Efficacy and cost-effectiveness of a community-based smoke-free-home intervention with or without indoor-air-quality feedback in Bangladesh (MCLASS II): a three-arm, cluster-randomised, controlled trial

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Summary

Background Exposure to second-hand smoke from tobacco is a major contributor to global morbidity and mortality. We aimed to evaluate the efficacy and cost-effectiveness of a community-based smoke-free-home intervention, with or without indoor-air-quality feedback, in reducing second-hand-smoke exposure in homes in Bangladesh.

Methods We did a three-arm, cluster-randomised, controlled trial in Dhaka, Bangladesh, and randomly assigned (1:1:1) mosques and consenting households from their congregations to a smoke-free-home intervention plus indoor-air-quality feedback, smoke-free-home intervention only, or usual services. Households were eligible if they had at least one resident attending one of the participating mosques, at least one adult resident (age 18 years or older) who smoked cigarettes or other forms of smoked tobacco (eg, bidi, waterpipe) regularly (on at least 25 days per month), and at least one non-smoking resident of any age. The smoke-free-home intervention consisted of weekly health messages delivered within an Islamic discourse by religious leaders at mosques over 12 weeks. Indoor-air-quality feedback comprised providing households with feedback on their indoor air quality measured over 24 h. Households in the usual services group received no intervention. Masking of participants and mosque leaders was not possible. The primary outcome was the 24-h mean household airborne fine particulate matter (<2·5 microns in diameter [PM$_{2.5}$]) concentration (a marker of second-hand smoke) at 12 months after randomisation. Cost-effectiveness was estimated using incremental cost-effectiveness ratios (ICERs). This trial is registered with ISRCTN, 49975452.

Findings Between April 11 and Aug 2, 2018, we enrolled 1801 households from 45 mosques. 640 households (35·5%) were assigned to the smoke-free-home intervention plus indoor-air-quality feedback group, 560 (31·1%) to the smoke-free-home intervention only group, and 601 (33·4%) to the usual services group. At 12 months, the adjusted mean difference in household mean 24-h PM$_{2.5}$ concentration was –1·0 µg/m³ (95% CI –12·8 to 10·9, p=0·88) for the smoke-free-home intervention plus indoor-air-quality feedback group versus the usual services group, 5·0 µg/m³ (–7·9 to 18·0, p=0·45) for the smoke-free-home intervention only group versus the usual services group, and –6·0 µg/m³ (–18·3 to 6·3, p=0·34) for the smoke-free-home intervention plus indoor-air-quality feedback group versus the smoke-free-home intervention only group. The ICER for the smoke-free-home intervention plus indoor-air-quality feedback versus usual services was US$653 per quality-adjusted life-year (QALY) gained, which was more than the upper limit of the Bangladesh willingness-to-pay threshold of $427 per QALY.

Interpretation The smoke-free-home intervention, with or without indoor-air-quality feedback, was neither effective nor cost-effective in reducing household second-hand-smoke exposure compared with usual services. These interventions are therefore not recommended for Bangladesh.

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Introduction

Approximately 1·2 million people worldwide die from exposure to second-hand tobacco smoke every year.[1] Around 47% of these deaths occur in women and 28% in children, and most occur in low-income and middle-income countries (LMICs).[2] About 11 million disability-adjusted life-years are lost due to second-hand-smoke exposure worldwide every year, and children bear approximately 61% of the burden of disease attributable to second-hand smoke.[2] In Bangladesh, 40·8 million adults (approximately 39%) and 31% of students age 12–16 years (school year groups 7–9) are exposed to second-hand smoke in their homes.[3,4] A 2015 survey of 12 schools in Dhaka, Bangladesh, found that 95% of children age 9–11 years had saliva cotinine levels consistent with second-hand-smoke exposure.[5] The mean cotinine value of children living with a smoker was approximately double that of

Research in context

Evidence before this study

We reviewed relevant literature identified from four databases: MEDLINE, Embase, CINAHL, and the Cochrane Central Register of Controlled Trials. We searched for randomised controlled trials of community-based interventions to reduce second-hand-smoke exposure from low-income and middle-income countries (LMICs), using the search terms "tobacco smoke pollution", "passive smoke", "indoor air pollution", "environmental tobacco smoke", and "second-hand smoke". The studies had to have reported biochemically verified second-hand-smoke exposure (eg, 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 each database until July, 2017, and did updated searches on Dec 18, 2018. We found six studies that met our eligibility criteria. All six studies evaluated counselling or educational interventions targeted at reducing second-hand-smoke exposure, particularly among children. Three studies evaluated interventions delivered to children within schools. Of these, two studies from China found that the interventions were effective in reducing mean urine cotinine concentration, and the remaining study from Bangladesh (done by our team) did not find any significant difference between groups on saliva cotinine concentrations. A study from China, where an intervention was delivered in people's homes, found that the intervention was effective in reducing mean urine cotinine concentration among children. Another study from Iran identified participants from health centres and showed that a community-based intervention was effective in reducing mean urine cotinine concentrations among children. The sixth study, done in Armenia, did not find any benefits from an intervention in terms of hair cotinine concentrations. Our review concluded that, although there is some evidence of the effectiveness of community-based interventions in reducing second-hand-smoke exposure, this evidence is scarce. Moreover, the potential of religion in promoting behaviours that are protective from second-hand-smoke exposure was yet to be explored. We did not identify any studies evaluating the costs or cost-effectiveness of community-based interventions to reduce second-hand-smoke exposure.

Added value of this study

To our knowledge, our trial is the first to investigate the efficacy 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 second-hand-smoke exposure within households. We found that the interventions were neither effective nor cost-effective when compared with usual services. However, we showed that it is feasible to do large studies of such interventions within faith-based settings in low-income countries.

Implications of all the available evidence

Current evidence on the effectiveness and cost-effectiveness of community-based interventions to reduce second-hand-smoke exposure in LMICs is scarce, and the findings are mixed. Unless future studies provide strong evidence for their effectiveness and cost-effectiveness, such interventions cannot be recommended for use within LMIC settings. There is a need for further studies to explore interventions that have shown promise in high-income countries, such as those that combine smoke-free-home interventions with smoking cessation advice and support for smokers within the home.

those not living with a smoker.[5] Thus, homes remain a key source of second-hand-smoke exposure for children in Bangladesh.

