Children Learning About Second-hand Smoke (CLASS) Trial

Final Report

Authors

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Abstract

Second-hand smoke (SHS) is a serious health hazard to non-smokers, especially children. A Cochrane review of interventions to reduce exposure to SHS in the home (Priest et al 2008) recommended that larger studies on the effectiveness of family-based interventions with robust methodologies and objective outcome assessments be carried out.

A cluster randomised controlled trial (CRCT) of Smoke Free Homes (SFH) delivered in a school setting, using cotinine testing as an objective outcome measure was therefore designed.

The conduct of this trial faced significant challenges in particular with regard to recruitment and gaining informed consent from parents/carers for children's participation. Following a low recruitment rate (2.5%) using an opt-in approach to parental consent, an opt-out approach was proposed. However an independent legal opinion on this strategy in relation to the Data Protection Act (1998) confirmed, in this case, such an approach would not be acceptable. The trial was therefore suspended and closed-down.

This study was not able to evaluate what recruitment methods may be effective with this population group on this topic of research; we would suggest future research evaluates face to face recruitment methods and incentives. Project achievements included successful recruitment of schools and refinement of SFH.

ISRCTN01118895

Contents

List of Abbreviations

CRCT - Cluster Randomised Controlled Trial
ISSC – Independent Study Steering Committee
LEAs - Local Education Authorities
NHS – National Health Service
NHS R&D – National Health Service Research and Development
NHS REC - National Health Service Research Ethics Committee
NIHR PHR – National Institute for Health Research, Public Health Research programme
PI – Principal Investigator
PO – Primary Outcome
SFH – Smoke Free Homes
SHS – Second-hand Smoke
SO – Secondary Outcome
SOA – Super Output Area
SSC – Study Steering Committee
WYCLRN – West Yorkshire Comprehensive Local Research Network

1. Introduction/Background

Second-hand smoke

Second-hand smoke (SHS) is a serious health hazard to non-smokers, especially children. Living with a smoking adult is one of the key determinants of exposure to SHS. It has been suggested that 45% of children in England and Wales live with at least one smoker in their homes (Jarvis et al 2000). Children living in poverty are more likely to be exposed to SHS compared to those from affluent families (King et al 2009). In the Smoke Free Homes feasibility study it was found that children living in poor households are more likely to live with smoker(s) and less likely to have smoking restrictions in the house (Alwan et al 2009).

SHS is estimated to be responsible for 10,700 deaths among adults per year in the UK (Jamrozik 2005). In adults, SHS is associated with cardiovascular diseases, chronic respiratory diseases, nasal and lung cancer (Rushton 2004). Asthma and wheezing are more prevalent in children exposed to SHS compared to those living in smoke free environments (Burr et al 1999). The risk of other lower respiratory illnesses, chronic middle ear disease and sudden infant death syndrome is also high among such children (Cook and Strachan 1999). In addition, SHS is also associated with dental caries and metabolic syndrome. There is a strong relationship between parental smoking and childhood admissions to hospitals (Cook and Strachan 1999). In fact, 25% of hospital admissions among children, secondary to respiratory illnesses, are attributable to SHS. Exposure to SHS in the ante-natal period results in low birth weight babies (Ward et al 2007) and problem behaviours in later life (Fergusson et al 1993). Children living in smoking households are at risk of poorer general and functional health (Spencer and Coe 2003). Exposure to parental smoking is also an independent determinant of failures at GCSE and A-level assessments (Collins et al 2007). Evidence for a causal link between exposure to SHS in childhood and increased smoking uptake in teenage years is inconclusive. However, a strong association has been suggested between smoking among teenagers and living with adult smokers (Amos et al 2009).

Benefits of smoking restrictions

Smoking restrictions primarily protect non-smokers from SHS. The presence of smoking restrictions in smoking households reduces children's exposure to SHS (Ronchetti et al 2003). Furthermore, it has been suggested that smokers who implement smoking restrictions at home are more willing to quit smoking (Borland et al 2006). Smoking restrictions at home are also likely to make smoking less socially acceptable for children. Young people living in homes with such restrictions have a reduced perception and visibility of smoking and a more negative attitude towards smoking, two important determinants for not starting smoking (Conley et al 2005).

Achieving smoking restrictions

Comprehensive tobacco control programmes are likely to positively influence people to have smoking restrictions at home (Thomson et al 2006). According to the social diffusion model, comprehensive smoking bans in public places encourage people to implement smoking restrictions at home (Borland et al 2006). The exposure of non-smokers to SHS living in non-smoking households dropped significantly in Scotland since the ban on smoking in public places. New Zealand and Ireland reported similar changes (Edwards et al 2008) but in Spain a more limited smoking ban in public places had minimal effect on smoking restrictions at home (Galan et al 2007).

However, non-smokers living in smoking households continue to have high levels of exposure to SHS (Haw and Gruer 2007).

Generally, families go through various processes in adopting smoking restrictions at home (Kegler et al 2007). Recognition of the risk to children's health is a major determinant in families agreeing on smoking restrictions. Sometimes this is precipitated by a physician's advice when attending a sick child. In many instances, children's abhorrence of cigarette smoke and their direct complaint to the smoking adults triggered household bans. It has been suggested that developing parents' confidence in providing a smoke-free environment and offering to support them in achieving this goal is likely to be effective (Arborelius et al 2000).

Existing research

A recent Cochrane review found 36 controlled studies aimed at reducing exposure to SHS in the home (Priest et al 2008). In four of these studies, interventions were targeted at populations in community settings. In others, parents were targeted in health care settings. The interventions were aimed at either avoiding smoking in front of children and/or smoking cessation. 11 studies showed a significant reduction in children's exposure to SHS. However, the authors concluded that there is insufficient evidence to support one strategy over another due to relatively weak methodologies, non-objective outcome measurements (for example using self-reported measures only) and varied settings and strategies. They also recommended that larger studies on the effectiveness of family-based interventions with robust methodologies and objective outcome assessments (for example cotinine testing) should be carried out.

Smoke Free Homes intervention

Smoke Free Homes (SFH) is an initiative which was developed and launched by West Yorkshire Smoking & Health (WYSH) in February 2003 after a successful bid to the Department of Health. The initiative was aimed at increasing both awareness of the health hazards of SHS and self-efficacy in being able to develop strategies to restrict smoking in homes and negotiate their implementation. The initiative was an adaptation of "Smoke-Free Home Pledge" launched in America in 2001 by the US Environmental Protection Agency (McCarthy 2001).

SFH has been adopted in certain parts of the country (e.g. Salford, Nottingham, and Bristol). However, there have been limited reported evaluations. One report from Doncaster showed that 69% of households, signing up for smoking restrictions, promised a complete ban on smoking (Al-alawy et al 2008). A survey from Salford highlighted the finding that nearly all smokers who promised to keep their homes smoke-free were able to maintain their commitment in the following six-months (Wigg 2008). Preceding the design of the CLASS trial a feasibility study was conducted to; (a) test the appropriateness of SFH intervention; (b) refine and standardise SFH; and (c) assess potential methods for its evaluation in a deprived urban locality (Alwan et al 2009). The feasibility study found that smoking in the presence of children more than halved in households with at least one smoker; 42% at baseline, 20% at 6 months. The proportion of households being completely smoke free increased from 35% at baseline to 67% at 6 months.

