Nicotine & Tobacco Research Advance Access published February 23, 2015

Nicotine & Tobacco Research, 2015, 1–8
doi:10.1093/ntr/ntv015
Original investigation

Original investigation

Children Learning About Second-Hand Smoking: A Feasibility Cluster Randomized Controlled Trial

Rumana Huque PhD[1], Omara Dogar MPH (Epi)[2], Ian Cameron FFPHM[3], Heather Thomson PGDip[4], Amanda Amos PhD[5], Kamran Siddiqi PhD[6]

[1]Department of Economics, University of Dhaka, Dhaka, Bangladesh; [2]Department of Health Sciences, University of York, York, UK; [3]Leeds City Council, Leeds, UK; [4]Office of the Director of Public Health, Leeds City Council, Leeds, UK; [5]Centre for Population Health Sciences Medical School, University of Edinburgh, Edinburgh, UK; [6]Department of Health Sciences/Hull York Medical School, University of York, York, UK

Corresponding Author: Rumana Huque, PhD, Department of Economics, University of Dhaka, Social Science Building, Nilkhet, Dhaka 1000, Bangladesh. Telephone: +88-01713018261; Fax: +88 (02) 8615583; E-mail: rumanah14@yahoo.com

Abstract

Background: Exposure to second-hand smoke is a threat to children's health. We developed a school-based smoke-free intervention (SFI) to support families in implementing smoke-free homes in Bangladesh, and gathered preliminary evidence of its effectiveness.
Methods: A feasibility cluster randomized controlled trial of SFI was conducted in 24 schools in Mirpur, an urban area within Dhaka. Using simple stratified randomization, schools were allocated to: Arm A (SFI only), Arm B (SFI plus reminders), and Arm C (the control group). A total of 781 year-5 children (10–12 years old) in the consenting schools, participated in the study. Outcomes including "smoke-free homes" and "social visibility" that is, not smoking in front of children at home were assessed through questionnaire-based children's surveys, administered by researchers, at baseline and at weeks 1, 12, 27, and 52 in all arms.
Results: "Smoke-free homes" were significantly higher in Arm A (odds ratio [*OR*] = 4.8; 95% CI = 2.6–9.0) and in Arm B (*OR* = 3.9; 95% CI = 2.0–7.5) than in Arm C, when controlled for the baseline levels, at year 1. Similarly, "social visibility" was significantly reduced in Arm A (*OR* = 5.8; 95% CI = 2.8–11.7) and in Arm B (*OR* = 7.2; 95% CI = 3.3–15.9) than Arm C, when controlled for the baseline levels, at year 1. We observed an increasing trend (Cochrane Armitage test statistic [*Z*] = 3.8; $p < .0001$) in homes becoming smoke-free with increasing intensity of the intervention (control < Arm A < Arm B), and a decreasing trend ($Z = -5.13$; $p < .0001$) in social visibility at homes.
Conclusion: SFI has the potential to encourage children to negotiate a smoke-free environment in their homes.

Introduction

Exposure to second-hand smoke (SHS) is harmful to children's health and increases their risk of acquiring lower respiratory tract and middle ear infections,[1,2] significant reduction in lung functions, invasive meningococcal disease,[3] and new cases, recurrent episodes, and increased severity of asthma.[1,2,4–6]

Since the introduction of comprehensive smoking bans in enclosed public and work places in many countries, homes and cars are the most likely places for children to be exposed to SHS.[5] Over 52% of children in Spain, 51% in Austria, 30% in United States, 15% in Lithuania, and 10% in Sweden are exposed to SHS in their homes.[7–9] Therefore, protecting children from SHS in homes and cars should be an additional dimension of any tobacco control programme.[6,10] However, in many countries, this has received little attention. While some studies suggest that smoking bans in public and workplaces encourage people to implement smoking restrictions at home[11]; others observe minimal effect[12,13] or even an increase in the likelihood of children being exposed to SHS in homes.[14] While there is some evidence to support a systematic approach to increase parents' awareness about SHS, and developing their confidence and skills in implementing and sustaining smoking restrictions at home,[6,15,16] the most recent systematic review did not find such parental education and counseling programmes effective in reducing children's exposure to environmental tobacco smoke.[17]

In Bangladesh, exposure to SHS is also a serious threat to children's health. Smoking bans in public and workplaces are only partially implemented. Furthermore, there are few national/local campaigns or health promotion programmes to protect children from exposure to SHS at home. Smoking being a predominantly male behavior in Bangladesh (44.7% of men, 1.5% of women) with smoking rate slightly higher in rural areas (23.6%) than in urban areas (21.3%)[18]; restricting it in homes is particularly challenging in a predominantly patriarchal society. A recent community survey of 722 households revealed that most households (55.5%) have at least one smoker and smoking indoors in front of children (40%) was a common practice.[10] The evidence to support interventions that encourages families to impose smoking restrictions at home and protect children from SHS, is limited. Previously, we conducted two relevant feasibility studies—one in an inner-city area in the United Kingdom[19] and another in a rural part of Pakistan.[6] We found that the school children were keen to act and willing to negotiate with their families to implement smoking restrictions at home. Based on the lessons learnt, we developed a school-based intervention to encourage children to negotiate with adults in their households to implement smoke-free homes. In this article, we describe the findings of a feasibility trial of the above intervention in Bangladesh, which examines whether this approach has the potential to increase the number of smoke-free homes, and reduce the incidence of smoking taking place in front of children.

