ISRCTN28878365 https://doi.org/10.1186/ISRCTN28878365

A trial to assess the effectiveness and cost-effectiveness of a school-based Smoke-Free Intervention in reducing children's exposure to second-hand smoke

Submission date
30/04/2020

Recruitment status
No longer recruiting

Registration date
13/05/2020

Overall study status
Completed

Last Edited
18/06/2024

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Breathing in other people's smoke is called second-hand smoking (SHS). SHS is harmful to children's health and leads to chest and ear infections, tuberculosis, meningitis and asthma. It also causes lung cancer and heart disease. Globally, 40% of children are exposed to SHS. Many countries have introduced bans on smoking in enclosed public spaces, but for the majority of children, cars and homes remain the most likely places for them to breathe in SHS. The only possible way to protect children from SHS is to make cars and homes completely smoke-free. The researchers have conducted a pilot study involving children, teachers and parents in schools in Bangladesh to develop and test a school-based intervention called 'Smoke-Free Intervention' (SFI). Their work has shown promising results showing that SFI can encourage children to negotiate smoking restrictions inside their homes. They have also conducted a feasibility study in Pakistan where SFI was culturally adapted and was found acceptable to be delivered in school. The aim of this study is to examine how effective SFI is at preventing respiratory and other smoking-related illnesses in Bangladesh and Pakistan by reducing children's exposure to SHS. Pakistan is included because of its comparable disease burden to Bangladesh.

Who can participate?
Children studying in year 5 (9 to 12 years old) at participating schools

What does the study involve?
The researchers are proposing to conduct this study in Dhaka, Bangladesh and Karachi, Pakistan. They will recruit a total of 74 primary schools, 34 from Bangladesh and 40 from Pakistan. They will conduct measurements including testing children's saliva for cotinine, a chemical detected in those exposed to SHS. Other measures will include questionnaires and diaries to be kept by children to record their chest symptoms and scales to measure school performance and attitudes to smoking. Once measurements have been taken, half of the schools will be randomly chosen to receive SFI while the other half will not receive the intervention until the end. The Smoke-Free Intervention (SFI) comprises six interactive lessons delivered by school teachers

including five fun activities and one take-home educational resources. Taught lessons increase pupils' knowledge about the associated harms of SHS. Fun activities including storytelling, role-playing, quizzes and games, motivate children to act and feel confident in persuading adults to take seven steps away from the house to smoke. The take-home resource also helps children to negotiate with their families to "sign-up" to a voluntary contract to make their homes smoke-free. The researchers will repeat the assessments at 3, 6 and 12 months after the intervention.

What are the possible benefits and risks of participating?
Some of the concerns are as follows. Children's participation raises issues around competence, vulnerability and powerlessness. In this study, children's wishes and their welfare will take precedence over the research requirements. Research burden will be kept to a minimum. Children and their families will not be reimbursed financially, however, small incentives in the form of school stationery will be offered. Based on the feasibility work, it is highly unlikely that the children will face any adverse reaction from their families. Obtaining saliva is also not harmful to children, neither it could disclose the presence of any medical condition. All participants' data will be kept confidential and in password-protected servers. The risks associated with this study are minimal, and it is unlikely that the questionnaires or interviews will lead to any potential legal, social, or psychological problems. The process of collecting saliva samples is also easy and safe. Each participant will place a cotton dental roll inside the cheek for 2 minutes to collect saliva. Soaked cotton rolls will be placed in a plastic container. Study personnel will provide detailed instructions to the participants for the saliva sample. The participant will be entitled to withdraw at any time of the research process even after s/he initially agreed to participate.

Where is the study run from?
The study will be centrally coordinated from The University of York (UK). In each country it will be run from Aga Khan University (Pakistan) and the ARK Foundation (Bangladesh).

When is the study starting and how long is it expected to run for?
December 2019 to June 2024

Who is funding the study?
1. Medical Research Council (MRC) (UK)
2. Wellcome Trust (UK)
3. National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Prof. Kamran Siddiqi
kamran.siddiqi@york.ac.uk

Contact information

Type(s)
Public

Contact name
Prof Kamran Siddiqi

Contact details
Department of Health Sciences
Seebohm Rowntree Building

The University of York
Heslington
York
United Kingdom
YO10 5DD
+44 (0)7970 544872
kamran.siddiqi@york.ac.uk

Type(s)
Scientific

Contact name
Prof Kamran Siddiqi

Contact details
Department of Health Sciences
Seebohm Rowntree Building
The University of York
Heslington
York
United Kingdom
YO10 5DD
+44 (0)7970 544872
kamran.siddiqi@york.ac.uk

Type(s)
Scientific

Contact name
Dr Rumana Huque

ORCID ID
http://orcid.org/0000-0002-7616-9596

Contact details
ARK Foundation
Flat C3 & C4, House No. 6
Road No. 109, Gulshan 2
Dhaka
Bangladesh
1212
+880 (0)255069866
rumanah14@yahoo.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 1.3, 20th February 2020

