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Title: Muslim Communities Learning About Second-hand Smoke in Bangladesh (MCLASS II): a three-arm, cluster randomised controlled trial of the effectiveness and cost-effectiveness of a community-based smoke-free homes intervention, with or without indoor air quality feedback

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SUMMARY

Background

Exposure to second-hand smoke (SHS) from tobacco is a major contributor to global morbidity and mortality. We evaluated the effectiveness and cost-effectiveness of a community-based smoke-free homes (SFH) intervention, with or without indoor air quality (IAQ) feedback, in reducing SHS exposure in homes in Bangladesh.

Methods

We conducted a pragmatic, three-arm, cluster randomised controlled trial in which we randomised mosques and consenting households from their congregations to SFH intervention plus IAQ feedback, SFH intervention only, or usual services. The SFH intervention consisted of health messages delivered within an Islamic discourse by religious leaders at mosques over 12 weeks. IAQ feedback comprised providing households with feedback on their 24-hour IAQ. The primary outcome was the 24-hour mean household fine particulate matter <2·5 microns in diameter ($PM_{2·5}$) concentration (a marker of SHS) at 12 months post-randomisation. Cost-effectiveness was estimated using incremental cost-effectiveness ratios (ICERs). Trial registration number: ISRCTN49975452.

Findings

45 mosques (1,801 households) were recruited between April and August 2018. At 12 months, the adjusted mean differences in the primary outcome were -1·0μg/m^3 (95% confidence interval (CI) -12·8 to 10·9, p=0·88) for SFH intervention plus IAQ feedback versus usual services (primary comparison), 5·0μg/m^3 (95% CI -7·9 to 18·0, p=0·45) for SFH intervention only versus usual services, and -6·0μg/m^3 (95% CI -18·3 to 6·3, p=0·34) for SFH intervention plus IAQ feedback versus SFH intervention only. The ICER for the primary comparison was US$653/QALY gained, which was above the US$427/QALY threshold. The SFH intervention only incurred higher costs, but generated less QALYs compared to usual services.

Interpretation

The SFH intervention, with or without IAQ feedback, was neither effective nor cost-effective in reducing household SHS exposure compared to usual services. These interventions are therefore not recommended for Bangladesh.

Funding

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Research in context

Evidence before this study

We reviewed relevant literature identified from four databases: MEDLINE, Embase, CINAHL, and the Cochrane Controlled Register of Trials. We looked for randomised controlled trials of community-based interventions to reduce second-hand smoke (SHS) exposure conducted in low- and middle-income countries (LMICs). The studies had to have reported biochemically verified SHS exposure (e.g., through measuring air quality, air nicotine concentrations, or cotinine concentration in the blood, urine, saliva or hair) as an outcome. We searched for English language publications from the inception of the databases till July 2017 and updated the searches in December 2018. We found six studies that met our eligibility criteria. All six studies evaluated counselling or educational interventions targeted at reducing SHS exposure, particularly among children. Three studies evaluated interventions delivered to children within schools. Of these, two conducted in China found that the interventions were effective in reducing mean urine cotinine concentration, and the remaining study conducted in Bangladesh by our team did not find any statistically significant difference between groups on saliva cotinine concentrations. A study conducted in China where the intervention was delivered in people's homes found that the intervention was effective on reducing mean urine cotinine concentration among children. Another study conducted in Iran identified participants from health centres: it demonstrated that the community-based intervention was effective in reducing mean urine cotinine concentrations among children. The sixth study was conducted in Armenia and did not find any benefits from the intervention on hair cotinine concentrations. Our review concluded that, whilst there is some evidence of the effectiveness of community-based interventions in reducing SHS exposure, this evidence is very limited. Moreover, the potential of religion in promoting behaviours that are protective from SHS exposure had yet to be explored. We did not identify any studies evaluating the costs or cost-effectiveness of community-based interventions to reduce SHS exposure.

Added value of this study

Our trial is the first to investigate the effectiveness and cost-effectiveness of community-based interventions, delivered within a faith-based discourse by imams and other religious leaders in mosques with or without an individual-level indoor air quality feedback intervention, for reducing SHS exposure within the home. Our interventions were neither effective nor cost-effective when compared to usual services. However, we demonstrated that it is feasible to conduct large studies of such interventions within faith-based settings in low-income country contexts.

