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The CLASS Trial

Children Learning About Second-hand Smoke

Evaluation of a school-based intervention (Smoke Free Homes) to protect children from second-hand smoke

Trial Protocol

The Public Health Research programme is managed by NETSCC - PHR as part of the NIHR Evaluation, Trials and Studies Coordinating Centre at the University of Southampton.

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Summary

Since the introduction of Smoke Free legislation, homes and cars are now the main locations where non-smokers are exposed to second-hand smoke. Children born in deprived households are at particular risk from second-hand smoke. Dangers of second-hand smoke in homes and cars, its potential influence on smoking behaviour of young people and its contribution to health inequalities is widely acknowledged. However, there is a lack of evidence for cost-effective solutions to restrict smoking in homes and cars.

We will conduct a cluster randomised controlled trial to evaluate the effectiveness of a school-based intervention known as 'Smoke Free Homes' in reducing children's exposure to second hand smoke reducing uptake of smoking among young people (11-15 years) and changing the smoking behaviours of adults in the home.. The trial will include qualitative work and an economic evaluation.

The intervention is designed to encourage families to implement smoking restrictions in their homes and therefore protect children and non-smokers from second-hand smoke.

Parents and children will be recruited from approximately 50 consenting primary schools from deprived communities in Yorkshire. Smoke Free Homes will be implemented in half of these schools on a random basis. The remaining schools will form the control group. We will assess children's exposure to second-hand smoke before and after the intervention at regular intervals using surveys and testing cotinine from children's saliva samples. We will follow-up children (aged 9 to 11 years at the time of recruitment) for a period of 63 months post intervention to assess if there is any difference in outcomes between children in the intervention group and control group. We will use qualitative methods such as interviews to understand related contextual factors.

Study Identifiers

Full title of trial: The CLASS Trial (Children Learning About Second-hand Smoke): Evaluation of a school-based intervention (Smoke Free Homes) to protect children from second-hand smoke

Acronym: CLASS – **C**hildren **L**earning **A**bout **S**econd-hand **S**moke

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Background

Smoking is the leading preventable cause of premature deaths in the UK. There are about 9 million regular smokers in England. Smoking causes 87,000 deaths per year and costs £1.5 billion to the NHS (1).

Smoking and inequalities
Smoking is associated with the lower end of the socio-economic gradient. In fact, it accounts for half of the difference in the risk of premature deaths among males between different social classes(2). Occupational social class, employment status and living in deprived areas are some of the key determinants of adult smoking in the UK. Poor people are also less likely to be aware of the risks of smoking and tobacco smoke. Smoking prevention and cessation programmes are more readily taken up by the affluent members of society compared to the rest which widens the health gap further(3).

Second-hand smoking (SHS)
Second-hand smoke (SHS) is a serious health hazard to non-smokers, especially children. Tobacco smoke contains 4000 toxic chemicals and does not have a safe exposure level. Living with a smoking adult is the key determinant 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(4). According to the Global Youth Tobacco Survey, 4 out of 10 young people (13-15 years) are exposed to SHS at home(5).

Determinants of exposure to SHS
Children living in poverty are more likely to be exposed to SHS compared to those from affluent families(6). Approximately, 49% of children from families with a low–income live with a smoker compared with 21% of children from affluent families, according to a US-based survey(6). In addition, poorer children are more likely to live with more than one smoker. We found that children living in poor households are more likely to have smoker(s) and less likely to have smoking restrictions in the house(7).

Health and economic risk of SHS

SHS is estimated to be responsible for 10,700 deaths among adults per year in the UK(8). In adults, SHS is associated with cardiovascular diseases, chronic respiratory diseases, nasal and lung cancer(9). Asthma and wheezing are more prevalent in children exposed to SHS compared to those in smoke free homes(10). The risk of other lower respiratory illnesses, chronic middle ear disease (Odds Ratio [OR] 1.2 - 1.6) and sudden infant death syndrome (OR 2.0) is also high among such children(11). There is a strong relationship between parental smoking and childhood admissions to hospitals(11). 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(12) and problem behaviours in later life(13). Children living in smoking households are at risk of poorer general and functional health(14). Exposure to parental smoking is also an independent determinant of failures at GCSE and A-level assessments(15). In addition, SHS is also associated with dental caries and metabolic syndrome.

Long term effects of SHS

Evidence linking exposure to SHS in childhood to increased smoking uptake in teenage years is inconclusive. However, an association has been suggested between smoking among teenagers and living with adult smokers. One of the authors of this proposal found that 25% of 11-15 year olds who considered themselves as regular smokers also reported that there were three or more smokers in their household compared to: 10% of those who lived with just one smoker; and 4% who had no smokers in the house. Moreover, only 46% of 11-15 year old current smokers smoked openly if they lived in a smoke free household compared with 76% who lived in a house with smoker(16).

Protection from SHS

Incidentally, only 15% of smokers in the UK live in a smoke free home(17). Presence of smoking restrictions in smoking households reduces children's exposure to SHS(18). Presence of a child and/or non-smoking adult and awareness about the harmful effects of SHS are associated with smoking restrictions(17). However, despite the vast majority of parents (86%) being aware of the harmful effects of SHS, only a fifth of them in smoking households are able to implement smoking restrictions(19).

Benefits of smoke free homes (see Appendix 1)

Smoking restrictions primarily protect non-smokers from SHS. However, it has been suggested that smokers who implement smoking restrictions at home are more willing to quit smoking(17). Such smokers are twice as likely to attempt to quit and half as likely to relapse after a successful quit attempt compared to smokers living without restrictions(20). To our knowledge, there is no evidence on the effectiveness of interventions that promote smoking restrictions at home in smoking cessation.

Smoking restrictions at home are 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, the two important determinants for not starting smoking(21). Young people between 13 and 15 years of age are only half as likely to smoke if they are not exposed to SHS at home compared to those who are(5). Similarly, adolescents living in households with smoking restrictions are less likely to smoke compared to those living in houses with no smoking restrictions(22). This influence is more profound where both parents are non-smokers. Children living with smoking restrictions at home are shown to be at an earlier stage of a smoking uptake scale compared to children living in houses with no smoking restrictions(23). It is possible that smoking restrictions protect children from peer pressure to experiment with smoking. Another study found that children from homes with smoking restrictions are less likely to start smoking between 12 and 17 years of age, when they have smoking parents (1.56; 95% CI 1.15, 2.13)

as well as non-smoking parents (OR = 1.75; 95% CI 1.29, 2.37)(24). To our knowledge, there is no evidence available for this based on experimental studies.

Existing research

Policy measures and their limitations

The evidence on the effectiveness and cost-effectiveness of specific measures to implement smoking restrictions at home is scanty. Comprehensive tobacco control programmes are likely to positively influence people to have smoking restrictions at home(25). According to the social diffusion model, smoking ban in public places encourages people to implement smoking restrictions at home(17). The exposure of non-smokers to SHS living in non-smoking households dropped significantly in Scotland since the ban on smoking in public places. However, non-smokers living in smoking households continue to have high levels of exposure to SHS(26). Smoking bans in public places have minimal effects on smoking restrictions at home in Spain(27). On the other hand New Zealand and Ireland reported a significant influence of smoking bans on exposure to SHS in houses(28).

Attitude to smoking restrictions at home

Generally, families go through various processes in adopting smoking restrictions at home(29). 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 towards cigarette smoke and their direct complaint to the smoking adults triggered household bans. One of the authors of this proposal identified key issues and challenges in persuading families to implement smoking restrictions at home(30). These include; (a) poor knowledge about the hazards of SHS for children, (b) realism in having a gradual or stepped approach towards a smoke free home, (c) sensitivities around the potential conflict between a smoke free programme, and the 'privacy' of homes, and (d) potential for the voice of children and their health protection to be central.

Interventions that support smoking restrictions at home

The evidence for the effectiveness of interventions to provide a smoke free environment at home is scarce. 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(31). A recent Cochrane review found 36 controlled studies aimed at reducing exposure to SHS in the home(32). 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 or its cessation or both. 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.

Rationale for current study

It has long been argued that protecting children from SHS in homes should be a cornerstone to any tobacco control policy and programme(33). Moreover, there is recognition of the lack of evidence on the effectiveness of existing interventions and an acknowledgment of it being a research priority. Smoke Free Homes (SFH) is an initiative developed and launched by West Yorkshire Smoking & Health (WYSH) in February 2003 after a successful bid to the Department of Health. The alliance was

already involved in several award-winning initiatives to protect non-smokers from SHS including: (a) the Roy Castle Good Air Award for smoke free places; (b) the Yorkshire Guide to Smoke-Free Air; (c) smoke-free zones table cards and stickers; and (d) "There's a baby in the house", smoke-free zones resources. This SFH initiative was aimed at increasing awareness of the health hazards of SHS and self-efficacy in being able to restrict smoking in homes. The initiative was an adaptation of "Smoke-Free Home Pledge" launched in America in 2001 by the US Environmental Protection Agency(34).

Smoke Free Homes – Theoretical framework
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 posted 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.

Smoke Free Homes has been adapted 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(35). 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(36). We carried out a feasibility study 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(37). We found that smoking in the presence of children had 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 need to evaluate interventions aimed at promoting smoke free homes is long established(32). Such evidence can help in developing an effective policy and programme on SHS. SFH has a firm theoretical basis, sound feasibility, broad acceptability, and the potential to improve children's health. However, we do not have the evidence of its cost-effectiveness based on objective outcome measures to support wide adoption. Therefore, NHS Leeds, following an exploratory study, in collaboration with West Yorkshire Smoking and Health (WYSH) Alliance (where SFH took its origin) is proposing to carry out a cluster randomised controlled trial of SFH using cotinine testing as an objective outcome measure.