Study information

Scientific Title
Children Learning About Second-hand Smoking (CLASS III): a cluster randomised controlled trial

Acronym
CLASS III

Study objectives
The aim of this study is to examine how effective SFI is at preventing respiratory and other smoking-related illnesses in Bangladesh and Pakistan by reducing children's exposure to SHS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/04/2020, Health Sciences Research Governance Committee (HSRGC) at The University of York (Department Of Health Sciences, York, YO10 5DD, UK; +44 (0)1904 323253; smh12@york.ac.uk), no ref number

Study design
Multi-centre cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

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
Prevention of respiratory illnesses in children

Interventions

1. Smoke Free Intervention (SFI):
The proposed trial (CLASS III) is the natural sequence, which follows the encouraging findings of the above studies and uses the MRC Framework for Developing and Evaluating Complex Interventions.
All participating children in the intervention arm will receive the SFI delivered by their teachers. Teachers will receive prior training in delivering the intervention. Their training will focus on their knowledge gaps around tobacco, their skills in using various teaching methods and their ability to build confidence within and teach negotiation skills to children.
The intervention will consist of:
Two 45-minute sessions delivered over two days by schoolteachers. The duration of these sessions is consistent with regular school lessons. These sessions will consist of a flip chart presentation and a full drama activity. These activities are especially designed to increase pupil's knowledge about SHS and related harms, and motivate them to follow one main step (7 steps away from home) to make their home smoke free. The seven acts of the drama will give children the opportunity to practice their negotiating skills and be confident within their cultural context. It will also serve as a visual incentive for the parents not to smoke inside homes.
A set of four follow-up sessions (15 minutes each) to reinforce key messages delivered in the initial sessions, to be delivered once a week over 6-7 weeks after the two initial sessions. The immediate first follow up session will be based on the feedback from parents about the drama activity. The second session will consist of a word search game followed by a discussion in order to enhance pupils' knowledge about SHS. The third follow up session will comprise a quiz game in which children will be asked questions and given answer options. This will be followed by a discussion as a means of reinforcement. The final follow up session will be based on small group discussions among the students about their experiences and if they faced any challenges. Children are given an achievement certificate to mark the seven achievements to make their homes smoke free. Children are also given a promise form that describes the main step to achieve a smoke-free home i.e to take seven steps away from the house to smoke. It also contains a tear-off slip to make a commitment to impose smoking restrictions at home. Children take promise forms to their parents, show them the messages, and negotiate with them to "sign-up" to the Smoke-Free Homes "promise" form. One of the implications is that even if parents are non-smokers, they will not allow other smokers (residents and visitors) to smoke inside homes. In addition to delivering the intervention, teachers will also be trained to support children in this process.

2. Treatment as usual:
Schools in the control arm will receive the intervention at the completion of the trial.

Intervention Type
Behavioural

Primary outcome measure
Exposure to second-hand smoking measured by checking salivary cotinine level at baseline and month 3

Secondary outcome measures
Current secondary outcome measures as of 07/06/2022:
1. Frequency and severity of respiratory symptoms recorded by asking children to keep a diary for 16 respiratory symptoms and record their severity on a validated four-point Likert scale for a whole month (4 weeks) in three follow up periods i.e. 3rd, 6th and 12th month. For each item, '0' represents the absence of a symptom, 1 represents mild, 2 represents moderate and 3 represents the greatest severity level

2. Smoking-related behaviour recorded by asking the children to self-report levels of smoking restrictions and social visibility of smoking at home through a questionnaire at baseline, and months 3, 6 and 12
3. Health service use recorded by using a health service utilisation questionnaire at baseline, and months 3, 6 and 12
4. Quality of life assessed using the EQ-5D-Y questionnaire at baseline, and months 3, 6 and 12
5. Absenteeism and academic performance measured by each participating school providing a report on the academic performance of participating children using the Academic Performance Questionnaire (APQ) measures at baseline and months 3, 6 and 12

Previous secondary outcome measures as of 13/04/2021:
1. Frequency and severity of respiratory symptoms recorded by asking children to keep a diary for 13 respiratory symptoms and record their severity on a validated four-point Likert scale for a whole month (4 weeks) in three follow up periods i.e. 3rd, 6th and 12th month. For each item, '0' represents the absence of a symptom, 1 represents mild, 2 represents moderate and 3 represents the greatest severity level
2. Smoking-related behaviour recorded by asking the children to self-report levels of smoking restrictions and social visibility of smoking at home through a questionnaire at baseline, and months 3, 6 and 12
3. Health service use recorded by using a health service utilisation questionnaire at baseline, and months 3, 6 and 12
4. Quality of life assessed using the EQ-5D-Y questionnaire at baseline, and months 3, 6 and 12
5. Absenteeism and academic performance measured by each participating school providing a report on the academic performance of participating children using the Academic Performance Questionnaire (APQ) measures at baseline and months 3, 6 and 12

