**AN EXPLORATORY RANDOMISED CONTROLLED TRIAL OF AN INTERVENTION TO REDUCE CHILDREN'S EXPOSURE TO SECONDHAND SMOKE IN THE HOME**

**Version 2.0**
**19/10/2015**

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| **Short title:** | RCT of an intervention to reduce children's exposure to SHS at home |
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**SYNOPSIS**

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| Title | An exploratory randomised controlled trial of an intervention to reduce children's exposure to second-hand smoke (SHS) in the home |
| Short title | RCT of an intervention to reduce children's exposure to SHS at home |
| Chief Investigator | Dr Elena Ratschen |
| Objectives | • To deliver an intervention to households in Nottingham where parents/carers of at least one child under five years smoke inside<br>• To monitor, evaluate and provide feedback on any changes in smoking behaviour in the home as a result of the intervention |

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| | • To test the effectiveness of the smoke-free homes (SFH) intervention<br>• To test the cost-effectiveness of the SFH intervention<br>• To assess the feasibility of a potential larger scale effectiveness trial by providing key trial design parameters including: randomisation, recruitment, attrition, data collection and feedback methods, outcome measures, and initial estimates of size of effect. |
| Trial Configuration | Parallel group exploratory randomised controlled trial. |
| Setting | The intervention will be delivered in the homes of smoking parents/carers living in Nottingham, UK. |
| Sample size estimate | <u>RCT</u><br>The power calculation is based on the primary outcome of change in average home air quality ($PM_{2.5}$) between baseline and the end of the study (12 weeks), which will be compared between treatment groups (intervention vs. usual care). We have used preliminary data from the REFRESH study (1), using average $PM_{2.5}$ at baseline and week 4, to inform our power calculation. Average $PM_{2.5}$ was skewed and was log transformed (log 10) for analysis. Using log transformed values, the standard deviation for change over time in the REFRESH study was 0.419 (the maximum of that for the intervention and usual care groups). We have powered the study to detect a 33% reduction in average $PM_{2.5}$ in the intervention compared to the usual care group (similar but slightly greater than that reported for the REFESH study – we would expect our effect to be greater than this as our intervention is more intensive), that is a difference in log10 transformed values of -0.187. With 100 families per treatment group, we will be able to detect an effect of this size with 88% power assuming alpha of 0.05.<br><br><u>Evaluative qualitative telephone interviews</u><br>This is an evaluative qualitative component in which a sufficient number of intervention arm participants will be interviewed to allow saturation of key themes. The numbers will however remain flexible to ensure that we collect sufficiently rich data to effectively evaluate the SFH intervention. |
| Number of participants | <u>RCT</u><br>100 smoking families in each treatment group, 200 in total.<br><br><u>Evaluative qualitative telephone interviews</u><br>Up to 20 interviews with successful and up to 20 interviews with unsuccessful intervention arm participants. |
| Eligibility criteria | Inclusion<br>• Caregivers who are smokers and who report smoking in their home<br>• Caregivers who have at least one child under the age of five years living with them<br>• Other smoking adult household members who cohabit with a caregiver who consents to participate and admits to smoking inside the home<br>• Caregivers who consent to their children having saliva samples taken at three time points during the intervention period |

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| | • Caregivers who consent to having the air quality of their home measured at three time points during the intervention period<br>• All caregivers/other adult participants will be over the age of 18 years (there is no upper age limit)<br>• All caregivers/other adult participants will have good spoken English<br><br>Exclusion<br>• Caregivers who live in refuges, sheltered or supported housing<br>• Caregivers who are currently signed up to the local stop smoking service<br>• Caregivers who have been signed up to the local smoke-free homes project within the last three months<br>• Caregivers who are planning to move residence during the intervention period<br>• Women who are pregnant, planning a pregnancy or breast feeding during the intervention period<br>• Caregivers who are contraindicated for the prescription of nicotine replacement therapy (NRT) |
| Description of interventions | <u>Usual care treatment group</u><br>Following consent and randomisation into the usual care treatment arm, caregivers will be signed up to the local Nottingham smoke-free homes ((NL SFH) run by New Leaf Stop Smoking Service) scheme. They will receive a resource pack which contains information on the harms of exposure to SHS, tips and practical support on how to make their home smoke-free and other items such as stickers, door hangers and tent cards to display in their home. Further support with cessation or avoidance of exposure of children will be provided in response to requests in accordance with current usual care protocols. At the end of the study, all smokers in usual care treatment group will be offered a further brief intervention to promote a smoke-free home, supported by 1 month's supply of free NRT and will receive graphical home air quality feedback.<br>**In the event that NL SSS discontinues provision of the scheme, the programme and associated materials will be delivered by the trial smoke-free homes advisors.**<br><br><u>Intervention treatment group</u><br>Following informed consent and randomisation to the intervention treatment arm, caregivers will receive a multicomponent intervention involving five face to face touch points (in the caregivers home) over a 12 week period (baseline, 24-48 hours after baseline, 3, 7 and 12 weeks) to help support them to make their homes completely smoke-free. The intervention consists of three components: (1) behavioural support from a specialist smoke-free homes advisor, (2) nicotine replacement therapy (NRT) dispensed for 12 weeks for temporary abstinence or for help to cut down the number of cigarettes smoked inside the home, and (3) impact feedback on the air quality ($PM_{2.5}$) of the main living area in their home on three separate occasions (baseline, 7 and 12 weeks). A purposive sample of intervention arm participants will be |