Justification for long follow-up
According to the General Household Survey 2007, 38% of regular adult smokers started smoking before the age of 15 years (38). The smoking prevalence among those aged 11-15 years increases up to the age of 15 according to the 2008 Smoking, Drinking and Drugs survey carried out by the National Centre for Social Research (39). A long follow up period will allow us to study the influence of a smoke free environment at home on the smoking initiation rates in teenage years. There is a dearth of longitudinal and experimental studies in this area. It would be a missed opportunity not to follow up these children in their teenage years and to attempt to address this key knowledge gap. In addition, interventions such as SFH can be seen as a long-term investment in public health, therefore, follow-up assessment is important to understand the sustainability of outcomes and to support on-going informed decision-making.

Research Aims and Objectives

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) changing smoking behaviour of adults in the house (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 Questions

Q1. Does SFH reduce children's exposure to SHS?

Q1A. Is SFH more effective in reducing the level of exposure to SHS at home compared to usual practice?

Q1B. Is SFH more effective in encouraging families to impose smoking restrictions at home compared to usual practice?

Q1C. To what extent are smoking restrictions at home sustained in the medium term?

Q1D. What are the processes and contextual factors associated with any variations in outcomes?

Q1E. To what extent has the SFH been implemented successfully to enable SFH messages to be delivered to families through children in the intervention arm?

Q1F: To what extent do contextual factors (family dynamics and neighbourhood features) influence the adoption and maintenance of SFH and resulting change of smoking behaviours?

Q1G: Is SFH cost-effective in reducing the level of exposure to SHS at home compared to usual practice?

Q2. Does SFH reduce the uptake of smoking among young people (11-15 years)?

Q2A. Are children, who were introduced to SFH at the age of 9-11 years, less likely to start smoking during teenage years compared to those who were not introduced to SFH?

Q2B. Are children, who were introduced to SFH at the age of 9-11 years, less likely to have the intention to start or experiment smoking during teenage years, compared to those who were not introduced to SFH?

Q2C. Among those children who were introduced to SFH, is there a difference in the above outcomes between children whose families imposed smoking restrictions at home compared to those whose families did not?

Q2D.What are the family and social determinants that influence smoking in teenage years in both SFH and non-SFH groups?

Q2E.What other contextual factors influence the uptake of smoking in teenage years in both SFH and non-SFH groups?

Q3. Does SFH change smoking behaviour of adults in the house?

Q3A. Are adult smokers, whose children were introduced to SFH, likely to change their smoking behaviour in the house compared to those who were not?

Research design

A cluster randomised controlled trial (CRCT) with an economic and qualitative component.

Conceptual framework

SFH, a multi-faceted public health scheme, is a 'complex' intervention. It consists of several inter-connected elements which are all important for its functioning(38). Evaluation is difficult as complex interventions are not easy to define, develop, document, standardise and reproduce(40). The Medical Research Council (MRC) has a framework to evaluate such interventions. By carrying out a feasibility study of SFH, we have completed the first two phases within this framework. This protocol describes the third phase. We propose a mix of research methods to achieve the study objectives (Table 1).

Table 1: A conceptual framework

	Research objectives	Research questions	Methods
1	Effect Evaluation	1A, 2A, 3A	Cluster RCT
2	Intermediate outcomes Evaluation	1B, 1C, 2B, 2C	Indicators built within the Cluster RCT
3	Contextual Evaluation	1D, 1E, 1F, 2D, 2E	A combination of qualitative methods
4	Economic Evaluation	1G	Cost-effectiveness analysis built within the RCT

Cluster Randomised Controlled Trial (CRCT)

A cluster randomised controlled trial (CRCT) has been designed in order to meet Objectives 1 & 2:

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)

The randomised controlled trial (RCT) is the best study design for investigating the effectiveness of interventions since it controls for potential confounders (e.g. seasonal or temporal changes). Due to the possibility of contamination and for practical and logistical reasons, children cannot be randomised to the intervention and control arms individually. A simple RCT is therefore not suitable. A CRCT (the CLASS Trial) has consequently been designed in which schools (clusters of children) will be randomised to the intervention and control groups (see Appendix 3).

Study population

Study clusters
We aim to recruit at least 50 primary schools into the CLASS trial. We will include schools from neighbourhoods with high deprivation, from the lowest 20% super output areas ascertained from the 2007 Total Deprivation data.

Primary participants
All children in years 5 and 6 in the 2011/2012 school academic year will be eligible for the CLASS trial. Informed consent will be sought from parents/carers on an opt-out basis. After baseline data has been collected only a sample of children will be followed up for the remainder of the trial. This sample will include 90% of children who test positive for cotinine at baseline and 10% of children who test negative for cotinine at baseline. We aim to recruit at least 40 children with a positive cotinine test from each school.

Secondary participants
Secondary participants will be all the parents /carers of participating children. *(For the remainder of this document where the word 'Parent' is used this refers to the parent or carer with legal responsibility for the participating child.)*

Recruitment and Baseline Data Collection

Recruitment of Primary Schools
Identified primary schools will be sent an invitation letter including a summary of the CLASS trial to find out more about taking part in the trial. We will provide full details about the study and meet head teachers or other school staff when possible. We will explain random allocation, parent and child recruitment and consent procedures, and assure them that schools randomly allocated to the control arm will also receive the SFH intervention in approximately 24 months, if shown to be effective. We will use healthy school leads, other local education authority and public health contacts to help us make contact with eligible schools and to assist with the recruitment of schools. Interested primary schools will be provided with a detailed information sheet. In our experience teachers are usually well disposed to let their schools take part in research, particularly where an

intervention is subsequently offered to control schools as well. Primary school head teachers will be asked to sign a written consent form for their school to take part in the CLASS trial. This will act as an agreement by the head teachers to support SFH in their schools. This should also help in sustaining support if specific school staff leave the school.

Baseline Data from Primary Schools
Primary schools will be asked to provide the names of the secondary schools where most of their children move on to and the proportion of children in their school who receive Free School Meals (FSM), and the proportion of eligible children who receive Free School Meals

Recruitment of Secondary Schools
All secondary schools which have participating primary schools in their catchment area, or which have been identified by primary schools will be sent an invitation letter and information sheet. Secondary schools will be able to contact the trial co-ordinators should they have further questions. We will ask secondary school head teachers to sign and return a written consent form to allow us to follow up participating children who move to their schools in the later years of the study.

Baseline Data from Secondary Schools
No baseline data will be required from secondary schools.

Recruitment of Parents
We will ask each school to post out a 'CLASS Trial Information Pack' to all parents of eligible children. Each pack will contain a covering letter from the school (if they chose to insert one), , a user-friendly information sheet for parents/carers, including the Parent/Carer Withdrawal Form. The Information Sheet will explain the purpose of the CLASS trial and what taking part would entail. Contact details for the trial coordinators will also be provided should parents have further questions. A short DVD clip for parents explaining the trial will also hopefully be produced.

We will be guided by schools on the need to provide the documentation in other languages and will work with schools to provide this wherever possible. Schools may also meet face to face with or phone some parents if they feel this would be more appropriate.

We will ask parents to discuss the trial with their child/children. If either parents or children are unwilling or unable to take part in the study, we will request parents to send us a withdrawal form in a self-addressed envelope or call/text/email us on the contact details provided within the information pack. Parents and children will be consented before we collect any baseline data and randomise schools to minimise recruitment bias. Just before data collection, we will send another reminder one-page letter to parents (of children for whom no withdrawal forms have been received), requesting them to either call/text/email us or send us a withdrawal form if they like to withdraw their child/children from the study at any stage.
In schools allocated to the intervention group, all participating children (in years 5 and 6 in the 2011/2012 school academic year) will take part in the SFH activities. We will ask schools to let us know which participating children were absent for the activities..

Recruitment of Children
All the children participating in this trial will be under 16 and therefore we will seek parental/carer consent as above for them to take part. However we feel that at the time of recruitment the children will be of an age (9 to 11 years) where they are able to understand, to some degree, the research. Children will therefore be provided with an age appropriate information sheet, which will be given

out to them at school. We will ask the teachers to take the children through the information sheet and answer any questions the children may have. We will also provide schools with a short DVD clip which can be shown to the children in school describing the research. The children will be encouraged to discuss the research with their parents. If children are unwilling or unable to take part in the study, they can either let their teachers or parents know, as they feel appropriate. We hope this will also ensure the children's commitment to the project. All participating children will be allocated a unique identification number and a register linking this number with other identifiable details will be kept on secure password protected computers or at YTU in a locked cabinet separate from all other data collection forms.

Baseline Data from Children
Each primary school will be sent a children's survey (paper form) for each child to complete 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 (SO1, SO2, SO3, SO4). The school will be asked to oversee the completion of the survey and return completed surveys to the YTU. Each school will also be sent a container for each child in which each child will be asked to provide a saliva sample. The school will be asked to return the saliva samples to a laboratory for testing (PO). The children's survey and the saliva samples will be anonymised and when completed and returned will have nothing that can identify the child's name or address. Saliva samples will be destroyed immediately after cotinine testing and recording of their results in the database. The database entries will also be anonymous containing only children's unique identification number. All information will be kept completely confidential.