88% of the total population of Bangladesh are Muslim.[6] Religion has an influence on both health-risk behaviours and health,[7–9] and is an important conveyor of social norms, potentially through direct precepts of pursuing a healthy life, or 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 controlling tobacco use, and thereby reducing second-hand-smoke exposure in the home, but evidence on the effectiveness of faith-based interventions in changing smoking behaviours is scarce.[13] Indoor-air-quality feedback, based on markers of second-hand smoke, such as the concentration of airborne particulate matter less than 2·5 microns

($PM_{2.5}$) in diameter, can potentially motivate households to make their homes smoke-free.[14] However, using indoor-air-quality feedback in this way is under-researched, particularly in LMICs.

We designed our interventions on the basis of theoretical work on the role of faith-based interventions to reduce smoking and the potential motivational effects of indoor-air-quality feedback.[10,13,14] Our methods were based on a pilot trial done in England, which found that a smoke-free home intervention was acceptable to Muslim communities and feasible to be delivered through mosques.[15] We designed a community-based smoke-free-home intervention in which religious leaders (ie, imams and khatibs) encouraged their mosque congregations to change their smoking behaviours. We aimed to evaluate the efficacy and cost-effectiveness of this community-based smoke-free-home intervention, with or without indoor-air-quality feedback, in reducing exposure to second-hand smoke in the home, frequency and severity of respiratory symptoms, and health service use, and in improving quality of life.

Methods

Study design and participants

We did a three-arm, open-label, cluster-randomised, controlled trial and cost-effectiveness analysis in which mosques in Mirpur, Dhaka, Bangladesh were recruited and households from their catchment communities enrolled (Muslim Communities Learning About Second-hand Smoke [MCLASS II] trial). The mosques were situated in residential areas of Dhaka, hosted regular communal prayers (including Friday Jumu'ah prayers), had a non-smoking religious leader (imam or khatib), and were affiliated with the Islamic Foundation under the Ministry of Religious Affairs, Bangladesh. Households (ie, single housing units shared by one or more people) were eligible if they had at least one resident attending one of the participating mosques, at least one adult resident (age 18 years or older) who smoked cigarettes or other forms of smoked tobacco (eg, bidi, waterpipe) regularly (on at least 25 days per 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 if they used coal or biomass fuel for domestic cooking or heating. A resident was defined as an adult or child who had been living in the home for the preceding 3 months and planned to continue living in the household for at least 1 more year. Trial investigators recruited mosques by providing the mosque leaders with trial information and screening the mosques for eligibility. They also approached heads of household 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.

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

Randomisation and masking

After recruitment and baseline data collection were completed, mosques and the consenting households from their congregation were centrally randomly assigned (1:1:1) to the smoke-free-home intervention plus indoor-air-quality feedback, smoke-free-home intervention only, or usual services. Minimisation, via MinimPY, was used to balance the average estimated size of the Friday Jumu'ah prayer congregation (≤1500 or >1500 people) and geographical location (wards within Mirpur). Randomisation was done by a statistician (CF) at the University of York, York, UK who was not involved in recruiting mosques or households. Mosques were input into MinimPY in a random order unknown to everyone except

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. Masking of participants and imams or khatibs was not possible. Outcome data collection and statistical analyses were also not masked.

Procedures

The smoke-free-home intervention consisted of health messages relating to smoking and second-hand-smoke 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 or khatibs to those attending Friday Jumu'ah prayer in mosques over 12 weeks (one message per week; see appendix 2 p 2 for examples). The messages addressed key determinants of current smoking behaviours including: poor knowledge on and attitudes towards smoking and second-hand-smoke exposure, by providing information on health consequences of smoking and second-hand-smoke 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 [eg, attempting to quit] and the desired outcome of a smoke-free home), self-efficacy, commitment, action planning, coping planning, and sources of social support (appendix 2 p 22). Imams or khatibs in mosques that were randomly assigned to deliver the smoke-free-home intervention received an intervention booklet-based half-day training on the intervention and its delivery. They also received copies of the 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.

Indoor-air-quality 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. $PM_{2.5}$ concentration was measured in homes using the Dylos DC 1700 (Dylos, Riverside, CA, USA), an optical particle counter validated for use in domestic settings.[16] Feedback included a comparison of the household's mean $PM_{2.5}$ concentration over 24 h with the WHO guidance limit[17] of 25 µg/m³, the total time the household's $PM_{2.5}$ concentration exceeded this guidance limit, and the maximum concentration measured in the household. Feedback also included pictorial information about the household's mean $PM_{2.5}$ concentration (>150 µg/m³ was classified as hazardous, 36–150 µg/m³ as unhealthy, 12–35 µg/m³ as moderate, and <12 µg/m³ as good), information about adverse effects of second-hand-smoke exposure, recommendations to reduce

second-hand-smoke exposure in the home, and a target air quality that was achievable by implementing smoke-free-home rules within the household. The leaflet was designed in consultation with lay community members. Trial investigators delivered and discussed the indoor-air-quality feedback with household members in person for approximately 10 min per household. After completing the final follow-up, all households in the three trial groups received feedback on indoor-air-quality measurements at 12 months after randomisation.

Households and mosques that were assigned to the usual services group received no intervention; however, following trial completion, mosques in the usual services group were offered the smoke-free-home intervention toolkit free of charge.

Data were collected at enrolment (baseline), and 3, 6, and 12 months after randomisation (appendix 2 p 2) using paper-based questionnaires administered by 16 investigators after they received 3 days training on trial procedures. Household air quality was measured at baseline, 3 months, and 12 months, by the same investigators. The data was entered into a password-protected database on a secure web application, Research Electronic Data Capture (REDCap). Further details on study design, participants, and procedures are provided in our published protocol.[18]

Outcomes
The primary outcome was 24-h mean household $PM_{2.5}$ concentration at 12 months after randomisation. Household-level secondary outcomes were: 24-h mean household $PM_{2.5}$ concentration at 3 months after randomisation; and smoking restrictions at home, assessed through a questionnaire directed at adults in the households at 3, 6, and 12 months. Participant-level secondary outcomes assessed at each follow-up visit were: frequency and severity of respiratory symptoms, assessed using part one (eight questions) of the validated St George's Respiratory Questionnaire (SGRQ)[19] for participants aged 11 years or older, and the severity scale developed and validated by Chauhan and colleagues[20] for participants aged younger than 11 years; health-related quality of life, assessed using the EQ-5D-5L[21] for adults (aged 18 years or older), EQ-5D-Y[22] for adolescents (aged 11–17 years), and the paediatric quality of life inventory (PedsQL)[23] for children (aged younger than 11 years); and health-care service use, measured using a questionnaire previously used in a pilot trial[15] in England and adapted to the Bangladesh context.