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| | contacted at the end of the intervention period and invited to participate in an evaluative telephone interview. |
| Duration of study | Planned start date: 1st October 2012. End date: 28th February 2015. Each caregiver will be enrolled for a maximum period of 12 weeks in the usual care arm and for a maximum period of 16 weeks in the intervention arm. The baseline and 12 week appointments will last no longer than two hours. The three and seven week appointments will last no longer than one hour. The proactive phone calls between the face to face appointments will last no longer than 30 minutes each. The qualitative telephone interviews (which will take place within 4 weeks of the 12 week appointment in the intervention arm group only) should take no longer than 30 minutes. |
| Randomisation and blinding | Participants will be randomised to one of the two treatment arms based on a computer generated pseudo-random code using random permuted blocks of randomly varying size, created by the Nottingham Clinical Trials Unit (CTU) in accordance with their SOP and held on a secure server. Access to the sequence will be confined to the CTU Data Manager. Allocation to treatment arms will be in the ratio 1:1 and investigators will access the treatment allocation for each subject by means of a remote, internet-based randomisation system developed and maintained by the Nottingham CTU. STATA will be used to generate the treatment allocations list using the RALLOC function.<br>As this is an exploratory randomised controlled trial there will be no blinding of treatment groups of either the participants or the research staff. |
| Outcome measures | Primary outcome<br>• The primary outcome will be the change in average home air quality ($PM_{2.5}$) between baseline and the end of the study (12 weeks), which will be compared between treatment groups (intervention vs. usual care).<br><br>Secondary outcomes<br>• Changes in home air quality including 24h average concentration of PM2.5, the peak concentration of PM2.5, the percentage of time when household PM2.5 concentrations exceeded a health-based threshold of 25 mg/m3 between baseline, week 7 and week 12 between and within treatment groups<br>• Changes in salivary cotinine levels from the index child between baseline and week 12, between baseline, week 7 and week 12, between and within treatment groups<br>• Changes in self-reported child SHS exposure in the home, home smoking rules, overall cigarette consumption, mental health, SHS risk knowledge, and motivation to quit between treatment groups<br>• The number of quit attempts and referrals to New Leaf cessation services overall and between treatment groups<br>• The number of caregivers who are quit at 12 weeks between groups<br>• We will assess the use of any stop smoking medications including NRT |
| Statistical methods | <u>RCT</u><br>In our primary analysis, we will compare the change in average PM2.5 between baseline and the end of the study between intervention and usual care groups, |

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| | using multiple linear regression. We will also compare change in maximum PM2.5 and the percentage of time during 24 hour measurement period that is spent greater than 25 μg/$m^3$ (WHO reported safe level for 24 hours of exposure) using similar methods. In all cases, PM2.5 measurements will be log transformed if appropriate for analysis. Other continuous outcomes will be analysed similarly and binary and rates outcomes using logistic and Poisson regression respectively. Mixed models will be used for analysis of repeated measurements, and multiple imputation will be used to deal with missing data, including baseline covariates and outcome data at intermediate time points in the imputation model.<br><br><u>Evaluative qualitative telephone interviews</u><br>The transcripts from each interview will be systematically analysed to identify emergent main and sub themes using the framework method. Analysis will be facilitated by the use of NVivo software. |

