate the feasibility of selection and recruitment of schools and study participants	a. Time required to recruit schools and students. b. Recruitment rates for schools and students. c. Attrition rates at the various follow-up points for schools and students d. Reasons for ineligibility of schools and students. e. Reasons for non-participation of schools and students.	
Demonstrate the feasibility and acceptability of study procedure and tool (questionnaire).	The rate of completed survey questionnaires.	Student, head teacher and class teachers' feedback on feasibility and acceptability of the study procedure and tool (questionnaire).
Assess if the questionnaire is able to measure tobacco uptake and potential explanatory variables of the envisaged main study.	The proportion completing the questions on tobacco uptake and use and potential predictor of the envisaged main study.	The students' feedback on their tobacco behaviour and perception.

Main outcomes (related to objective 1)
Quantitative:

a. Time required to recruit schools and students.

b. Recruitment rates for schools and students.

c. Attrition rates at the first follow-up point for schools and students.

d. Reasons for ineligibility of schools and students.

e. Reasons for non-participation of schools and students.

Secondary outcomes (related to objective 2)
Quantitative: The proportion of completed survey questionnaires.

Qualitative: Student, headteacher and class teacher feedback on feasibility and acceptability of the study procedure and tool (questionnaire).

Secondary outcomes (related to objective 3)
Quantitative: The proportion completing the questions on tobacco uptake and use and potential predictors of the envisaged main study, such as: level of knowledge and awareness on tobacco products and perceived tobacco use norms of the students, exposure to tobacco products, tobacco related health promotion, exposure to tobacco advertisements, perceived ease of access, affordability, and self-reported exposure to other peoples' tobacco use.

Qualitative: Student feedback on their tobacco behaviour and perception.

Data collection methods

Collection of data from the students
Quantitative data: A self-administered questionnaire for the students was developed and translated into local language and checked by a native speaker. The questionnaire included questions from the Global Youth Tobacco Survey (GYTS), Youth Tobacco Policy Survey (YTPS) and International Tobacco Control (ITC) survey questionnaire, and was pre-tested among 8–10 students per country before the baseline data collection. All data collection took place in the classroom. The investigator team visited the school and the pre-tested questionnaire was distributed among the students by the investigating team to all the eligible consenting students present in class. Those who were ineligible or did not give consent were moved to another classroom during data collection. The investigator team members helped the students with any further clarification. The privacy of students answering was ensured without others (teachers, classmates) overlooking their responses by giving prior instruction. The schoolteachers were not involved in questionnaire administration.

Qualitative data: After baseline data collection, the FGDs with students explored their views and experiences of being informed about the study, discussing the study with their parents, providing assent, and completing the questionnaire. After the follow-up data collection, the FGDs focused on students' own and others' tobacco uptake and use, influences on this. Topic guides were used to ensure consistency of discussion across schools, although the format was flexible to allow the students to raise additional issues they considered important. The discussions were conducted at the school in a private room by a field investigator and were digitally audio-recorded. Verbal assent was obtained from the selected students before their participation and recording.

Collection of data from the headteacher or other school representative and class teachers. After baseline data collection, interviews with head teachers/other school representatives explored their views and experiences of hosting this study in the school. They also provided quantitative data at this time, on general information about the school, e.g. size, number of classes, the school tobacco policy and tobacco selling regulations. The interviews with class teachers focused on the process of informing parents and students about the study, organising consent, assent and survey administration. The field investigators conducted all interviews, which were digitally audio-recorded.

In addition, a logbook was maintained by each country throughout the process to record the time required to recruit schools and students, reasons for ineligibility of schools and students, and reasons for non-participation of schools and students.

Data analysis

Quantitative data. We will report recruitment, retention and attrition rates, percentage of completed questionnaires, missing data and summarised follow-up time. We will provide a diagram of flow of participants at baseline and at first follow-up. In addition, we will carry descriptive analyses for each phase of data collection. We will report the characteristics of students (e.g. demographic, socio-economic status, tobacco use) and information on ST uptake, and potential exposures. We will provide frequency and proportion for categorical variables and means and standard deviations for continuous variables. If a variable is skewed, we will provide medians and interquartile ranges and use graphical representation where appropriate. We will use STATA (2019) to carry the statistical analysis.