Methods

Research Design

We conducted a feasibility cluster randomized controlled trial of a smoke-free intervention (SFI) designed to educate year-five children (10–12 years old) about the harms of SHS and to encourage them to negotiate with their parents to implement smoke-free homes. It was a feasibility study as defined by the Medical Research Council (MRC) Framework for Evaluating Complex Interventions.[20,21] The trial had three arms: Arm A (SFI only) where children received two 45-minute educational sessions over 2 days; Arm B (SFI plus reminders) where children received the above two sessions followed by four 15-minute refresher sessions in subsequent weeks, and Arm C (the control group) with no intervention. Ethical approval was granted by the Bangladesh Medical Research Council (BMRC) and the University of York, United Kingdom. An independent steering committee provided oversight.

Settings and Participants

Mirpur is a typical densely populated urban area in Dhaka with majority of its population dependent on non-agricultural livelihood and have access to amenities like paved road, electricity, gas, water supply, and drainage systems.[22] It was chosen for its typical demographic and socioeconomic structure and its proximity to the research team. Schools were eligible if they followed mainstream curricula, and had ≥10 and ≤60 year-five children (10–12 years old) per class. We first identified all primary schools in the area, and recruited those that were eligible and willing to participate. All schools followed "no-smoking" policy and all participating teachers were self-reported nonsmokers. A total of 781 participants were enrolled in 24 schools. Only year-five children were recruited after seeking their assent and their parents' written consent through schools permitting them to attend the sessions at school and participate in the surveys. Being the oldest in primary schools, we considered this being the optimal age group to understand the message and persuade their family members to implement smoke-free homes. Assent meant that all eligible children received age appropriate information sheet and if a child was unwilling, he or she was asked to let their teacher or parents know. In addition, we also asked parents to seek their child's willingness to participate before giving consent.

The Smoke-Free Intervention

SFI was developed by a technical working group including schoolteachers, representatives of civil society organizations, public health practitioners, educational experts, and behavioral scientists from Bangladesh and United Kingdom. Once agreed on the key messages, a range of educational materials, both in Bangla and English, were developed addressing different learning styles. The training materials for schoolteachers were pre-piloted and revised according to the suggestions made by a user group and the technical working group. A manual was also prepared to help schoolteachers in delivering SFI. It was envisaged that at least two year-five teachers (one class teacher and one support teacher) would be trained in each school.

SFI is designed to work at two levels. At level one, it empowers children to become agents of change, and at level two; it persuades family members to make their homes smoke-free. The key educational activities were:

Level 1: Empowering children to become agents of change (Supplementary Figure 1)

1. Two 45-minute sessions delivered over two consecutive days by schoolteachers. The duration of these sessions is consistent with regular school lessons. Each session consists of a range of educational activities including classroom presentations, quiz, interactive games, storytelling, and role-play—vicarious learning techniques are utilized in many of the activities. The presentation, quiz and games were designed to increase childrens' knowledge about SHS and related harms, and motivate them to follow three easy steps to make their homes smoke-free. The storybook and role-play focused on enhancing children's negotiation skills, building their confidence within Bangladeshi cultural context. While the storybook depicts challenges of negotiating with elders, the role-play has hypothetical scenarios where children had the opportunity to practice and demonstrate how and when they can discuss and negotiate with adults to persuade them not to smoke inside homes.
2. A set of four refreshers (each lasting 15 min) was also designed to reinforce key messages delivered in the initial sessions. These refresher sessions were delivered once a week over four consecutive weeks, 6–7 weeks after the two initial sessions. During each session, the teacher reminded children the key points of the main session by asking questions (5–7 min), and then encouraged children to share their experiences of whether they could initiate discussion at home, what challenges did they face, what was their plan to do next and what would be the best way to convince adults (8–10 min). The length of these sessions was consistent with the duration of school assembly.

Level 2: Child to parent—persuading family members to make their homes smoke-free (Supplementary Figure 2).

Children were given a promise form that contained pictorial and written messages on the hazards of SHS, a pictorial step-guide for families on how to make their homes smoke-free and a tear-off slip to make a commitment to implement smoke-free homes. After the second session, children were asked to take promise forms to their parents, show them the pictorial and written messages, and negotiate with their families to "sign-up" to a voluntary contract to make their homes smoke-free. One of the implications was that even if parents were nonsmokers, they would not allow other smokers (residents and visitors) to smoke inside homes. In addition to delivering the intervention, teachers were trained to support children in this process. We sensitized schoolteachers to look for signs of any adverse events resulting from the interactions between children and their parents. We also encouraged children to report any related adversities.