**ABBREVIATIONS**

| | |
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| CC | Children's Centre |
| CI | Chief Investigator overall |
| CV | Curriculum Vitae |
| EOT | End of Trial |
| GCP | Good Clinical Practice |
| HCPs | Health Care Professionals |
| HV | Health Visitor |
| ICF | Informed Consent Form |
| NHS | National Health Service |
| NL | New Leaf |
| NRT | Nicotine Replacement Therapy |
| PCT | Primary Care Trust |
| PI | Principal Investigator |
| PIS | Participant Information Sheet |
| $PM_{2.5}$ | Particular matter <2.5µm in diameter |
| REC | Research Ethics Committee |
| R&D | Research and Development Department |
| SFH | Smoke-Free Home |
| SFHA | Smoke-Free Homes Advisor |
| SHS | Secondhand Smoke |
| TSC | Trial Steering Committee |

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**TRIAL / STUDY BACKGROUND INFORMATION AND RATIONALE**

Globally, 40% of children are regularly exposed to second hand smoke (SHS). In the UK, around two million children are regularly exposed to SHS and close to half of all children live in households with at least one smoker. Exposure to SHS has been causally linked with a number of childhood morbidities including upper and lower respiratory tract infections, middle ear infections, sudden infant death syndrome, asthma and wheeze symptoms and bacterial meningitis (2-4). A recent report by the Royal College of Physicians (4) estimates that childhood cases of disease, related specifically to SHS exposure generates an additional 300 000 UK general practice consultations and 9500 hospital admissions each year.

Smoking by caregivers (parents and other carers such as grandparents) and whether smoking is allowed in the home are the two main determinants of a child's level of exposure to SHS (5, 6). The home is the primary source of SHS exposure in children (7, 8) and although exposure in England has declined markedly over the previous decade (6), 63% of children who live with one parent who smokes and 79% of children who live with both parents who smoke, are still regularly exposed to SHS in the home (5). Exposure is highest for the most deprived children because their caregivers are more likely to smoke and smoke more heavily (6, 9).

Children's exposure to SHS is therefore an on-going and significant public health burden. However, any measure to reduce or prevent smoking in the home has social and political implications, in that it is difficult to implement, monitor, and evaluate behaviour change within private residential settings (10), as well as being particularly difficult to enforce. The most reliable way to reduce SHS exposure in children would be to encourage caregivers to quit smoking altogether. However, for those caregivers who cannot or will not quit, the next best option is to promote homes that are completely smoke-free. Nevertheless, there is evidence to suggest that some caregivers, particularly those who are disadvantaged, may face significant barriers when trying to implement and maintain a smoke-free home (SFH) for their children, given the substantial behaviour change that may be required (11-15). For some caregivers, in particular women, the ability to initiate and maintain a smoke-free environment for their children competes with their other caring and life responsibilities, which is further restricted by the physical environment in which they live (14, 15).

In a recent systematic review of 36 intervention studies for reducing SHS exposure in children, Priest el al. (16) concluded that, at present, there is insufficient evidence to recommend one particular strategy to reduce the prevalence of childhood SHS exposure and that in general, few intervention studies have reported objectively validated reductions in childhood SHS exposure. There is clearly a need for innovative intervention strategies that help to reduce the barriers to initiating and maintaining a smoke-free home and ultimately help to reduce the impact of childhood morbidity associated with caregiver smoking. The recent advent of temporary abstinence and cutting down to quit licences for several nicotine replacement therapies (NRT) offers a novel opportunity for caregivers to use NRT for temporary abstinence or cutting down as a support mechanism whilst trying to make their homes smoke-free.

The current study builds on three previous qualitative interview studies (REC references: A/5/2009 & 10/H0403/18) and one, two-phase feasibility trial (REC reference: E 03 2011) conducted by the applicants. The qualitative studies have explored the views of 36 smoking caregivers and 29 healthcare professionals (HCPs) as to what families and HCPs can do to help caregivers to initiate and maintain a smoke-free home. The findings from the qualitative studies indicated that a four component intervention may be appropriate to help families to initiate and maintain a smoke-free home. The four components include: (a) smoke-free homes support from an experienced smoke-free homes advisor, (b) education and information resources, (c) nicotine replacement therapy for temporary abstinence or cutting down smoking in the home and (d) cotinine biochemical feedback on the youngest child (under five years of age) living within the household.

This four component intervention model was tested in the first phase of the feasibility study with six disadvantaged families in Nottingham with the primary outcome being change in salivary cotinine of the index child between baseline and the end of the intervention period (12 weeks). The intervention showed significant promise, although some revision of the protocol was required prior to the initiation of the second wave including: providing more intensive support at the start of the intervention period, incorporating the educational information provision into the behavioural support component, and introducing a further measure of home air quality ($PM_{2.5}$) as salivary cotinine measures were proving to be very variable given that these children tend to spend significant periods of time away from the index household, where the caregiver has little, if any, control over the child's exposure to SHS. A recently published study (1) has shown that providing personalised feedback on air quality within the home can lead to changes in home smoking behaviour and thus potentially reduce the risk of harm to children living in those households. Measuring PM2.5, or the amount of airborne particles less than 2.5µm in size in the air has been shown to be a reliable method for estimating SHS exposure, as cigarette smoke is the chief source of these particles when environmental levels of PM2.5 are low (17, 18). We therefore decided to add the air quality monitoring to the protocol for the second wave of the feasibility trial and for the current study.

**TRIAL / STUDY OBJECTIVES AND PURPOSE**

**PURPOSE**
Overall, this study aims to test the effectiveness and cost-effectiveness of a multi-component intervention which helps caregivers to protect their children from second hand smoke exposure in the home

**PRIMARY OBJECTIVE**
To test the effectiveness and cost-effectiveness of a multi-component intervention which supports caregivers to protect their children from second hand smoke exposure in the home.

**SECONDARY OBJECTIVE**
To assess the feasibility of a potential larger scale effectiveness trial by providing key trial design parameters including: randomisation, recruitment, attrition, data collection and feedback methods, outcome measures and initial estimates of size of effect.

**TRIAL / STUDY DESIGN**

**TRIAL / STUDY CONFIGURATION**
Parallel group exploratory randomised controlled trial.

**Primary endpoint**
The primary outcome of this study and the study end point will be a detailed description of the key components of an intervention and its delivery that appears to be acceptable to as many families as possible and an initial estimate of its effectiveness and cost-effectiveness.

**RANDOMIZATION AND BLINDING**
Participants will be randomised to one of the two treatment arms based on a computer generated pseudo-random code using random permuted blocks of randomly varying size, created by the Nottingham Clinical Trials Unit (CTU) in accordance with their SOP and held on a secure server. Access to the sequence will be confined to the CTU Data Manager. Allocation to treatment arms will be in the ratio 1:1 and investigators will access the treatment allocation for each subject by means of a remote, internet-based randomisation system developed and maintained by the Nottingham CTU. STATA will be used generate the treatment allocations list using the RALLOC function.

Members of the research team (Rebecca Thorley, Juliette Cook and Alexandra Larwood) or one of the smoke-free homes advisors (Liz Clarke, Jacqueline Purdy and Elizabeth Aspell) will be involved in the recruitment of the families to the study, with only members of the research team obtaining written informed consent. Once consent has been obtained, a unique identification number will be allocated to the participant and the researcher will then contact the randomisation database (online or via telephone) and will establish which treatment group the participant has been allocated to, based on their identification number.

**Maintenance of randomisation codes and procedures for breaking code**
The sequence of treatment allocations will be concealed until interventions have all been assigned and recruitment, data collection, and laboratory analyses are complete.

**TRIAL MANAGEMENT**
The Chief Investigator has overall responsibility for the study and shall oversee all study management. The data custodian will be the Chief Investigator. The study will be co-ordinated and managed on a day to day basis by Rebecca Thorley.

**DURATION OF THE TRIAL / STUDY AND PARTICIPANT INVOLVEMENT**
Planned start date: 1st October 2012. End date: 28th February 2015. Each caregiver will be enrolled for a maximum period of 12 weeks in the usual care arm and for a maximum period of 16 weeks in the intervention arm. The baseline and 12 week appointments will last no longer than two hours. The three and seven week appointments will last no longer than one hour. The proactive phone calls between the face to face appointments will last no longer than 30 minutes each. The qualitative

telephone interviews (which will take place within 4 weeks of the 12 week appointment in the intervention arm group only) should take no longer than 30 minutes.

**End of the Trial**

The end of the study will be the 12 week appointment of the final participant enrolled into the trial – (if the final participant is in the usual care arm or in the intervention arm and is not selected for participation in a telephone evaluation interview). If the final participant is in the intervention arm and is selected for a telephone evaluation interview then the end of the telephone interview will form the end of the trial.

## SELECTION AND WITHDRAWAL OF PARTICIPANTS

**Recruitment**

This trial will be based in primary care. Given our previous experience of finding it very difficult to recruit caregivers into the qualitative and feasibility phases of this study, we will endeavour to recruit families through as many different pathways as possible to ensure that we enrol and randomise sufficient numbers of families to meet the aims and objectives of the trial. Initially, we will start recruitment in Nottingham City and will move into Nottingham County if we are unable to recruit sufficient numbers.

The following recruitment pathways will be used and supported by the local Primary Care Research Network (East Midlands and South Yorkshire – Trent CLRN) where appropriate:

1. We will attempt to recruit from purposively sampled (based on ward smoking prevalence and the number of children under the age of five years in that health visitor (HV) team/clinic caseload) health visitor clinics/teams across Nottingham City and/or County via three different ways. Initially, we will visit each HV clinic/team and explain the purpose of the study, what is expected of the families enrolled and the inclusion/exclusion criteria. The initial approach to families will always come from a member of the caregivers usual care team, in this instance their health visitor team.
    a. Participants will be identified from purposively sampled health visitor caseloads across City and/or County. Families who are accessing services and who are not flagged as requiring high support will be contacted by letter and invited to participate in the study. Invitation letters will be sent out from the clinic on behalf of the HV and will be supported logistically by the research team (the research team will pack the letters at the University of Nottingham and provide the required number to the HV clinics, they will not have access to identifiable data). Letters will go to all families identified in the search as currently there are very poor HV data around smoking status to allow us to purposively sample smokers.
    b. In addition, having explained the study to all HVs, we will ask them to proactively identify and refer families who they feel may benefit from being enrolled in the study. HVs will ask the families if they are happy for them to pass on their contact details to the research team directly, or if they would prefer to contact the research team themselves.
    c. At the HV team meetings, we will ask HVs if we can attend their drop in and appointment based clinics across the City and/or County. We will then ask the HVs to give each caregiver an information sheet about the study during their routine

appointment and explain that a member of the research team will be present in the waiting room, should they wish to learn more about the study or to enrol.

2. We will attempt to recruit from each of the Sure Start Children's Centres (CC) across Nottingham City and/or County via two different ways. Initially, we will visit each CC and explain the purpose of the study, what is expected of the families enrolled and the inclusion/exclusion criteria. The initial approach to families will always come from a member of the caregivers usual care team, in this instance their family support workers.
    a. We will ask CC staff to proactively identify and refer families who they feel may benefit from being enrolled in the study. CC staff will ask the families if they are happy for them to pass on their contact details to the research team directly, or if they would prefer to contact the research team themselves.
    b. At the CC team meetings, we will ask CC staff if we can attend their sessions across the City and/or County, including all those sessions run in the community and at community events. We will then ask the CCs to give each caregiver an information sheet about the study when they sign into the session and told that a member of the research team will be present in the waiting room, should they wish to learn more about the study or to enrol.
3. Posters will then be distributed to each HV Clinic and CC and will be placed in prominent positions to attract attention. The posters will state that interested caregivers can contact a member of the HV or CC staff or the research team (via phone or text) for further information about the study.
4. The Children's services team (managed by Michelle Battlemuch, who has given permission for us to work with HVs and other related health care professionals within the City) in Nottingham City also run a number of outreach programmes which are mainly delivered in the caregivers own home, such as peer supported breast feeding for under and over 25 year old mothers. The health care professionals (HCPs) who lead these outreach services will be contacted by the research team and will be asked to pass on an information sheet to all families they think that could benefit from participating in the study. The initial approach will therefore come from the HCPs and interested families will be asked to contact the research team directly (via phone or text), or if they give permission for the HCP to pass their contact details on to the research team directly.
5. We will also recruit families via the local Nottingham smoke-free homes ((NL SFH) project run by New Leaf Stop Smoking Service. The scheme encourages parents/carers/adults to introduce a ban or restriction on smoking within their home and provides them with the resources to help. It offers parents/carers/adults a number of benefits: to act as positive role models by not smoking in front of their children, to help protect the health of themselves and visitors to the home, to keep the home fresh and clean and to help smokers stop smoking. This is achieved by making a SFH promise. A promise can be made on two levels: Gold or Silver.
        i. Silver Promise "I/we promise to allow smoking only in one well ventilated room and never smoke in the presence of the children"
        ii. Gold Promise "I/we promise to make the house totally smoke-free at all times"

    Three months after registering for the NL SFH scheme, each participant is contacted by a member of the NL SFH team for follow up and asked whether they have stuck to their promise. For those participants who have been unable to initiate and maintain a gold promise, they will be told about the current trial and it will be explained that the trial will offer further support. The NL SFH staff member will then ask the participant

if their contact details can be passed on to the research team, for those who consent NL will share details and the research team will contact the family directly. **In the event that NL SSS discontinues provision of the scheme, the programme and associated materials will be delivered by the trial smoke-free homes advisors, who will have NHS honorary contracts.**

6. We will also use snowball sampling techniques (this sampling technique is often used in hidden populations which are difficult for researchers to access) where we will ask families already enrolled into the study if any of their friends/family/acquaintances would like to take part. For family members who live in the same household as the caregiver enrolled, we will ask the caregiver to pass on an invitation letter and participant information sheet. For other family and friends who do not live in the same household, we will then give the enrolled family the contact details of the research team and ask them to pass them on to the friend and state that they can contact the research team directly (via phone or text) if they are interested.

Evaluative qualitative telephone interviews

Of the participants who are randomised to the intervention treatment arm we will purposively sample those who successfully make their homes smoke-free (where they have a change in air quality PM2.5 of greater than 33% between baseline and 12 weeks) and those who fail to make their home smoke-free (where they have a change in air quality PM2.5 of less than 33% between baseline and 12 weeks) for an evaluative telephone interview. We will attempt to recruit successes and failures from a range of different locations within Nottingham City (following the area specific targeted family recruitment strategy discussed above) and potentially Nottingham County up to a maximum of 20 in each group or until theme saturation is reached.

The investigator or their nominee, e.g. from the research team or a member of the participant's usual care team, will inform the participant of all aspects pertaining to participation in the study. It will be explained to the potential participant that entry into the trial is entirely voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

**Eligibility criteria**

**Inclusion criteria**

- Caregivers who are smokers and who report smoking in their home
- Caregivers who have at least one child under the age of five years living with them
- Other smoking adult household members who cohabit with a caregiver who consents to participate and admits to smoking inside the home
- Caregivers who consent to their children having saliva samples taken at three time points during the intervention period
- Caregivers who consent to having the air quality of their home measured at three time points during the intervention period
- All caregivers/other adult participants will be over the age of 18 years (there is no upper age limit)

- All participants will have good spoken English

**Exclusion criteria**

- Caregivers who live in refuges, sheltered or supported housing
- Caregivers who are currently signed up to the local stop smoking service
- Caregivers who have been signed up to the local smoke-free homes project within the last three months
- Caregivers who are planning to move residence during the intervention period
- Women who are pregnant, planning a pregnancy or breast feeding during the intervention period
- Caregivers who are contraindicated for the prescription of nicotine replacement therapy

**Expected duration of participant participation**

Each caregiver will be enrolled for a maximum period of 12 weeks in the usual care arm and for a maximum period of 16 weeks in the intervention arm.

**Removal of participants from therapy or assessments**

Participants may be withdrawn from the trial either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care or access to services. Participants will be made aware (via the information sheet and consent form) that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

**Informed consent**

All caregivers and other adult smokers will provide written informed consent. The primary caregiver (parent or legal guardian) will provide consent for their child to participate. If the child is not willing to take part by providing a small saliva sample then their caregivers will be withdrawn from the study. Children will not be provided with participant information sheets. The parents/carers of the index child will be provided with detailed information about the study and will provide written informed consent on behalf of the child. The children in the current study will all be under the age of five years and so it is not appropriate to provide them with written or pictorial information. A verbal explanation will be provided by the researchers and where necessary and visual demonstration will be made by a member of the research team to make it clear how the sample should be collected.

The Informed Consent Form will be signed and dated by the participant before they enter the trial. The Investigator will explain the details of the trial and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

Informed consent will be collected from each participant before they undergo any interventions related to the study. One copy of this will be kept by the participant and one will be kept by the Investigator.

Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the trial, continuing consent will be obtained using an amended Consent form which will be signed by the participant.

**TRIAL / STUDY TREATMENT AND REGIMEN**

**Usual care treatment arm (see Figure 1)**

Following consent and randomisation into the usual care treatment arm, caregivers will be signed up to the local Nottingham smoke-free homes ((NL SFH) run by New Leaf Stop Smoking Service) scheme. The scheme encourages parents/carers/adults to introduce a ban or restriction on smoking within their home and provides them with the resources to help. It offers parents/carers/adults a number of benefits: to act as positive role models by not smoking in front of their children, to help protect the health of themselves and visitors to the home, to keep the home fresh and clean and to help smokers stop smoking. This is achieved by making a SFH promise. A promise can be made on two levels: Gold or Silver.

1. Silver Promise "I/we promise to allow smoking only in one well ventilated room and never smoke in the presence of the children"
2. Gold Promise "I/we promise to make the house totally smoke-free at all times"

Members of the research team, including the smoke-free homes advisors will provide the caregiver with a Smoke Free Homes promise postcard and ask them to complete it during the baseline appointment. The card will then be posted by the research team to the SFH team based at NL. The usual care participants will then be contacted by the NL Smoke Free Homes team who will discuss the project and the levels of promise available, help the usual care participant to make their promise and send out a free 'Nottinhere' support pack to help them achieve their promise. This pack contains a certificate, door hangers, stickers, a fridge magnet, top tips for going smoke-free, information on what's in a bit of smoke and further information to keep the family and home safe. Further support with cessation or avoidance of exposure of children will be provided in response to requests in accordance with current usual care protocols**. In the event that NL SSS discontinues provision of the scheme, the programme and associated materials will be delivered by the trial smoke-free homes advisors, who will have NHS honorary contracts.**

At the end of the study, all smokers in the usual care treatment group will be offered a further brief intervention to promote a smoke-free home, supported by 1 month's supply of free NRT, basic behavioural support and will receive graphical home air quality feedback.

**Intervention treatment arm (see Figure 2)**

**Intervention components**

The aim of this intervention is to help families (including both the primary caregiver and other smoking adults who live in the same household) to reduce their children's exposure to second hand smoke by supporting them to make their homes completely smoke-free. Caregivers and other adult smokers (who give consent to participate) who live in the same household will not be asked to quit smoking (although this is a positive secondary outcome if caregivers do make a successful quit attempt), but will be asked to make their homes completely smoke-free and will be offered support via the following three component intervention:

**Behavioural support**

Face to face behavioural support to help caregivers to stop smoking in the home will be offered on four occasions (24-48hrs, three, seven and 12 weeks) for up to an hour in the home by an experienced and appropriately trained specialist smoke-free homes advisor (SFHA). The SFHA will follow the Nottingham Stop Smoking Service, New Leaf, standard operating procedures and smoke-free homes protocols for helping families to stop smoking in the home (not the SOPs for cessation) and will adhere to policy relating to safeguarding and lone working. In addition to the four home based support sessions, caregivers will be informed that they will receive a minimum of two proactive phone calls (one to two and five weeks) from the SFHA and that they can contact the SFHA via a reactive phone/SMS service for ad hoc telephone/SMS support during the intervention period (office hours only). The content of each face to face touch point will be tailored to the needs of the particular caregiver and their household circumstances and aims to support them to make their homes completely smoke-free and maintain this, whilst not asking them to quit smoking. In addition, each caregiver will be provided with a SHS/SFH factsheet which provides them with hints and tips to support them between visits.

**Nicotine replacement therapy**

All participants will be offered free nicotine replacement therapy (NRT). For those who accept the offer of NRT, products that have the appropriate licences for temporary abstinence and/or cutting down will be dispensed by the SFHA to the participant in their own home (following New Leaf General Sales License (GSL) protocols) for one of two different uses: (1) temporary abstinence from smoking whilst in the home or (2) cutting down the number of cigarettes smoked in the home. At the 24-48 hour appointment, each participant will be given a sample bag containing a small number of each of the NRT products that are available to them allowing them to make an informed choice about which product may work best for them in the longer term. Mixed-therapy (a combination of two different NRT products such as gum and the inhalator) will be offered to those who request it. During the 1-2 week proactive phone call, a mutual decision will be made between the caregiver and the SFHA about which product or product is most suitable and a 1-2 week (depending on the time of the call) supply of NRT will be posted to the participant. The caregiver's use of NRT will be reviewed at each home visit and a further four to five weeks of product dispensed at the 3 and 7 week visits if appropriate. Up to a maximum of 12 weeks of free NRT will be prescribed. Caregivers will be able to contact the SFHA for help and advice around NRT between each of their home appointments and will be able to switch between NRT products if required at their next appointment.

**Air quality feedback**

At three time points during the intervention period (baseline, 7 and 12 weeks) home air quality samples ($PM_{2.5}$) will be collected for between 24 and 48 hours from the main living area of the participant's home. The air quality monitors will be set up by a member of the research team on each occasion. All that is expected of the family is that they leave it plugging in and switched on during the data collection period. Graphical feedback with information on the average and maximum PM2.5 levels in the home will be given to the caregiver on three occasions and this will be used to form part of the motivational interviewing techniques employed by the SFHA to help initiate home smoking behaviour change.