Previous secondary outcome measures:
1. Frequency and severity of respiratory symptoms recorded by asking children to keep a diary for 13 respiratory symptoms and record their severity on a validated four-point Likert scale for a whole month (4 weeks) in three follow up periods i.e. 3rd, 6th and 12th month. For each item, '0' represents the absence of a symptom, 1 represents mild, 2 represents moderate and 3 represents the greatest severity level
2. Smoking-related behaviour recorded by asking the children to self-report levels of smoking restrictions and social visibility of smoking at home through a questionnaire at baseline, and months 3, 6 and 12
3. Health service use recorded by using a health service utilisation questionnaire at baseline, and months 3, 6 and 12
4. Quality of life assessed using the CHU-9D questionnaire at baseline, and months 3, 6 and 12
5. Absenteeism and academic performance measured by each participating school providing a report on the academic performance of participating children using the Academic Performance Questionnaire (APQ) measures at baseline and months 3, 6 and 12

Overall study start date
01/12/2019

Completion date
30/06/2024

Eligibility

Key inclusion criteria

1. Studying in year 5 in the participating school and their age range is between 9 and 12 years
2. Self-reported non-tobacco users (i.e. smoked or smokeless)

Participant type(s)
Learner/student

Age group
Child

Lower age limit
9 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
Number of clusters: 68 (34 from each site); participants per site (total two sites): 1360

Total final enrolment
2752

Key exclusion criteria
1. Serious medical condition which is either life-threatening or requires regular hospitalisation
2. History of domestic violence and abuse (in any form)

Date of first enrolment
02/05/2022

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
Bangladesh

Pakistan

Study participating centre
ARK Foundation
Dhaka
Bangladesh
Dhaka 1212

Study participating centre
Aga Khan University
Pakistan
74800

Sponsor information

Organisation
University of York

Sponsor details
Heslington
York
England
United Kingdom
YO10 5DD
+44 (0)1904 435138
rdteam@york.ac.uk

Sponsor type
University/education

Website
http://www.york.ac.uk/

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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 issue of SHS is already a national priority in Bangladesh and Pakistan. If SFI is found to be effective, the researchers will use advocacy, their existing linkages, and impact enhancement schemes to maximise the impact of their results (see below) in these countries and beyond.

Priority: Widespread SHS exposure in women and children and its impact has recently caught public and policymakers' attention in Bangladesh and Pakistan. Two of the team's recent papers on the topic were reported widely in national newspapers and TV channels. The Bangladesh government has responded by promising to prioritise this issue.

Advocacy: The researchers have partnered with NGOs within the two countries with expertise in advocating for tobacco control measures. Together, they will develop a dissemination strategy, which will target academic and non-academic audiences using a variety of media. In Bangladesh, their partner Work for a Better Bangladesh Trust has an expert advocacy team in reducing SHS exposure. In Pakistan, they are in liaison with the Director of Schools office within the Ministry of Education in Sindh, Pakistan who have extended their advocacy support.

Partnerships: Since its adaptation and piloting in the CLASS II trial, policymakers at the ministry and the WHO have shown a keen interest in the intervention and have been kept engaged through stakeholder events and policy briefs. Beyond the two countries, the study team is also connected to international funders and agencies supporting tobacco control efforts. These include the Global Alliance against Chronic Diseases (co-chair of the respiratory group), The Union (office bearers within tobacco control section), WHO Geneva, EMRO and SEARO offices and WHO FCTC secretariat (through existing partnerships - EU-H2020 TB & Tobacco consortium, NIHR_RESPIRE Unit and NIHR_ ASTRA Group). The researchers will use these partnerships to disseminate and seek support for their research findings.

Impact enhancement: the study team is currently leading an NIHR Global Health Unit (RESPIRE) and a Group (ASTRA), both based in south-east Asia. This gives them the opportunity to enhance their trial's impact through their interface with relevant policymakers, professional bodies and third sector organisations, and also to extend this work to other countries such as India and Malaysia in due course. Through GCRF and ESRC schemes, the researchers have been successful in securing grants to enhance the impact of their research recently (TB & Tobacco plus). They use these schemes to demonstrate scale-up beyond trial sites and generate useful knowledge and momentum for a national scale-up. They will apply for these schemes towards the end of the CLASS III trial. They will also partner with governments and NGOs to seek implementation grants from funders like World Bank for a national/provincial roll-out. They will also support governments' funding mechanisms (e.g. PC1 in Pakistan) to support scale-up.

Intention to publish date
28/02/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Kamran Siddiqi (kamran.siddiqi@york.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V1.3.1		18/05/2020	No	No
Protocol file	version 1.4.1	30/05/2020	07/06/2022	No	No
Statistical Analysis Plan	version 1.0	20/04/2023	28/04/2023	No	No

Protocol article	14/07/2023	17/07/2023	Yes	No