Statistical analysis
We planned to recruit 45 mosques and 40 households per mosque (n=1800), and to follow-up 30 households per mosque at 3 months after randomisation (n=1350), prioritising those with a baseline 24-h mean $PM_{2.5}$ concentration of 35 µg/m³ or greater. Assuming an intracluster correlation coefficient of 0·02 and 20% attrition at 12 months, this would provide 90% power to detect an effect size of 0·3 SDs (equivalent to a difference of –13·5 µg/m³, from 76 µg/m³ to 62·5 µg/m³, assuming an SD of 45) for each pairwise comparison between groups, using a two-sided α of 0·05.

Analyses followed a prespecified analysis plan, approved by the trial steering committee before the completion of the 12-month data collection. No post-hoc analyses were done. All analyses used the intention-to-treat population and two-sided statistical tests at the 5% significance level in Stata version 15. Baseline and outcome data were summarised by trial group.

The primary analysis compared household 24-h mean $PM_{2.5}$ concentrations between the groups using a covariance pattern, mixed-effect linear regression model incorporating the two post-randomisation timepoints (3 months and 12 months). The model included baseline $PM_{2.5}$ concentration (household-level), geographical area, and size of Friday Jumu'ah prayer congregation in its continuous form (mosque-level), and timepoint, trial 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, on the basis of minimising the Akaike information criterion. Visual inspection of model assumptions showed substantial deviations (appendix 2 pp 1, 23–24). Log-transformation of the outcome data improved model fit (appendix 2 pp 25–26) and was explored in sensitivity analyses. The pairwise mean differences between groups with 95% CI and p values at 3 and 12 months were extracted from the model.

The primary comparison was between the smoke-free-home intervention plus indoor-air-quality feedback group and usual services group at 12 months after randomisation. All other comparisons were secondary investigations. To account for non-compliance with trial group, we did a complier-average causal effect analysis[24] for the primary outcome. A two-stage, least-squares instrumental variable approach was used, with trial group as the instrumental variable. Two analyses compared the 12-month outcome for each intervention with usual services. Within the smoke-free-home 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 smoke-free-home intervention from any mosque at any timepoint. Within the smoke-free-home intervention plus indoor-air-quality feedback group, compliance additionally included self-reported receipt of indoor-air-quality feedback by the 3-month follow-up.

Calibration of the Dylos machines before the 12-month follow-up indicated that they were consistently underestimating $PM_{2.5}$ 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 3-month assessments. This underestimation

was corrected for in the primary analysis; details of sensitivity analyses assessing the effect of this correction are provided in the appendix 2 (p 1).

We did a subgroup analysis of whether any benefits from the interventions were greater among households with a baseline mean $PM_{2.5}$ concentration of 35 µg/m³ or greater compared with households with a baseline concentration of less than 35 µg/m³, by including an interaction between dichotomised baseline $PM_{2.5}$ concentration and trial 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 done separately for the SGRQ symptoms component score for adults, for adolescents aged 11–17 years, and for the total symptoms severity scale for children aged younger than 11 years. Since both these instruments measure the same construct (respiratory symptoms), we did an additional analysis that included all participants using standardised scores. Model assumptions were assessed as for the primary analysis; no major deviations were observed, so data transformation was unnecessary.

We did a within-trial cost-effectiveness analysis comparing the smoke-free-home intervention, with and without indoor-air-quality feedback, versus usual services. The analysis used a health-care sector and intervention-provider perspective to include health-care 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 staff to deliver the intervention (eg, teaching materials, support) were estimated on the basis of the cost incurred alongside the trial, whereas information on health-care resource use (eg, number of inpatient stays, outpatient visits) was collected from participants. The unit costs of home visits by doctors or nurses were obtained from the Bangladesh Bureau of Statistics,[25] costs of inpatient stays and outpatient visits were derived from WHO's Bangladesh-specific unit costs,[26] and costs of emergency department visits were extracted from the Bangladesh essential health service package (table 1).[27] All costs were expressed in 2018–19 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 health-related quality of life (ie, 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] which 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 was done to test the robustness of the results. Quality-adjusted life-years (QALYs) for individuals were calculated using the area under the curve method over the trial period.[31]

	Unit cost (US$)	Source
Intervention costs		
Training cost for indoor-air-quality feedback		
Trainers (staff time)	39·4 per day	Trial team
Trainees (staff time)	12·2 per day	Trial team
Materials	2·7 per person	Trial team
Logistics	1·0 per person	Trial team
Venue	48·8	Trial team
Training cost for smoke-free-home intervention		
Trainers (staff time)	4·9 per h	Trial team
Trainees (staff time)	3·7 per h	Trial team
Food	3·1 per person	Trial team
Travel	640·0	Trial team
Venue	48·8	Trial team
Delivery cost for indoor-air-quality feedback		
Adaptor	30·75 each	Trial team
Battery	332·5 each	Trial team
Shipping cost	1046·3	Trial team
Tax at airport	9648·3	Trial team
Staff time	12·2 per day	Trial team
Travel cost	1·2 per visit	Trial team
Consumables (eg, booklets, food)	219·8	Trial team
Delivery cost for smoke-free-home intervention		
Religious leaders (staff time)	3·7 per h	Trial team
Consumables	0·4 per copy	Trial team
Booklets	4·9 per copy	Trial team
Health-care costs		
Inpatient stays	54·4 per stay	WHO[26]
Outpatient visits	1·9 per visit	WHO[26]
Emergency department visits	2·5 per visit	Islam and colleagues[27]
Home visits (doctor)*	13·5 per visit	Bangladesh Bureau of Statistics[25]
Home visits (nurse)*	8·5 per visit	Bangladesh Bureau of Statistics[25]

*The average time for a home visit was assumed to be 1 h 40 min, including travel time.