Implications of all the available evidence

Current evidence on the effectiveness and cost-effectiveness of community-based interventions to reduce SHS exposure in LMICs is limited and the findings are mixed. Unless future studies provide strong evidence demonstrating their effectiveness and cost-effectiveness, such interventions cannot be recommended for scale up within LMIC settings. There is a need for more studies exploring interventions that have shown promise in high-income countries such as those that combine smoke-free home interventions with smoking cessation advise and support for smokers within the home.

BACKGROUND

Every year approximately 1·2 million people die worldwide from exposure to second-hand smoke (SHS) from tobacco.[1] 47% and 28% of these deaths occur in women and children respectively, mostly in low- and middle-income countries (LMICs).[2] About 11 million disability-adjusted life years are lost due to SHS exposure worldwide every year, with children carrying approximately 61% of the burden of disease attributable to SHS.[2] In Bangladesh, 39% (40.8million) of adults and 31% of students aged 12 to 16 years (classes 7-9) are exposed to SHS in their homes.[3,4] A survey of 12 schools in Dhaka, Bangladesh found that 95% of 9-11 year olds had saliva cotinine levels consistent with recent SHS exposure.[5] The mean cotinine value of those living with a smoker was approximately double that of those not living with a smoker.[5] Thus, homes remain a key source of SHS exposure in children in Bangladesh.

In Bangladesh, 88% of the total population are Muslims.[6] Religion has an influence on both health-risk behaviour and health.[7-9] It is a far-reaching conveyor of social norms, potentially through clear and direct precepts regarding the pursuit of a healthy life, or religious tenets that have an indirect effect on health.[7] Religion, including the Islamic faith, can have a prohibitive influence against tobacco use and promote quitting among smokers.[10,11] Reinforcing health messages in interventions using Islamic scripture to change smoking behaviours has been reported as acceptable.[12] Islamic faith-based teachings and teachers thus have a potential role in tobacco control, including in reducing SHS exposure in the home; but evidence on the effectiveness of faith-based interventions on changing smoking behaviours is lacking.[13] Indoor air quality (IAQ) feedback based on markers of SHS such as the concentration of airborne particulate matter less than 2·5 microns ($PM_{2\cdot5}$) in diameter can potentially motivate households to make their homes smoke-free.[14] However, using IAQ feedback this way is under-researched, particularly in LMICs.

For the Muslim Communities Learning About Second-hand Smoke (MCLASS) II trial, we built our interventions on theoretical work on the role of faith-based interventions to reduce smoking and the potential motivational effects of IAQ feedback.[10,13,14] We also built our methods on a pilot trial conducted in England that found that a Smoke-Free Homes (SFH) intervention was acceptable to Muslim communities and feasible to deliver through mosques.[15] We designed a community-based SFH intervention in which religious leaders (i.e., imams and khatibs) encouraged their mosque congregations to change their smoking behaviours. In this paper, we report results from the evaluation of the effectiveness and cost-effectiveness of the community-based SFH intervention, with or without IAQ feedback, in reducing exposure to SHS in the home, the frequency and severity of respiratory symptoms, health service use and in improving quality of life.

METHODS

Study design and participants

We conducted a pragmatic, three-arm, open label, cluster randomised controlled trial (RCT) and economic evaluation in which mosques in Mirpur, Dhaka, Bangladesh were randomised and households from their catchment communities enrolled. The mosques were situated in residential areas of Dhaka, hosted regular communal prayers (including Friday Jumu'ah prayers) and had a non-smoking religious leader (imam/khatib). They were affiliated with the Islamic Foundation under the Ministry of Religious Affairs, Bangladesh. A household (i.e., a single housing unit shared by one or more people) was eligible if it had at least one resident attending one of the participating mosques**,** at least one adult resident who smoked cigarettes and/or other forms of smoked tobacco (e.g., bidi, waterpipe) regularly (at least 25 days/month), and at least one non-smoking resident of any age. Households were excluded if they were planning to move home in the next 12 months, or used coal or biomass fuel for domestic cooking or heating. A resident was defined as an adult or child who had been staying in the home for the preceding three months and planned to stay for at least one more year.

Written informed consent was obtained from imams/khatibs for their and their mosques' participation, household heads for recruiting their households, adults in respective households for data collection and if they are parents/guardians then also for collecting data on their children. Ethics approval was obtained from the Bangladesh Medical Research Council's National Research Ethics Committee (Ref: BMBC/NREC/2016–2019/358) and the University of York's Health Sciences Research Governance Committee.

Randomisation and masking

Once recruitment and baseline data collection were completed within a mosque, it was ready for central randomisation 1:1:1 to: SFH intervention plus IAQ feedback, SFH intervention only, or usual services. Minimisation, via MinimPY (https://sourceforge.net/projects/minimpy/), was used to balance on the average estimated size of the Friday Jumu'ah prayer congregation (≤1500/>1500) and geographical location (wards within Mirpur). Randomisation was performed by a statistician at the University of York who was not involved in recruiting mosques or households. Mosques were input into MinimPY in a random order unknown to anyone but the statistician. Thus, even if the minimisation factors for the mosques were known, the allocations could not be predicted in advance and allocation concealment was assured. Blinding of participants or imams/khatibs was not possible. Outcome data collection and statistical analyses were also not conducted blind to allocation.

Procedures

The SFH intervention consisted of health messages relating to smoking and SHS exposure, each supported by at least one Qur'an verse (ayah), or an Islamic faith-based decree. The messages were developed through iterative workshops involving Islamic scholars, public health professionals and behavioural scientists. The messages were delivered by imams/khatibs to those attending Friday Jumu'ah prayer in mosques over 12 weeks (one message per week- see examples in Supplementary Table S1). The full intervention manual is available at https://www.york.ac.uk/healthsciences/research/public-health/projects/mclass11/#tab-3. The messages addressed key determinants of current smoking behaviours including: lack of knowledge on, and attitudes towards, smoking and SHS exposure by providing information on health consequences of smoking and SHS exposure including addressing misconceptions; and perceptions about social norms by providing general information on others' approval. The messages also targeted prompting intentions, goal setting (both for behaviour, e.g., quit attempt, and the desired outcome of SFH), self-efficacy, commitment, action planning, coping planning, and sources of social support. The intervention logic model is provided as Supplementary Figure S1.
Imams/khatibs in mosques randomised to deliver the SFH intervention received an

intervention booklet-based half-day training on the intervention and its delivery. They also received copies of the SFH intervention booklet to distribute to their congregation members after Friday Jumu'ah prayers or in study circles. Intervention delivery started immediately after training and continued for 12 weeks.

IAQ feedback comprised providing households with personalised information on the $PM_{2·5}$ concentration measured within their home at baseline, in the form of a two-page bespoke leaflet, aimed at motivating changes in smoking behaviour in households. The leaflet is available at https://www.york.ac.uk/healthsciences/research/public-health/projects/mclass11/#tab-3. $PM_{2·5}$ concentration was measured in homes using the Dylos DC 1700 (Dylos, California, USA), an optical particle counter validated for use in domestic settings.[16] Feedback included a comparison of the household's 24-hour mean $PM_{2·5}$ concentration to the World Health Organization (WHO) guidance limit of 25µg/m^3,[17] the total time the IAQ was above this guidance limit, and the maximum concentration measured. Feedback also included pictorial information about the household $PM_{2·5}$ concentration (with classifications: hazardous if >150µg/m^3, unhealthy if 36-150µg/m^3, moderate if 12-35µg/m^3, and good if <12µg/m^3), information about adverse effects of SHS exposure, recommendations to reduce SHS exposure in the home, and a target that was achievable by implementing SFH rules within the home. The leaflet was designed in consultation with lay community members. Trial field investigators delivered and discussed the IAQ feedback with household members in person in approximately 10 minutes. All followed-up households in the three groups received feedback on their 12-month IAQ measurements after the final follow-up.

No intervention was offered to households in mosques randomised to receive usual services; however, following trial completion, mosques in the usual service group were offered the SFH toolkit free of charge.

Field investigators recruited mosques by providing their leaders with trial information and screening the mosques for eligibility. They also approached household heads living in the catchment area and attending prayers at any of the participating mosques, either at the mosque or through a home visit, and provided them with study information; those interested were screened for eligibility.

Data were collected at baseline, and three, six and 12 months post-randomisation (Supplementary Table S2) using paper-based questionnaires administered by 16 field investigators after receiving three-days training on trial procedures. The data was entered into a password-protected database on a secure web application, Research Electronic Data Capture (REDCap) (https://projectredcap.org/software/). More details on study design, participant and study procedures are provided in our published protocol.[18]

Outcomes

The primary outcome was 24-hour mean household $PM_{2·5}$ concentration at 12 months post-randomisation. Household-level secondary outcomes were: 24-hour mean $PM_{2·5}$ concentration at three months; and smoking restrictions at home assessed through a questionnaire directed at adults in the households. Participant-level secondary outcomes assessed at each follow-up were: frequency and severity of respiratory symptoms assessed using Part 1 (eight questions) of the validated St. George's Respiratory Questionnaire (SGRQ)[19] for participants 11 years and over, and the severity scale developed and validated by Chauhan et al[20] for participants younger than 11; health-related quality of life (HRQoL) assessed using the EQ-5D-5L[21] for adults (≥18 years), EQ-5D-Y[22] for adolescents (11-17 years inclusive) and PedsQoL[23] for children younger than 11 years. A questionnaire previously used in a pilot trial in England,[15] and adapted to the Bangladesh context was used for healthcare resource utilisation.

Statistical analysis

We planned to recruit 45 mosques and 40 households per mosque (n=1,800), and to follow-up 30 households per mosque at three months (n=1,350) prioritising those with an average baseline $PM_{2·5}$ ≥ 35μg/m^3. Assuming an intra-cluster correlation coefficient (ICC) of 0·02 and 20% attrition at 12 months, this would provide 90% power to detect an effect size of 0·3 of a standard deviation (SD; equivalent to a difference of 13·5, from 76μg/m^3 to 62·5μg/m^3, assuming a SD of 45), for each pairwise comparison, using a two-sided alpha of 0.05.

Analyses followed a pre-specified analysis plan, approved by the Trial Steering Committee prior to the completion of 12-month data collection. No post-hoc analyses were conducted. Analyses were conducted using intention-to-treat and two-sided statistical tests at the 5% significance level in Stata v15. Baseline and outcome data were summarised by group.

The primary analysis compared household 24-hour mean $PM_{2·5}$ measurement between the groups using a covariance pattern, mixed-effect linear regression model incorporating the two post-randomisation time points (three and 12 months). The model included baseline $PM_{2·5}$ value (household-level), geographical area and size of Friday Jumu'ah prayer congregation in its continuous form (mosque-level), and time point, randomised group, and a time by group interaction as fixed effects. Household and mosque were specified as random effects. An unstructured covariance pattern for the correlation of observations within households over time was specified, based on minimising the Akaike information criterion. Visual inspection of model assumptions demonstrated substantial deviations (Supplementary material S1: Primary analysis model assumptions; and Supplementary Figures S2 and S3). Log-transformation of the outcome data improved model fit (Supplementary Figures S4 and S5) and was explored in sensitivity analyses. The pairwise mean difference, 95% confidence interval (CI) and p-value at three and 12 months was extracted from the model.

The primary comparison was between SFH intervention plus IAQ feedback and usual services at 12 months. All other comparisons served as secondary investigations. To account for non-compliance with randomised group, a complier average causal effect (CACE) analysis[24] for the primary outcome was conducted. A two-stage, least squares instrumental variable (IV) approach was used, with randomised group as the IV. Two analyses compared the 12-month outcome for each intervention with usual services. Within the SFH intervention only group, compliance was defined at the household-level as the lead adult reporting that they or another member of their household had received the SFH intervention from any mosque at any time point. Within the SFH intervention plus IAQ feedback group, compliance additionally included self-reported receipt of IAQ feedback by the three-month follow-up.

Calibration of the Dylos machines prior to the 12-month follow-up indicted that they were consistently underestimating $PM_{2\cdot5}$ concentrations, relative to a 'gold standard', factory calibrated device, due to degradation of the laser particulate counter caused by heavy use at the baseline and three-month assessments. This underestimation was corrected for in the primary analysis; details of sensitivity analyses assessing the impact of this correction are provided in Supplementary material S2: Sensitivity analyses.

A subgroup analysis considered whether the benefits of the interventions were greater among households with a baseline $PM_{2\cdot5}$ value $\geq 35\mu g/m^3$ than those with $<35\mu g/m^3$, by including an interaction between dichotomised baseline $PM_{2\cdot5}$ value and group in the primary analysis.

Participant-level respiratory symptom scores were analysed in an analogous way to the primary outcome. Participant, household, and mosque were nested random effects. Analyses were performed separately for the SGRQ Symptoms component score for adults, for children aged 11-17 years, and for the total symptoms severity scale for children aged less than 11 years. Since both these instruments measure the same construct, respiratory symptoms, an additional analysis that included all participants was conducted using standardised scores. Model assumptions were assessed as for the primary analysis; no major deviations were observed so data transformation was unnecessary.

Cost-effectiveness analysis

We conducted a within-trial cost-effectiveness analysis comparing the SFH intervention with and without IAQ feedback to usual services. The analysis used a healthcare sector and intervention provider perspective to include healthcare resource use and intervention delivery costs. No discounting was applied as the follow-up period was 12 months.

All costs were calculated using a bottom-up approach. Costs for training and delivering the interventions (teaching materials, support, etc.) were estimated based on the cost incurred alongside the trial, while information on health care resources use (number of inpatient stays, outpatient visits, etc.) was collected from participants. The unit costs of home visits by doctors or nurses were obtained from the Bangladesh Bureau of Statistics,[25] those of inpatient stay and outpatient visit were derived from WHO's Bangladesh-specific unit costs,[26] and those of emergency department visits were extracted from the Bangladesh essential health service package (Table 1).[27] All cost results were expressed in 2018/19 US dollars (US$) using the 2018 World Development Indicators exchange rates.[28]

Due to the absence of unified and established tariffs from Bangladesh for the three instruments used to measure HRQoL (i.e. PedsQL, EQ-5D-Y and EQ-5D-5L), relevant UK value sets were used and mapped to the corresponding EQ-5D-3L values.[23,29] This allowed us to obtain unified utility estimates across individuals. A sensitivity analysis using Thailand value sets[30] for EQ-5D-Y and EQ-5D-5L were conducted to test the robustness of the results. Quality-adjusted life-years (QALYs) of individuals were calculated using the area under the curve method over the trial period.[31]

Cost-effectiveness was evaluated using the pairwise incremental cost-effectiveness ratios (ICERs) method[31] at a household level and assessed based on the Bangladesh willingness-to-pay (WTP) threshold: US$30 to US$427 per QALY gained.[32] Seemingly unrelated regression was used to account for potential correlations between costs and QALYs, and adjust for prognostic baseline covariates.[33] Uncertainty was estimated using the non-parametric bootstrapping technique with 5,000 replications that were presented on a cost-effectiveness plane.[31]

Role of funding source
This trial was funded by the Medical Research Council UK under the Global Alliance for Chronic Diseases (GACD) research programme [MR/P008941/1]. The funder had no role in the design of the trial and collection, analysis, interpretation of data or in writing the manuscript.

RESULTS

Trial population

116 mosques were assessed for eligibility and 45 were recruited (Figure 1). Reasons for exclusion were: being less than half a kilometre from another mosque (n=54); imams/khatibs not providing consent to participate (n=7), mosque catchment area having entry restrictions (n=7), small catchment area (n=2), and not performing Friday Jumu'ah prayers (n=1). Between 11th April and 2nd August 2018, 4,430 households were screened for eligibility; 1,801 (40·7%) were eligible and recruited. Reasons for ineligibility are in Supplementary Table S3. Every mosque recruited 40 households except one (allocated to usual services), which recruited 41. 16 mosques were randomised to the SFH intervention plus IAQ feedback, 14 to SFH intervention only and 15 to usual services (Supplementary Table S4).

Of the 712 households with average baseline $PM_{2·5}$ ≥35µg/m^3, 614 (86·2%) were followed-up at three months; 98 had either moved away from the study area or did not wish to continue the study. To achieve the target of 1,350 households followed-up at three months, we randomly selected another 736 households with average baseline $PM_{2·5}$ <35µg/m^3 to follow-up as per our trial protocol. Household baseline data as randomised and as followed up are summarised in Table 2, and Supplementary Tables S5-S12. The 1,350 households were contacted for follow-up again at 12 months and 1,314 completed it (2·7% attrition rate; usual services 2·0%, SFH intervention only 3·6%, SFH intervention plus IAQ feedback 2·5%).

Primary outcome

At 12 months, the average 24-hour $PM_{2·5}$ measurement was 65·2µg/m^3 (SD 44·7), 68·9µg/m^3 (SD 49·5) and 65·8µg/m^3 (SD 39·6) for usual services, SFH intervention only and SFH intervention plus IAQ feedback, respectively (Table 3). No evidence of a difference was observed at 12 months for any pairwise comparison, including when the outcome data were log-transformed (Table 4; Supplementary Figure S6). The adjusted mean differences were: SFH intervention plus IAQ feedback vs. usual services (primary comparison) -1·0µg/m^3 (95% CI -12·8 to 10·9, p=0·88); SFH intervention only vs. usual services 5·0µg/m^3 (95% CI -7·9 to 18·0, p=0·45); and SFH intervention plus IAQ feedback vs. SFH intervention only -6·0µg/m^3 (95% CI -18·3 to 6·3, p=0·34). The log-transformed sensitivity analysis indicated that the average $PM_{2·5}$ concentrations in the SFH intervention plus IAQ feedback households were expected to be 1·02 times larger (95% CI 0·86 to 1·21, p=0·79) than the usual services group. The mosque-level ICC was estimated at 0.08 (95% CI 0.05 to 0.14).

Secondary outcomes

There was no evidence of a difference in the average 24-hour $PM_{2·5}$ concentration at three months for any pairwise comparison, including when the outcome data were log-transformed (Table 4; Supplementary Figure S6). There was evidence of small differences in some secondary comparisons between SFH intervention only and SFH intervention plus IAQ feedback favouring SFH intervention plus IAQ feedback (SGRQ adults at six months: 2·4, 95% CI 0·3 to 4·6, p=0·03; respiratory symptoms <11 years at three months: 2·0, 95% CI 0·5 to 3·4, p=0·01; standardised respiratory scores all participants at six months: 0·14, 95% CI 0·00 to 0·29, p=0·04). No other differences were observed at three, six or 12 months (Supplementary Tables S13-S18).

Overall, 22·9% of households (usual services n=110, 24·9%; SFH intervention only n=76, 18·8%; SFH intervention plus IAQ feedback n=115, 26·6%) reported at 12 months that residents were permitted to smoke anywhere inside the home (Supplementary Table 18).

Sensitivity analyses

Within the SFH intervention only group, 331 (78·8%) households received the intervention; in addition, 91 (20·2%) of households in the usual services group reported receiving some element of the intervention. The CACE estimate of receipt of the SFH intervention was an increase in $PM_{2·5}$ concentration of 11·3μg/m^3 (95% CI -6·7 to 29·2). In the SFH intervention plus IAQ feedback group, 351 (73·1%) households received the SFH intervention and IAQ feedback by the three-month follow-up: the CACE estimate of receipt of the SFH intervention and an IAQ report was a decrease in $PM_{2·5}$ concentration (-3·0μg/m^3, 95% CI -17·4 to 11·4).

No differences were observed at three or 12 months in the other sensitivity analyses (Supplementary Tables S19 and S20; Supplementary Figures S7 and S8).

Subgroup analysis

There was no evidence of an interaction with baseline $PM_{2·5}$ value (<35/≥35μg/m^3) in the subgroup analysis (Supplementary Table 21; Supplementary Figures S9 and S10).

Cost-effectiveness results

Based on the 1,350 households followed up at three months, 4,893 out of 5,143 participants (95·1%) had complete cost and QALY data at all follow-ups. After removing households with members showing incomplete data, a total of 1,237/1,350 (91·7%) households were included in the cost-effectiveness analysis. The SFH intervention plus IAQ feedback group incurred the highest mean total cost ($32·8, SD 22·0) and generated the highest mean QALYs (3·31, SD 1·20) (Table 5). The SFH intervention only group incurred higher costs, but generated less QALYs, compared to the usual services group, and was therefore dominated. Due to high delivery cost of IAQ ($16.1), intervention cost was the key cost driver for the SFH intervention plus IAQ feedback group but not for the SFH intervention only group (Supplementary Table S22). The SFH intervention plus IAQ feedback group was found not to be cost-effective as the ICER of US$653/QALY against the usual services group was above the threshold of US$30 to 427/QALY gained. The results of the 5,000 bootstrapped SUR models are shown in Table 5 and Supplementary Figure S11. The bootstrapped ICERs fell within the top left quadrant of the cost-effectiveness plane and above the WTP threshold lines, indicating that both the SFH intervention only, and the combination of the SFH intervention plus IAQ feedback, were not cost-effective even when taking uncertainly into consideration. The results of sensitivity analysis were similar to the main findings (Supplementary Table S23 and Supplementary Figure S12).

DISCUSSION

Compared to usual services, the SFH intervention alone or in combination with IAQ feedback did not reduce exposure to SHS measured as the mean 24-hour $PM_{2\cdot5}$ concentration within households. The economic evaluation suggests that both the SFH intervention only and the combination of the SFH intervention and IAQ feedback were not cost-effective due to high intervention costs and minimal QALY improvements.

To the best of our knowledge, our trial is the first to investigate the effectiveness and cost-effectiveness of community-based interventions, delivered within an Islamic discourse by imams/khatibs in mosques, for reducing SHS exposure within the home. We demonstrated that it is feasible and acceptable to conduct large studies of such interventions within mosques. The trial is also the largest of its kind to provide 24-hour household-level $PM_{2\cdot5}$ concentration data, and explore the usefulness of using IAQ feedback as a motivational tool for reducing SHS exposure in the home, in a LMIC setting. Other strengths were the rigour and quality with which the trial was conducted, including a cluster RCT design, achieving the required sample size, high follow-up rates, high levels of data completeness, and the assessments of 12-month outcomes.

There are a number of potential explanations for the lack of effectiveness of our interventions. Sermons where the intervention messages were delivered are not mandatory and therefore some people may have joined the prayers, but not attended or paid the desired level of attention to the sermons. Although intervention compliance as defined in our trial was high, it is likely that individuals might have received some, but not all, messages. Because of the nature of the intervention, it was not possible to calculate the 'dose' of the intervention received by household members. The interventions targeted reducing SHS exposure in the home directly and did not offer smoking cessation support to smokers within the home. Aspirations to make SFH might have been constrained by limited social and environmental opportunities to change behaviour.[34,35] Thus, a standalone community-based intervention delivered over a limited period might have been insufficient to change smoking behaviours in Bangladesh where regulatory and fiscal measures for tobacco control are weak, cigarettes and bidis are cheap, and smoking cessation services are scarce. In addition, the personalised feedback was delayed due to the need to take the IAQ machine back to the office to download the data and generate the graphical and numerical feedback, and was not targeted specifically at the smokers.

The intervention effects on $PM_{2\cdot5}$ concentration in the home could have been diluted due to a Hawthorne effect across all trial groups during the baseline 24-hour measurement period when the Dylos devices were present in the home.[36] Measuring $PM_{2\cdot5}$ concentrations over a longer period of time could have reduced this potential bias by making it more difficult to sustain behaviour change over the whole measurement period.[36] However, this would have been more costly due to the need for more devices.

$PM_{2.5}$ is not specific to tobacco smoke – it can also be generated by non-tobacco sources such as using solid fuels and vehicle and industrial emissions. Our trial addressed other $PM_{2.5}$ influences by excluding households that used coal or biomass fuel for domestic use and restricting measurements to the period April-October when outdoor air pollution levels are lowest in Dhaka.[37] We also used a cluster RCT design in order to balance such confounders across the two arms. Therefore, any change observed in the primary outcome between the two arms would have been most likely due to change in smoking behaviour. Confidence in our findings is also enhanced by the fact that baseline $PM_{2.5}$ concentrations were significantly lower in smoke-free homes when compared to smoking permitted homes despite high ambient air pollution.[38]

Participants' HRQoL was measured using three different instruments (i.e. the EQ-5D-5L for adults,[21] EQ-5D-Y for adolescents[22] and PedsQoL for children[23]) due to the absence of a universal instrument that could measure the HRQoL across all age groups. As HRQoL may differ depending on which instruments are being used, this approach can result in household QALY estimations being sensitive to the number of people and the age composition in each household. However, this is unlikely to have affected our conclusion as the household composition was controlled for in the analysis. With no established Bangladesh population tariffs, the UK population tariffs were used for QALY calculations as they are the only tariffs that can convert all three instrument measurements into consistent EQ-5D-3L values. Future studies on Bangladesh tariffs, and for other LMICs, across all age groups are required in order to obtain more precise estimates.