The theoretical framework for SFH is based on the following:

- Negotiated goals: giving families a menu of options on how to reduce their children's exposure to tobacco smoke; letting them decide for themselves which of the options is achievable for the

family, then signing the application at the bottom of the 'Promise' form before they post it back.

- Signing a contract: requiring parents to sign a 'contract' increases their commitment and the likelihood of their maintaining smoking restrictions in the home
- Positive feedback: praising parents for the positive consequences of reducing their children's exposure to tobacco smoke increases self-esteem and self-efficacy in making changes in their lives.
- Immediate benefits: A basic principle of social marketing is that of 'exchange'; people expect to receive a benefit in exchange for giving up something.

Rationale for CLASS trial

SFH has a firm theoretical basis, sound feasibility, broad acceptability, and the potential to improve children's health. However, evidence of its effectiveness and cost-effectiveness based on objective outcome measures does not yet exist to support wide adoption. A cluster randomised controlled trial (CRCT) of SFH using cotinine testing as an objective outcome measure was therefore designed to attempt to address this gap in the current knowledge.

A long follow up period was also planned to allow the influence of a smoke free environment at home on the smoking initiation rates in teenage years to be studied. According to the General Household Survey 2007, 38% of regular adult smokers started smoking before the age of 15 years (Ali et al 2009). The smoking prevalence among those aged 11-15 years increases up to the age of 15 (Fuller et al 2008). There is a dearth of longitudinal and experimental studies examining what is effective in youth smoking prevention. Planning to follow up the children in their teenage years was an opportunity to begin to address this key knowledge gap. In addition, interventions such as SFH can be seen as a long-term investment in public health; therefore, long-term follow-up assessment is important to understand the sustainability of outcomes and to support on-going informed decision-making.

As will be described in this report, the conduct of this trial faced significant challenges. We describe the original CRCT design, the recruitment challenges faced, in particular in gaining consent from parents/carers for children's participation, the proposed strategy of an opt out approach to parental consent, the resulting legal opinion on this strategy in relation to the Data Protection Act (1998) and the eventual suspension of the trial.

The trial was registered on the ISRCTN register: ISRCTN01118895.

2. Proposed Trial Design and Methods

Original design

Aim

To investigate the potential effectiveness and cost-effectiveness of a school-based intervention, 'Smoke Free Homes'(SFH), in protecting children from second-hand smoke (SHS) at home, reducing uptake of smoking in young people, and improving smoking quit rates.

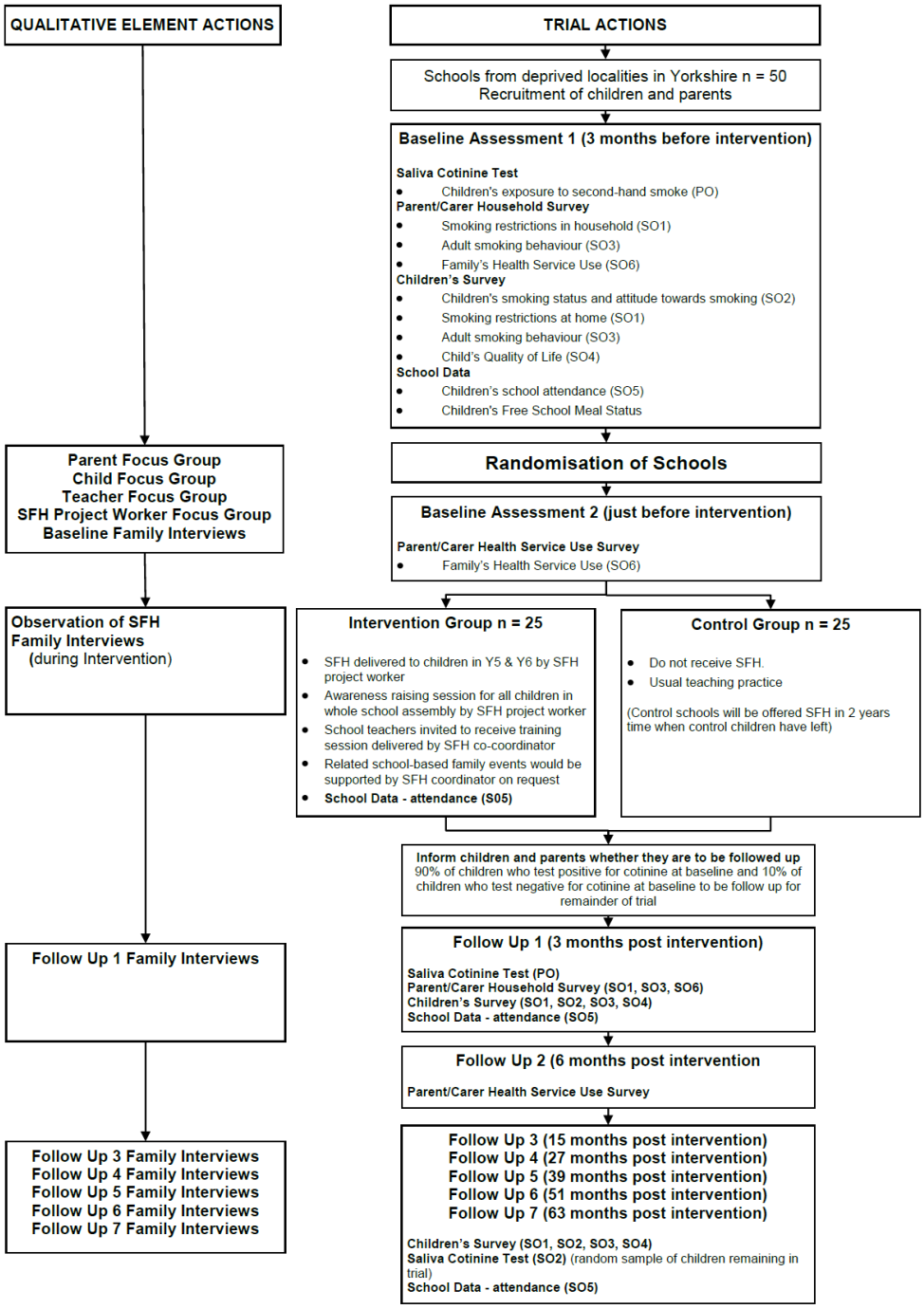
Objectives

1. To estimate the effectiveness of SFH in (a) reducing children's exposure to SHS, (b) discouraging them to take up smoking in their teenage years (11-15) and (c) encouraging adult smokers in their households to quit smoking (Effect Evaluation)
2. To estimate the effectiveness of SFH in encouraging families to impose and sustain smoking restrictions at home (Intermediate Outcomes Evaluation)
3. To assess the integrity and fidelity of the implementation process and other contextual factors that might contribute to the variation in outcomes (Contextual Evaluation)
4. To estimate the cost-effectiveness and understand the budgetary implications of SFH in obtaining its intended outcomes (Economic Evaluation)

Research design

A cluster randomised controlled trial (CRCT) with an economic and qualitative component was designed (see Figure 1). Due to the possibility of contamination and for practical and logistical reasons, children could not be randomised to the intervention and control arms individually. A CRCT was consequently designed in which schools (clusters of children) were to be randomised to the intervention and control groups.

