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Protecting Bangladeshi and Pakistani origin Muslim communities from second-hand smoke by delivering the "Smoke Free Homes" educational programme through faith leaders: Muslim Communities Learning About Second-hand Smoke (MCLASS)

Submission date
18/04/2012

Recruitment status
No longer recruiting

Registration date
15/05/2012

Overall study status
Completed

Last Edited
18/12/2017

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims

In the UK, 40% of Bangladeshi and 29% of Pakistani men smoke cigarettes regularly compared to the national average of 24%. Second-hand smoking (SHS) is also common in their households, which is a serious health hazard to non-smokers, especially children. Smoking restrictions in households reduces childrens exposure to SHS. In adults, SHS is associated with heart disease, lung disease, and nose and lung cancer. Womens exposure to SHS during pregnancy increases risk of miscarriage, stillbirth, under development and cot death. It has been suggested that 45% of children in England and Wales live with at least one smoker in their homes. Studies also suggest that teenagers are more likely to take up smoking if their parents are smokers.

SHS is also common in Bangladeshi and Pakistani households. For example, our study in a locality in which nearly 50% of the population is of South Asian origin found that smoking takes place regularly in front of children in 42% of all households with at least one smoker. Other studies also report higher levels of SHS exposure among Bangladeshi-origin children in households with smokers compared to children from other ethnic backgrounds. Moreover, smoking quit rates are lower than the UK average in these groups despite a high motivation to quit. There is a feeling of isolation and marginalisation from the existing smoking cessation services and lack of benefit from smoke-free initiatives. There is limited evidence on the effectiveness of protecting non¬smoking adults and children from SHS, particularly in regards to interventions which are acceptable, feasible and sensitive to the needs of ethnic minorities (i.e., Bangladeshi¬ and Pakistani¬ origin communities). Therefore we plan to conduct a pilot trial of Smoke Free Homes, which is an educational programme delivered by Muslim religious teachers in mosques in the UK to reduce second-hand smoke exposure among Bangladeshi- and Pakistani-origin ethnic communities. Our main aim is that the pilot trial will inform the design of a future definitive trial.

Who can participate?
The trial will be carried out in 14 mosques that either host communal prayers, convene study circles for women or have regular Quran classes for children. Around 50 households per mosque will be asked to participate.

What does the study involve?
We have developed a package titled Smoke Free Homes: A resource for Muslim religious teachers, which consists of a series of fact sheets detailing key information on smoking and SHS, and Smoke Free Homes, a series of activities through which the key information can be circulated. We will randomly divide the 14 mosques into two equal groups. Mosques in one group will be trained and offered the Smoke Free Homes (SFH) programme and asked to carry out the SFH activities within their role and routine at the mosque. Mosques in the other group will not receive any intervention (i.e., training and/or the SFH programme) and therefore they will not carry out the SFH activities at their mosques.
From each of the 14 mosques, we will recruit at least 50 households where there is at least one adult resident who smokes cigarettes or other forms of tobacco, and at least one child or a non-smoking adult. Each of the households will participate in a survey and provide a saliva sample at two points in time (i.e., beginning and after the intervention has run for at least 3 months). The saliva sample will be used to test levels of cotinine, which is a substance found in cigarette smoke and is an indicator of SHS exposure. We will also conduct focus groups discussions and interviews with the mosque chairpersons, religious teachers and members who attend the SFH activities (i.e., adults and children). Using data from these sources, we will evaluate the feasibility and design issues relevant to conducting a definitive trial which aims to investigate whether Smoke Free Homes delivered through mosques is an effective way of protecting non¬smokers from second-hand smoke, and to reduce uptake of smoking and improve smoking quit rates in Bangladeshi-¬ and Pakistani-origin Muslim communities in the UK, as well as understanding the extent to which Smoke Free Homes can be integrated into mosques routines.

What are the possible benefits and risks of participating?
Although the SFH programme has been highlighted in previous studies for reducing the levels of second-hand smoke, there are no particular benefits for the participants and mosques to take part in the trial. Participants in the intervention group will be offered the SFH package, and religious leaders/teachers will receive training as well, which can be perceived as potential benefits by the participants. Our preliminary work suggests that mosques are usually willing to take part in research projects that have the potential to directly benefit the communities they serve.
The SFH programme is an educational package, and the messages used are not harmful. Providing the saliva sample and completing the surveys presents very minimal risks, if any risk, to participants. The content of the SFH package was developed with the active participation of a number of Muslim faith leaders based in mosques in Leeds during our initial feasibility study and our work to ¬date suggests that it is acceptable to use and poses no harm to the participants.

When is the study starting and how long is it expected to run for?
This study will run for around 24 months, staring in April 2012. However, we predict that participants will be involved for considerably less time, since the recruitment of participants and the intervention stage (mosques implementing the SFH programme) will be staggered over a period of four months. We expect participants to be involved for around six to nine months.