Primary schools will be asked to provide the following baseline data about each child taking part in the study:

- Gender
- DOB
- Ethnicity
- 12 month attendance records for participating children including reasons for absence if known (SO5)
- Free School Meal status of participating children

Randomisation

Once necessary baseline data has been logged into a database, the participating schools will be randomly allocated to each of the two arms, intervention and control on an equal basis (i.e. 25 schools in each arm). Each intervention school will be paired with a control school for follow up purposes. We will not use simple randomisation, because this may cause cluster level imbalances. We will use a restricted method of allocation called minimisation, which achieves balanced groups more efficiently than other allocation methods. We will minimise (i.e., ensure balance) on size of eligible sample and proportion of eligible children receiving Free School Meals (which is a proxy for socioeconomic status).
There is a possibility of potential contamination through siblings attending different primary schools. For example one sibling may be at a school allocated to be in the intervention arm and another sibling may be at school allocated to be in the control arm. In this example the child attending the control school and their parent/carer would be contaminated with the intervention from the child attending the intervention school. However, it is unusual to have siblings in different primary schools; therefore it is unlikely to be an issue in a vast number of cases.

Trial Intervention

Intervention Group

Schools in the intervention arm will receive SFH when the participating children are in Years 5 and 6. SFH is a school-based intervention to encourage families to implement smoking restrictions in their homes and, as a consequence, to protect children and non-smokers from SHS. A trained SFH project worker will visit each school and take Years 5 and 6 children (on two separate occasions if necessary) through a series of educational activities using a SFH toolkit. Children, whose parents asked for their children to be withdrawn from this study, will continue to attend their regular classes or appropriate provision will be made.
The SFH activities consist of a class-room presentation and activities lasting approximately two hours. Children will be given a promise form which contains pictorial and written messages on the hazards of SHS, a pictorial step-guide for families to make their homes smoke free, a puzzle to help families learn about the benefits of a smoke free home and a tear-off slip to make a commitment to impose smoking restrictions at home. Children are expected to bring this slip back to school and receive a SFH Gold certificate should their home be totally smoke free. These 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 will be offered a training session on SFH to help them in reinforcing SFH messages, (b) a brief session on SFH for all children through a whole school assembly, could be supported by the SFH co-coordinator at the schools request and (c) school-based family events could also be supported by the SFH co-ordinator at the schools request. A detailed description of the intervention is available in a report titled "Smoke Free Homes Campaign Report"(41).

Data Collection
Schools will be asked to provide attendance details for all participating children on the days when SFH activities are conducted.

Acceptability and feasibility of SFH
We have recently evaluated the above activities, related materials and training sessions for the appropriateness and acceptability of their content, layout and format through a series of focus group discussions with children and school teachers(37). We also spoke to parents and as a result of these discussions made minor but required modifications to the above. The delivery of SFH in our pilot was carried out by the SFH co-ordinator with the co-operation of school staff. Schools welcomed this initiative and were accommodating towards our SFH team to deliver these sessions. School staff also helped in retrieving promise forms and supporting relevant follow-up activities. Focus group discussions within schools highlighted broad acceptability and interest in the initiative. There are several other places in the UK where this scheme has been up and running and their reports suggest its wider acceptability(35;36). We expect the Black and Minority Ethnic (BME) population to be well represented in our sample. In fact our pilot study was carried out in an area with a significant South Asian community. Our Smoke Free Homes work in Pakistan and West Yorkshire has enabled us to develop Smoke Free materials in South Asian languages which have been evaluated for cultural appropriateness and acceptability. SFH coordinators will use prescribed methods of delivery using identical tools and materials. In our experience, it would be possible to deliver SFH in 25 schools in a standardised manner over a short period of time.

Control Group

Schools randomly allocated to the control group will not receive the SFH activities immediately. Children will of course continue with normal teaching and this will include the schools meeting the National Curriculum guidelines within Key Stage 2 of teaching children about developing a healthy safer lifestyle. If SFH is shown to be effective, schools in the control arm will be offered the SFH activities after 24 months when all participating children have left the primary schools and moved to secondary schools.

Follow Up

All participating children will provide baseline data and will take part in the SFH activities if they are allocated to the intervention group, however only a sample of the participants will be followed up for the remainder of the trial. This sample will include a random sample of 90% of the children who test positive for cotinine at baseline and a random sample of 10% of children who test negative for cotinine at baseline. This sampling will be done using assigned unique identification number only. The CLASS trial is primarily focussed on investigating the effect of SFH on children who are exposed to second-hand smoke and therefore we are interested in the children who test positive for cotinine at baseline. However we need to inform parents and children who will not be followed up for the remainder of the trial that this is the case and thank them for their willingness to take part. It is important therefore that a mixture of children who test both positive and negative for cotinine are followed up in the trial so that parents cannot work out their child's cotinine test result. This will ensure complete anonymity and act as a further safeguard against identifying children with a positive cotinine test preventing schoolteachers or investigators from working out children's cotinine test results. Following up a random sample of 10% of children who test negative to cotinine at baseline will also allow us to investigate the proportion of these children who subsequently test positive for cotinine.

We will inform all parents and children by letter if they are to be followed up for the remainder of the trial or not and thank them for their participation in the trial.

The first follow up will take place 4 weeks post intervention. All children who remain in the trial will be asked to complete a children's survey (SO1, SO2, SO3, SO4) and provide a saliva sample (PO). Primary schools will oversee this data collection and will provide data on school attendance of participating children (SO5). As before, both survey and saliva samples will be anonymous containing no identifiable information other than the unique identification number.

We will ask primary schools to let us know which secondary school participating children move on to.

At follow up 2 (11 months post intervention), follow up 3 (24 months post intervention), follow up 4 (36 months post intervention, follow up 5 (48 months post intervention), and follow up 6 (60 months post intervention) we will ask all children who remain in the trial to complete a children's survey (SO1, SO2, SO3, SO4). We will ask for a random sample of children who remain in the trial to provide a saliva sample at each follow up. This is to test the validity of the children's self reported smoking status in the survey (SO2) at different ages. The size of the random sample will be decided after baseline data collection, at which point we will be able to investigate how well children's self reported smoking status is validated by the results of the cotinine tests. Primary schools will oversee

the data collection for children who remain at their school. Secondary schools will oversee the data collection for participating children who have moved to their school.

Follow-up in secondary schools

Children will inevitably move to secondary schools during the course of follow-up. We will track these children from school leaving lists and the local education authority database to their secondary schools. We will exclude secondary schools (and children) with less than 5 children from the original cohort. This strategy was adopted by Rudolph et al who studied prevalence of obesity and high BMI in a cohort study of school children carried out in Leeds, Yorkshire(42). They were able to track 87% of children (608 out of 694) from primary to secondary schools. After excluding those children who went to distant schools (<5 children from the original cohort), they were still able to approach 72% (500 out of 694) of children in the original cohort. After re-consenting, 348 (50% of the original cohort) agreed to take part in the second assessment. We expect higher follow up rates in our study as Rudolph et al carried this out as two separate studies and had to re-consent at the follow up.

Outcome measures

Primary outcome

Salivary cotinine levels among children (Primary Outcome - PO)

Salivary cotinine measurement is a widely recognised method for detecting both active and passive smoking and has been used in several surveys and studies. It is measured by collecting saliva in the mouth and blowing it in a plastic container through a straw or by using a swab. The samples are subsequently analysed and a gas-liquid chromatography technique can detect cotinine levels as low as 0.1ng/ml. Based on cotinine measurements taken as part of the national household survey, various thresholds for active and passive smoking have been defined for different age groups(44). Salivary cotinine concentration, a sensitive biochemical marker, is strongly associated with the exposure to SHS at home(41). It has a half life of 20 hours(45) and therefore, we will ask for saliva samples to be given first thing in the morning to avoid any loss of sensitivity. The level of exposure according to the cotinine estimates can be grouped in several categories depending on the level of smoking and smoking restrictions at home. We will measure salivary cotinine levels at baseline for all participating children and at follow up 1, after the intervention, for all children who remain in the trial (90% of children who test positive at baseline and 10% of children who test negative at baseline) in both arms of the trial. At follow ups 2 to 6 we will measure salivary cotinine levels on a selected sample of the children who remain in the trial to test the validity of the report on their smoking status at different ages. We will analyse this as a continuous measure.

Secondary outcomes

Smoking restrictions at home (Secondary Outcome 1 - SO1)

We will assess the level of smoking restrictions at home through a questionnaire completed by participating children. We assessed the feasibility of this tool in our exploratory study and modified it accordingly. The assessment is based on two questions; (a) Do people in the house smoke in front of children? (b) Where do people smoke? Responses to question (a) will be assessed as a binary outcome. However, responses to question (b) will be grouped in one of three categories. Smoking takes place; (i) in any part of the house; (ii) in one room only; (iii) only outside the house. We will add additional questions to assess smoking restrictions on the visitors. Our assessment is similar to the approaches used by other researchers(23;46).

We acknowledge the gradual shift in the smoking behaviour in households in the UK and the importance of a complete smoking ban inside the house as a key objective. However, one of the researchers in our team identified key issues and challenges in implementing smoking restrictions at home(30). One of the considerations was that in poor households, having a gradual or stepped approach towards a 'smoke free home' is more acceptable. This is also applicable in single parent families and people living in tower blocks. Given our focus on deprived communities, we are going to assess and consider various levels of smoking restrictions at home as an acceptable outcome.

Children's attitude and behaviours towards smoking and intention to start (SO2)
We will use a five-point smoking uptake scale to assess children's attitude towards smoking and intention to start(23). It will be categorised as: (a) Non-susceptible non-smokers ; (b) Susceptible non-smokers; (c) Early experimenters; (d) Advanced experimenters; (e) Established smokers. From the above, we will assess a difference in smoking uptake among children. We will carry out a saliva cotinine test on a selected sample to test the validity of the report on their smoking status.

Smoking behaviour of adults' (SO3)
We will assess the smoking behaviour of the adults living in participating children's households based on children's survey.

Quality of life (SO4)
Reduction in exposure to tobacco smoke may improve children's quality of life through the reduction of respiratory conditions (e.g., asthma attacks). We will use a short quality of life questionnaire with children for this purpose (PedsQol)(48).

School attendance (SO5)
Reductions in SHS exposure may improve school attendance. We will collect data on school attendance from school registers.

Statistical Considerations

Proposed sample size

We plan to recruit 50 schools (25 in each arm) in the study. We plan 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 expect a sample size of 2200 children and their parents to be followed up until the completion of the trial. The primary outcome is to detect a difference in the salivary cotinine levels between children who test positive for cotinine at baseline (estimated 2000 children) and therefore we base our sample size on that as per convention. However, we believe that our sample size will have sufficient power to detect significant difference in secondary outcomes as well.

Sample Size Primary outcome

Our sample size estimation for the primary outcome is 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

1. Effect size: We expect that the difference in the cotinine levels between children who are exposed to second-hand smoke and those who are not exposed is going to be more than 0.20. In addition, we expect that the difference in the cotinine levels between children who have different levels of exposure according to the smoking restrictions at home will also be more than 0.20. We believe that this is a clinically meaningful difference. We derive this difference from the research carried out by Ronchetti et al(18), who studied the relationship between cotinine levels among children and the place where the household members smoked while they were at home (specifically, if they smoked >4 cigarettes·day-1 "at the dinner table" or "in the television room after dinner"). The smoking behaviour was classified in four categories accordingly. They found that the difference detected in the cotinine levels of children between different categories was greater than 0.20. Therefore, we are assuming that a shift of 0.20 in the cotinine levels in our study population will be of clinical significance; for example, this can be an important difference in the levels of exposure of children to SHS between adults smoking in one room only and not smoking inside the house. The calculations are based on an SD of 1.38 which would bring the detectable difference of 0.28 to 0.20 of a standard deviation. We think that 0.20 of a standard deviation is a relatively small effect to look for and in observational data is what we might expect to find.
2. Intra-cluster correlation coefficient is selected on the basis of what has been used for continuous outcomes in school based studies on tobacco, drug and alcohol use(49-51).
3. Size of the cluster (children in each school): We plan to recruit 40 children from each school with a positive cotinine test as baseline. We believe that this is achievable based on the following assumption. In an average primary school in Yorkshire & Humber, we expect three classes of 30 children each in a year which will give us a potential recruitment pool of 180 per school. Given that 40% children are expected to be exposed to SHS, we should have at least 100 participating children to give us a sample of at least 40 children with positive cotinine levels from both years.
4. Correlation between baseline covariate and outcome: We assume a relatively conservative correlation co-efficient between baseline and outcome covariate of 0.6. Cook et al(45) shows a correlation of greater than 0.8 between pre- and post salivary cotinine levels, which if holds for our study, will significantly increase its power.
5. Attrition rate: In terms of attrition, for the primary outcome, we assume a very low attrition (<5%) in line with previous trials we have undertaken in schools. For our sample size calculations we have been deliberately conservative in our estimates; if we had a 15% attrition, which we think unlikely, then our sample size would be 1700, which would give us power to show a 0.20 difference in effect size. Even if we end up following only 25 children in each school then based on SD of 1.38, d = 0.28, alpha = 0.05, ICC = 0.05 and corr = 0.6 the power will be around 0.85. Clearly, if attrition is lower (likely) and the ICC is lower (likely) and pre and post test correlation is higher (likely) then we would have more power to show a smaller difference.
6. Design effect: The design effect we used here is 2.95 (i.e., [40-1] x 0.05 + 1).

Sample Size Secondary outcomes

We expect that the effect size of SFH on smoking restrictions at home will be close to what we observed in our feasibility study in Leeds. Our before-and-after study found that smoking in the presence of children had more than halved in households with at least one smoker; 42% at baseline, 20% at 6 months. We also found that the proportion of households reporting being completely smoke free increased from 35% at baseline to 67% at 6 months (52). Accordingly, a sample size of 732 and 386, respectively, are needed to detect such differences at $\alpha = 0.01$ and $\beta = 0.9$.

It is difficult to predict the effect size (and therefore estimate appropriate sample size) of SFH on children smoking initiation and adults smoking cessation rates as there are no relevant experimental studies to our knowledge. We, therefore, predict our effect size based on longitudinal studies. For adult smoking cessation our assumption is based on a recent systematic review of longitudinal studies examining the influence of smoke free homes on adult smoking. It revealed that living in smoke free homes can increase the smoking cessation rates by four-fold in 12 months(53). Using the study(54) mentioned in this review we estimate that a sample size of 1550 would be sufficient to detect statistically significant smoking cessation at 12-moths in people who smoke between 5-14 cigarettes a day and a sample of 980 would be sufficient for smokers who smoke >14 cigarettes a day.

We base our assumptions for the predicted effect size on smoking initiation rates among young people on another longitudinal study that followed up children for four years and found that children living in houses with smoking restrictions are less likely to start smoking when they have smoking parents (1.56; 95% CI 1.15, 2.13) as well as non-smoking parents (OR = 1.75; 95% CI 1.29, 2.37)(24).

High attrition rate can be detrimental in detecting any change in children's smoking initiation and adults' smoking cessation rates in the follow-up assessments. However, we expect to trace and follow up at least 72% (1440 out of 2000) of children from primary to secondary schools. We base this on the attrition rates observed in study carried out by Rudolph et al in Leeds(42). A systematic review of school-based smoking prevention trials with long-term follow-up showed a median attrition rate of 38% in eight studies with an average follow-up period of six years(55). A 10% attrition rate every year will still leave us with 50% children followed up for the entire duration of the study.

Usefulness of secondary outcomes

SO1 Smoking restrictions at home- A child completed questionnaire based assessment of smoking restrictions at home will provide more information on the various types of restrictions imposed at home, which will help us to better define the various categories identified primarily by estimating cotinine levels (primary outcome). It will also test the validity of the use of questionnaire based assessment of smoking restrictions as a stand-alone assessment for future research and evaluation of smoke free homes programme.

SO2 Children's attitude and behaviours towards smoking- In our review of the literature, we found no studies that assessed the effect of interventions designed to establish smoke free homes on the smoking behaviour of young people. There is also a lack of longitudinal studies investigating the relationship between a smoke free home environment and the attitude and behaviour of young people towards smoking. We wish to measure this outcome to address this knowledge gap.

SO3 Smoking status of adults: There is some evidence (based on observational studies) to suggest that a smoke free environment is associated with quitting smoking. However, again we were not able to identify any longitudinal or experimental studies of the influence of smoke free homes on adult smoking behaviour.

SO4, SO5, Quality of life and school attendance: We wish to measure these secondary outcomes to account for other related benefits that smoke free homes may have on improving children's health, quality of life, and school attendance..

Statistical analysis

The analysis plan will include:

- 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 will also include 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 main outcomes at both cluster and individual level after adjusting for the cluster design. We will also adjust for the baseline characteristics and other covariates using generalised estimating equations.

We will only be measuring the salivary cotinine levels of a sample of children at follow up (90% of children who test positive for cotinine at baseline and 10% of children who test negative for cotinine at baseline).

Our principal analysis will be an adjusted analysis of salivary cotinine levels (for children who test positive for cotinine at baseline and remain in the trial – 90% of children who test positive for cotinine at baseline will remain in the trial). Consequently we do not need to adjust the main outcome for multiple testing. For all secondary outcomes we will adopt a more conservative p value (i.e., p = 0.01) to reduce the risk of a type 1 error. We will adjust for the minimisation variables and In terms of the secondary analyses we will adjust for minimisation factors and baseline measures if taken (e.g., quality of life). We will estimate a difference in the mean of salivary cotinine of all children irrespective of their smoking status.

A detailed plan will be produced before any analysis has taken place. We do not anticipate a high attrition and we will use multiple imputation methods for any attrition that does occur. A sensitivity analysis will be undertaken to assess whether or not different methods produce different results (e.g. complete case analysis vs multiple imputation). At this stage it is difficult to specify all variables on which to undertake sub-group analyses or test for treatment interactions; however these are likely to include interaction terms for: baseline cotinine values; gender of child; and certain other variables. Only the primary analysis (4 weeks post intervention - cotinine testing) will use a p value of 0.05 other analyses will use p = 0.01. We acknowledge that these sub-group analyses will carry reduced power compared to the primary analysis. However, we see these sub-group analyses as hypothesis generating.

Our principal analysis will be an ITT analysis – if children move school we will attempt to follow them up in their new school for the primary outcome and, if appropriate, for secondary outcomes. Per protocol analyses can be biased so we will avoid these. However, if there is significant non-compliance with the protocol by schools or pupils we will use Complier Average Causal Effect (CACE) analysis to adjust for non adherence to the protocol, which will, in principle, produce an unbiased estimator. The statistical analysis will be carried out using STATA statistical software and R language (www.r-project.org).

It is potentially possible that some of the children in our study are established smokers and will therefore generate analytical issues. We expect such children to be small in number. However, we

can carry out a further sub-analysis to assess its effect on the outcomes. Our five-point smoking uptake and behaviour assessment questionnaire can identify both experimenters and established smokers. Besides, cotinine estimates can distinctly differentiate between active and passive smokers. In the analysis, we will adjust for baseline covariates. We will use CACE analysis to deal with non-adherence to the intervention, which adjusts for another source of possible confounding. Furthermore, we will use multiple imputation methods in a sensitivity analysis to adjust for missing data.

Clustering in secondary schools and families
A cross-classified mixed model approach will be used for outcomes measured at the secondary school level to account for the additional clustering at the secondary school level. (This approach is used since students attending the same primary school might not necessarily attend the same high school).

As children will move to secondary schools in the follow up years, they will not remain in their original clusters. However, this will not pose any problems for the statistical analysis. We will still use cluster specific methods for analysing secondary outcomes based on the primary school clusters. Given that children will be randomised on the basis of their primary schools and the intervention will have finished before they move on, only these will be the relevant clusters for the statistical analysis. We expect that as children grow up and move into new schools their smoking behaviour will be influenced by other factors (e.g. new peer networks) independent of the original clusters. However, we expect these factors to have a non-differential influence on children both in the control and intervention arms.

Sensitivity Analysis to take into account qualitative work
We will carry out a sensitivity analysis to take into account that 30 families in the intervention arm will be interviewed for the qualitative part of the study. As detailed below, these 30 families will be matched with 30 comparable families in the control arm. We will carry an additional analysis that excludes children of those 60 families in the analysis.

Qualitative Study

A variety of qualitative methods will be employed in order to meet Objective 3.

1. To assess the integrity and fidelity of the implementation process and other contextual factors that might contribute to the variation in outcomes

Methods

The qualitative component will support the trial by:
1) conducting focus groups to explore parents', teachers', children's, and SFH coordinators' views towards the interventions and to identify themes to inform observational protocols and interviewing guides;
2) using 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.

Research activities will be planned in step with the trial in the following stages:

Engagement and participation
In order to understand the process by which parents and teachers are engaged in the trial, we will conduct four focus groups in which parents, teachers at participating schools, children and SFH facilitators will be invited respectively to share their views, expectations and concerns about the intervention, and what might motivate families to be involved in the trial.

Sampling strategy: The members of the parent focus groups will consist of existing smokers, men and women with children attending participating schools. The teachers' focus group will comprise teachers from participating and invited schools. Healthy schools coordinators, PSHE coordinators or KS2 managers will be invited to join. The children's focus group will consist of Year 5 and 6 pupils from participating schools. These focus groups will be conducted prior to the intervention. 7-8 participants will be invited to join each focus group. Focus group interviews will be audio-taped and transcribed verbatim. Results will be analysed to inform observational protocols for SFH activities and the construction of family interviewing guides. The SFH facilitators' focus group will be held after the intervention has been delivered. This is to enable SFH facilitators to share their experiences of delivering SFH.

Observing the process of SFH intervention
Observational protocols will be constructed with reference to information gained from the focus groups. We will observe 6 intervention sessions delivered by the SFH project workers.
Sampling strategy: selection of intervention sessions will be based on year groups of pupils and school/neighbourhood contexts - Year 5 and 6 sub-divided into inner-city, suburb and small town environments. Other observations will also be made on the delivery of message reinforcement at: a) teachers training session; b) briefing sessions at school assemblies; and c) school-based family events.

Understanding the influence of contextual factors: Neighbourhood and the Family.
Context is both material/structural context and familial context in this study (56).The former is typified by features of neighbourhoods that are pro-smoking or anti-smoking i.e. organisations or

agents through their regular activities encourage the uptake, maintenance, or prevention of smoking e.g. tobacco sellers, local sport clubs, convenience stores. The latter is defined by the number of smokers at home and the family power dynamics with which the intervention will interact.

Neighbourhood mapping: A neighbourhood mapping study will be conducted in order to find out how children in participating schools perceive the environment in which they live. Three schools will be selected to take part in this study, one from each of the categories of neighbourhood (inner-city, suburban and small town). In these schools, focus groups will be conducted, with a maximum of twelve children in each focus group. The focus groups will take the form of a mapping exercise. Participants will be provided with a GIS map of the area (1 mile radius from school). They will be asked to populate the map with identified features which are of significance and relevance to them in relation to smoking e.g. features of access to smoke free public spaces and agents that act as either enforcers or interrupters of smoking.

Family interviewing: The family interviewing method is based on the family theory derived from family therapy(57), and previous work in this area(58). Different concepts are used in different family theories. We will investigate the extent to which concepts of the structure and composition (number of parents, siblings, age and gender), locus of control, interaction in the family, and the wider environment (neighbourhood) will influence the adoption of SFH and the change and maintenance of smoking behaviours. We will select thirty families from the intervention arm who will be interviewed before the intervention (baseline) and after the intervention (Follow Up 1). We will also carry out follow-up interviews at each follow up point. The interviews will explore the process families go through in adopting SFH. Specifically, they will explore (i) the motivating factors that convince families to adopt SFH e.g. protecting children from SHS (ii) learning outcomes from SFH materials and behavioural actions to create and maintain smoke-free homes e.g. negotiation within family (iii) the strategies that families take in implementing SFH e.g. degree of restriction in the home, change of smoking behaviour, banning visitors' smoking (iv) impact on the smoking behaviour of the child and families as a whole e.g. taking up or quitting smoking.

Sampling strategy: The purpose of the sampling strategy is to explore the journey of each child and their families in a variety of contexts as they participate in the trial, and the relative significance of family and neighbourhood contexts. Therefore, it is necessary to employ a flexible and maximally expansive approach to sampling.
There will be a total of 30 families in the sample. Using the baseline results, we will select six children from each of the following five categories of smoking behaviours: (i) Non-susceptible non-smokers, (ii) Susceptible non-smokers, (iii) Early experimenters, (iv) Advanced experimenters, (v) Established smokers. Included in the sample are 5 categories of children from non-smoking families (see shaded column of figure below), who are identified by surveys and salivary Cotinine testing to have the listed behavioural types. These families (the non-smoking families) will form useful comparators. Schools will be selected from three categories of neighbourhood: inner-city; suburban and small towns. For example schools from districts of Leeds such as Harehills and Chapletown would be classified as inner city, suburbs of Leeds such as Moortown and Cookridge would be sub-urban, while Keighley or Shipley near Bradford would be classified as small towns . Ten families of different types (including the 5 non- smoking families) will be drawn from each of inner-city, sub-urban and small town settings identified.

In order that the qualitative work undertaken with participants can be taken into account in the trial analysis, the trial coordinators will identify a minimum of 3 pairs of schools from the schools randomised. The pairs will be chosen in order to ensure that: of the intervention schools, there is

one school in an inner-city location, one in a suburban location and one in a small town location and of the control schools, there is one school in an inner-city location, one in a suburban location and one in a small town location.

The trial coordinators will then provide the qualitative researchers with a set of a minimum of three intervention schools and a set of a minimum of 3 control schools, but will not inform the qualitative researchers which set is intervention and which set is control. The qualitative researchers will select 30 families from each set of schools, following the sampling strategy detailed above. The trial coordinators will then inform the qualitative researchers which schools were intervention schools, the 30 families selected from the set of intervention schools will form the qualitative sample. The 30 families selected from the set of control schools will be used as controls when the qualitative work with participants is taken into account in the trial analysis.

Child smoking intention & behaviour	Household type					
	2 adults (at least one smokes)	1 adult (smokes)	2 adults (at least one smokes) + children (at least one smokes)	2 adults (both smoke) + child (non smoker)	1 adult (non-smoker) + children (smoker(s))	Adult (non smoker) + child non smoker
NSN (i)	A1	B1	C1	D1	E1	F1
SN (ii)	A2	B2	C2	D2	E2	F2
EE (iii)	A3	B3	C3	D3	E3	F3
AE (iv)	A4	B4	C4	D4	E4	F4
ES (v)	A5	B5	C5	D5	E5	F5

These criteria for selection are designed to be maximally expansive; the aim is to include as many different types of family as possible. Flexibility in the application of the criteria is essential. It is not possible to know in advance whether the baseline data will yield results identifying potential participants to fit the criteria exactly as laid out here. In the case that there are no participants available in any one of the specified categories, we will alter some of the criteria, maintaining as much difference between family types as possible. For example, it may be that the cotinine sample results do not reflect all five categories of behavioural intention included in the sampling frame. In this case, it will become necessary to collapse these categories into reasonable behavioural types that are sufficiently different to have theoretical value.

Data collection from focus groups, observations, and family interviews

Focus group interviews will be conducted at schools or community centres using a guide. Family interviews will be conducted at the homes of selected families (or a mutually convenient alternative location) using a semi-structured guide. The focus groups and interviews will be tape recorded and transcribed verbatim. Researchers will also record field observations on protocols. Field notes will be regularly maintained.

Analysis of data from focus groups, observations, and family interviews

Using a thematic approach(59), a codebook of major themes will first be developed. Two coders will code each transcript independently. Codes will be compared and discrepancies will be resolved by

consensus. Data will be fed into NVivo.8 (qualitative analysis software). These codes will then be grouped and re-grouped to generate themes.
With the family interviews, a formative analysis will help to understand the relationship between the types of smoking behaviours of the child and his/her family and the neighbourhood context at the baseline assessment stage. Outcome matrices (see indicative matrix below) will be created based on results from assessments from the trial to facilitate analyses of themes and the similarities and differences between the typography of families and neighbourhood contexts by outcomes (e.g. household smoking restriction, exposure of SHS, change of smoking status of children & families) at each stage of the trial for each case and across cases to explore plausible explanations of the variation in outcomes.

Family type Child's smoking behaviour and intent	Outcomes				
	Impose and sustain SFH partially	Imposed and sustain SFH completely	Exposure to SHS	Taking up of smoking	Adult changing smoking behaviour
A1-F1					
A2-F2					
A3-F3					
A4-F4					
A5-F5					
Context	Neighbourhoods/ availability of smoke free environment inner-city/ suburban/small town				

The analyses will foreground the processes, negotiations and shared meanings in families, rather than focusing on the individual child or on aggregate patterns of family behaviour. This is to avoid the implicit assumption that it is the child's responsibility to persuade the family to adopt SFH. We can centralise the dynamics of 'family' in our family theory relating to smoking behaviour; explaining the variety of outcomes obtained from the trial. It is important to recognise that the analyses will be recursive, cycling back and forth between cases and outcomes.

Interviewing skills and conduct
Like the focus group method, family interviewing data are developed in interaction(57) and we do not intend to elicit private thoughts and opinions of individual family members. We anticipate that the researcher's presence will affect family members' responses. We will take care to put the family at ease when eliciting multiple and perhaps conflicting views while remaining engaged with the entire family and avoiding appearing to align or coalesce with any particular sub-group. It will be important to ensure that the researchers are fully trained in family interviewing. While researchers will try their utmost not to provoke conflicts or to trigger distress among the interviewees, situations may arise in which families may be in need of brief intervention. In such cases, they will be referred to a family counsellor.

Economic Evaluation

An economic evaluation had been designed to meet Objective 4.

2. To estimate the cost-effectiveness and understand the budgetary implications of SFH in obtaining its intended outcomes

Methods

This component of the study will estimate the cost of providing the intervention in schools. These costs will include the time of staff involved in programme delivery and materials costs. The estimated costs will be combined with outcome rates to compute a cost-effectiveness ratio. This will take the form of a cost per smoke free child (defined as having zero cotinine levels). However, most of the benefit of this intervention is likely to be in the longer term, with substantial health benefits accruing to the children and possibly their parents. Consequently, we will need to undertake economic modelling to capture these longer term impacts. The longer term follow up will provide estimates of the number of pupils who do not take up smoking in the intervention groups over and above the control scenario. These data can 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 do not take up smoking. We will obtain QALY estimates from the existing literature. Thus, we will assess the QALY losses due to smoking and then estimate the gains that would be achieved should we demonstrate a significant reduction in smoking uptake. The data will also allow the modelling of potential health care cost savings amongst this population, as smokers are known to impose considerable costs on the NHS due to the treatment of smoking-related disease. These costs were estimated at £5.2 billion for the UK in 2005-6, some 5.5% of the total health care budget(43). We will produce Cost Effectiveness Acceptability Curves (CEACs), where we will plot the probability of the intervention against the willingness to pay for a QALY. The current decision rule is that if the cost per QALY has a 50% or greater probability of being less than £20,000 per QALY this is deemed to be cost effective. All future costs and outcomes will be discounted at a rate of 3.5%; however, this will be varied in a sensitivity analysis. We will undertake extensive sensitivity analyses one of which will be a threshold analysis. This will help in estimating the minimum long term effectiveness required by the programme to justify costs.

Individual cost and outcome data will be bootstrapped to adjust for the expected skewness in the distributions. The bootstrapped data are then used to construct cost-effectiveness acceptability curves that estimate the probability of the intervention being the preferred option based on uncertainty in the threshold value of the outcome domain. The trial data will be modelled using existing quality of life values based on smoking status and age, which will be projected forward to construct the expected QALY gains as a result of changes in smoking behaviour. The model will incorporate an extensive sensitivity analysis which will generate cost-effectiveness estimates based on different parameter values. The sensitivity analysis will be important to the model since many of the modelled parameters will be literature based estimates which are used to extrapolate the data from the trial. The modelling will adjust for natural quit rates in the population, so those smoking who would have given up anyway will be accounted for. Qualitative data will also inform about changes in the locations of smoking and thus the impact of passive smoking as well and quitting.

Ethical arrangements

Rationale for carrying out this research
The Smoke Free Homes intervention has the potential to address a major public health issue i.e. second-hand smoke and its influence on the health of children. Given that this is now a problem largely among families with socio-economic disadvantage in the UK, the intervention also has a potential to address the health gap between rich and poor. However, there is no evidence for its effectiveness and cost-effectiveness that is based on objective outcome measure (cotinine test). Therefore these research questions address a priority need for deprived communities where both active and passive smoking are common.
Cost justification: If SFH is found effective in our study, it would provide justification to continue to expand this scheme which could potentially cost only 3 million pounds per year approximately at a national level. However, if found ineffective, the NHS would be able to divert this money to other cost-effective strategies. The low cost of intervention should not be a deterrent to invest in a robust evaluation. A cheap intervention, if found effective, is likely to be highly cost-effective. Developing robust evidence for the cost-effectiveness of a cheap intervention provides good value for money.

Children's participation
We understand that children's participation in such studies raises issues around incompetence, vulnerability and powerlessness. We will ensure that our approach to children is participatory and as less intrusive and confrontational as possible. In addition, our research team has previous experience of working with children.

Any changes in the routine that may be potentially harmful
No participating child or family will be deprived of any service that she or he would ordinarily receive. There will be no extra burden, financial or otherwise, on the participants. Children or their families will not incur any cost for participating in this study. They will not receive any financial incentive to participate in the CLASS trial, although they will receive a small sum of money for taking part in the additional qualitative elements of the study (£20 per participant taking part in teacher or parent focus groups, £20 for the parents of children taking part in a focus group, £50 per family taking part in family interview). Travel expenses will be reimbursed

Potential harms related to intervention
This is not a clinical trial. The educational messages in SFH programme are not harmful. We have explored initial concerns about the potential of children confronting their families about their smoking behaviour. In our feasibility study, no adversities were highlighted by the children or parents in focus group discussions. However we have made provisions for families to be referred to a family counsellor, if they feel the intervention has caused any issues which need to be discussed further.

Primary outcome and Sample size
We have selected salivary cotinine test as the primary outcome. Cotinine is the only objective measure that can detect the difference between active and passive smoking and therefore, be used as a valid measure in this study. Any alternative measure selected as primary outcome for this study will compromise its validity and invariably make the study less ethical. Providing the saliva sample for salivary cotinine testing is also not harmful to children.
Under-powered trials are considered unethical; therefore our sample size calculations are based on conservative estimates and high power. We have also taken account for the potential attrition.

Confidentiality and anonymity of participants
All efforts will be made to maintain participant confidentiality. All data collected will be anonymised, being identified with a unique participant identification number only. Data entered in databases will be password protected and will not contain any other identifiable information other than the unique identification number. A copy of the database will be kept on the York Trials Unit's secure server. Copies of paper data will be preserved until the youngest child in the study is at least 21 years. We will ensure that participants' names and identifiable information remain confidential and remains locked in a cupboard in YTU separate from all other study data at all times. The only occasions that this information will be used are to identify children for first and subsequent follow-ups or in case of any adverse incident. While retrieving information to identify children for follow up, we will ensure that our lists only contain their unique identifier number and not any other information such as cotinine test results. This will preserve anonymity of participants' results even from the investigators. We will also ensure that no such information is presented in any reports or other materials.
In the unlikely event that something was disclosed, either during the qualitative work or on completed surveys, which required action, such as reporting to Social Services, then confidentiality would have to be broken. The appropriate action would be taken, including reporting the issue as an Adverse Event (AE) or Serious Adverse Event (SAE). This has been made clear on the participant information sheets.

Informed consent and no obligation to participate
Schools will receive written information and will also have an opportunity to meet the trial coordinators. A written consent form will be obtained in they agree to participate. Schools will be made aware that they can leave the study at any time without giving a reason.
Informed consent on an opt-out/withdraw basis will be sought from parents to obtain saliva from their children to measure cotinine; and to conduct children surveys about children's exposure to second hand cigarette smoking. Parents will have the right to withdraw their child from the research at any stage with no consequences. Parents will be sent written information on all aspects of the research project. It will be made clear that parents and their children are under no obligation to participate in the study and no change in their routine education will take place if they refuse to participate. Parents will be told that any information disclosed will be treated with confidentiality. Parents will also hopefully be able to watch a short DVD clip on the trial website explaining the study. We will ask parents to discuss the trial with their child/children. If either parents or children are unwilling or unable to take part in the study, we will request parents send us a withdrawal form in a self-addressed envelope or call/text/email us using the contact details provided within the information pack. Just before data collection, we will send another reminder one-page letter though schools, to parents (for whom no opt-out consent forms have been received), indicating the date for the data collection and SFH activities, and requesting them to either call/text/email us or send us a withdrawal form if they would like to withdraw their child/children from the study at any stage.

Children will also be provided with age appropriate written information at school, which we will ask the school teacher to take them through. We will also provide a short DVD clip which can be shown to the children in class.

After speaking to several staff members at the potential participating schools, we have learned that getting parents to engage with school activities and return forms is a recurring difficulty, not just with research consent forms, particularly in schools in deprived areas. We believe that this opt-out approach is ethical, as it will allow us to recruit the required number of participating children (therefore meet the sample size requirements) and use the most valid measure to complete this study of high public health importance. We have built enough safeguards in our research procedures to maintain complete confidentiality and anonymity to the highest possible degree, inform parents

sufficiently and regularly and provide them plenty of opportunities to withdraw their child at all stages of the study.

Additional information
All participating children will be involved in the SFH classroom activities about passive smoking. These activities are consistent with activities within the Key stage 2 of the National Curriculum. As part of developing a healthy, safer lifestyle within Key stage 2, pupils should be taught: (a) what constitutes a healthy lifestyle, including the benefits of exercise and healthy eating, what affects mental health, and how to make informed choices; (b) which commonly available substances and drugs are legal and illegal, their effects and risks; (c) to recognise the different risks in different situations and then decide how to behave responsibly, including sensible road use, and judging what kind of physical contact is acceptable or unacceptable; (d) that pressure to behave in an unacceptable or risky way can come from a variety of sources, including people they know, and how to ask for help and use basic techniques for resisting pressure to do wrong; school rules about health and safety, basic emergency aid procedures and where to get help.

Schools in Yorkshire have previously taken part in Smoke Free Homes. If schools have agreed to take part in the research we envisage that all children within the school will take part in the Smoke Free Homes activities. This is consistent with usual school procedures and the method adopted in pilot work. However, given that the classroom activities still form part of a research project, parents will be given the right to choose to withdraw their child from this element of the research. Thus an 'Opt Out' approach will be used for the intervention too. This is consistent with procedures for parental rights to withdraw children under the age of 15 years from sex education lessons.

The SFH intervention is designed to raise children's awareness about the harmful effects of passive smoking and empower them to influence their home and car environment. There is a potential risk that we may raise their anxieties and potentially cause distress amongst families. In our exploratory study of SFH, we carried out focus groups with parents as well as children. We specifically asked parents: "Did you feel comfortable/ happy to discuss the issue with your children if it was raised by them? If no, why not? Does it create tension or interfere with parenting roles?" We asked children: "Did you feel comfortable/ happy to discuss the issue with your parents/other household members? If no, why not?". The analysis of these focus groups has given us some insights into the receptivity of the issue amongst families who chose to participate. Children felt confident in raising the issue of second-hand smoking with parents. Parents also did not find this an "awkward" discussion. However, we will be vigilant in our preparation of parents and children who might wish to participate in the trial and will ask similar questions in the focus groups to spot any potential tensions. We have also built-in support from Leeds Family Therapy Training Unit for this project. All family interview participants will be provided with contact details for a family counsellor.
Children will be asked to return signed promise forms back to the teachers. However, all children will be given a 'gold certificate' for taking part in the smoke free homes programme. Children who are not able to return signed promise forms will also be appreciated and 'rewarded' as above.

We have consulted with the chair of the ethics committee (Prof. Darren Shickle) at the Faculty of Medicine and Health, University of Leeds. He has kindly agreed to be an independent ethics advisor to our research team.

It is important that we are able to respond appropriately should any participant express a wish to quit smoking, either through the qualitative work or on completed surveys. In the case of children, we are unable to send a letter to them as this would break confidentiality; we have therefore suggested that children should contact their school nurse or a member of staff at school should they

wish to discuss any issues related to smoking. This guidance will be given on each survey they are asked to complete. We envisage the role school nurses will play in the trial as very minimal. We expect most children to speak to a teacher they know at school. The school nurse would only be expected to carry out normal responsibilities and procedures should a child approach them.

Research governance

The trial will be conducted to protect the human rights and dignity of the participant as reflected in the 1996 version of the Helsinki Declaration. Participants will not receive any financial inducement to participate in the trial. In order to protect the trial participants the following provisions will be made/upheld; the trial has been designed to minimise the burden of participants and any foreseeable risk in relation to the intervention involved; the explicit wishes of the participant will be respected including the right to withdraw from the trial at any time; the interest of the participant will prevail over those of science and society; provision will be made for indemnity by the investigator and sponsor.

We will approach a regional NHS Research Ethics Committee to grant ethical approval for the study. We will ensure that our study complies with the Research Governance Framework (1994) including having independent expert advice. We will set up a Study Steering Committee (SSC) to oversee and guide the research. We will invite a leading public health expert to chair the SSC. In addition, we will invite two other independent experts to join this group. We will also invite observers from NIHR to the meetings of SSC. The committee's terms of reference and meetings minutes will be sent to NIHR regularly.

Monitoring

In the context of this study we think it is very unlikely that any Serious Adverse Event (SAE) would be related to the intervention or research procedures. The intervention is an educational intervention and is not harmful to children. Providing the salvia sample and completing the surveys present very minimal risks, if any risk, to participants. We will however strongly endeavour to record SAE and Adverse Events (AE) as defined below, which may well be unrelated to the research study. We are aware that children are likely to experience some of the criteria below connected to common childhood illness or accidents.

Adverse Event (AE) – is defined as 'any undesirable experience occurring to a participant, whether or not considered related to the intervention being used in the trial or research procedures'.

Serious Adverse Event (SAE) – is defined as one that fulfils at least one of the following criteria

- Results in death
- Is life threatening
- Requires hospitalization or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity, or
- Consists of a congenital anomaly or birth defect
- Is otherwise considered medically significant by the investigator (60)

We are aware that the intervention may possibly cause distress or unrest within families. For this reason we have made provision for families to be referred to a family counsellor. If a member of school staff, qualitative researcher or participant was to report that the intervention had caused any

family problem, this would be recorded as a related AE and the option of seeing a family counsellor would be made available to individuals concerned. In an exceptional circumstance this may be reported as a related SAE. This decision would be taken by the Chief Investigator (CI) and 2 members of the Study Working Group (SWG). In this case the event would be reported to the REC and to other appropriate bodies (for example social services).

We have adopted a number of strategies to enable us to record SAE and AE as defined above:

- School staff will be asked to phone the trial manager to report any SAE or AE.
- Participants will be made aware that they can phone the trial manager should they have any issue they would like to discuss.
- Each school will ask be asked to provide regular attendance details for participating children throughout the duration of the trial.

If any related SAE or AE event was to occur we expect that it would have occurred within 6 months post intervention. After this period therefore we will not actively collect data on SAE or AE, although we will continue to record any SAE or AE that are highlighted as a consequence of a contact being made with the trial manger.

The Trial Manager should be informed of all AE and SAE by telephone. Individuals reporting an AE or SAE could include school staff, qualitative researcher, or participants themselves. The trial manager will record any information received through telephone calls or through other means (e.g. surveys, school attendance records) on either a SAE Reporting Form) or an AE Reporting Form as required, a copy will be stored in the participant's records. The Trial Manager will inform the Chief Investigator (CI) and 2 members of the Study Working Group (SWG) who will jointly decide if the event should be reported to the main REC as an SAE. Related SAEs which are fatal or life threatening will be reported to the main REC within 7 days of the CI becoming aware of the event. Related SAEs which are not fatal or life threatening will be reported to the main REC within 15 days of the CI becoming aware of the event.

The occurrence of SAE and AE during the trial will be monitored by the Study Steering Committee (SSC). The SSC will immediately see all SAEs thought to be related to the intervention or research procedures. They will see all SAEs not thought to be related to the intervention or research procedures by the Study Working Group at the next scheduled meeting. They will see non-serious adverse events both thought to be related or unrelated to the intervention or research procedures by the Study Working Group at the next scheduled meeting.

There will be no formal analysis of SAE or AE.

Trial Management

Sponsorship

The University of Leeds will act as sponsor for the CLASS trial.
Claire Skinner
Faculty Head of Research Support
Faculty of Medicine and Health Research Office
Level 10, Room 10.110
Worsley Building
University of Leeds

Indemnity

The University of Leeds will provide relevant cover.

Funding

Research funding had been secured from the National Institute for Health Research Public Health Research Programme

The cost towards the salary support of our NHS colleagues (PH, IC, HT, AF) will be met by the NHS.

Cost of the intervention
The cost of the intervention is estimated at £36,000 to deliver SFH in 50 schools per year for a population of approximately 750,000 based on our experience in West Yorkshire.

Study Steering Committee (SSC)

A Study Steering Committee (SSC) will be set up and will include an independent chair, at least two other independent members, at least one lay member (whom we hope will be representative from a participating school), a representative of the funder, along with the lead investigator and other study collaborators. The Study Steering Committee is likely to meet every six months in years 1, 2 and 6 and every year in years 3, 4 and 5, but the timing of meetings will be decided by the Committee when it meets.(see Appendix 2).

The main features of the SSC are as follows:

- The role of the SSC is to provide overall supervision for a study on behalf of the Study Sponsor and Study Funder and to ensure that the study is conducted to the rigorous standards set out in The Research Governance Framework. It should be noted that the day-to-day management of the study is the responsibility of the investigators and the Principal Investigator and the Study Working Group (SWG).
- In particular, the SSC should concentrate on progress of the study, adherence to the protocol, participant safety and the consideration of new information of relevance to the research question.
- The safety and well-being of the study participants are the most important considerations and should prevail over the interests of science and society
- The SSC should provide advice, through its chair, to the Principal Investigator, the study sponsor, the study funder, the host institution and the contractor on all appropriate aspects of the study.
- Membership of the SSC should be limited and include an independent chair, at least two other independent members, one or two principal investigators and, where possible, a consumer representative. Involvement of independent members provides protection for both study participants and the principal investigator(s).
- Representatives of the study sponsor and the study funder should be invited to all SSC meetings.
- Responsibility for calling and organising SSC meetings lies with the Principal Investigator, in association with the Chair. The SSC should meet at least annually, although there may be periods when more frequent meetings are necessary.

- There may be occasions when the study sponsor or the study funder will wish to organise and administer these meetings for particular studies. In the PHR Programme's case this is unlikely, but it reserves the right to convene a meeting of the SSC in exceptional circumstances.
- The SSC will be asked to comment in detail on extension requests or substantial changes to protocol.

Study Operational Committee (SOC)

We will establish a Study Operational Committee (SOC). SOC will consist of all investigators and one representative from all collaborating organisations and institutions. It will be chaired by AA. The purpose of this committee will be to set the direction of the project and ensure that it meets its objectives. The committee will meet regularly throughout the duration on the study. The group will be briefed on the progress against the project schedule, interim results, potential challenges and outputs. This group will make all strategic decision on the study management. SOC will also communicate this work to the audience and stakeholders. (see Appendix 2).

Study Working Group (SWG)

We will also have a Study Working Group (SWG). This will consist of the principal investigator, social scientist, statistician, health economist, qualitative researcher, trial manager, data manager and other researchers as required. SWG will be chaired in alternation by KS and DT and meet monthly. This group will deal with all management issues.
The qualitative researcher will report to LFC. The data manager will report to the trial manager who will report to KS. All investigators will be accountable to the SOC. (see Appendix 2).

Recruiting Centres

The York Trials Unit (University of York) will coordinate the recruitment of participants to the CLASS trial. The University of Leeds will coordinate the recruitment of CLASS trial participants into the qualitative aspects of the study.

Team Expertise and Responsibilities

We are a multidisciplinary team with an appropriate mix of skills, expertise and experience. The team consists of expertise in public health (KS), health promotion (AA, LFC), tobacco control (AA, PH, HT) and educational research (CT, HA). We are supported by York Trials Unit with expertise in trial methodology, particularly methodology of cluster trials (DT), epidemiology (JA) statistics (DT, MK), trial management (HA, HET) and health economics (SP). We are also supported by senior public health (PJ, AF, IC) and tobacco control (AF, PH) regional leads.
KS is a public health physician with an interest in tobacco control and broad research experience. As the project leader, he will coordinate different components of the study. LFC is an experienced qualitative researcher with expertise in health promotion. As the senior research fellow, she will lead the qualitative study. AA is a senior academic in health promotion with expertise and interest in preventing tobacco use in young people. As the senior specialist advisor, she will chair the Study Operational Committee and give advice on the qualitative components of the study. DT is the director of the YTU at York University he will provide methodological support in sampling, assessment tools and analysis of the results. CT is an educational researcher. She has been PI on four large pragmatic randomised trials in the field of education. She will be the senior educational advisor and is going to bring expertise of running trials in education. MK is the statistician in the team and will provide statistical support in sampling and the analysis of the results. HA is experienced in

coordinating RCTs in health and education. She has the experience of recruiting and working in schools. She will be the trial manager/trial coordinator along with HET. JA is an epidemiologist with an interest and expertise in mixed methods. SP is a health economist and will undertake the economics analysis of the study. This will involve costing the programmes using local cost data, combining cost and outcome data to perform a cost-effectiveness analysis and projections to estimate future health and economic gains. PH is the regional tobacco control lead and with HT, developed the SFH Scheme. PH has extensive managerial and academic expertise in tobacco control and will support the implementation of SFH across the region. AF is the regional lead director of public health for tobacco control. AF will help in securing wider support for this project. HT is a senior tobacco control manager. She will supervise the coordination of SFH activities in each locality. PJ is the regional director of public health for Yorkshire and Humber. IC is the director of public health at NHS Leeds. PJ and IC will provide expert input at various stages.

Dissemination and Publication Policy

We will conduct a stake-holding mapping exercise in order to identify all related stake-holders, suggest appropriate communication methods and propose timelines for communication.

We will publish papers relating to this trial that will include (as a minimum) the results of the trial and cost effectiveness comparisons and the results of the qualitative analysis. A publication policy will be produced and agreed by all Committees.

The first publication of trial results will follow the first follow up at which the main outcome will be collected.

We will produce a short summary of the results that can be distributed to all trial participants, including primary and secondary schools, as well as other relevant groups. NHS collaborators will ensure wide disseminations of the findings within policy forums. Finally, we will aim to ensure coverage of our findings in the wider media by issuing a press release. This will serve to bring public attention to our findings.

We may provide participating schools with annoymised aggregate data, for example the proportion of children in their school who are exposed to second-hand smoke, or how they compare with other schools, for example on a bar chart on which only their school is identified. Individually children or families would not be identifiable. This type of data would not be provided to schools until after all participating children had moved on to secondary school, as the impact of providing the data may constitute an intervention in itself and may result in changed behaviour within the school.

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Appendix 1: Benefits of a Smoke Free Home

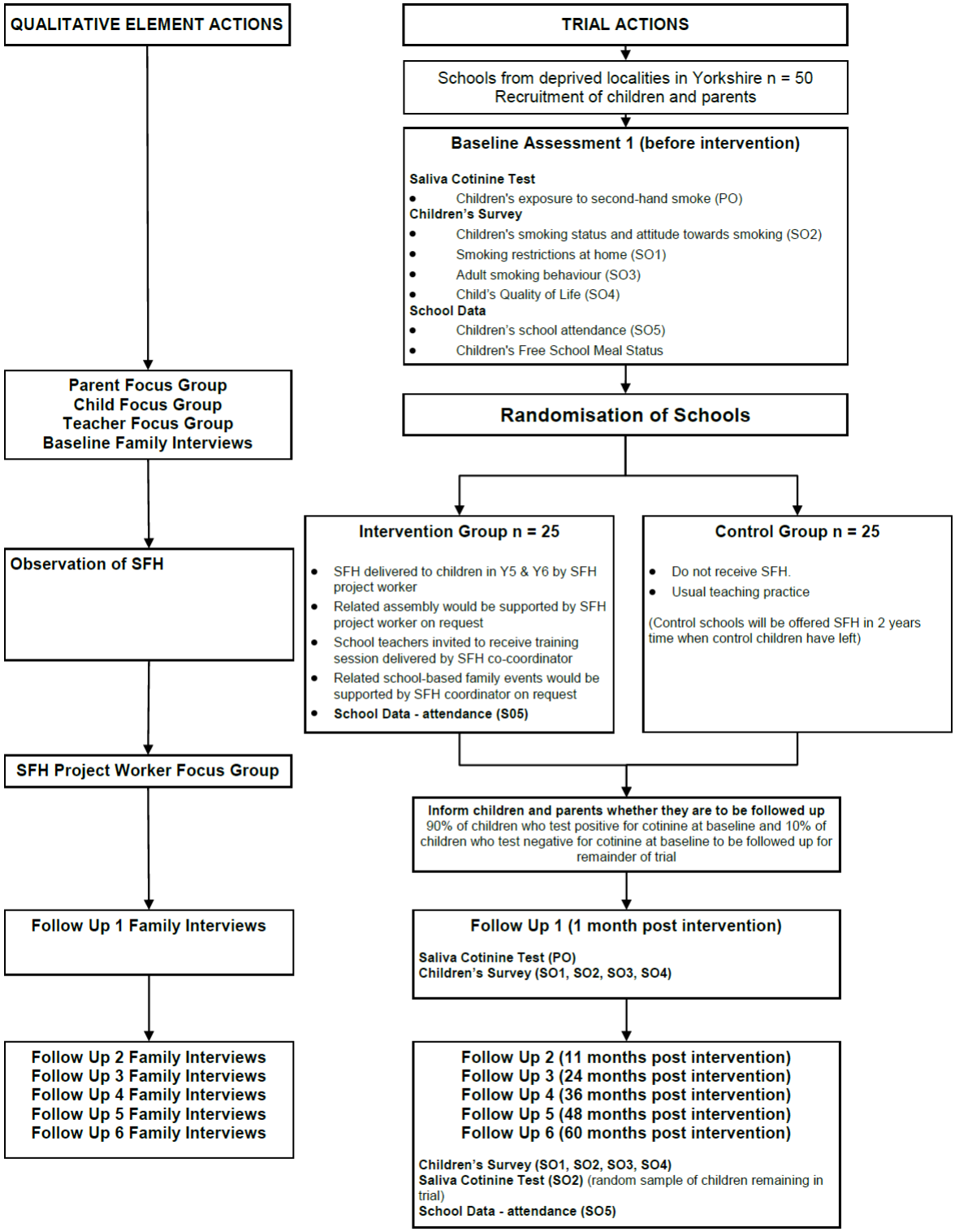
Potential benefits of a Smoke Free Home

- Greater increases in quitting
- Increases likelihood of quit attempts
- Prolongs time to relapse
- Reduces tobacco consumption
- Decreases uptake of smoking by young people
- Provides an unequivocal message that smoking is socially unacceptable
- Decreases likelihood of children becoming tolerant to tobacco smoke, i.e. maintains sensitivity to the noxious deterrence of the first cigarette.
- Reduces exposure to second-hand smoke and consequent health benefits

Appendix 2: Meetings

Meetings	SSC (Study Steering Committee)	SOC (Study Operational Committee)	SWG (Study Working Group)	Trial progress meeting via telephone
Participants	Linda Bauld (Chair) Paul Aveyard Rob Coe Teacher NIHR observer KS HA *Other SOC members as required*	All Collaborators	University Investigators	KS (Project leader) HA (trial manager) LFC (senior research fellow - as required)
Purpose	Governance	Guide and steer research	Project management	Update on trial progress
Timing	Every six months in year 1, 2 & 6 and every year in years 3, 4 & 5 **timings to be confirmed when group meets*	Every second month in year 1, 2 & 6 and every quarter in year 3, 4 & 5 **timings to be confirmed when group meets*	Every month	As required

Appendix 3: Trial Design



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