Figure 1: Original CLASS Trial Design



Study population and recruitment

Study clusters (primary schools)

We planned to recruit at least 50 primary schools into the CLASS trial, from neighbourhoods with high deprivation, initially from the lowest 10% super output areas ascertained from the 2007 Total Deprivation data. We also intended to use ASH maps (http://www.mapsinternational.co.uk/jc/ash/ash.html) to help identify schools in neighbourhoods with above average (21%) smoking prevalence rates. However this data was dated and was therefore removed as a criterion. Schools where SFH or any similar activities had taken place in the last two years were to be excluded.

In order to follow up participating children over the longer term, all secondary schools with participating primary schools in their catchment area would have been sent written information and asked to give written consent to allow children to be followed up.

We began school recruitment by sending an invitation letter to eligible schools inviting them to a recruitment conference or offering to visit the school. This letter was followed up with emails and phone calls from researchers. However this recruitment strategy was not as effective as expected. Two hundred and eleven schools were contacted, and only two schools attended the recruitment conference in March 2011 at which Fiona Castle (widow of the late Roy Castle) spoke and gave encouragement for schools to take part. A further six schools expressed an interest in participating in the trial at this time.

We implemented the following strategies to increase school involvement:

- Initially, primary schools in the lowest 10% Super Output Areas (SOAs) in West Yorkshire (Bradford, Calderdale, Kirklees, Leeds and Wakefield) were invited to participate (n = 132). The inclusion criteria were widened to include schools in the 11 % to 20% SOA range and to include schools from others areas of Yorkshire and the Humber (Sheffield, Hull and Barnsley): a total of 304 schools.
- We worked with Healthy Schools teams within each Local Education Authority (LEA) to cascade CLASS Trial information to eligible schools and invite schools to take part. Some areas were able to send invitation letters with endorsement from Directors of Public Health and the Education Service. Healthy School team members and researchers gave presentations at school network events and made phone calls and visits to eligible and interested schools to follow-up on the trial information sent out.
- We increased the cash incentive offered to school for participation from £50 to £100.
- We continued to make it clear that all schools would receive the SFH intervention even if they were allocated to the control group (waiting list design).

Primary participants (children)

All children in years 4 and 5 in the 2010/2011 school academic year at participating schools were eligible for participating in the CLASS trial. The Trial Information Packs were sent out to parents/carers, which included written information and an information DVD. Teachers also used the information DVD for children to explain the study to children in the classroom, as well as providing them with an Information Sheet. Parents/Carers were asked to give informed written

consent for them to take part (opt in consent). Children were also asked to give written assent (further details on recruitment are provided in Section 3). After baseline data had been collected, it was planned that only a sample of children would be followed up for the remainder of the trial. This sample was to include 90% of children who tested positive and 10% of children who tested negative for cotinine at baseline. We aimed to recruit at least 40 children with a positive cotinine test from each school.

Secondary participants (parents/carers)

Secondary participants were the parents /carers of participating children. Parents/Carers were asked to give informed written consent for their own involvement as well as the involvement of their child.

Baseline data

The following baseline data were to be collected from primary schools: catchment secondary schools, proportion of children receiving Free School Meals (FSM) (which is a proxy for socioeconomic status), and for each individual child participating, attendance records and FSM status. Parents were to be asked to complete household surveys assessing the level of smoking restrictions and smoking behaviour of adult smokers at home and the household's health service use. Children were to be asked to provide a saliva sample for cotinine testing, and complete a survey assessing the level of smoking restrictions at home, their own attitude towards smoking, the smoking behaviour of adults in their home and their quality of life. (Details of the data enquiry tools are presented below, page 12).

Randomisation

Once necessary baseline data had been logged into a database, the participating schools would have been randomly allocated to each of the two arms, intervention and control on an equal basis (i.e. 25 schools in each arm) using a restricted method of allocation called minimisation. We planned to minimise (i.e., ensure balance) on size of eligible sample and proportion of eligible children receiving FSM. Each intervention school would have been paired with a control school for follow up purposes.

Intervention group

Schools in the intervention arm were to receive SFH at the beginning of the autumn term 2011 (September 2011) by which time participating children would be in Years 5 and 6. Schools would have been asked to provide attendance details for all participating children on the days when SFH activities were conducted. It was planned that all children in year 5 and 6 would receive the SFH intervention even if they did not participate in the research unless specially withdrawn by their parents/carers.

SFH is a school-based intervention which provides children with the knowledge and skills to encourage and support their families to implement smoking restrictions in their homes and, as a consequence, to protect themselves and other non-smokers from SHS. A trained SFH project worker would visit each school and take Years 5 and 6 children through a series of educational activities using a SFH toolkit. This would have taken approximately one and half hours and was designed as a one off session. The SFH activities are designed to raise awareness among children about the hazards of SHS and empower them to negotiate smoking restrictions with other family members at home. Families are encouraged to "sign-up" to a voluntary contract not to allow

smoking inside their houses and in front of children. In addition; (a) school teachers were to receive a training session on SFH to help them in reinforcing SFH messages, (b) a brief session on SFH for all children was to be provided through a whole school assembly, and (c) school-based family events could be supported by the SFH project worker at the schools request. A detailed description of the intervention is available in a report titled “Smoke Free Homes Campaign Report” (Hodgson 2004).

Control group

Schools randomly allocated to the control group would not have received the SFH activities immediately. Children would have continued with normal teaching and this would have included the schools meeting the National Curriculum guidelines within Key Stage 2 of teaching children about developing a healthy safer lifestyle. Schools in the control arm were assured that they would be offered the SFH activities after 24 months when all participating children would have left the primary schools and moved to secondary schools (if the intervention was found to be effective). This design is known as a waiting list design (Ainsworth et al 2010).

Follow up

The first follow up was planned to take place at 3 months post intervention. Parents who were selected to remain in the trial (parents of 90% of children who tested positive for cotinine at baseline. would have been asked to complete a Parents Household Survey (Secondary Outcome 1, (SO1) and SO3). Children who were selected to remain in the trial would have been asked to complete a Children’s Survey (SO1, SO2, SO3 and SO4) and provide a saliva sample (Primary Outcome (PO)). Primary schools were expected to oversee this data collection and provide data on school attendance of participating children (SO5). The second follow up was planned to take place 6 months post intervention. At this time point parents were to be asked to complete a Health Service Use Survey (SO6). (Enquiry tools can be found in Appendix 8.)