Qualitative data. The interviews and FGDs were transcribed verbatim, and translated into English. A categorization matrix for each data set (head teachers/class teachers/students) was developed, organized by the steps of the study procedure. The data from the three countries has been coded into the same matrix, using Excel software (Microsoft, 2018). The data analysis will be conducted using deductive content analysis (Elo & Kyngäs, 2008).

Ethical issues relating to the study and ethical approval received

In order to protect the study participants, the following provisions have been made/upheld:

Recruitment

The most appropriate approaches to recruiting participants into the study were carefully considered. In addition, investigators involved in recruitment of study participants underwent suitable

training and be provided with appropriate support. In order to ensure that participants of this study do not feel any inappropriate pressure or coercion, cautious attention was given to all recruitment procedures and materials.

Consent

Consent forms and information sheets was carefully prepared and appropriate procedures was planned, in order to obtain a full-informed written consent in an acceptable and suitable manner. The participants acquired sufficient information and had the capacity to make the decision on whether to take part in the study. Furthermore, those participating in the study were informed of the right to stop their participation at any point throughout the study. Additionally, it was made very clear that participation, withdrawing from the study or not participating at all would not affect participants' school results in any way.

Risk, burdens and benefits

All research projects carry certain risks and burdens for the participants. Although this study does not involve any invasive procedures, it concentrates on tobacco use issues that potentially are of sensitive nature. Careful consideration was given in order to minimize the potential risks and burdens to participants. While developing the procedures and policies, every effort was made to reduce participants' feeling of shame, guilt and pressure. Furthermore, attention was given to minimize participants' time involvement. Additionally, the investigators participating in the study were appropriately trained and supported to decrease any burdens of taking part in the study. Consideration was given to avoid any pressure or coercion.

Confidentiality

Every effort was undertaken to ensure confidentiality at all times throughout the study, including its design, conduct and reporting of the results. This study strictly followed ethical principles governing confidentiality. Participation in this study was anonymous so any name or any identifiable details would not be disclosed. The questionnaires were identifiable and were coded with a study enrolment number. The participants were assured that no names would be associated with the data, which would be kept in a locked secured facility.

Provision was made for indemnity by the investigator and sponsor.

The study obtained formal ethics review and approvals from the University of York (4-87/NBC-355/19/1695), the Indian Council of Medical Research (HMSC approval proposal ID 20182675, dated 13/04/2019', Bangladesh Medical Research Council (BMRC/ NREC/2016-2019/969, dated 07/01/2019.), National Bioethics Committee Pakistan (NBC: 4-87/NBC 355/Amend+Extension/20/1990?, dated 28/02/2019), and institutional level approval from Maulana Azad Medical College and associated hospitals, India; Aga Khan University, Karachi and, Khyber Medical University, Peshawar sites. Approvals from the participating school administrations have been obtained.

Data protection

Appropriate data protection and security procedures are put in place. Identifiable information collected on the consent form and codes were stored separately from the questionnaires. Interview and FGD data were entered using the IDs allocated to the schools and student participants.

All information collected during the course of the study was kept strictly confidential and will only be available to those involved in the research. Information was held securely on paper and electronically at the central research office. Any digital data was accessed only through use of security passwords. The researchers also complied with all aspects of related Data Protection Acts.

Plans for dissemination of the findings once completed

We will disseminate the findings to academic audiences via publication in open access, high impact, and peer-reviewed scientific journals of relevant discipline and via related scientific presentations at national and international conferences and seminars. We will also disseminate to non-academic audiences, like national and regional stakeholders for tobacco control in SEARO and EMRO regions, community representatives and local administrations and participating schools and families.

Data availability

Underlying data

No data are associated with this article.

