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Children learning about second-hand smoke (CLASS II)

Submission date
22/04/2015

Recruitment status
No longer recruiting

Registration date
05/05/2015

Overall study status
Completed

Last Edited
26/05/2021

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Breathing in other people's smoke is called passive smoking. It is also sometimes called involuntary or second-hand smoking (SHS). Second-hand smoke contains 4000 chemicals, 70 of which can cause cancer. SHS is particularly harmful to children's health and can lead to chest and ear infections, tuberculosis, meningitis and asthma. It is also associated with lung cancer and heart disease. Globally, 40% of children are exposed to SHS. Many countries have introduced bans on smoking in enclosed public spaces, which has significantly reduced adults' exposure to SHS. However, 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. For the last three years, we have been working with teachers, children and their parents in primary schools in Dhaka, Bangladesh to develop a programme called 'Smoke Free Homes'. It’s made up of six teaching lessons delivered by schoolteachers, four fun activities and one educational take home resource. Teaching lessons help to increase pupils' knowledge about the harms caused by breathing in other people's smoke. Fun activities include storytelling, role-playing, quizzes and games. These activities help to motivate children to act and feel confident in talking to adults to persuade them not to smoke inside homes. The take-home resource helps children to show what they have learned in school and to negotiate with their families to ‘sign-up’ to a voluntary contract to make their homes smoke-free. The results of our work so far show that it is possible to encourage children to discuss with their families ways of restricting smoking inside their homes. Inspired by what we found, we now wish to plan for a large study, but first we want to carry out a smaller study to see if it works. The aim of this study is to see how effective 'Smoke Free Homes' is in reducing children's exposure to SHS. We are also interested to see if the programme improves their lung health, general quality of life, school attendance and school performance. We will also see if it helps in changing their attitude towards smoking and makes it less likely for them to take up smoking in future.

Who can participate?
Children aged 10-12 in Year 5 attending participating schools.

What does the study involve?
Participating schools are randomly allocated into one of two groups. Those in group 1 (intervention group) have 'Smoke Free Homes' training given to teachers. The teachers then

teach 'Smoke Free Homes' education to the children in their class. Those in group 2 (control group) have no 'Smoke Free Homes' training for teachers initially, but this is given at the end of the study. All participating children give saliva samples using a sterile swab, have basic lung function tests and complete questionnaires at the start of the study, and again after 2 months.

What are the possible benefits and risks of participating?
The results of this study will be used to construct a larger study to help reduce passive smoking in children.

Where is the study run from?
Participating schools from Mirpur and Savar, Dhaka Division (Bangladesh)

When is the study starting and how long is it expected to run for?
April 2015 to March 2017

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr R Huque

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Children Learning About Second-hand Smoke (CLASS II): a pilot cluster randomised controlled trial

Acronym
CLASS II

Study objectives
Smoke free homes (SFH) can encourage children to negotiate smoking restrictions inside their homes, and reducing children's exposure to second-hand smoke (SHS) improves their lung health, quality of life, school attendance and performance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Bangladesh Medical Research Council (BMRC), Bangladesh
2. University of York Ethics Committee, 16/03/2015.

Study design
Pilot cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Smoke Free Intervention (SFI) education programme.

Interventions
1. Schoolteachers are trained to deliver Smoke Free Intervention (SFI) education to children in their class. All participating children in the intervention group will have SFI delivered by their teachers.
2. Schoolteachers give two 45-minute SFI session to children over two days. Each session consists of a range of educational activities including classroom presentations, quiz, interactive games, storytelling and role-play - vicarious learning techniques are utilised in many of these activities. The presentation, quiz and games are designed to increase pupils' knowledge about SHS and related harms, and motivate them to follow three easy steps to make their homes smoke-free. The storybook and role-play focuses on enhancing children's negotiation skills, building their confidence within Bangladeshi cultural context. While the storybook depicts challenges of negotiating with elders, the role-play has hypothetical scenarios where children had opportunity to practice and demonstrate how and when they can discuss and negotiate with elders to persuade them not to smoke inside homes.
2. A set of four refresher SFI sessions (15 minutes each) are given to children by schoolteachers to reinforce the key messages delivered in the initial sessions. Refresher session are delivered once a week, 6-7 weeks after the first two sessions. During the refreshers, the teacher reminds children of the key points of the main session by asking questions (5 to 7 minutes), and then encouraging students to share their experiences of whether they could initiate discussion at home, what challenges did they face, what is their plan to do next and what would be the best way to convince the elders (8 to 10 minutes). The length of these sessions is consistent with the duration of school assembly.
3. Children are given a promise form that contains pictorial and written messages on the hazards of second-hand smoke (SHS), a pictorial step-guide for families on how to make their homes smoke free and 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.

Intervention Type
Behavioural

Primary outcome(s)
Children’s exposure to SHS is measured by testing their salivary cotinine levels using a sterile swab. Salivary cotinine concentration is strongly associated with the exposure to SHS at home. Saliva samples will be obtained from all participating children at baseline and also two-months post intervention.