At follow up 3 (15 months post intervention), follow up 4 (27 months post intervention), follow up 5 (39 months post intervention), follow up 6 (51 months post intervention), and follow up 7 (63 months post intervention) we planned to ask all children who remained in the trial to complete the Children’s Survey again. We also planned to ask a random sample of the children to provide a saliva sample. This was to test the validity of the children’s self reported smoking status in the survey. Primary schools were to oversee the data collection for children who remained at their school. Secondary schools were to oversee the data collection for participating children who have moved to their school.

Primary outcome (PO)

Salivary cotinine levels among children at Follow Up 1 (PO)

Secondary outcomes (SO)

Salivary cotinine levels among children at Follow Up 3 to 7

Smoking restrictions at home as reported by parents and children (SO1) - the feasibility of this tool was assessed in an exploratory study (Alwan et al 2009) and we modified it accordingly. The assessment is based on two questions; (a) Do people in the house smoke in front of children? and (b) where do people smoke? With possible responses being (i) in any part of the house; (ii) in one room only; (iii) only outside the house. The same questions were included in relation to smoking restrictions on visitors. This assessment is similar to the approaches used by other researchers

(Borland et al 1999, Wakefield et al 2000). We planned to validate the responses by asking the children and parents the same questions.

Children's attitude and behaviours towards smoking and intention to start (SO2) - We planned to use a five-point smoking uptake scale to assess children's attitude towards smoking and intention to start, based on previous tools (Pierce et al 1995, Pierce et al 1996, Wakefield et al 2000). The categories being: (a) Non-susceptible non-smokers ; (b) Susceptible non-smokers; (c) Early experimenters; (d) Advanced experimenters; (e) Established smokers.

Smoking behaviour of adults (SO3) – The Parent/Carer Household survey asked the respondent to document the smoking behaviour of each adult in the household, including their intention to quit.

Quality of life (SO4) - We planned to use the PedsQol (Varni et al 1999, Chan et al 2005) with children for this purpose.

Health Service Use (SO6) – We planned to collect data on health service use for each member of the household in the 6 months before the intervention and in the 6 months after using the Parent/Carer Health Service Use Survey.

School attendance (SO5) – to be collected from schools.

Household Characteristics – The Parent/Carer Household Survey also asked questions in relation to household type and socio-demographic indicators.

Proposed sample size

We planned to recruit 50 schools (25 in each arm) in the study. We planned to recruit 40 children with positive cotinine tests at baseline and 4 children with negative cotinine tests at baseline from Years 4 and 5 from each of these schools. In total therefore we expected a sample size of 2200 children and their parents to be followed up until the completion of the trial. The primary outcome was to detect a difference in the salivary cotinine levels at Follow up 1 between children who tested positive for cotinine at baseline (estimated 2000 children) and therefore we based our sample size on that as per convention. However, we believed that our sample size would have had sufficient power to detect significant difference in secondary outcomes as well.

Our sample size estimation for the primary outcome was based on following assumptions:

- Significance level i.e. $\alpha = 0.05$ and 90% power
- Difference in the mean cotinine levels between control and intervention arms = 0.28 Standard Deviation = 1.38
- Intra-cluster correlation coefficient = 0.05
- Correlation between baseline covariate and outcome = 0.6

Statistical analysis

The analysis plan was:

- Preliminary analysis consisting of a series of descriptive tables summarising; (a) basic characteristics of the data collected; (b) baseline characteristics of schools and children; (c) attrition rates; and (d) intra-cluster correlation coefficient for the outcomes. This would also

have included a comparison between participants with detectable levels of cotinine at baseline and zero levels of cotinine at baseline.

- A comparison of the means of the primary and secondary outcomes at both cluster and individual level after adjusting for the cluster design. We also planned to adjust for the baseline characteristics and other covariates using generalised estimating equations.

Qualitative study

The qualitative component (contextual evaluation) was designed as follows:
1) Focus groups to explore the views of parents, teachers, children, and deliverers of the SFH intervention towards the intervention and to identify themes to inform observational protocols and interviewing guides;
2) Observational methods to investigate the engagement and educational process of SFH to ensure implementation integrity and fidelity;
3) Exploring contextual factors at two levels: a) the neighbourhoods of the selected sample of families by geographical mapping b) the families' dynamics, interactions, and resulting behaviours in relation to the SFH messages through family interviews.

Before suspension of the study a focus group was conducted with teachers to explore parent/carer and child recruitment and consent and their opinions of the SFH intervention.

Economic study

The economic component of the study (economic evaluation) planned to estimate the cost of providing the intervention in schools. The estimated costs were to be combined with outcome rates to compute a cost-effectiveness ratio, taking the form of a cost per smoke free child (defined as having zero cotinine levels). We also planned to undertake economic modelling to capture longer term impacts. The longer term follow up was to provide estimates of the number of pupils who did not take up smoking in the intervention groups over and above the control scenario. These data were to be combined with Quality Adjusted Life Year (QALY) estimates indicating the expected quality of life for smokers and non-smokers to project the potential QALY gains in the intervention group for those pupils who did not take up smoking.

3. Results

The following section, details the results of parent/carer and child recruitment, the subsequent proposed changes to the study design and eventual suspension of the trial. We then outline the project achievements and other issues encountered.

Parent/carer and child recruitment

In total, 1391 CLASS trial Information Packs were sent out to parents/carers at 20 schools. Only 35 parent/carer consent forms were returned to the York Trials Unit, resulting in an extremely low recruitment rate of 2.5%.

A total of 27 forms withdrawing children from the intervention were returned, in most cases (n = 23) reasons were not provided. Where reasons were provided (n = 4) the reason given was that the child was not exposed to smoke in the home (we are not smokers and my child knows smoking kills, no one in extended family smokes, don't live in a smoky home, not exposed to smoke neither parents or relatives smoke).

This extremely low recruitment rate was disappointing. Although we did not run the focus groups with parents/carers, we did conduct a focus group with teachers from participating schools exploring the views towards recruitment of parents/carers and children and consent. The focus group highlighted that teachers were concerned that parents/carers would not return consent forms for a variety of reasons. They noted it was often difficult and time consuming to get signed forms back for other school activities too. They also noted that they felt the topic could put some parents off and could be seen as unwelcome involvement from school.

Based on the focus group with teachers, other informal feedback from schools and our own reflections, the following are our suggested reasons why recruitment was so low:

- The information packs contained a lot of documents; on reflection there was too much information which some parents might have found too complicated. Given a low withdrawal rate (from the intervention), it is possible that the vast majority of parents/carers simply would not have read the information in the trial pack.
- Parents/carers may have been apprehensive about research procedures, possibly the saliva sampling.
- Parents/carers may have been apprehensive about the topic of research, perhaps feeling that their individual choices were being challenged.
- Parent/carer reading and language difficulties may be a problem in deprived and diverse communities and although we provided an information DVD in English and Urdu, potential participants may still have had difficulty completing written information.
- An opt in approach to parent consent may not have been the typical approach adopted by schools for gaining agreement from parents for unusual school activities, with many schools adopting an opt out approach for activities such as school trips.
- There was no incentive for parents/carers to take part.