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Wahyu Septiono
Faculty of Public Health, Universitas Indonesia, Jakarta, Indonesia

Comments:

1. "Thus, it is important to prevent the initiation of ST in adolescents, which would protect against the health risks of ST use in adult life." This statement is not quite strong as authors only wrote about the ST prevalence which are 4.5% - 9.0% and added a reference about early smoking in adolescence. Perhaps authors can incorporate the prevalence over years in order to make this statement stronger and ST is a very important issue.

2. I am not really familiar with the educational system/stage in the study area. Is it similar in those three countries? Please add more detail about this.

3. For the FGD, please be more specific. How many participants per FGD?

4. In order to increase the validity (I may say the honest response) authors have clarified that schoolteachers were not involved in questionnaire. However, I think there is a missing important point here. Were teachers also in the class or around students during the data collection? Teacher presence may give less comfort ability for students to fill in the questionnaire and this leads to weak validity. Authors may consider this.

5. I would prefer to mention which version of STATA that was used.

6. Longitudinal study is a quite long study and this study has mentioned that the follow up will be undertaken the next year (one year). I wonder if students move to another school due to higher educational stage, will there be any follow ups or will they be declared missing? The investigators need to consider this.

7. Although this is a feasibility study, I wonder whether the instrument for the quantitative study has been piloted or not. If it was not piloted, I may say the study outcomes are incomplete. Translating questionnaire into a local language especially for a study among adolescents is a bit challenging. Authors need to add more detail about this (e.g., piloting

the translation, third party who translated, etc). I think this should be included as the study outcome. For example, 1) during the survey how many students were asking specific questions because some words or sentences from the local language in the questionnaire that they might not understand, and 2) feedbacks or comments from students about each specific questions during the FGD.

Is the rationale for, and objectives of, the study clearly described?
Partly

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: tobacco control, health policy, statistics, epidemiology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 23 Feb 2022

Masuma Pervin Mishu, The University of York, Heslington, UK

We would like to thank the peer reviewer for the valuable comments.
Comment:
Thus, it is important to prevent the initiation of ST in adolescents, which would protect against the health risks of ST use in adult life." This statement is not quite strong as authors only wrote about the ST prevalence which are 4.5% - 9.0% and added a reference about early smoking in adolescence. Perhaps authors can incorporate the prevalence over years in order to make this statement stronger and ST is a very important issue.
Response:
Thanks for your suggestion.
No GYTS had been conducted in Bangladesh and Pakistan after 2013. Hence we could not report the prevalence over time as the data before 2013 will be too old. We have therefore not made any changes to this section.
However, we added the following sentence to make the statement strong,
'Evidence showed that most smokers start smoking in adolescence (NCBI 2012) and between one-third and one-half of adolescents who experiment with smoking become regular smokers (ASH 2018). The prevalence of ST use in adult population is high in these countries that poses serious disease burden (Siddiqi 2020). Since most adult tobacco users

start ST use in adolescence, Since most adult tobacco users start ST use in adolescence, young people are targeted by the tobacco industry (Wen et al., 2005) and ST manufacturers (Connolly, 1995; Tobacco Free Initiative & WHO, 2002). Thus, it is important to to address tobacco use and prevent the initiation of ST in adolescents, which would protect against the health risks of ST use in adult life.'

Comment:
I am not really familiar with the educational system/stage in the study area. Is it similar in those three countries? Please add more detail about this.

Response:
Now we have added that-
'The educational system is almost similar in these three countries. The age group of students in class 6-8 is almost similar in these three countries. '
Comment:

1. For the FGD, please be more specific. How many participants per FGD?

Response:
We have now added number of participants per FGD
Comment:
In order to increase the validity (I may say the honest response) authors have clarified that schoolteachers were not involved in questionnaire. However, I think there is a missing important point here. Were teachers also in the class or around students during the data collection? Teacher presence may give less comfort ability for students to fill in the questionnaire and this leads to weak validity. Authors may consider this.
Response:
We have now added the following sentence under 'Risk, burdens and benefits' to make the point clear-
'Teachers were not involved in the process of quantitative data collection from students and were not present in the classroom during data collection keeping in mind that their presence might develop insecurity among students to answer honestly to fill in the questionnaire.'