Children in Arm A received training on Level 1a and Level 2 components while children in Arm B received training on all components of Level 1 and 2. Children in Arm C received no training.

Randomization and Allocation

Using simple stratified randomization, schools were allocated to three trial arms. Computer-generated random-number lists were used for allocation, with stratification on number of children to ensure a balance across the trial arms.

Schoolteachers in Arm A received training and materials to deliver the two initial sessions only (Level 1a and Level 2); those in Arm B received training and materials to deliver the two initial and four refresher sessions (Level 1a, Level 1b, and Level 2); and those in the control arm received no training. We trained 16 male and 16 female teachers—two from each school; year-five main teacher and classroom support teacher. Lasting a day, the training consisted of presentations, interactive question-answer sessions, group work and role-play focusing on the adverse effects of SHS and how to deliver the intervention.

The data entry clerk and the statistician were blinded to the conditions in each arm.

Outcomes and Follow-Up

The primary outcomes were self-reported (by children) "smoke-free homes" and "social visibility" of smoking. We defined smoke-free homes as smoking taking place exclusively outside the home, and social visibility as smoking taking place in front of children. Smoke-free homes were assessed using the following questions: (a) "Where do people smoke in your house who live with you? (any where inside the house, in some rooms, only in one room, or only outside the house)" and (b) "Where do smokers who visit your house smoke? (any where inside the house, in some rooms, only in one room, or only outside the house)." We defined "open space outside house" as those spaces which are still within house premises but not covered by a ceiling, such as, veranda, balcony, yard, garden, lawn, patio, and open roof. Social visibility was assessed by the following questions: (a) "Do people who live with you smoke in front of children?" and (b) "Are people who visit your house allowed to smoke in front of children?". For each outcome, the response categories across the two questions were combined to form a composite variable (index) for analysis purposes.

Administered by researchers, questionnaire-based children's surveys assessed these outcomes in all three trial arms—at baseline and at weeks 1, 12, 27, and 52. The structured questionnaire was translated in Bangla and pre-tested with 61 year-five children in one school outside the study area. Based on the findings of the pre-test, the questionnaire was revised to ensure logical flow and to make the language clear and self-explanatory to children. In addition to a number of sociodemographic variables, the questionnaires also collected information on the number of smokers at home, their smoking behavior, children's attitude towards smoking and their perceived quality of life (see Supplementary Document Annex 1 for the full questionnaire).

Participant Flow and Recruitment

Out of 781 participants in 24 schools, 174 (22%) were lost to follow-up at year 1, the main reason being absence from school on the day of survey (Figure 1). The loss to follow-up was non-differential across the three arms. The intervention was delivered in June 2012, and the refresher sessions in August 2012.

Statistical Analysis

For this feasibility trial, we did not carry out formal sample size calculations, as we did not intend to provide definitive evidence of efficacy.[23] Analyses were done in general accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement and its extension to cluster trials.[24] All analyses were performed using SAS, version 9.3 (SAS Institute).

As this was a cluster trial, the baseline characteristics of the individuals and the clusters (school) were described. Generalized estimating equations (GEE in SAS PROC GENMOD) analysis, which is an advanced multilevel modeling technique for analyzing correlated data was used to derive the estimates and the intra-cluster coefficients (ICCs), using a logit link with clusters (schools) treated as a random effect. GEEs driven from logistic regression were used to characterize the probability of the intended outcome as a function of "survey time" and "intervention/control group" (i.e., intervention × year 1 survey time-point). Therefore, the analyses accounted for corresponding baseline levels (thus controlling for the time-variability) of smoke-free homes or social visibility to enable estimation of the true measure of change in intervention/control comparison that is attributable to the intervention alone.

Univariate distributions and frequencies were examined to describe and dichotomize categorical (multinomial) variables (smoke-free homes and social visibility). Bivariate and single-factor associations between the potential covariates (gender, open space outside the house, and availability of a smoker in the household) and the primary outcomes were assessed for inclusion in the multivariable regression models. Covariate-covariate interactions and covariate-intervention interactions were also explored and only those with significant interactions were included in the multivariable model. The odds ratios (*OR*s) and corresponding 95% CIs were estimated for these independent associations as well as adjusted for significant predictors.

ICCs were calculated for all analyses using the following formula: [between-group variance/(between-group variance + $\pi 2/3$)]. Cochrane Armitage Trend test was computed for both binomial outcomes taking intervention as an ordinal variable (control = 0, SFI = 1, and SFI plus reminder = 2). Trends of smoke-free homes and social visibility over time were also presented for all households, those with at least one smoker, and nonsmoking households. A sensitivity analysis was performed where missing data on the primary outcomes in all three groups were imputed as failures (smoke-free homes: "no" and social visibility: "yes").