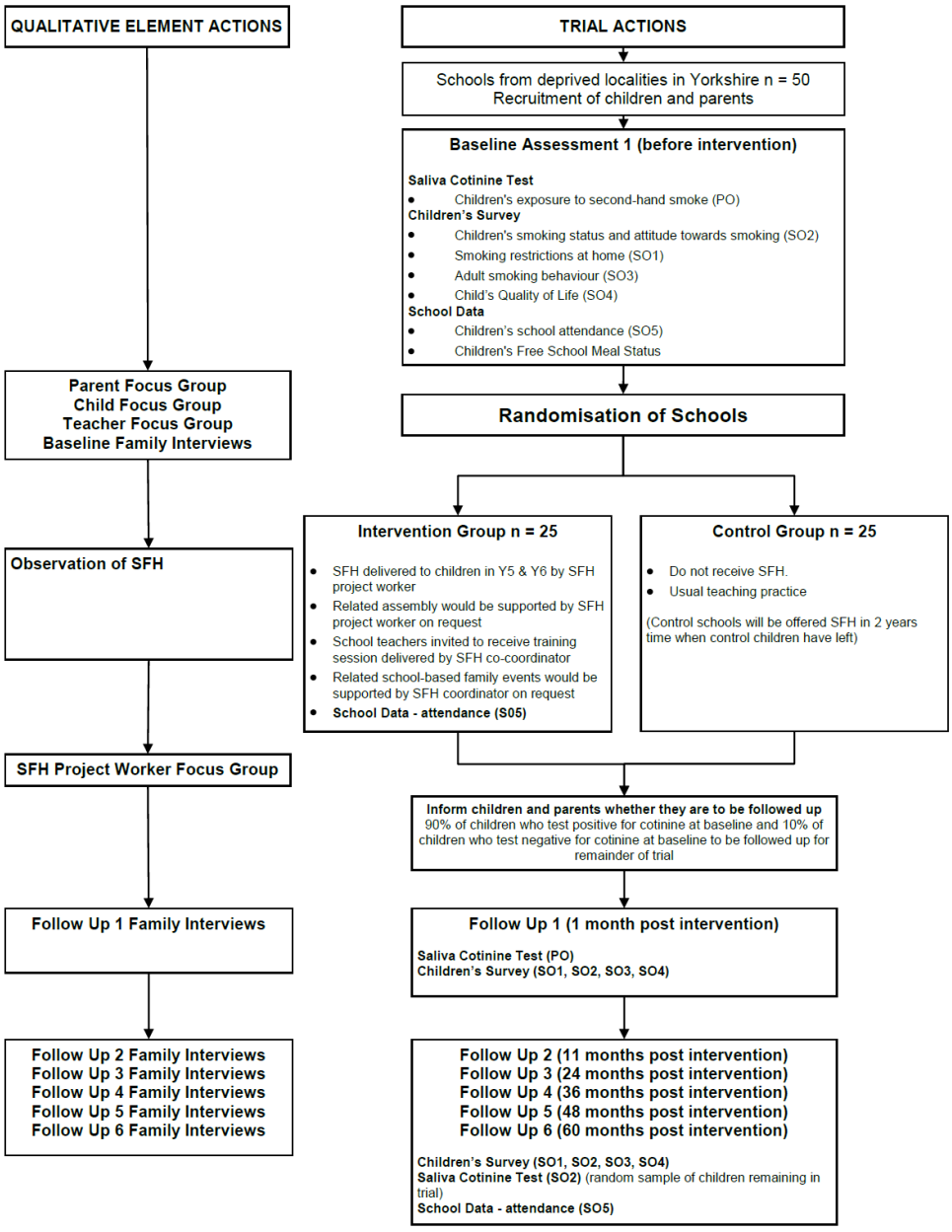
Revised design

Following low recruitment of parents/carers and children two options were considered: removal of the parental element of the study only; and, removal of parental element and opt-out consent for

child participation. It was decided by the trial team, Independent Study Steering Committee (ISSC) and funders to go with the latter approach. The following substantial changes were proposed to the design of the study (see Figure 2).

1. All elements of the trial which required parent involvement were removed. Parents/carers would therefore no longer be asked to complete Household Surveys or Health Service Use Surveys. This meant we would no longer have been able to collect data on family health service use and household smoking behaviours from adults. Additional questions were added to the Child Survey to collect adult smoking behaviour and household characteristics (in less detail than originally planned).
2. An opt out approach to parent consent was proposed rather than an opt in approach. Parents were to be sent simple information about the trial in written and DVD form and given the opportunity to withdraw their child. A second letter was to be sent to parents just before data collection to remind them of the study and give them a second opportunity to withdraw their child. As previously, children were to be provided with an age appropriate information sheet and asked to watch an information DVD. Children would have only participated if they verbally expressed a willingness to do so.
3. The baseline and follow up time points were altered taking into account that data from parents was no longer to be collected. The first follow up was therefore to be conducted at one month post intervention rather than 3 months post intervention.
4. The timing of qualitative elements of the study was brought in line with the revised trial design.

Figure 2: Revised CLASS Trial Design



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Opt out approach to parent/carer consent for child participation

Ethical approval for an opt out approach to parent/carer consent for child participation was sought and obtained. Subsequently, the data protection officer at the University of York advised that the opt-out consent procedure may be in breach of the Data Protection Act (1998), since schools would not have explicit parental permission to pass sensitive personal data about children to the research team. The PI raised this concern to the sponsor representative at the University of Leeds and to the NIHR PHR and all trial activities were suspended on 08.11.11.

The issue was discussed with the sponsor representative and independent SSC and representatives from NIHR PHR in a teleconference held on 28.11.11. It was decided at this meeting that an independent legal opinion should be sought. The resulting legal opinion concluded that the trial would be collecting and using sensitive personal data, and the use of such data from children of this age strongly indicates the need for explicit consent from a parent/guardian save in exceptional and justified cases. Although there is a condition for processing sensitive personal data for medical purposes, it was felt that the trial did not meet the relevant requirements for this condition.
The advice received noted that disclosures by each school from its existing records to the University would be a data controller to data controller disclosure and must be made by the school in accordance with the Data Protection Act.

The Legal Firm advised that the University should not rely solely on the implied consent of minors to justify the collection of their personal data and in particular their sensitive personal data. They therefore recommended that explicit and fully informed written consent should be obtained from the parents of the children and that the children should also given the ability to refuse to participate in the collection of their data and of saliva samples on the day of the research study.

Since an opt-out approach to parental consent in this case was not deemed legally acceptable in relation to the Data protection Act (1998) and an opt-in approach to consent (fully informed written consent) had not resulted in a sufficient recruitment rate to make the trial viable, the decision was therefore taken to formally close down the CLASS trial. (Close down communication is provided in Appendix 10).

Other issues encountered

Here, we will discuss the other key challenges encountered during the conduct of this study.

i. School recruitment

Seeking agreement from schools to take part in the trial was initially challenging. We were unable to engage with a large proportion of schools. There are a number of possible reasons for this recruitment challenge.

Firstly, because smoking prevalence is higher in deprived communities, we were approaching schools in the most deprived areas of the region. Many of the schools had challenging circumstances, and were reluctant to take on the added responsibility of being involved in a research project, even when extra support was offered.

Secondly, the contact routes to schools were not easy to navigate. Letters and emails to schools resulted in very little response. It may be that these were not passed on from the secretarial staff

on to a member of staff who would have been interested in the research. Following up schools by telephone did not improve this as the gate keeper (head teacher's secretary in most cases) was cautious not to disturb busy teaching staff, especially when the call came from an organisation or individual unknown to the school. Despite leaving many messages, return phone calls from schools were minimal. Engagement with schools improved when individuals (healthy school team members) known to the school, were able to make contact and use their existing relationships with specific members of staff to encourage the school to consider participating.

In addition, the conference date was quite short notice and schools often needed up to a term's advance notice to organise classroom cover. We always gave schools the option of a researcher visiting them but even this was found to be difficult for teachers who had only few hours outside of the classroom environment available.

Also initially we were only offering £50 to schools to cover their participation costs. We were subsequently able to increase this to £100 with some additional funding. However, this remained a token amount, and some schools might have felt it to be insufficient.

ii. Sample size

Our sample size estimations were based on an average recruitment pool of 180 children in each school, and a resulting cluster size of 40 children. However in reality, based on the schools which agreed to take part in the CLASS trial, the average number of children was likely to be around 73 and this varied widely from school to school depending on school size. Also considering the recruitment challenges, even with a more effective recruitment strategy our predicted recruitment rate of 55% (of which 40% were expected to be exposed to SHS) would have been unlikely to succeed. We would therefore have needed to plan for more than 50 schools. If for example a cluster size of 25 children had been achieved, around 60 schools would have been needed to detect a difference of 0.28 at 90% power.

iii. Approvals

This study required ethical approval from a NHS Research Ethics Committee NHS REC) because of the collection of saliva samples from participants. Ethical approval was sought and gained. NHS Research and Development (R&D) approval was sought from Wakefield district as the individual training SFH project workers and delivering the intervention was employed by Wakefield district. However West Yorkshire Comprehensive Local Research Network (WYCLRN) found it difficult to confirm whether R&D approval would be needed from other areas where schools were being approached. They sought national advice and spoke to local R&D departments; however, there appeared to be no consensus. After a long delay, we sought confirmation from the Study Steering Committee that R&D approval from other areas would not be required and we informed WYCLRN that we would be proceeding on this basis (22.03.11).

It took a considerable amount of time to acquire NHS REC approval and R&D approval for Amendments 2.1, 2.2, 2.3, 2.4, and 2.6 (Detailed in Appendix 4), which were first submitted to the NHS REC on 22 March 2011. Confirmation of NHS REC approval was received on 13th May 2011 and confirmation of R&D approval was received on 10th June 2011. We encountered time delays at each stage: validation, receiving NHS REC approval letter and receiving R&D approval letters (specific dates are documented in Appendix 4). These problems delayed approach to further schools in Barnsley, Hull and Sheffield whilst we waited for a new invitation letter to be approved. It also

delayed being able to prepare the documentation and Information DVD for the Parent/Carer Information Packs and the paperwork and Information DVD for children, resulting in a delay to approaching parents/carers and children.

On two occasions we submitted to the NHS REC changes to documentation, which we felt were non-substantial amendments. On both occasions, we were advised that a substantial amendment should be submitted. Because of the time delay that NHS REC and R&D approval would have entailed we had to make a decision to use paperwork that had been previously approved. We therefore felt we had been restricted from making sensible improvements and clarifications to paperwork, changes which we felt did not have ethical implications.

iv. Service support cost

Despite this study being registered on the NIHR as a portfolio study we were unable to acquire Service Support Costs because the study was conducted in a non-NHS setting. This meant we were unable to access any additional resources to help with recruitment.

Project achievements

Despite the premature closing down of the CLASS trial, there were a number of project achievements which are now presented as follows:

i. Recruitment process for schools

Subsequent to the initial difficulties in recruiting primary schools, a successful recruitment strategy emerged resulting in 47 schools agreeing to participate in the trial. Before the break for summer holidays in July 2011, we received consent forms or verbal agreement to take part from 34 schools. We made provision for a staggered start to the trial, to allow recruitment of schools to continue after the summer holidays.

School recruitment continued in September 2011 whilst the new approach to parent/carer consent was reviewed by the NHS REC and NHS R&D. Subsequently, we gained written or verbal agreement to take part in the CLASS trial from another 13 schools, resulting in a total of 47 schools recruited at that time. During this period 2 schools withdrew, one school didn't feel they had a large proportion of children exposed to second hand smoke, and the other felt they had a parent group who it would be difficult to engage. Table 1 shows the number of schools approached and recruited in each local authority area.

Table 1: School Recruitment

LA Area	Number of eligible schools	Number of schools who agreed to take part.	% of schools who agreed to take part
Leeds	62	9	14.5
Calderdale	14	3	21.4
Kirklees	34	3	8.8
Bradford	73	16	21.9
Wakefield	18	8	44.4
Barnsley	25	3	12
Hull	39	4	10.2
Sheffield	39	1	2.6
Total	**304**	**47**	**16.5**

When ethical approval had been received to implement an opt out approach to parent consent, schools which had previously agreed to take part in the CLASS trial were contacted by letter and the new approach was explained to them. They were asked to sign and return a new version of the school consent form to indicate their willingness to implement the new opt-out approach. Before the study was suspended, 20 schools had returned the new consent form, and we anticipate this would have increased had we followed schools up. Five schools withdrew after being informed of the new approach for a variety of reasons (don't want to take part anymore, don't have the staff capacity, can't engage parents, school closing, too busy), but none specifically mentioned the opt-out approach as a reason.

Summary
304 Primary schools were invited to take part
58 Primary schools refused to take part
47 schools signed the original consent form or give verbal agreement to take part
7 schools withdrew (2 before and 5 after being informed of new approach to parent consent)
20 schools signed new consent from

ii. Refinement of the 'Smoke Free Homes' intervention

A literature review and a series of formative workshops helped in defining a logic model and refining the 'Smoke Free Homes' intervention respectively.

A literature review was conducted from February to May 2011, which included identifying the techniques found effective in behaviour change interventions and mapping these across the behavioural determinants of implementing smoking restrictions at home. Literature describing examples of intergenerational influence was also reviewed and it was found that children have successfully influenced their parents to change their behaviour particularly as a result of receiving environmental education (Evans et al 1996). Further literature on 'pester power', primarily from the sphere of marketing, was examined and it was found that children have significant influence over their parents' purchasing decisions (McDermott et al 2006). Theoretical development work supplemented this activity, including the production of logic models describing the anticipated change processes that the intervention aims to bring about.

Figure 3: Intervention stage 1: Teacher to child - Empowering children to become change agents

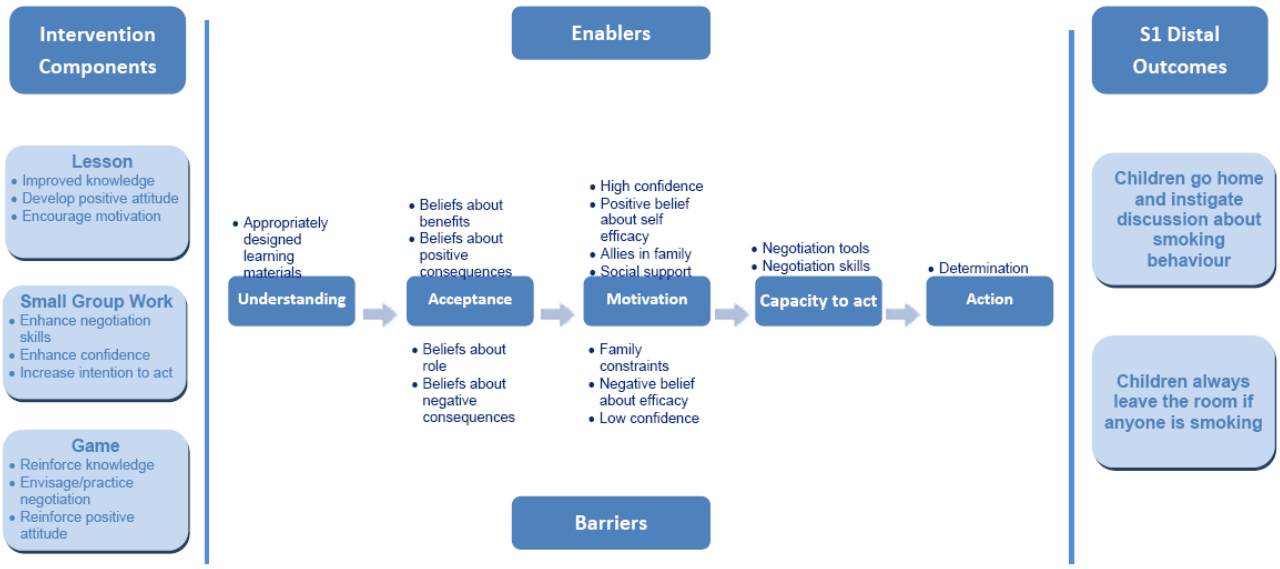
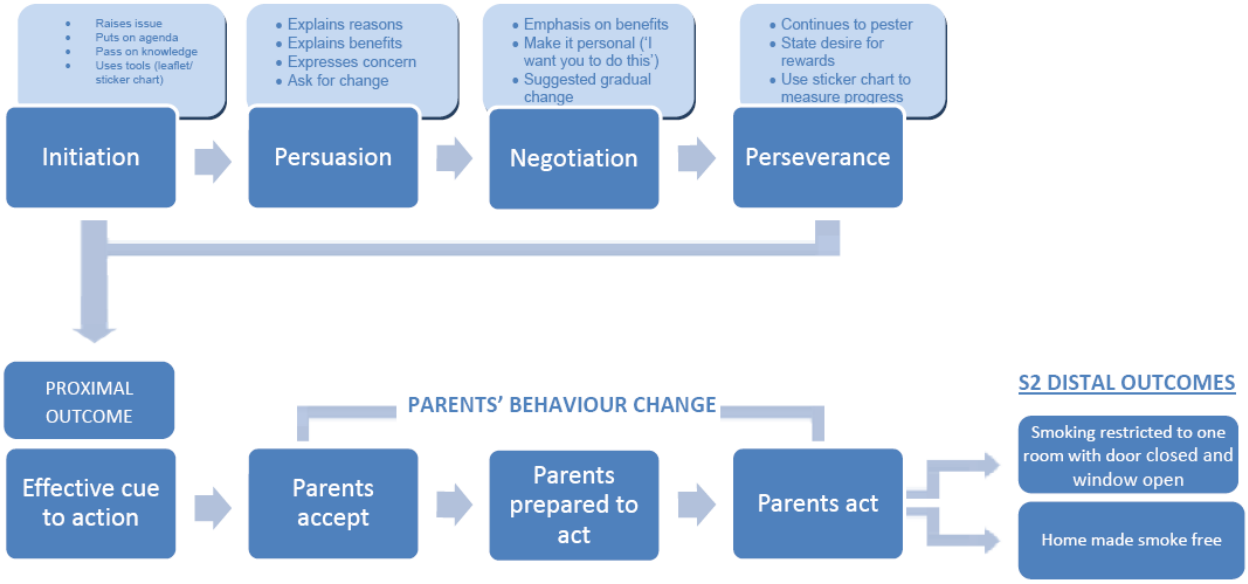


Figure 4: Intervention stage 2: Child to parent – Having a go at being a change agent



A routine delivery of the intervention was observed in February 2011. This included filming the SFH lessons and taking comprehensive field notes. The film was used as a simulated recall device in an interview with a SFH project worker. It was noted that there were four separate small group activities forming part of the lesson, meaning that children were receiving different inputs. It was also noted that the lesson focused mostly on delivering facts about second-hand smoke with little emphasis on helping children to develop skills such as negotiation and persuasion thus weighting the intervention towards a limited number of behaviour change techniques.

In light of these observations, it was felt that the intervention would benefit from being refined, particularly so as to ensure consistency and fidelity. A working group was formed which held a

series of meetings/workshops, and led to improvements to specific aspects of the intervention. It also aided the development of observation protocols, which were to be used to gauge implementation fidelity.

The intervention tool has now been produced as a CD, including notes for delivery, and will be made available to schools and public health departments.

iii. Development of enquiry tools

We developed three enquiry tools (Appendix 8) including a Household Survey, a Household Health Service Use Survey and Child Survey. The surveys were designed by the research team, which included the statistician, health economist, intervention practitioner and policy makers and have resulted in comprehensive tools which could be used in similar research in future: indeed we have received requests for use of these tools.

iv. Collaboration with partners

This study allowed us to establish a real partnership between academics, policy makers and practitioners. The team consisted of multidisciplinary researchers, NHS colleagues including public health practitioners and commissioners, policymakers and individuals with expertise of developing and delivering the SFH intervention. In addition, the independent Study Steering Committee included experts in the academic field and representatives from participating schools. This strong partnership allowed us to bring a wide variety of expertise to the study and created a strong collaboration resulting in the successful submission of two other research proposals detailed below.

v. Research in other settings

Although this trial was unsuccessful in recruiting parents and children in a UK context, the strong collaboration formed between partners, the considerable development of the Smoke Free Homes intervention, experience gained though recruiting primary schools, development of the enquiry tools, and the cluster design used in CLASS trial has led to the development and evaluation of a number of similar SFH interventions for use in other settings and population groups both in the UK and other countries.