Table 1: Cost breakdown for interventions and health care

Cost-effectiveness was evaluated using the pairwise incremental cost-effectiveness ratios (ICERs) method[31] at a household level and assessed on the basis of the Bangladesh willingness-to-pay threshold: $30–427 per QALY gained.[32] Seemingly unrelated regression was used to account for potential correlations between costs and QALYs, and to adjust for prognostic baseline covariates.[33] Uncertainty was estimated using the non-parametric bootstrapping technique, with 5000 replications that were presented on a cost-effectiveness plane.[31]

Role of the funding source
The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results
116 mosques were assessed for eligibility and 45 were recruited (figure). Reasons for exclusion were: being less

Enrolment

116 mosques assessed for eligibility

71 excluded
    54 situated <0·5 km from another mosque
     7 imams did not provide consent to participate
     7 mosque catchment area was hard to reach due to entry restrictions
     2 small catchment area
     1 did not perform Friday prayers

45 mosques eligible and recruited

4430 households assessed for eligibility

2629 excluded*
    1875 no adult resident who smoked tobacco regularly
     474 unwilling to give written informed consent
     441 planning to move home in the next 12 months
     296 unable to give written informed consent
      85 did not attend a participating mosque
      84 used coal or biomass fuel
      72 no resident who attended mosque for regular or Friday prayers
      19 no resident who was a non-smoker

45 mosques and 1801 households randomly assigned

Randomisation

16 mosques and 640 households assigned to smoke-free-home intervention plus indoor-air-quality feedback

14 mosques and 560 households assigned to smoke-free-home intervention only

15 mosques and 601 households assigned to usual services

8 households PM$_{2.5}$ measured for <22 h and excluded

18 households PM$_{2.5}$ measured for <22 h and excluded

29 households PM$_{2.5}$ measured for <22 h and excluded

632 households with valid PM$_{2.5}$ data (mean per mosque 39·5, SD 1·3, range 35–40)
1484 adults (mean per mosque 92·8, SD 7·3, range 81–109)
329 adolescents (mean per mosque 20·6, SD 6·5, range 7–30)
614 children (mean per mosque 38·4, SD 9·5, range 20–56)

542 households with valid PM$_{2.5}$ data (mean per mosque 38·7, SD 1·8, range 35–40)
1370 adults (mean per mosque 97·9, SD 10·6, range 83–125)
306 adolescents (mean per mosque 21·9, SD 6·8, range 10–33)
448 children (mean per mosque 32·0, SD 8·6, range 12–41)

572 households with valid PM$_{2.5}$ data (mean per mosque 38·1, SD 2·9, range 30–41)
1461 adults (mean per mosque 97·4, SD 10·9, range 84–130)
263 adolescents (mean per mosque 17·5, SD 4·6, range 10–24)
538 children (mean per mosque 35·9, SD 8·3, range 19–52)

3-month follow-up

152 households with PM$_{2.5}$ <35 µg/m³ not randomly selected for follow-up

122 households with PM$_{2.5}$ <35 µg/m³ not randomly selected for follow-up

122 households with PM$_{2.5}$ <35 µg/m³ not randomly selected for follow-up

480 households with valid PM$_{2.5}$ data (30 per mosque)
1107 adults (mean per mosque 69·2, SD 5·9, range 60–83)
259 adolescents (mean per mosque 16·2, SD 5·3, range 3–23)
456 children (mean per mosque 28·5, SD 8·2, range 14–44)

420 households with valid PM$_{2.5}$ data (30 per mosque)
1024 adults (mean per mosque 73·1, SD 8·0, range 63–95)
233 adolescents (mean per mosque 16·6, SD 5·4, range 7–25)
335 children (mean per mosque 23·9, SD 8·2, range 7–35)

450 households with valid PM$_{2.5}$ data (30 per mosque)
1087 adults (mean per mosque 72·5, SD 8·9, range 62–99)
191 adolescents (mean per mosque 12·7, SD 2·9, range 9–19)
409 children (mean per mosque 27·3, SD 7·4, range 14–37)

6-month follow-up

1084 adults (mean per mosque 67·8, SD 5·8, range 60–83)
249 adolescents (mean per mosque 15·6, SD 4·8, range 3–23)
447 children (mean per mosque 27·9, SD 8·7, range 14–44)†

1013 adults (mean per mosque 72·4, SD 8·3, range 59–93)
228 adolescents (mean per mosque 163, SD 5·3, range 7–25)
332 children (mean per mosque 23·7, SD 8·2, range 7–35)‡

1083 adults (mean per mosque 72·2, SD 8·8, range 61–98)
190 adolescents (mean per mosque 12·7, SD 2·8, range 9–19)
408 children (mean per mosque 27·2, SD 7·5, range 14–37)§

12 households withdrew from follow-up

15 households withdrew from follow-up

9 households withdrew from follow-up

12-month follow-up

468 households with valid PM$_{2.5}$ data (mean per mosque 29·3, SD 1·5, range 24–30)
1073 adults (mean per mosque 67·1, SD 6·4, range 58–83)
243 adolescents (mean per mosque 15·2, SD 4·7, range 3–23)
437 children (mean per mosque 27·3, SD 8·3, range 14–44)

405 households with valid PM$_{2.5}$ data (mean per mosque 28·9, SD 1·6, range 24–30)
977 adults (mean per mosque 69·8, SD 9·9, range 56–93)
219 adolescents (mean per mosque 15·6, SD 5·5, range 7–25)
319 children (mean per mosque 22·8, SD 7·8, range 7–34)