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

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

Contact information

Type(s)
Scientific

Contact name
Dr Kamran Siddiqi

Contact details
Department of Health Sciences
Seebohm Rowntree Building
University of York
York
United Kingdom
YO10 5DD

Additional identifiers

Study information

Scientific Title
Protecting Bangladeshi and Pakistani origin Muslim communities from second-hand smoke by delivering Smoke Free Homes educational programme through faith leaders: Muslim Communities Learning About Second-hand Smoke (MCLASS) - a pilot cluster randomised controlled trial

Acronym
MCLASS

Study objectives
Smoke Free Homes (SFH) package for religious teachers is aimed at faith leaders to encourage people to implement smoking restrictions at homes with positive effects. The null hypothesis for the MCLASS trial is that there will be no difference in cotinine levels in saliva samples between intervention and control groups. If this trial can demonstrate the role and influence of religious leadership in shifting social norms within Bangladeshi and Pakistani ethnic origin Muslim communities; there is potential for the same principle to be applied to tackle other relevant health issues such as obesity and exercise.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics approval received from the local NRES Committee (REC reference: 12/YH/0242) and has also been approved by the University of York, Health Sciences Research Governance Committee in May 2012.

Primary study design
Interventional

Study design
Pilot cluster randomised control trial with an embedded qualitative study and preliminary health economic analysis component

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Reducing levels of second-hand smoke exposure among deprived communities in the UK

Interventions
The intervention group clusters (i.e. mosques) will be offered the SFH package and training on how to adapt the SFH activities into their daily role and routine at mosques. Mosques in the intervention group will be expected to implement the SFH educational programmes in their premises. Whereas, mosques in the control group will not receive the SFH package.

No intervention will be offered to mosques that are randomised to the control group. Following the completion of our trial, mosques in the control group will also be offered the "Smoke Free Homes" pack free of charge and provided with a detailed guide on how to train religious teachers to use the SFH package.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Our proposed project will carry out a pilot MCLASS trial with the aim to assess the feasibility of conducting a large definitive trial to investigate the effectiveness of the Smoke Free Homes intervention in a mosque setting and to answer the following key research questions:
1. Number of clusters (mosques) and the size of each cluster (participants) for the main trial
1.1. What are the recruitment and attrition rates for mosques (clusters) and participants?
1.2. How willing are mosques and participants to be randomised?
1.3. What is the likely effect size in relation to the primary outcome measure (i.e. salivary cotinine)?
1.4. What is the Intra-class coefficient (ICC) for the primary outcome among participants?
1.5. What is the likely potential of contamination between clusters?
2. Feasibility and resource requirements to deliver the intervention and assess its outcomes
2.1. What are the costs associated with delivering Smoke Free Homes through mosques?
2.2. What is the feasibility and acceptability of measuring the primary outcome (salivary cotinine)?
2.3. What is the response rate for the household survey to assess smoking behaviour?

3. Integration of Smoke Free Homes in mosques
3.1. What are the facilitators & barriers for integration of Smoke Free Homes into mosque practice and how might facilitators be enhanced / barriers be addressed?
3.2. What are the views and experiences of faith leaders and participants regarding the intervention?
3.3. What are peoples (i.e. men, women and children) views and attitudes on the appropriateness of religious leaders taking on a health promotion role?

The primary outcome measure in a definitive trial would be salivary cotinine levels in non-smokers in the households at follow up. This will allow us to assess the levels of exposure in households to compare intervention and control group outcomes, particularly groups who are at high risk of SHS (i.e. children).

Key secondary outcome(s)
1. Smoking restrictions at home: We will assess the level of smoking restrictions at home through a questionnaire directed at the adults in the households
2. Smoking status of adults and their intention to quit: We will assess the smoking status of the adults living in participating households.
3. Family health service use: We will ask about the health service use of members of the household in the three months before the intervention and in the three months during the intervention.
4. In addition we will measure a number of other variables, which will be built into our enquiry tools for assessing the above outcomes. These will include children (gender, ethnicity), family (structure and composition e.g. number of adults, children, their age and gender, socio-economic status, employment status, number of rooms in the house) and neighbourhood variables (e.g. availability of smoke free environments, rural, urban, cigarette shops etc.). In addition, we will also ask about the frequency and mode of contact with the mosques i.e. prayers, study circles, Quran classes.

Completion date
01/04/2014

Eligibility

Key inclusion criteria
1. Mosques:
1.1. Have a mosque committee and an appointed Imam
1.2. Are located in a area with Muslim residents of Pakistani and/or Bangladeshi ethnic groups
1.3. At least one mile apart from another participating mosques; please note: Some mosques serve different denominations (Barelvi, Deobandi, Shia etc.) and happen to be in one mile radius. A mosque serving a different denomination would be included even if it is within a one mile radius of another mosque.
1.4. Hold regular Friday prayers with an average of at least 50 attendees
1.5. Hold regular Quran classes for children
1.6. Hold or to be able to organise womens circle(s)
2. Households:
2.1. Residents of the participating household must have at least one adult resident who smokes cigarettes or other forms of tobacco on a regular basis and at least one child or a non--smoking adult
2.2. A male adult attends the mosque or a female adult who attends the women circle or a child who attends the Quran classes at least once a week

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
1. Mosques:
1.1. Have taken part in a "Smoke Free Homes" activity before
1.2. Within a one mile radius of another cluster (participating mosques), unless the mosques serves different denominations (Barelvi, Deobandi, Shia etc.)
2. Households:
2.1. All household adult residents smoke cigarettes or other forms of tobacco on a regular basis, and there is no child resident
2.2. There are no residents in the household who smoke on a regular basis
2.3. Household members are regularly attending more than one mosque that is in the trial

Date of first enrolment
01/04/2012

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of York
York
United Kingdom
YO10 5DD

Sponsor information

Organisation

University of York (UK)

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK) ref: MR/J000248/1

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

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/08/2015		Yes	No
Protocol article	protocol	13/09/2013		Yes	No