An intervention similar to the one proposed in CLASS trial is currently being evaluated in a randomised controlled trial in primary schools in Bangladesh due for completion in March 2013.
A feasibility study of SFH in Mosques funded by NHS Leeds led to the development of 'Smoke Free Homes: A toolkit for Muslim religious leaders' to be used by faith leaders for the benefit of Bangladeshi and Pakistani origin Muslim communities and has lead to a pilot trial (MCLASS: Muslim Communities Learning About Second-hand Smoke) funded by the MRC (Ref: MR/J000248/1) due for completion in 2014.
The SFH intervention has also been developed for use in antenatal and post-natal care and is currently being evaluated as part of MLASS (Mothers Learning About Second-hand Smoke) funded by Cancer Research UK (Ref: C40275/A13007) and due for completion in March 2015.

Another similar intervention is being developed and will be evaluated in a randomised controlled trial in Pakistan. This intervention will be delivered by health professionals to those TB patients who are exposed to second-hand smoke at homes and likely to encounter poor outcomes as a result.

4. Discussion and Conclusions

As we have described we faced a number of difficulties in conducting this research. Recruitment of schools and families was challenging. We implemented a number of successful strategies which increased school recruitment, perhaps most importantly using the existing relationship of Healthy Schools Teams. It should be noted however that the Healthy Schools teams were undergoing change throughout the period and many of them now no longer exist. Should comparable research be conducted in the future similar existing links into schools would need to be identified.

Recruitment of families was extremely challenging and although we proposed and tried to implement a number of strategies, within the confines of this research proposal we were unsuccessful in recruitment of families and this eventually led to the trial being closed down. The results of this trial are unable to establish definitive evidence as to why recruitment was so challenging, however in the interests of future research we summarise our reflections below.

Recruitment of participants to research is widely accepted to be challenging. In addition this trial involved the recruitment of children and their families from deprived communities in which there was a high proportion of minority ethnic groups. Previous research has alluded to and commented on the added challenges of recruitment in these groups (Ford et al 2008).

We would suggest that our approach of postal recruitment was not an effective strategy in this population for this topic of research. This could be due to language and reading difficulties. However we attempted to address this problem by providing information in other languages and also by creating an information DVD in English and Urdu which was sent out to every eligible participant.

The SFH intervention is designed to take place in schools, therefore recruitment of families necessarily needs to be conducted through school channels and indeed one would expect a family's existing relationship with a school to aid recruitment, as might be the case for patients when research is endorsed by their GP, an individual they trust. However many of the schools which agreed to take part in the CLASS trial reported that they had difficulty in engaging parents/carers with normal school activities such as assemblies and school trips. It is also possible that that this research may have been viewed by some families as not something which their child's school should be concerned with, in the sense they may not have considered it to be directly related to their child's education.

A further consideration in this trial is that there was no incentive for parents/carers to take part. Unlike in some educational trials, in which the parent/carer maybe very keen for their child to receive the novel educational intervention, in this case the intervention is unlikely to lead to such a response and indeed it is possible that it may have had the opposite effect on some families, therefore acting as a disincentive to participate. The teachers who took part in the focus group highlighted this issue, noting that they expected it to be very difficult to engage smoking parents/carers, who may feel the school was interfering with their personal choices at home. Since the intervention was being delivered as part of a research project parents/carers were given the opportunity to withdraw their child from the SFH activities. This situation would be unlikely to occur outside of the research environment, since the SFH activities meet national curriculum guidelines, most schools would be unlikely to offer this option to parents/carers as it would be seen as part of

normal school activities. Almost the same number of forms withdrawing children from the SFH activities were returned as consent forms, which may suggest that the intervention itself acted as a disincentive to take part, although the reason for this is unclear with only 4/27 stating a reason and in these cases the reason being that they already had smoking restriction in place in their homes.

There was also no incentive for children to participate, since all children were to receive the intervention even if they did not take part in the research elements (unless they were specifically withdrawn from the intervention by their parents/carers.

We would suggest that face to face recruitment is likely to be very important in this population not only to overcome language and reading barriers but also to develop trust between participants and researchers.

Other research studies exploring children's exposure to SHS through school-based surveys and salivary cotinine measurement, have adopted an opt out approach to parental consent (Holliday et al 2009). However within the specific circumstances of this trial the legal interpretation of the DPA did not allow implementation of an opt out approach. This makes it very difficult to carry out research on school children where parents' engagement with schools is minimal and face to face recruitment is therefore challenging. The consequence of this is that the ability to develop evidence as to effective interventions to protect children from second-hand smoke is significantly impeded.

However individuals within local authorities, those with responsibility for public health and school leaders remain interested in using the SFH resources in schools despite a lack of robust evidence to support its effectiveness and cost effectiveness.

Lessons learnt

i. School recruitment

Lessons learnt in school recruitment particularly from deprived areas:

- Seek involvement and support from local partners (in this case Healthy Schools Teams) known to schools from the outset, use existing relationships and events to gain access to decision makers within schools.

- Head teachers and school staff often need to seek the permission of the school governing body or senior management team before they can agree to take part in research; this can take time. The recruitment procedure should include a sufficient period for such decisions to be taken.

- Offer schools suitable funding for taking part in the research, which reflects the effort and extra tasks the school will be expected to conduct as part of the research.

- Identify at least one member of staff within the school who would be appropriately placed to bring the research to the attention of other decision makers within the school. Send invitation letters to named individual as well as to the head teacher.

- Plan for making individual visits to schools for recruitment and on a regular basis throughout the research.

- Give schools at least a term's advanced notice for information events/meetings or training days that involve school staff being out of the classroom environment. Offer appropriate expenses to compensate for classroom cover and travel to events/meetings.

ii. Parent/carer and child recruitment – opt in

This study demonstrated that it is extremely difficult to obtain written informed consent from this population using a postal recruitment approach, even with significant support from school staff on the ground. This study was not able to evaluate what recruitment methods may be effective, but we would suggest evaluating face to face recruitment methods and incentives. Information should also be provided in as simple a format as possible. Finding the balance between simple information and the need to convey information so as to meet ethical requirements is difficult and needs further exploration.

iii. Parent/carer and child recruitment – opt out

Implementing an opt out approach to parental consent for child participation in similar school based trials must be considered with caution. Although in terms of research ethics it may be deemed acceptable and justifiable, on data protection grounds its acceptability and legality will depend upon a number of factors including but not limited to: age of children, nature of data to be collected and if it can be collected in a completely anonymous form. We would advise seeking an independent legal opinion taking into account the specific details surrounding the research in question.

iv. Pilot trial

This study demonstrates the importance of pilot trials, in this case important information regarding effective recruitment strategies could have been ascertained before implementation of a full scale trial.

Recommendations for future research

- Consider and pilot possible recruitment strategies with this population, these may include face to face contact, incentives and simplified documentation.
- Consider evaluation strategies that do not involve data collection from parents.
- Consider evaluation strategies which allow data to be collected in a fully annoymised form.

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Appendix Contents

The appendices to this report can be found in a separate document 'CLASS Trial Final Report Appendices'

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