Key secondary outcome(s))
1. Frequency and severity of respiratory symptoms: participating children will be given diaries to record respiratory symptoms on a nominal severity scale from 0 to 3. Children will record their symptoms using facial expressions stickers to show how they feel. These diaries will have three sections. Section 1 will record symptoms from the day intervention is delivered till the end of month-two. Section 2 from the start of month-three till the end of month-six and section 3 from the start of month-seven till the end of month-twelve. At each follow up, one section will be taken out of the diary by the researchers and data will be entered in the database. All children will provide data on section 1. However, only those children will provide data on section 2 and 3 whose cotinine levels are indicative of passive smoking at the baseline. Children will be told whether to stop or keep collecting information in their diaries in a letter. The assessments will be carried out at both baseline and follow ups.
2. Lung Functions: we will measure lung functions on all participating children at the baseline and on children with positive salivary cotinine at month-two, six and twelve. For this we will use a spirometer as per British Thoracic Society guidelines. This would involve measuring forced vital capacity (FVC), forced expiratory volume in the first second (FEV1), peak expiratory flow (PEF), and maximal mean expiratory flow (MMEF). We will first record, height and body weight of all participating children at the baseline. We will enter details of the patient’s sex, race, age and height into the spirometer. We will then ask each child to blow into a disposable mouthpiece attached to the spirometer at least three times as per guidelines. Best of the three readings will be taken. The spirometer will also calculate the percentage of the predicted normal values as they have the reference data already programmed into them. The spirometer will print out a lung function test report for each participant, which will be attached to the participant baseline or follow up questionnaire, respectively. Spirometer will be cleaned according to the manufacturer’s guidelines and its accuracy will be checked regularly. The assessments will be carried out at both baseline and follow ups.
3. Smoking related behaviours: we will ask the children to self-report levels of smoking restrictions and social visibility of smoking at home using a questionnaire. Using the same questionnaire, we will also assess children’s self-reported attitude towards smoking and intention to start smoking. We will use a five-point smoking uptake scale19 to categorise children as non-susceptible non-smokers, susceptible non-smokers, early experimenters, advanced experimenters and established smokers. The assessments will be carried out at both baseline and follow ups.
4. Health service use: we will use a health service utilisation questionnaire previously used in the MCLASS trial, to collect number and type of contacts with doctors, hospital admissions, pharmacy visits and antibiotic prescriptions. This information will be part of the baseline questionnaire but will also be assessed at all follow-up time points.

5. Quality of Life (QoL): QoL (generic) will be assessed by using a short QoL questionnaire for children, PedsQoL. The questions will be included in the baseline and follow up questionnaires.
6. Other confounding variables: at baseline, we will also ask children to report on some of the basic socio-demographic details on the questionnaire. These will include age, gender, household amenities, family structure, co-habiting smokers – including parents, pet ownership, overcrowding - number of rooms and residents, built environment, neighbourhood, presence of mould/moisture in the child's home, and use of gas for cooking or gas/kerosene/oil heater. Furthermore, we will include information on children's medical history (particularly asthma and chest infections) and use of any regular medications.
7. Absenteeism and academic performance: each participating school will be asked to provide a report on the academic performance of participating children using the Academic Performance Questionnaire (APQ), a 10-item questionnaire to be completed by teachers. Using 4- and 5-point ordinal scales, it measures child's performance in reading, mathematics, writing, and homework. This questionnaire will be completed at the baseline and at all follow-ups. In addition, schools will also be requested to provide a record of child's absenteeism from school including number of days missed every month in between two assessments.
8. Fidelity Index: the research team will use a fidelity index, mapped onto the behaviour change techniques that underpin SFI, to assess intervention adherence. This will be in the form of a check list, which will used to monitor the delivery of SFI sessions. One of the members of the research team will attend all SFI sessions and using the above check list will score fidelity to SFI.

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Eligible schools (public and private) are following mainstream curricula approved by the educational authorities
2. Eligible schools have year-five classes, with >40 and <120 year-five children (10-12 years old) per class.
3. Eligible schools have a 'no-smoking' policy and all participating year-five teachers are self-reported non-smokers
4. Eligible students aged 10-12 in year five attending participating schools
5. Eligible students have parental consent to participate
6. Eligible students are non-smokers

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
12 years

Sex
All

Key exclusion criteria
Children are excluded if they have any of the following conditions/situations that the school is aware of:
1. Physical or mental disabilities
2. Learning difficulties and/or special learning-needs
3. Behavioural problems and/or conduct disorder
4. Serious medical condition which is either life threatening or requires regular hospitalisation
5. History of domestic violence and abuse (in any form)

Date of first enrolment
30/04/2015

Date of final enrolment
29/10/2015

Locations

Countries of recruitment
Bangladesh

Study participating centre
Participating schools from Mirpur and Savar
Dhaka Division
Bangladesh
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Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Research council

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/04/2019		Yes	No
Protocol article	protocol	25/08/2015		Yes	No
Other publications	process evaluation	24/05/2021	26/05/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes