ISRCTN49975452 https://doi.org/10.1186/ISRCTN49975452

Muslim communities learning about second-hand smoke in Bangladesh (MCLASS II)

Submission date
24/12/2017

Recruitment status
No longer recruiting

Registration date
11/01/2018

Overall study status
Completed

Last Edited
12/10/2022

Condition category
Respiratory

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

Plain English summary of protocol
Background and study aims
Second-hand smoke (SHS) is a serious health hazard costing 600,000 lives a year. Women and children in developing countries are worst affected as smoke-free laws are only partially implemented and homes remain a source of SHS exposure. There is limited evidence on interventions designed to reduce SHS exposure in homes, especially in community settings. Following a successful pilot study, the plan is to evaluate a community-based approach to promote smoke-free homes in Bangladesh – a country with a strong commitment to smoke-free environments but with high levels of SHS exposure in children. The aim is to assess the effectiveness and cost-effectiveness of a community-based intervention – Muslims for better Health (M4bH), with or without Indoor Air Quality (IAQ) feedback, in reducing non-smokers' exposure to SHS in the home.

Who can participate?
45 mosques and their catchment communities in the Mirpur area of Dhaka, Bangladesh

What does the study involve?
Participating mosques are randomly allocated to deliver both M4bH and IAQ feedback, M4bH alone, or usual services. M4bH and IAQ feedback are behavioural interventions designed to discourage people from smoking indoors. M4bH consists of a set of messages and activities couched within mainstream Islamic discourse, delivered by faith leaders (Imams) in places of worship (mosques). IAQ feedback consists of anonymised information on indoor air quality measured by a particulate matter (PM2.5) monitor. Indoor air quality, frequency and severity of respiratory symptoms, healthcare service use and quality of life are measured.

What are the possible benefits and risks of participating?
It is hoped that the mosques will help to promote healthier communities within Bangladeshi populations and will also help to create awareness of second-hand smoke exposure. No personal incentives are offered to household members for taking part in the study, but payments of Taka 200 will be made at each follow-up point, to compensate for the time they are giving, and to cover any expenses associated with travel. There is no risk of taking part in this study. It takes around 40 minutes to answer the questions. The device to measure indoor air quality is safe to use.

Where is the study run from?
45 mosques and their catchment communities in the Mirpur area of Dhaka, Bangladesh

When is the study starting and how long is it expected to run for?
January 2018 to December 2019

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
064 13 08 2017

Study information

Scientific Title
Muslim Communities Learning About Second-hand Smoke in Bangladesh (MCLASS II): an effectiveness-implementation hybrid trial

Acronym
MCLASS II

Study objectives
A community-based intervention with or without IAQ feedback will be equally effective and cost-effective in reducing:
1. Non-smokers' exposure to SHS in the home
2. Frequency and severity of respiratory symptoms
3. Healthcare service use; and in iv) improving quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Bangladesh Medical Research Council (BMRC), 19/10/2017, ref: BMBC/NREC/2016-2019/358
2. Health Sciences Research Governance Committee, University of York, 08/08/2017

Study design
Pragmatic three-arm open-label cluster randomised controlled trial with concurrent economic evaluation

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Second hand smoke

Interventions
A trial will be conducted over 24 months in 45 mosques and their catchment communities in Mirpur area of Dhaka, Bangladesh. An effectiveness-implementation hybrid study design will be used that blends components of effectiveness and implementation research. The distinct advantage of this approach is that it allows for the gathering of data on the delivery of an intervention during an effectiveness trial that inform its potential for implementation and scaling-up in the 'real world'. The study thus consists of three study components: I) effectiveness and cost-effectiveness evaluation; II) process evaluation; and III) implementation and scale-up.

45 mosques are randomised to the three trial arms:
Arm 1 – M4bH and IAQ feedback
Arm 2 – M4bH alone
Arm 3 – usual services

1. Muslims for better Health (M4bH) intervention
Culturally adapted to Bangladeshi context, the M4bH intervention will consist of a set of messages and activities that address key determinants of current smoking behaviours including lack of knowledge and misconceptions on the specific harms associated with M4bH. Where appropriate, these messages will be worded within the mainstream Islamic discourse, using faith-based decrees on addiction, hygiene, health promotion, self-harm and inflicting harm to others, and sanctity of human life. A set of educational materials designed to deliver these key messages /activities and a 'How to…' guide to support Imams in delivering these messages/activities, will be part of the intervention. Designed to encourage positive change in smoking behaviours, M4bH will comprise of group discussions, key take-home messages, role-plays, quizzes, games and take-home leaflets. The activities will be tailored to suit different audiences and age groups and will be adapted to be delivered in-between regular prayers/circle meetings/Qur'an classes. The imams in mosques allocated to the two intervention arms will be trained to deliver M4bH to their respective congregations. These will consist of men in mosques during prayer congregations, in study circles, Qur'an classes and informal groups, and young people during Qur' an and madrassa classes. It is envisaged that these activities will be integrated within mosques' and madrassas' routine.

2. Indoor air quality (IAQ) feedback intervention
IAQ will be measured in ALL participating homes at baseline. The IAQ feedback intervention will be provided to those homes in Arm 1 of the study, and will comprise personalised information on the IAQ measured within their home in order to motivate changes in smoking behaviour in households. The information will be based on data gathered at baseline (see below) using a monitor called the Dylos DC1700 (Dylos, California, USA). Based on the principles of visual communication and pre-tested in Phase I, the information leaflet will use visual aids to help family members understand the significance of IAQ feedback figures and provide a target that can is achievable by implementing smoke-free household rules within that home. This will be accessible to individuals with a diverse range of literacy and numeracy skills. Follow-up measurements will take place at 3 months and 6 months in those homes where high levels of SHS were identified at baseline and in about 10% of those where baseline measurements suggested a smoke-free environment. Homes in Arm 1 will receive further IAQ feedback at 3 months and on completion at 6-months. All homes (in Arms 2 and 3) will receive details of their IAQ measurements on completion of the study at 6 months.

3. Usual services
No intervention will be offered to mosques minimised to usual services arm until the trial has completed. Following the completion of the pilot trial, mosques will be offered the M4bH toolkit free of charge.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 14/01/2019:
24-hour mean household concentration of indoor fine particulate matter (PM2.5) at 12 months post randomisation:
PM2.5 will be measured in homes using the Dylos DC 1700 (Dylos, California, USA) a low-cost particulate counter validated for use in domestic settings. Data from Scotland indicate that a smoke-free home will have PM2.5 concentrations that are generally about 5-10 times lower than a home where smoking takes place. Data from smokers' homes in Scotland suggest that there is little difference between PM2.5 levels measured on the first day compared with levels measured over the following period of up to six days. This suggests that installation of these monitors for 24 hours will provide a good representation of SHS levels within that home.

Previous primary outcome measure:
Household SHS concentration, measured as fine Particulate Matter less than 2.5 microns diameter (PM2.5) at 3 months post-randomisation:
PM2.5 will be measured in homes using the Dylos DC 1700 (Dylos, California, USA) a low-cost particulate counter validated for use in domestic settings. Data from Scotland indicate that a smoke-free home will have PM2.5 concentrations that are generally about 5-10 times lower than a home where smoking takes place. Data from smokers' homes in Scotland suggest that there is little difference between PM2.5 levels measured on the first day compared with levels measured over the following period of up to six days. This suggests that installation of these monitors for 24 hours will provide a good representation of SHS levels within that home.