In relation to faith-based behaviour change intervention, our findings can be generalised to other community-based interventions delivered primarily through mosques. When considering IAQ feedback, our study findings can be generalized to other urban centres similar to Dhaka with high population density, high levels of ambient air pollution and limited opportunities to smoke outside.

Contrary to our findings, studies in other areas such as cardiovascular diseases, obesity, and breast cancer screening have suggested that health programmes in faith-based organisations can improve outcomes.[8,9] Islamic faith-based smoking cessation interventions have also been found to be effective in encouraging Muslim smokers to stop smoking during Ramadan, although the sustainability of the behaviour change is unclear.[12,39] Nevertheless, our findings are consistent with those from other studies targeting reduction of SHS exposure within the home using behavioural interventions and IAQ feedback. A recent review found that the effectiveness of several counselling and educational interventions that have been used to try to reduce SHS exposure has not been clearly demonstrated.[40] More successful interventions seem to be those that combine SFH interventions with smoking cessation advice and support for smokers within the home, or those that target smoking cessation as a pathway to reducing SHS exposure.[41] In addition, a recent study showed that real-time particle feedback and coaching contingencies reduced indoor air pollution from behaviours such as smoking cigarettes or burning candles.[42] Hence, future research in LMICs should investigate the effectiveness of interventions that include offering smoking cessation to smokers within the household, and measures that offer real-time or immediate, rather than delayed, feedback on IAQ. Nevertheless, these technologies need to be low cost if they are to be cost-effective and scalable in LMICs.

In conclusion, the SFH intervention, alone or in combination with IAQ feedback, was not effective or cost-effective in reducing exposure to SHS in the home when compared to usual services and should therefore not be recommended in Bangladesh.

DATA SHARING STATEMENT

De-identified individual participant data on which summary statistics and tables are based will be at made available from the point of, and up to five years after the, acceptance for publication of the main findings from the final dataset. These data can be requested from the Principal Investigator (Professor Kamran Siddiqi, kamran.siddiqi@york.ac.uk) and will be shared after the provision of a methodologically sound proposal, and only under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed. The proposals will be assessed and approved by members of the Programme Management Group.

The intervention manual and indoor air quality feedback leaflet are available on the study webpage: https://www.york.ac.uk/healthsciences/research/public-health/projects/mclass11/#tab-3

Other material such as participant information sheets, informed consent forms and questionnaires will be made widely and freely available to anyone who wishes to access them from the point of, and up to five years after the, acceptance for publication of the main findings from the trial. They can be requested from the Principal Investigator.

The study protocol is available in the public domain for free: Mdege N, Fairhurst C, Ferdous T, et al. Muslim Communities Learning About Second-hand Smoke in Bangladesh (MCLASS II): study protocol for a cluster randomised controlled trial of a community-based smoke-free homes intervention, with or without Indoor Air Quality feedback. Trials 2019; 20: 11. doi: 10.1186/s13063-018-3100-y.

CONTRIBUTORS

NDM drafted the manuscript, contributed to study design, conduct and interpretation of findings. CF contributed to the writing of the methods and results sections of the manuscript, and designed and conducted the statistical analysis. H-IW and QW conducted the health economic analysis contributed to the writing of the methods and results sections of the manuscript. TF coordinated the implementation of the study in Bangladesh including data collection and management. AMM coordinated the study. CH participated in study design and oversaw the statistical analysis. RH contributed to study design, oversaw the implementation and conduct of the study in Bangladesh, and provided critical inputs to interpretation of results. CJ contributed to study design, and particularly led on process evaluation. IK contributed to the design of the interventions including the intervention logic model. ZAA contributed to intervention design and process evaluation. SP contributed to study design and specifically led the design of the health economic evaluation. SS contributed to study design and led the design of IAQ measurement and IAQ feedback. AS contributed to study design, interpretation of results and manuscript writing. KS conceived the study idea and contributed to the study design, conduct, interpretation of results and manuscript writing. All authors participated in manuscript revisions, and read and approved the final manuscript.

DECLARATION OF INTERESTS

The authors declare that they have no competing interests.

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