Comment: I would prefer to mention which version of STATA that was used.
Response: We mentioned that STATA 16 will be used

Comment: Longitudinal study is a quite long study and this study has mentioned that the follow up will be undertaken the next year (one year). I wonder if students move to another school due to higher educational stage, will there be any follow ups or will they be declared missing? The investigators need to consider this.
Response: Due to practical considerations, students who move to another school due to higher educational stage will not be followed up. Longitudinal analysis techniques can accommodate varying follow-up points per participant.

This point is now mentioned in the data analysis section.

Comment:

1. Although this is a feasibility study, I wonder whether the instrument for the quantitative study has been piloted or not. If it was not piloted, I may say the study outcomes are incomplete. Translating questionnaire into a local language especially for a study among adolescents is a bit challenging. Authors need to add more detail about this (e.g., piloting the translation, third party who translated, etc). I think this should be included as the study outcome. For example, 1) during the survey how many students were asking specific questions because some words or sentences from the local language in the questionnaire that they might not understand, and 2) feedbacks or comments from students about each specific questions during the FGD.

Response: Many thanks for your suggestion-
We have now added the following sentences in the Methods,
'A questionnaire, to be self-administered, for the students was developed and translated into the local language and checked by a native speaker. A pilot study to check all the arrangements before moving onto the feasibility study was conducted with at least 8-10 students in one school in each of the three counties two weeks prior to the baseline data collection for the feasibility study. We will revise the data collection tools in the light of feedback from the baseline data collection before carrying out follow-up data collection one year after the baseline data collection. We will revise the follow-up questionnaire if needed, based on the responses during the survey on how many students were making queries on some words or sentences from the local language in the questionnaire that they might not understand, and feedback or comments from students about each specific question.'

Competing Interests: The authors declare no competing interests

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Praveen Jodalli
Department of Public Health Dentistry, Yenepoya Dental College, Mangalore, Karnataka, India

Title

1. Has to be modified and can be more specific

Abstract study

1. objectives: objective 3 can be modified

Methods and analysis:

1. Mention whether the self administered questionnaire is for pilot study or longitudinal study.

Keywords

1. Feasibility can be replaced

Introduction

1. Use latest GATS statistics for India.

2. 5-7 are secondary school in India or primary school? Justify.

3. Second last paragraph mentioned that questionnaire will cover both cigarette and ST, but Title says only about ST.

Study aim and objectives

1. Modify third objective.

2. Change “assess” to evaluate for third objective.

Methods

1. Study has already started?

2. Mention the time period for the pilot study?

Sampling strategy

1. Last sentence: “Those schools provided written informed consent”-Who provided informed consent?

2. Consent from students?

Selecting the sample and recruitment

1. Two study groups?

2. Study groups doesn’t match with the title of the article.

3. Criteria for selecting 25 students?

4. Figure 1 is incomplete. Total sample size, information on informed consent etc are missing (mention n=?)

5. Figure 1- in text it is mentioned that participants are already recruited. But in figure it is mentioned that “will finally recruited”.

6. Number of investigators are missing.

7. What is parent/carer consent? For children under what age group?

8. Written assent or oral assent?(mention age group also).

9. Students were randomly selected- Method of randomization?

10. Why teachers are included in the study?

11. Eligibility criteria for teachers?

Inclusion and exclusion criteria(Table 1)

1. Mention 6-8 age group or class?

2. Mention about written or oral assessment?

3. Reason for exclusion of criteria 1,2,3

Table 2

1. Study outcomes- Why head teacher and class teachers.

Outcomes to be measured

1. Repetition of Table 2

Collection of data from the students

1. Why school teachers are included under this heading?

Qualitative data

1. Follow up period is not mentioned.

2. Verbal assent is enough for this age group?

3. What are the procedures for FGD?

4. How to assess the impact? Will you use same questionnaire for follow up?

Collection of data from head teacher or other school representative and class teachers

1. Why they are included in the study where the study population is students?

2. Will this data be included in the analysis?

Data analysis

1. How will you get the information on ST uptake and potential exposure?

2. How to evaluate the data?

3. How to compensate the attrition of participants?

Method

1. CONSORT reporting for pilot/feasibility trials?

Consent

1. Mention withdraw criteria.

2. What are the potential risk and burdens to the participants?

Confidentiality

1. How to maintain the confidentiality of the participants?

2. All eligible participants are in one class rooms, isn't a breach of confidentiality?

Data protection

1. Why is identifiable information collected on the consent form?

2. Which method is used for data collection- questionnaire or interview?

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Tobacco control, surveillance, public health, dental public health, clinical dentistry

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 23 Feb 2022

Masuma Pervin Mishu, The University of York, Heslington, UK

We would like to thank the peer reviewer for the valuable comments. The response of each comments are mentioned in the following Table:
Reviewer 1
Comment
Response

Title

1. Has to be modified and can be more specific

The title has been changed to 'Protocol for a feasibility study of longitudinal surveys to assess the impact of policies on tobacco use among school-going adolescents in South Asia'.

Abstract study

1. objectives: objective 3 can be modified

The third objective has changed to
'To evaluate if the questionnaire can assess tobacco uptake and use, and their potential predictors.'

Methods and analysis:

1. Mention whether the self administered questionnaire is for pilot study or longitudinal study.

The question was changed to clarify that point, 'At each time point, data on tobacco uptake and potential predictors will be collected from students via self-administered questionnaires

that were designed for the longitudinal study.'

Keywords

1. Feasibility can be replaced

Feasibility was be replaced Feasibility study

Introduction

1. Use latest GATS statistics for India.

2. 5-7 are secondary school in India or primary school? Justify.

3. Second last paragraph mentioned that questionnaire will cover both cigarette and ST, but Title says only about ST.

1. Thanks for the suggestion. We have used the latest GATS statistics for India, GYTS 4 (2019). Reference: https://ntcp.nhp.gov.in/assets/document/National_Fact_Sheet_of_fourth_round_of_Global_Youth_Tobacco_Survey_GYTS-4.pdf
2. Secondary education in India is from 14 to 18 years as per reference. Elementary level education is till 14 years which is divided into two: 1. Primary education (Grade 1 to 5) and Upper primary level (Grade 6 to 8)

Reference:
https://niti.gov.in/planningcommission.gov.in/docs/plans/planrel/fiveyr/10th/volume2/v2_ch2_3.pdf
https://niti.gov.in/planningcommission.gov.in/docs/plans/planrel/fiveyr/10th/volume2/v2_ch2_2.pdf

1. We have now revised the term as school going adolescents throughout the manuscript to be consistent in reporting across three countries rather than saying secondary school. Now the title has been revised to tobacco use that captures both smoking and smokeless form of tobacco.

Study aim and objectives

1. Modify third objective.

2. Change "assess" to evaluate for third objective.

We have modified the third objective as suggested:

'To evaluate if the questionnaire can assess tobacco uptake and use, and their potential predictors.'

Methods

1. Study has already started?

2. Mention the time period for the pilot study?

response:

1. The study was already started at the time when the manuscript was written. We mentioned that in the Methods and in the third sentence of the first paragraph of Methods:

'In this section the processes that have already been conducted are described in past tense, and those still to do are described in the future tense.'

2. We mentioned the time period for the feasibility study, 'The schools and students have been recruited and baseline data were collected between October 2019 and February 2020.' We mentioned that the follow-up data collection will be done one year after the baseline data collection

We have now added the time period for the pilot study:
'The pilot study to check all the arrangements before moving onto the feasibility study was conducted with at least 8-10 students in one school in each of the three counties two weeks prior to the baseline data collection'.

Sampling strategy

1. Last sentence: "Those schools provided written informed consent"-Who provided informed consent?

2. Consent from students? Response: We have now added the following sentence to make it clear Who provided informed consent?