441 households with valid PM$_{2.5}$ data (mean per mosque 29·4, SD 1·1, range 27–30)
1047 adults (mean per mosque 69·8, SD 8·5, range 60–91)
187 adolescents (mean per mosque 12·5, SD 2·7, range 9–18)
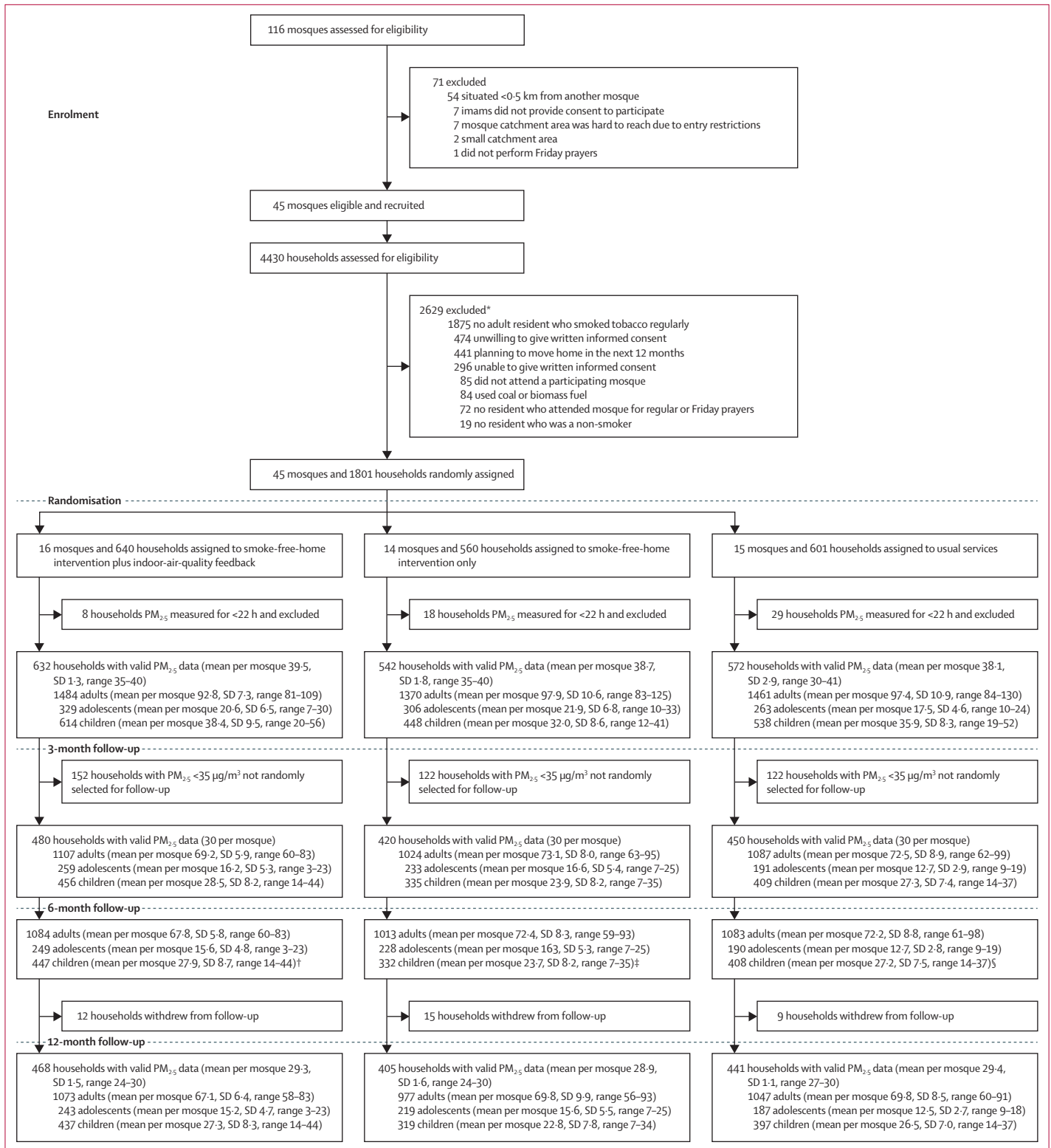397 children (mean per mosque 26·5, SD 7·0, range 14–37)

Figure: Trial profile
Adults were those aged 18 years or older, adolescents were those aged 11–17 years, and children were those aged younger than 11 years. PM$_{2.5}$=airborne particulate matter less than 2·5 microns in diameter. *Some households met more than one exclusion criterion. †Data from 472 households. ‡Data from 418 households. §Data from 450 households.

