

# 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

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| <b>Submission date</b><br>30/04/2020   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>13/05/2020 | <b>Overall study status</b><br>Completed          | <input checked="" type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results            |
| <b>Last Edited</b><br>18/06/2024       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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

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**Additional identifiers**

**Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

## **Protocol serial number**

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

## **Study type(s)**

Prevention

## **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(s)

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

## Key secondary outcome(s)

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

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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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

9 years

**Upper age limit**

12 years

**Sex**

All

**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

ROR

## **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

**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? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a>              |                               | 14/07/2023   | 17/07/2023 | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |
| <a href="#">Protocol file</a>                 | version V1.3.1                |              | 18/05/2020 | No             | No              |
| <a href="#">Protocol file</a>                 | version 1.4.1                 | 30/05/2020   | 07/06/2022 | No             | No              |
| <a href="#">Statistical Analysis Plan</a>     | version 1.0                   | 20/04/2023   | 28/04/2023 | No             | No              |