Key secondary outcome(s))
A number of secondary outcome measures will be used in this study. The following will be measured for the household:
1. SHS concentration measured as fine PM less than 2.5 microns diameter (PM2.5) at 6 months

post-randomisation
2. Smoking restrictions at home: The level of smoking restrictions at home will be assessed through a questionnaire directed at the adults in the households at 3, 4, 5 and 6 months post-randomisation

These will be measured for each member of the household:
3. Frequency and severity of respiratory symptoms: For participants aged 11 and over, Part 1 (eight questions) of the validated St George's Respiratory Questionnaire (SGRQ) will be used to assess participants' recollection of their respiratory symptoms over the preceding month at 3, 4, 5 and 6 months post-randomisation. SGRQ is a validated questionnaire and a Bangla translation is available for use. For participants younger than 11, respiratory symptoms will be assessed by another severity scale developed and validated by Chauhan et al at 3, 4, 5 and 6 months post-randomisation.
4. Quality of life, measured using EQ-5D29,30 for adults aged 18 and over, EQ-5DY for adolescents (11-17 years inclusive) and PedsQoL for children younger than 11 years, at 3 and 6 months post-randomisation

5. Health service use: number and type of contacts with doctors, hospital admissions, pharmacy visits and antibiotic prescriptions for all participants, collected using a health service utilisation questionnaire previously used in the MCLASS pilot trial. This will be assessed at 3 and 6 months follow-up. Resource use data for each member of the household will be collected in all three trial arms for utilisation of health care resources including physician visits, hospitalisations and medications using the service use questionnaires as developed in the MCLASS pilot. Quantities of resource use are multiplied by local unit costs of care to calculate per individual cost.
6. Mediators of intervention effectiveness: attitude, social norms, intentions and action planning, self-efficacy and coping planning with regards to smoking and SHS exposure, assessed using a pre-tested questionnaire at 3 months follow-up

In addition to socio-demographic variables, other confounders identified through literature a priori will also be measured including:
7. Number of residents
8. Building environment
9. Neighbourhood
10. Presence of mould/moisture in homes
11. Use of gas for cooking or gas/kerosene/oil heater
12. Mosque attendance and receipt/participation in M4bH programmes

13. Knowledge of the imams trained to deliver the study intervention on smoking and second-hand smoke exposure, measured using a semi-structured questionnaire post-training

Completion date
31/08/2019

Eligibility

Key inclusion criteria
Clusters: The study is to be conducted in 45 mosques and their catchment communities in Mirpur area of Dhaka, Bangladesh

Eligibility criteria for mosques:
1. Be based in the residential parts of Mirpur, Dhaka

2. Host communal prayers (including Friday prayers)
3. At least half a kilometre from another cluster (participating mosques)
4. Be led by a Imam or Khateeb who is a self-reported non-smoker
5. Be enlisted with the Islamic Foundation (IF). These mosques will be under a government ministry and will be monitored by the government. This is important in the Bangladesh context

The aim is to enroll a total of 1,800 households for the trial (average 40 per each participating mosque)

For a household to be eligible for the study, it should have:
1. At least one resident attending one of the participating mosque
2. At least one adult resident who smokes cigarettes or other forms of smoked tobacco (e.g. biri, hukka, shisha) regularly (at least 25 out of 30 days/ month)
3. At least one non-smoking resident of any age
4. Not planning to move home in the next 12 months
A resident is defined as an adult or child who has been staying in the home for 3 months and plans to stay at least 1 year in that home

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
1801

Key exclusion criteria
A household is not eligible if:
1. It uses coal and/or biomass fuel for domestic use
2. The household head is unwilling/unable to give written informed consent

Date of first enrolment
01/04/2018

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
Bangladesh

Study participating centre
45 mosques and their catchment communities in Mirpur area of Dhaka, Bangladesh
Bangladesh
-

Sponsor information

Organisation
University of York

ROR
https://ror.org/049ysg747

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

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

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 and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2021	19/04/2021	Yes	No
Results article	process evaluation results	11/10/2022	12/10/2022	Yes	No
Protocol article	protocol	05/01/2019		Yes	No