	Usual services group (n=450)	Smoke-free-home intervention only group (n=420)	Smoke-free-home intervention plus indoor-air-quality feedback group (n=480)	Total (n=1350)
Age of head of household, years				
Mean (SD)	40·8 (12·8)	40·7 (12·7)	40·3 (12·1)	40·6 (12·5)
Median (range)	38·2 (20·1–85·4)	37·3 (22·1–85·5)	38·1 (20·2–84·7)	38·1 (20·1–85·5)
Gender of head of household				
Male	429 (95·3%)	387 (92·1%)	461 (96·0%)	1277 (94·6%)
Female	21 (4·7%)	33 (7·9%)	19 (4·0%)	73 (5·4%)
Number of adult residents				
Mean (SD)	2·4 (0·8)	2·5 (0·8)	2·3 (0·7)	2·4 (0·8)
Median (range)	2·0 (1·0–6·0)	2·0 (1·0–6·0)	2·0 (1·0–5·0)	2·0 (1·0–6·0)
Number of child residents				
Mean (SD)	1·3 (1·1)	1·4 (1·1)	1·5 (1·1)	1·4 (1·1)
Median (range)	1·0 (0·0–7·0)	1·0 (0·0–5·0)	1·0 (0·0–6·0)	1·0 (0·0–7·0)
Homes with outside space	244 (54·2%)	243 (57·9%)	237 (49·4%)	724 (53·6%)
Number of bedrooms				
Mean (SD)	1·5 (0·7)	1·5 (0·7)	1·3 (0·6)	1·4 (0·7)
Median (range)	1·0 (0·0–5·0)	1·0 (1·0–5·0)	1·0 (1·0–4·0)	1·0 (0·0–5·0)
Type of fuel used for cooking				
Electricity	41 (9·1%)	71 (16·9%)	11 (2·3%)	123 (9·1%)
LPG, natural gas, or biogas	401 (89·1%)	362 (86·2%)	479 (99·8%)	1242 (92·0%)
Kerosene	27 (6·0%)	5 (1·2%)	21 (4·4%)	53 (3·9%)
Number of adult resident smokers				
Mean (SD)	1·1 (0·3)	1·1 (0·3)	1·1 (0·3)	1·1 (0·3)
Median (range)	1·0 (1·0–3·0)	1·0 (0·0–3·0)	1·0 (0·0–3·0)	1·0 (0·0–3·0)
Number of child resident smokers				
Mean (SD)	0·0 (0·1)	0·0 (0·1)	0·0 (0·2)	0·0 (0·1)
Median (range)	0·0 (0·0–1·0)	0·0 (0·0–1·0)	0·0 (0·0–1·0)	0·0 (0·0–1·0)
Residents allowed to smoke				
Anywhere inside the home	197 (43·8%)	180 (42·9%)	262 (54·6%)	639 (47·3%)
Only in some rooms in the home	5 (1·1%)	6 (1·4%)	1 (0·2%)	12 (0·9%)
Only in one room in the home	14 (3·1%)	36 (8·6%)	15 (3·1%)	65 (4·8%)
Only outside	233 (51·8%)	196 (46·7%)	199 (41·5%)	628 (46·5%)
Not known	1 (0·2%)	2 (0·5%)	3 (0·6%)	6 (0·4%)
Visitors allowed to smoke				
Anywhere inside the home	178 (39·6%)	146 (34·8%)	247 (51·5%)	571 (42·3%)
Only in some rooms in the home	4 (0·9%)	6 (1·4%)	1 (0·2%)	11 (0·8%)
Only in one room in the home	11 (2·4%)	30 (7·1%)	12 (2·5%)	53 (3·9%)
Only outside	250 (55·6%)	229 (54·5%)	213 (44·4%)	692 (51·3%)
Not known	7 (1·6%)	9 (2·1%)	7 (1·5%)	23 (1·7%)
Residents allowed to smoke in front of children in the home				
Yes	132 (29·3%)	142 (33·8%)	194 (40·4%)	468 (34·7%)
No	221 (49·1%)	179 (42·6%)	191 (39·8%)	591 (43·8%)
Not known	6 (1·3%)	3 (0·7%)	10 (2·1%)	19 (1·4%)
No child residents	91 (20·2%)	96 (22·9%)	85 (17·7%)	272 (20·1%)
Visitors allowed to smoke in front of children in the home				
Yes	118 (26·2%)	112 (26·7%)	196 (40·8%)	426 (31·6%)
No	234 (52·0%)	201 (47·9%)	185 (38·5%)	620 (45·9%)
Not known	9 (2·0%)	12 (2·9%)	14 (2·9%)	35 (2·6%)
No child residents	89 (19·8%)	95 (22·6%)	85 (17·7%)	269 (19·9%)

Data are n (%) unless otherwise stated. Adults were defined as those aged 18 years or older, children were those aged younger than 18 years. LPG=liquified petroleum gas.

Table 2: Baseline characteristics of households (as followed-up)

	Usual services group (n=601)	Smoke-free-home intervention only group (n=560)	Smoke-free-home intervention plus indoor-air-quality feedback group (n=640)	Total (n=1801)
Baseline (as randomised)				
Households, n	572	542	632	1746
Mean (SD)	41·9 (38·5)	39·5 (29·3)	44·6 (43·7)	42·2 (38·0)
Median (range)	29 (2–251)	30 (8–166)	30 (1–422)	30 (1–422)
Baseline (as analysed)				
Households, n	447	419	480	1346
Mean (SD)	44·2 (40·8)	42·1 (30·7)	46·6 (42·3)	44·4 (38·6)
Median (range)	30 (2–251)	34 (8–166)	30 (5–334)	31 (2–334)
3 months				
Households, n	450	420	480	1350
Mean (SD)	85·3 (86·8)	75·6 (83·7)	74·9 (76·9)	78·6 (82·5)
Median (range)	44·5 (1–417)	38 (6–459)	38 (1–353)	39 (1–459)
12 months				
Households, n	441	405	468	1314
Mean (SD)	65·2 (44·7)	68·9 (49·5)	65·8 (39·6)	66·5 (44·6)
Median (range)	54 (11–340)	57 (13–389)	56 (14–244)	55 (11–389)

$PM_{2.5}$ concentrations are in µg/m³. $PM_{2.5}$=airborne particulate matter less than 2·5 microns in diameter.

Table 3: Household $PM_{2.5}$ concentrations by trial group over time

than 0·5 km from another mosque participating in the trial (n=54), imams or 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 April 11 and Aug 2, 2018, 4430 households were screened for eligibility; 1801 (40·7%) were eligible and enrolled. For the households that were ineligible, the reasons are provided in appendix 2 (p 2). Every mosque recruited 40 households, except one (allocated to usual services), which recruited 41. 16 mosques (640 households [35·5%]) were randomised to the smoke-free-home intervention plus indoor-air-quality feedback, 14 (560 [31·1%]) to the smoke-free-home intervention only, and 15 (601 [33·4%]) to usual services (appendix 2 pp 3–4).

Of the 712 households with mean baseline $PM_{2.5}$ concentration of 35 µg/m³ or greater, 614 (86·2%) were followed-up at 3 months; 98 (13·8%) had either moved away from the study area or did not wish to continue the study. To achieve the target of 1350 households followed-up at 3 months, we randomly selected another 736 households with mean baseline $PM_{2.5}$ concentration less than 35 µg/m³ to follow-up, as per protocol (table 2, appendix 2 pp 4–11). Of these 1350 households, 1314 (97·3%) completed follow-up again at 12 months (2·7% attrition rate; 2·0% in the usual services group, 3·6% in the smoke-free-home intervention only group, and 2·5% in the smoke-free-home intervention plus indoor-air-quality feedback group).

At 12 months follow-up, the mean 24-h $PM_{2.5}$ concentration was 65·8 µg/m³ (SD 39·6) in the smoke-free-home intervention plus indoor-air-quality feedback group, 68·9 µg/m³ (49·5) in the smoke-free-home intervention only group, and 65·2 µg/m³ (44·7) in the usual services group (table 3). No evidence of a difference was observed at 12 months for any pair-wise comparison, including when the outcome data were log-transformed (table 4, appendix 2 p 26). The adjusted mean differences in $PM_{2.5}$ concentration were –1·0 µg/m³ (95% CI –12·8 to 10·9) for the smoke-free-home intervention plus indoor-air-quality feedback group versus usual services group (p=0·88); 5·0 µg/m³ (–7·9 to 18·0) for the smoke-free-home intervention only group versus usual services group (p=0·45); and –6·0 µg/m³ (–18·3 to 6·3) for the smoke-free-home intervention plus indoor-air-quality feedback group versus the smoke-free-home intervention only group (p=0·34). The log-transformed sensitivity analysis indicated that the mean $PM_{2.5}$ concentrations in the smoke-free-home intervention plus indoor-air-quality feedback group were expected to be 1·02 times larger (95% CI 0·86 to 1·21; p=0·79) than the usual services group. The estimated mosque-level intracluster correlation coefficient was 0·08 (95% CI 0·05 to 0·14).