'The principal or head teacher of the school provided the written informed consent to participate in the study on behalf of the school.'

Consent form were signed by the parents of the students then assent forms were signed from the students to participate in the study. The information on student assent was included in the manuscript.

Selecting the sample and recruitment

1. Two study groups?

2. Study groups doesn't match with the title of the article.

3. Criteria for selecting 25 students?

4. Figure 1 is incomplete. Total sample size, information on informed consent etc are missing (mention n=?)

5. Figure 1- in text it is mentioned that participants are already recruited. But in figure it is mentioned that "will finally recruited".

6. Number of investigators are missing.

7. What is parent/carer consent? For children under what age group?

8. Written assent or oral assent?(mention age group also).

9. Students were randomly selected- Method of randomization?

10. Why teachers are included in the study?

11. Eligibility criteria for teachers?

Response:

1. The study was planned to be conducted among two groups of study participants: school students and schoolteachers which included head teacher or a representative of the school and class teachers.

2. In this feasibility study we wanted to test the feasibility of conducting the longitudinal study from the context of the students but also ensure we took account of views of the schoolteachers to inform the main study. However, the overall aim of the planned future longitudinal study is to 'assess the impact of tobacco control policies on tobacco use among school going adolescents in South Asia' as mentioned in the title

3. The inclusion criteria for selecting the students are mentioned in Table 1. However, as a feasibility study we did not conduct formal sample size calculations. The minimum number of 25 students per class was selected based on the discussion with the study partners from each country.

4. Figure 1 is an illustration of the process and stages of recruitment that we used. We did not present the actual numbers (n) here as these were not known at the time of writing the protocol (data compilation of three countries were under process).

5. We have changed the tense as past tense in Figure 1.

6. We have now added the number of Investigators in the first paragraph of the Methods section- 'On average the number of investigators was 10-15 per country who conducted the data collection.'

7. We mentioned that 'All students participating in this study were under 16 years old and therefore parental/carer consent was required for them to take part.'

8. We have added the age and made it clear that it was written assent.'Students under the age of 16 years were asked to sign the assent form if they were willing to participate in the study.'

9. For the FGD we made the point clear-'6-8 students per class were randomly selected by their class teachers to take part in the FGD, having previously secured parental consent and written assent from the students.'

10. Teachers were involved in conducting the study in schools in terms of the process of selection, recruitment and collecting consent and assent forms from parents and students. It was important therefore to involve teachers in our research so that we

could understand and be able to take into account any feedback they had when conducting the future longitudinal study.

11. We mentioned the eligibility criteria for teachers –'schoolteachers which included headteacher or a representative of the school and class teachers of the classes participating in the study'

Inclusion and exclusion criteria(Table 1)

1. Mention 6-8 age group or class?

2. Mention about written or oral assent?

3. Reason for exclusion of criteria 1,2,3

Response:

1. Now we mentioned that 'Students of 6th, 7th and 8th classes from the selected schools, who have the ability to give written assent.

2. Addressed in previous response

3. As we wanted to get the data on tobacco use from the general students and not from the students of special needs, therefore, we set the exclusion criteria 1,2,3

Table 2

1. Study outcomes- Why head teacher and class teachers. Response: Please see above. (Response of point 10 of 'Selecting the sample and recruitment')

Outcomes to be measured

1. Repetition of Table 2

Response:

We presented Table 2 to show the objectives in parallel to the study outcomes to make it easy to read and in the text we explained the points in detail.

Collection of data from the students

1. Why school teachers are included under this heading?

Under the point 'Data collection methods' we have two subheadings:

1. Collection of data from the students

2. Collection of data from the headteacher or other school representative and class teachers

Response:

School teachers are included under the second subheading. To make the point clear, we have now added numbers in the subheadings.

Qualitative data

1. Follow up period is not mentioned.

2. Verbal assent is enough for this age group?

3. What are the procedures for FGD?

4. How to assess the impact? Will you use same questionnaire for follow up?

Response:

1. We have now mentioned the follow up time

2. We already mentioned before-

'6-8 students per class were randomly selected by their class teachers to take part in the FGD, having previously secured parental consent that included the FGD and written assent from the students. In addition, verbal assent was obtained from the selected students again before the FGD commenced.'

To avoid the repetition, we have now deleted the sentence related to assent from this paragraph.

3. We briefly described the procedure of FGD:'6-8 students per class took part in the FGD. Topic guides were used to ensure consistency of discussion across schools, although the format was flexible to allow the students to raise additional issues they considered important. The discussions were conducted at the school in a private room by a field investigator and were digitally audio-recorded.'

4. As mentioned, in baseline FGD we will assess, 'their views and experiences of being informed about the study, discussing the study with their parents, providing assent, and completing the questionnaire'

We aimed to 'assess the impact of tobacco control policies….' in our main future longitudinal study not in this feasibility study.

A different topic guide will be used in the follow up FGD. We mentioned that-
'The FGDs during the follow-up data collection will be focused mainly on students' own and others' tobacco uptake and use, and influences on this to assess the relevance and appropriateness of the questions in the follow-up questionnaire.'

Collection of data from head teacher or other school representative and class teachers

1. Why they are included in the study where the study population is students?

2. Will this data be included in the analysis?

Response:
Please see above (Response of point 10 of 'Selecting the sample and recruitment')

Yes, the qualitative data from the teachers will be used in qualitative analysis to assess the feasibility of conducting the longitudinal study in school setting from the perspective of the teachers.

Data analysis

1. How will you get the information on ST uptake and potential exposure?

2. How to evaluate the data?

3. How to compensate the attrition of participants?

Response:

1. We have now added that-

'The questionnaire used for the survey incorporates questions related to tobacco uptake and potential exposure.' The questionnaire will be available upon request to the corresponding author.

2. We have now added that- 'We will triangulate the findings obtained from the quantitative data related to the feasibility assessment and the qualitative study findings to evaluate the overall feasibility of conducting the future longitudinal study.'

3. The feasibility study was set up to assess the attrition rates, not to compensate for them

Method

1. CONSORT reporting for pilot/feasibility trials?

Response:
As it was not a pilot/ feasibility trial, so CONSORT reporting was not reported

Consent

1. Mention withdraw criteria.

2. What are the potential risk and burdens to the participants?

Response:

1. We have now added the withdraw criteria -

'It was mentioned in consent and assent form that participants were free to withdraw any time as per their wish without showing any reason. In that case, no more data would be collected. The information already collected will be kept secure and still used in the analysis unless the participant specifically asks for the information to be removed.'

2. We have added-'Participants may have concerns about the risk of disclosure of their tobacco consumption practices and/or any breaches of confidentiality concerning their data or information provided. '

Confidentiality

1. How to maintain the confidentiality of the participants?

2. All eligible participants are in one class rooms, isn't a breach of confidentiality?

Response:

1. We mentioned that- 'Participation in this study was anonymous so any name or any identifiable details would not be disclosed. The questionnaires were identifiable and were coded with a study enrolment number. The participants were assured that no names would be associated with the data, which would be kept in a locked secured

facility.'
2. We have added that-

'The data collection was monitored by the investigators to ensure that no participant can view another participant's responses in the questionnaire to maintain confidentiality'.

Data protection

1. Why is identifiable information collected on the consent form?

2. Which method is used for data collection- questionnaire or interview?

Response:

1. To make the point clear, we have now added- 'Appropriate data protection and security procedures are put in place. Identifiable information was collected on the consent form in order to be able to match the students in the follow-up data collection. Identifiable information collected on the consent form and codes were stored separately from the questionnaires (used for the quantitative data collection). Interview and FGD (related to the qualitative data collection) data were entered using the IDs allocated to the schools and student participants and also kept separate from the codes.'
2. The questionnaire was used for collection of quantitative data whereas In-depth interviews and focus group discussions were used for collection of qualitative data to explore feasibility aspects of the study.

Competing Interests: The authors declared no competing interests