Findings

Baseline Characteristics

The three trial arms were not balanced with respect to a number of baseline individual characteristics, summarized at cluster level (Table 1). The average number of male participants and the number of households with at least one resident smoker per cluster were higher in the control than in the intervention arms. Compared to other arms, baseline smoke-free homes per cluster were higher in Arm B and social visibility per cluster was higher in the control arm.

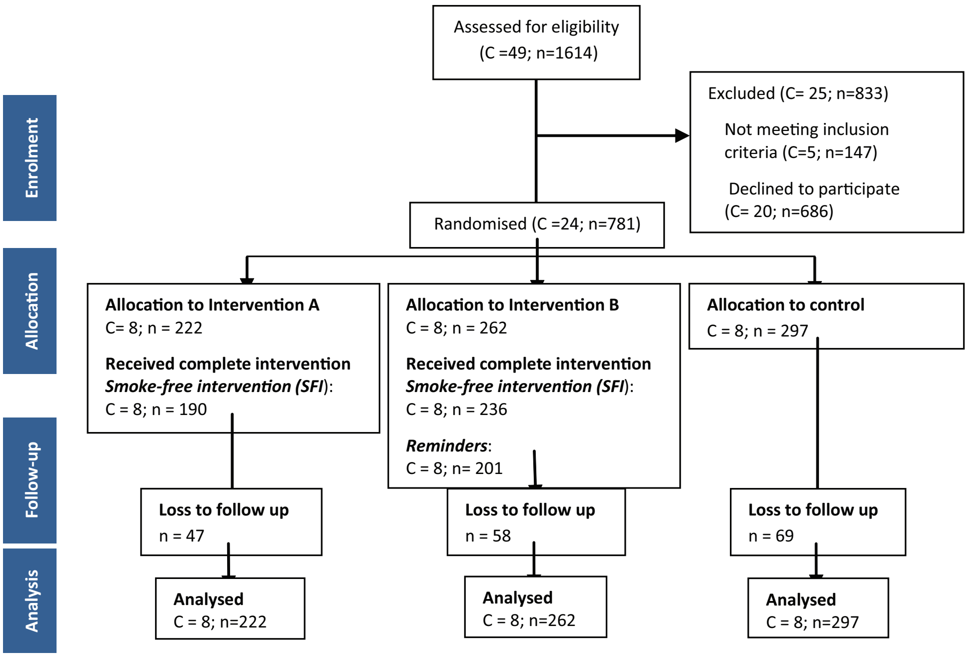

Figure 1. Study flow diagram.

Table 1. Baseline Characteristics of Individuals and Clusters (Values at Individual Level are Numbers [Percentages] and at Cluster Level are Means [Standard Deviations] Unless Stated Otherwise)

Variables	Arm A[a], *n* = 8, *N* = 222	Arm B, *n* = 8, *N* = 262	Arm C, *n* = 8, *N* = 297
Cluster level			
Age of child(years)	12.3 (0.49)	12.2 (0.42)	12.4 (0.42)
Males (no./cluster)	11.7 (3.1)	14.2 (9.5)	23.2 (7.6)
Open space outside the house (no./cluster)	16.5 (8.3)	15.5 (6.0)	14.1 (4.3)
Presence of a smoker in the household (no./cluster)	9.9 (7.2)	6.5 (4.1)	12.8 (11.5)
Smoking indoors—residents (no./cluster)	4.5 (4.5)	3.1 (2.9)	7.7 (6.8)
Smoking indoors—visitors (no./cluster)	3.4 (2.3)	3.1 (2.8)	7.2 (6.1)
Smoking in front of child—residents (no./cluster)	2.6 (2.7)	1.6(1.7)	7.2 (6.5)
Smoking in front of child—visitors (no./cluster)	2.8 (2.5)	1.5 (1.5)	6.5 (5.8)
Smoke-free homes (no./cluster)	21.9 (6.4)	28.0 (11.9)	22.7 (6.5)
Social visibility (no./cluster)	3.5 (3.0)	2.0 (2.2)	8.0 (7.7)
Individual level			
Median (IQR) age of child (years)	11 (2)	11 (2)	11 (2)
Males	100 (45.1)	117 (44.7)	209 (70.4)
Open space outside the house	137 (61.7)	157 (59.9)	225 (75.8)
Presence of a smoker in the household	128 (57.7)	117 (44.7)	122 (41.1)
Proportion of adult smokers per household[b]	0.28 (0.36)	0.20 (0.27)	0.20 (0.28)
Smoking indoors—residents	78 (35.1)	47 (17.9)	41 (13.8)
Smoking indoors—visitors	57 (25.7)	56 (21.4)	54 (18.8)
Smoking in front of child—residents	61 (27.5)	51 (19.5)	46 (15.5)
Smoking in front of child—visitors	53 (23.9)	51 (19.5)	54 (18.8)
Smoke-free homes	128 (57.7)	189 (72.1)	233 (78.5)
Social visibility	75 (33.8)	70 (26.7)	61 (20.5)

Note. IQR = interquartile range; SFI = smoke-free intervention; *n* = number of clusters; *N* = number of individuals.
[a]Arm A = SFI only; Arm B = SFI plus reminder; Arm C= control.
[b]The proportion of adult smokers (regular) per household = adult smoker/total adults in the household.

Outcomes and Estimation

Primary Outcome

At 1 year, the odds of "smoke-free homes" were greater among those randomized to Arm A (*OR* = 4.8; 95% CI = 2.6–9.0)—an increase from 57.7% (128/222) to 84.6% (148/175) and to Arm B (*OR* = 3.9; 95% CI = 2.0–7.5)—an increase from 72.1% (189/262) to 89.2% (182/204), compared to those in control group, after adjusting for baseline levels (Table 2). When adjusted for availability of a smoker in the household, the figures for Arm A and Arm B reduced slightly but remained statistically significant. Almost 20% (ICC = 0.198) of the unexplained variation in the outcome was observed to be at the school (cluster) level, and is thus, due to the differences between schools. An increasing trend was observed in households becoming smoke-free (trend test = 3.8; p value <.0001) with increasing intensity of the intervention (control < Arm A < Arm B).

At 1 year, the odds of "not smoking in front of children" inside the house (social visibility: no) were greater among those randomized to Arm A (*OR* = 5.8; 95% CI = 2.8–11.7)—a fall from 33.8% (75/222) to 8.9% (15/175) and to Arm B (*OR* = 7.2; 95% CI = 3.3–15.9)—a fall from 26.7% (70/262) to 5.4% (11/204), compared to those in the control group, after adjusting for baseline levels (Table 3). When adjusted for availability of a smoker in the household, the estimates for both arms (A and B) remained significant. Thirty-eight percent (ICC = 0.378) of the unexplained variation in social visibility was observed to be at the school (cluster) level; the presence of this large clustering effect indicates a strong influence of the schools in determining the success of the intervention. A decreasing trend (Trend test = −5.13; p value < .0001) in social visibility was also observed with increasing intensity of the intervention (control < Arm A < Arm B).

As expected, presence of a smoker was an independent predictor of the effect achieved in the study. However, presence of an open space outside the house and child's gender did not predict the outcome.

We also looked at time trends in the number of houses that implemented smoke-free homes and those where smoking took place in front of children, respectively. These are grouped as: all households; those with at least one smoker; and those without smokers. If SFI had an effect, we would expect the numbers to increase overtime for both intervention arms (A and B), while remaining flat for Arm C. Conversely, the trend in the number of houses with smoking taking place in front of children is expected to move towards opposite direction.

Overall the number of smoke-free homes in the intervention arms increased with time while the numbers in the control arm remained constant (Supplementary Figure 3). In all households, number of smoke-free homes peaked at week 1 (to about 91%) for Arm A and then gradually declined over the following weeks to maintain the trend (between 80% and 85%). In Arm B, numbers constantly rise over time until week 27 to maintain the trend (at 89%). In the households with at least one smoker, the number of smoke-free homes inclined acutely at week 1 (to about 80%) in Arm A and then declined gradually to maintain the trend (between 51% and 55%); in Arm B the numbers increased at week 1 (to about 67%), remaining constant until week 27 and then dropping to levels (56%) similar to baseline; in control arm, numbers declined constantly (from 62% at baseline to 34% at week 52). In the nonsmoking households, the number of smoke-free homes increased gradually over time, with the most visible increase happening in Arm B.

In all households, the number of houses with smoking taking place in front of children dropped sharply (to 8.6%) at week 1 in Arm A and then gradually inclined in the following weeks (to about 15%) and declined again at week 57 (to 8.6%) (Supplementary Figure 4). In Arm B the numbers declines gradually while remaining constant over time in Arm C. In households with at least one smoker, the number of houses with smoking taking place in front of children, shows a sigmoid pattern for Arm A, with a large dip at week 1. In the non-smoking households, the numbers in both intervention arms decline gradually while remaining more constant in the control group.

Findings from the sensitivity analysis when loss to follow-up was imputed as all failures did not differ substantially from the primary analysis (Supplementary Table 1).

Discussion

Consistent with the findings of the two previous feasibility studies,[6,19] this feasibility trial suggests that by using classroom based lessons and activities; children can be taught to influence adult smoking behavior. It demonstrates a proof of concept for the intervention; the study provides a sound methodology to carry out further definitive studies. Our findings provide cluster and participant recruitment and retention rates, likely effect size and expected ICC to estimate the design effect for a future cluster randomized controlled trial in such settings.

This study is an advance on the existing knowledge on the effectiveness of interventions reducing children's exposure to environmental tobacco smoke in homes. A recent Cochrane review found 57 studies, out of which 27 evaluated counseling offered to parents in children's healthcare settings.[17] Only two studies were carried out in schools; one slightly weaker study in China involved children writing letters to their smoking fathers persuading them to quit,[25] and in the other with a stronger study design in United States, teachers implemented smoke-free policies in schools and classrooms and persuaded children to do the same in homes.[26] Only the former study found a statistically significant reduction in SHS exposure to children attributable to the intervention. Since the publication of the above review, only a handful of studies were found that have evaluated interventions designed to reduce children's exposure to SHS.[27,28] However, except for the two aforementioned school-based feasibility studies[6,19] the rest evaluated interventions in healthcare or community settings.

The study has a number of methodological limitations, most of which are inevitable in a feasibility trial. As per convention of a feasibility trial, no formal sample size estimation was carried out. Therefore, the study does not provide an accurate power estimate to detect a statistically significant difference between intervention and control arms. Similarly, the absence of randomization by minimization led to an imbalance across the three trial arms; clusters in the control arm ended up with more boys and smokers at home than those in the two intervention arm. Twenty out of 49 schools approached, refused to participate in the trial. Reasons included, not having enough teachers to attend training and conduct the sessions, burden on children in year-five when they were expected to appear for scholarship examination, clash with school holidays, Ramadan and other school activities, apathy to work with non-governmental sector, requirement to seek permission from Trustees/Directors—which is time consuming and not enough financial incentives. The trial outcomes were assessed by conducting follow-up surveys at different time points and might not have captured the prevalent home adult smoking behavior.

Table 2. Effect of Smoke-Free Intervention (SFI) on Implementing Smoke-Free Homes, at 1 Year

	Smoke-free homes				
	Households' *n*/*N* (%)				
Variables	Baseline	Follow-up year 1	**Odds ratio**[d] **(95% CI)**	***p* value**[a]	**ICC**[b]
Crude estimates					
Intervention vs. control					
SFI	128/222 (57.7)	148/175 (84.6)	4.82 (2.58–8.99)	<.0001	0.198
SFI plus reminders	189/262 (72.1)	182/204 (89.2)	3.86 (1.99–7.47)	<.0001	
Control	233/297 (78.5)	172/228 (75.4)	1	–	
Gender					
Male	285/351 (81.2)	–	1.08 (0.88–1.34)	.4568	–
Female	217/256 (84.8)	–	1	–	
Open space outside the house					
Yes	264/315 (83.8)	–	1.16 (0.96–1.39)	.1341	–
No	238/292 (81.5)		1	–	
Presence of a smoker in the household					
Yes	81/176 (46.0)	–	9.94 (7.85–12.58)	<.0001	–
No	421/431 (97.7)	–	1	–	
Adjusted estimates[c]					
Intervention vs. control					
SFI	–	–	4.01 (2.07–7.79)	<.0001	0.180
SFI plus reminders	–	–	3.41 (1.70–6.86)	.0006	
Control	–	–	1	–	

Note. CI = confidence interval.
[a]*p* value < .05 is a significant predictor of the outcome.
[b]Intra-cluster coefficient.
[c]Adjusted for presence of a smoker in the household.
[d]All analyses account for clustering and baseline levels of intended outcome.

Table 3. Effect of Smoke-Free Intervention (SFI) on Social Visibility Inside the House, at 1 Year

	Social visibility				
	Households' *n*/*N* (%)				
Variables	Baseline	Follow-up year 1	**Odds ratio**[e] (95% CI)	***p* value**[a]	**ICC**[d]
Independent estimates					
Intervention vs. control					
SFI	75/222 (33.8)	15/175 (8.96)	5.77 (2.84–11.7)	<.0001	0.378
SFI plus reminders	70/262 (26.7)	11/204 (5.4)	7.20 (3.25–15.9)	<.0001	
Control	61/297 (20.5)	49/228 (21.5)	1	–	
Gender					
Male	49/351 (14.0)	–	0.87 (0.69–1.10)	.2342[c]	–
Female	26/256 (10.2)	–	1	–	
Open space outside the house					
Yes	41/315 (13.0)	–	0.97 (0.79–1.19)	.7547	–
No	34/292 (11.6)		1	–	
Availability of a smoker in the household					
Yes	67/176 (38.1)	–	0.09 (0.07–0.12)	<.0001	–
No	8/431 (1.9)	–	1	–	
Adjusted estimates[b]					
Intervention vs. control					
SFI	–	–	4.51 (2.09–9.71)	.0001	0.363
SFI plus reminders	–	–	6.74 (3.00–15.2)	<.0001	
Control	–	–	1	–	

Note. CI = confidence interval.
[a]*p* value < .05 is a significant predictor of the outcome.
[b]Adjusted for availability of a smoker in the household.
[c]In the model that included independent variables defining SFI plus reminders, gender, and the SFI plus reminders × gender interaction, a significant interaction was detected (*p* = .0004), indicating that the effect of SFI plus reminders is dependent on gender.
[d]Intra-cluster coefficient.
[e]All analyses account for clustering and baseline levels of intended outcome.

For example, smoking might have taken place in homes in children's absence and would have still exposed them to third-hand smoke without their knowledge. A major weakness was that we did not validate the self-reported outcomes with cotinine estimation due to absence of such facilities in Bangladesh. On the other hand, a large survey assessing children's exposure to SHS found that children's self-reports of exposure are more likely to be in agreement with the salivary cotinine levels than their parents.[29] Finally, we did not formally assess any potential adverse effects of the intervention in the children. However, we did alert schoolteachers to look out for any signs of distress among children in case their negotiations with adults about smoke-free homes led to any adverse reaction. No such adverse events were reported.

The study findings encourage us to progress to a future definitive trial with a bigger sample size and objective outcomes assessment. As part of the anti-tobacco alliance in Bangladesh, we aim to collaborate with National Tobacco Control Cell (NTCC) and the Ministry of Primary and Mass Education (MOPME) to incorporate smoke-free intervention into the national curriculum and a definitive trial, if proven effective, will help us achieving this goal. Other outcomes of interest would include clinical outcomes and smoking uptake rates among children. The outcomes measuring quality of life and healthcare use will also be of interest particularly in a comprehensive cost-benefit analysis of the intervention. Relevant literature recognizes the existing complexities in people's understanding of a smoke free space and its dynamic nature and other factors competing with their desire to protect their children from SHS.[30,31] A bigger trial will allow us to explore this in detail. We found that 20% and 38% variation at the cluster level in the two outcomes, "smoke free homes" and "social visibility" respectively, indicating an effect modification at schools. An embedded qualitative study can examine such interplays between the effect of schools, children's health literacy skills, family dynamics, competing parental responsibilities, and physical space in homes. A process evaluation plan can document the relationship between specific elements of the intervention and programme outcomes.

In conclusion, this feasibility trial informs the methods and statistical requirements to conduct a future definitive trial to evaluate the effectiveness of such an intervention. Its findings also suggest that the school-based smoke-free intervention has the potential to make children aware of the harms of SHS and motivate them to negotiate smoke-free environment in their households.

Supplementary Material

Supplementary Table 1, Figures 1–4, and Document Annex 1 can be found online at http://www.ntr.oxfordjournals.org

Funding

This study was funded by the National Health Service (NHS), Leeds, United Kingdom. However, the information contained in it is not necessarily endorsed by NHS-Leeds, UK.

Declaration of Interests

None declared.

Acknowledgments

We would like to thank all the study participants. Also, thanks to colleagues at the NHS, Leeds; United Kingdom for their support, contributions and valuable suggestions. We are grateful to Professor Aziz Sheikh, University of Edinburgh, for proof reading the manuscript and providing helpful comments. We are also grateful to the Trial Steering Committee for their oversight. RH coordinated the study implementation and data collection and participated in the preparation of the manuscript; OD participated in data analysis and preparation of the manuscript; IC, HT, and AA advised on the design and methodology of the study and participated in the preparation of the manuscript. KS conceived and designed the study, advised on data collection and analysis, and contributed to the preparation of the manuscript.

References

1. Kriz P, Bobak M, Kriz B. Parental smoking, socioeconomic factors, and risk of invasive meningococcal disease in children: a population based case-control study. *Arch Dis Child*. 2000;83:117–121.
2. Hofhuis W, Jongste JC, Merkus PJFM. Adverse health effects of prenatal and postnatal tobacco smoke exposure on children. *Arch Dis Child*. 2003;88:1086–1090.
3. Murray RL, Britton J, Leonardi-Bee J. Second hand smoke exposure and the risk of invasive meningococcal disease in children: systematic review and meta-analysis. *BMC Public Health*. 2012;12:1062–1072. http://www.biomedcentral.com/1471–2458/12/1062. Accessed December 5, 2013.
4. US Department of Health and Human Services. *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General*. Centers for Disease Control and Prevention, Coordinating Center for Health Promotion, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2006. http://www.surgeongeneral.gov/library/reports/secondhandsmoke/fullreport.pdf. Accessed December 5, 2013.
5. World Health Organization. *Protection from Exposure to Second-Hand Tobacco Smoke: Policy Recommendations*. Geneva, Switzerland: WHO; 2007. http://whqlibdoc.who.int/publications/2007/9789241563413_eng.pdf. Accessed September 20, 2014.
6. Siddiqi K, Sarmad R, Usmani RA, Kanwal A, Thomson H, Cameron I. Smoke-free homes: an intervention to reduce second-hand smoke exposure in households. *Int J Tuberc Lung Dis*. 2010;14:1336–1341. http://www.ncbi.nlm.nih.gov/pubmed/20843427. Accessed January 17, 2014.
7. Butz AM, Breysse P, Rand C, et al. Household smoking behavior: effects on indoor air quality and health of urban children with asthma. *Matern Child Health J*. 2011;15:460–468.
8. Health & Consumer Protection Directorate-General. Towards a Europe Free from Tobacco Smoke: Policy Options at EU Level. Brussels, Belgium: European Commission; 2007. http://ec.europa.eu/health/archive/ph_determinants/life_style/tobacco/documents/r-058_en.pdf. Accessed December 12, 2013.
9. Been JV, Nurmatov UB, Cox B, Nawrot TS, van Schayck CP, Sheikh A. Effect of smoke-free legislation on perinatal and child health: a systematic review and meta-analysis. *Lancet*. 2014;383:1549–1560.
10. Zafar Ullah AN, Huque R, Akter S, et al. Children's exposure to second-hand smoke at home in Bangladesh: a community survey. *BMJ Open*. 2013;3:e003059.
11. Rogers EMA. Prospective and retrospective look at the diffusion model. *J Health Commun*. 2004;9:13–19.
12. Haw SJ, Gruer L. Changes in exposure of adult non-smokers to second-hand smoke after implementation of smoke-free legislation in Scotland: national cross sectional survey. *BMJ*. 2007;335:549–558.
13. Galan I, Mata N, Estrada C, et al. Impact of the 'tobacco control law' on exposure to environmental tobacco smoke in Spain. *BMC Public Health*. 2007;7:224–232. http://www.ncbi.nlm.nih.gov/pubmed/17760974. Accessed March 5, 2014.
14. Ho SY, Wang MP, Lo WS, et al. Comprehensive smoke-free legislation and displacement of smoking into the homes of young children in Hong Kong. *Tob Control*. 2010;19:129–133. http://tobaccocontrol.bmj.com/content/19/2/129. Accessed April 21, 2014.
15. Lund KE, Helgason AR. Environmental tobacco smoke in Norwegian homes, 1995 and 2001: changes in children's exposure and parents attitudes and health risk awareness. *Eur J Public Health*. 2005;15:123–127.
16. Yousey YK. Household characteristics, smoking bans, and passive smoke exposure in young children. *J Pediatr Health Care*. 2006;20:98–105.

http://www.ncbi.nlm.nih.gov/pubmed/16522486. Accessed January 14, 2014.

17. Baxi R, Sharma M, Roseby R, et al. Family and carer smoking control programmes for reducing children's exposure to environmental tobacco smoke. *Cochrane Database Syst Rev*. 2014;3:CD001746.
18. Global Adult Tobacco Survey. Bangladesh Report 2009. Ministry of Health and Family Welfare of Bangladesh; 2009. http://ban.searo.who.int/LinkFiles/Publication_Global_Adult_Tobacco_Survey_Bangladesh_Report_2009_web.pdf?ua=1. Accessed December 5, 2013.
19. Alwan N, Siddiqi K, Thomson H, Lane J, Cameron I. Can a community-based 'smoke-free homes' intervention persuade families to apply smoking restrictions at homes? *J Public Health (Oxf)*. 2011;33:48–54.
20. Campbell NC, Murray E, Darbyshire J, et al. Designing and evaluating complex interventions to improve health care. *BMJ*. 2007;334:455–459.
21. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008;337:a1655.
22. Bangladesh Bureau of Statistics. *Population Census 2001, National Report (Provisional)*. Dhaka, Bangladesh: Bangladesh Bureau of Statistics; 2003.
23. Begh RA, Aveyard P, Upton P, et al. Promoting smoking cessation in Pakistani and Bangladeshi men in the UK: pilot cluster randomised controlled trial of trained community outreach workers. *Trials*. 2011;12:197–210. http://www.trialsjournal.com/content/12/1/197. Accessed February, 2014.
24. Campbell MK, Elbourne DR, Altman DG; CONSORT group. CONSORT statement: extension to cluster randomised trials. *BMJ*. 2004;328:702–708. http://www.ncbi.nlm.nih.gov/pubmed/15031246. Accessed March, 2014.
25. Zhang D, Qiu X. From the Centers for Disease Control and Prevention. School-Based Tobacco-Use Prevention—People's Republic of China, May 1989-January 1990. *JAMA*. 1993;269:2972.
26. Elder JP, Perry CL, Stone EJ, et al. Tobacco use measurement, prediction, and intervention in elementary schools in four states: the CATCH Study. *Prev Med*. 1996;25:486–494.
27. Harutyunyan A, Movsisyan N, Petrosyan V, Petrosyan D, Stillman F. Reducing children's exposure to secondhand smoke at home: a randomized trial. *Pediatrics*. 2013;132:1071–1080.
28. Wilson I, Semple S, Mills LM, et al. REFRESH–reducing families' exposure to secondhand smoke in the home: a feasibility study. *Tob Control*. 2013;22:e8.
29. Abidin EZ, Semple S, Omar A, Rahman HA, Turner SW, Ayres JG. A survey of schoolchildren's exposure to secondhand smoke in Malaysia. *BMC Public Health*. 2011;11:634–645.
30. Robinson J, Kirkcaldy A. Disadvantaged mothers, young children and smoking in the home: Mothers' use of space within their homes. *Health and Space*. 2007;13(4):894–903.
31. Ritchie D, Amos A, Phillips R, Cunningham-Burley S, Martin C. Action to achieve smoke-free homes—an exploration of experts' views. *BMC Public Health*. 2009;9:112–121.