At 3-months follow-up, there was no evidence of a difference in the mean 24-h $PM_{2.5}$ concentrations for any pairwise comparison, including when the outcome data were log-transformed (table 4; appendix 2 p 26). There was evidence of small differences in some secondary comparisons between the smoke-free-home intervention only group and the smoke-free-home intervention plus indoor-air-quality feedback group, favouring intervention plus feedback (SGRQ for adults, at 6 months: adjusted mean difference in outcome score 2·4 [95% CI 0·3–4·6], p=0·028; respiratory symptoms in children aged younger than 11 years, at 3 months: 2·0 [0·5–3·4], p=0·0083; standardised respiratory scores in all participants, at 6 months: 0·14 [0·00–0·29], p=0·044). No other differences were observed at 3 months, 6 months, or 12 months (appendix 2 pp 12–17).

22·9% of households (usual services group n=110 [24·9%]; smoke-free-home intervention only group n=76 [18·8%]; smoke-free-home intervention plus indoor-air-quality feedback group n=115 [26·6%]) reported at 12 months that residents were permitted to smoke anywhere inside the home (appendix 2 p 17).

In the sensitivity analysis, we found that 331 (78·8%) of 420 households in the smoke-free-home intervention only group received the intervention; in addition, 91 (20·2%) of 450 households in the usual services group reported receiving some element of the intervention; the complier-average causal effect estimate after receiving the smoke-free-home intervention was an increase in mean $PM_{2.5}$ concentration of 11·3 µg/m³ (95% CI –6·7 to 29·2). In the smoke-free-home intervention plus indoor-air-quality feedback group, 351 (73·1%) of 480 households received the intervention and feedback by the 3-month follow-up; the complier-average causal effect estimate after receiving the intervention and indoor-air-quality

	Adjusted mean difference in PM$_{2.5}$ concentration (95% CI)	p value
Primary analysis		
3 months		
Smoke-free-home intervention plus indoor-air-quality feedback vs usual services	–12·6 (–26·3 to 1·0)	0·070
Smoke-free-home intervention only vs usual services	–9·3 (–24·0 to 5·4)	0·22
Smoke-free-home intervention only vs smoke-free-home intervention plus indoor-air-quality feedback	3·4 (–10·7 to 17·4)	0·64
12 months		
Smoke-free-home intervention plus indoor-air-quality feedback vs usual services	–1·0 (–12·8 to 10·9)	0·88
Smoke-free-home intervention only vs usual services	5·0 (–7·9 to 18·0)	0·45
Smoke-free-home intervention only vs smoke-free-home intervention plus indoor-air-quality feedback	6·0 (–6·3 to 18·3)	0·34
Log-transformed (sensitivity analysis)		
3 months		
Smoke-free-home intervention plus indoor-air-quality feedback vs usual services	–0·13 (–0·32 to 0·05)	0·16
Smoke-free-home intervention only vs usual services	–0·11 (–0·30 to 0·09)	0·30
Smoke-free-home intervention only vs smoke-free-home intervention plus indoor-air-quality feedback	0·03 (–0·16 to 0·22)	0·78
12 months		
Smoke-free-home intervention plus indoor-air-quality feedback vs usual services	0·02 (–0·15 to 0·19)	0·79
Smoke-free-home intervention only vs usual services	0·06 (–0·12 to 0·25)	0·50
Smoke-free-home intervention only vs smoke-free-home intervention plus indoor-air-quality feedback	0·04 (–0·13 to 0·21)	0·64

PM$_{2.5}$ concentrations are in µg/m³. PM$_{2.5}$=airborne particulate matter less than 2·5 microns in diameter.

Table 4: Differences in household PM$_{2.5}$ concentration over time between trial groups, presented for both raw and log-transformed outcome data

feedback was a decrease in PM$_{2.5}$ concentration (–3·0 µg/m³ [–17·4 to 11·4]). No differences were observed at 3 months or 12 months in the other sensitivity analyses (appendix 2 pp 18–19, 27–28).

In the subgroup analysis, we found no evidence of an interaction with baseline PM$_{2.5}$ concentration (<35 µg/m³ compared with ≥35 µg/m³; appendix 2 pp 20, 29–30).

From the 1350 households followed-up at 3 months, 4893 (95·1%) of 5143 participants had complete cost and QALY data at all follow-ups. After removing households with participants with incomplete data, 1237 (91·6%) of 1350 households were included in the cost-effectiveness analysis. The smoke-free-home intervention plus indoor-air-quality 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 smoke-free-home intervention only group incurred higher costs but generated less QALYs compared with the usual services group, and was therefore dominated. Due to high delivery cost of indoor-air-quality feedback ($16·1), intervention cost was the key cost driver for the smoke-free-home intervention plus indoor-air-quality feedback group, but not for the smoke-free-home intervention only group (appendix 2 p 20). The smoke-free-home intervention plus indoor-air-quality feedback was not cost-effective, as the ICER of $653 per QALY compared with usual services was more than the willingness-to-pay threshold of $30–427 per QALY gained. The results of the 5000 bootstrapped seemingly unrelated regression models are shown in table 5 and appendix 2 (p 31). The bootstrapped ICERs were within the top-left quadrant of the cost-effectiveness plane and above the

willingness-to-pay threshold lines, indicating that both the intervention only, and the combination of the intervention plus indoor-air-quality feedback, were not cost-effective, even when taking uncertainly into consideration. The results of the sensitivity analysis were similar to the main findings (appendix 2 pp 21, 32).

Discussion

The smoke-free-home intervention, with or without indoor-air-quality feedback, did not reduce exposure to second-hand smoke in the home, measured as the mean 24-h PM$_{2.5}$ concentration within households, compared with usual services. Our cost-effectiveness analysis suggests that both the smoke-free-home intervention only and the combination of the smoke-free-home intervention and indoor-air-quality feedback were not cost-effective compared with usual services, due to high intervention costs and minimal QALY gains.

To our knowledge, this trial is the first to investigate the efficacy and cost-effectiveness of community-based interventions, delivered within an Islamic discourse by religious leaders in mosques, to reduce second-hand-smoke exposure within the home. We found that it is feasible and acceptable to do large studies of such interventions within mosques. The trial is also the largest of its kind to provide 24-h household-level PM$_{2.5}$ concentration data, and explore the usefulness of using indoor-air-quality feedback as a motivational tool for reducing second-hand-smoke exposure in the home, in a LMIC setting. Other strengths of the trial were the rigour and quality with which it was done; the cluster-randomised, controlled design; achieving the required

	Households, n	Costs			QALYs (SD)	ICER
		Intervention, US$	Health care, US$ (SD)	Total US$ (SD)		
Trial group						
Smoke-free-home intervention plus indoor-air-quality feedback	429	21·9	11·0 (22·0)	32·8 (22·0)	3·31 (1·20)	$653 per QALY gained
Smoke-free-home intervention only	383	2·9	23·0 (61·0)	25·8 (61·0)	3·25 (1·18)	Dominated
Usual services	425	0	13·2 (30·4)	13·2 (30·4)	3·28 (1·22)	Reference
Bootstrapped seemingly unrelated regression models						
Smoke-free-home intervention plus indoor-air-quality feedback *vs* usual services	..	..	..	19·5 (14·2 to 24·9)	–0·05 (–0·05 to 0·05)	Dominated
Smoke-free-home intervention only *vs* usual services	..	..	..	12·1 (6·6 to 17·6)	–0·10 (–0·14 to –0·07)	Dominated

Costs and QALYs for bootstrapped seemingly unrelated regression models are incremental means with 95% CI. QALY=quality-adjusted life-year. ICER=incremental cost-effectiveness ratio.

Table 5: Costs, QALYs, and ICERs by trial group

sample size; high follow-up rates; high levels of data completeness; and the 12-month follow-up duration.

There are several potential explanations for the absence of effectiveness of the interventions. Sermons where the intervention messages were delivered are not mandatory, and therefore some people might 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, individuals might have received some, but not all, messages. Because of the nature of the intervention, it was not possible to calculate the so-called dose of the intervention received by household members. The interventions targeted reducing second-hand-smoke exposure in the home directly, and did not offer smoking cessation support to smokers within the home. Aspirations to make homes smoke-free might have been constrained by the scarcity of social and environmental opportunities to change behaviour.[34,35] Thus, a standalone community-based intervention delivered over a short 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 indoor-air-quality feedback was delayed, due to the need to take the Dylos machine back to the office to download the data and generate the graphical and numerical feedback, and was not targeted specifically at smokers.

The intervention effects on $PM_{2.5}$ concentration in the home could have been diluted due to a Hawthorne effect across all trial groups during the baseline 24-h measurement period when the Dylos devices were present in the home.[36] Members of the household, particularly smokers, might have modified their behaviour (perhaps by reducing smoking inside the house or near the Dylos machine) in response to being aware that the device was recording the air quality in their home. Measuring $PM_{2.5}$ concentrations over a longer period could have reduced this potential bias by making it more difficult to sustain behavioural change over the whole measurement period.[36]

However, this would have been more costly due to the need for more devices.

$PM_{2.5}$ concentration 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. We addressed other $PM_{2.5}$ concentration influences by excluding households that used coal or biomass fuel for domestic use and restricting measurements to the period of April–October, when outdoor air pollution levels in Dhaka are at their lowest.[37] We also used a cluster-randomised, controlled design to balance such confounders between the two groups. Therefore, any change observed in the primary outcome between the two groups 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 with homes where smoking was permitted, despite high ambient air pollution.[38]

Participants' health-related quality of life was measured using three different instruments (the EQ-5D-5L for adults, EQ-5D-Y for adolescents, and PedsQL for children) due to the absence of a universal instrument that could measure health-related quality of life across all age groups. As reported, health-related quality of life might differ depending on which instrument is 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 effect is unlikely to have affected our conclusion, as we controlled for household composition in the analysis. As there were 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 to obtain more precise estimates.

With regards to faith-based behavioural change interventions, our findings can be generalised to other

community-based interventions that are delivered primarily through mosques. When considering indoor-air-quality feedback, our study findings can be generalised to other urban centres similar to Dhaka, with high population density, high levels of ambient air pollution, and little opportunity 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 delivered through 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 behavioural change is unclear.[12,39] Nevertheless, our findings are consistent with those from other studies targeting reduction of second-hand-smoke exposure within the home using behavioural interventions and indoor-air-quality feedback. A review from 2018 found that the effectiveness of several counselling and educational interventions that have been used to try to reduce second-hand-smoke exposure has not been clearly shown.[40] More successful interventions seem to be those that combine smoke-free-home interventions with smoking cessation advice and support for smokers within the home, or those that target smoking cessation as a pathway to reducing second-hand-smoke exposure.[41] Additionally, a study from 2020 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 indoor air quality. Nevertheless, these technologies need to be low cost if they are to be cost-effective and scalable in LMICs.

Contributors
NDM drafted the manuscript, contributed to study design, conduct, and interpretation of findings. CF contributed to the writing of the manuscript, and designed and did the statistical analysis. H-IW and QW did the cost-effectiveness analysis, and contributed to the writing of the manuscript. TF coordinated the implementation of the study in Bangladesh, including data collection and management. A-MM coordinated the study. CH contributed to study design and oversaw the statistical analysis. RH contributed to study design, oversaw the implementation and conduct of the study in Bangladesh, and provided crucial inputs to interpretation of the results. CJ contributed to study design, and in particular 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 cost-effectiveness evaluation. SS contributed to study design and led the design of indoor-air-quality measurement and feedback. AS contributed to study design, interpretation of results, and writing of the manuscript. KS conceived the study idea and contributed to the study design, conduct, interpretation of results, and writing of the manuscript. CF, H-IW, QW, TF, RH, and NDM accessed and verified the data. All authors participated in manuscript revisions, and read and approved the final manuscript. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

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