In the event of air monitor settings becoming accidently altered during data collection period (12 weeks). Data will be retrieved and recalibrated using the Track-pro software supplied with the Side-Pack AM510 air monitor. Participants will be informed of these changes in their next meeting with

the researcher, or via a letter with an invitation to discuss their results. Data that has been re-calibrated in this manner will be clearly identified in the results.

**Data collection from all participants (usual care and intervention treatment arms)**
**Biochemical data collection**
At three time points during the intervention period (baseline, 7 and 12 weeks) saliva samples will be collected from the youngest child (under the age of five years – index child) who lives (the majority of the time) in the household with the smoking caregiver. Saliva will be collected using a children's collection swab (recommended for children under the age of six years) during the home visit by a member of the research team in the presence of the caregiver (all staff will have completed appropriate safeguarding and infection control training etc.). The saliva samples will then be analysed for cotinine (the major proximate metabolite of nicotine and a biological marker of second hand smoke exposure) via a fully quantitative assay using liquid chromatography tandem mass spectrometry (ABS Laboratories). Caregivers will not receive feedback on saliva cotinine unless they specifically request it. Should they request it, it will be given at the end of the study (12 weeks) and only once all other research data have been collected.

**Data collection from study participants** (caregivers and other adult smokers within the household who consent to participate)
Quantitative data will be collected at baseline, seven and 12 week home visits via interviewer administered questionnaire. The questionnaires will be administered by a member of the research team: Rebecca Thorley, Juliette Cook and Alexandra Larwood.

**Data collection at the baseline home visit**
At baseline, the interviewer administered questionnaire (administered independently to all household members who have consented to participate) will cover topics including demographics, secondhand smoke exposure of the children living within the household, family and household dynamics, characteristics of the home, home smoking behaviour and beliefs, and general health. A saliva sample will also be collected from the youngest child (under the age of five years – index child) who lives within the household and the air quality monitor will be set up (in the usual care group this will be collected 24-48 hours after the baseline visit but with no interaction with the caregiver).

**Data collection 24-48 hour home visit (intervention group only)**
The home air quality data will be collected and then analysed in the home on a laptop and a graphical representation produced and shown to the caregiver (and any other adult smokers who have consented to participate).

**Data collection seven week home visit**
The interviewer administered questionnaire for the caregiver and other adult smokers will cover topics including: NRT use, second hand smoke exposure of the children living within the household, family and household dynamics, home smoking behaviour and beliefs, general health and access to other support services around smoking and smoke-free homes. A saliva sample will also be collected from the youngest child (under the age of five years) who lives within the household. Air quality monitoring will have occurred in the 24-48 hour period prior to the seven week appointment, and during the appointment the data will be collected, analysed and a graphical representation produced and shown to the caregiver (intervention group only).

**Data collection at 12 week home visit**
The interviewer administered questionnaire for the caregiver and other adult smokers will cover topics including: NRT use, second hand smoke exposure of the children living within the household, family and household dynamics, home smoking behaviour and beliefs, general health, children's visits to the GP or hospital and access to other support services around smoking and smoke-free homes. A saliva sample will also be collected from the youngest child (under the age of five years) who lives within the household. Air quality monitoring will have occurred in the 24-48 hour period prior to the 12 week appointment, and during the appointment the data will be collected, analysed and a graphical representation produced and shown to the caregiver (in both the intervention and usual care treatment groups). A purposive sample of intervention arm participants will be invited to take part in an audio recorded evaluative qualitative telephone interview that will cover topics such as the importance of the different components of the intervention and how the intervention might be improved.

**Compliance**
We will assess compliance to the three components of the intervention as follows; the number of completed sessions of behavioural support in the home and by phone will be recorded, the number of time points at which air quality feedback was provided will be recorded, and the number of weeks for which NRT was prescribed and use of NRT will be recorded. We will use this information to describe compliance to each component of the intervention and hence to evaluate the overall acceptability of the intervention and to adapt the intervention if appropriate for larger scale evaluation. However, this is a pragmatic trial, in which the purpose is to determine the acceptability and effectiveness of the intervention in real practice, so all participants will be included in primary intention to treat analysis, regardless of compliance.

**Criteria for terminating trial**
Not applicable.

**TRANSPORT AND STORAGE OF THE TISSUES**

Appropriately anonymised and labelled saliva samples will be stored in specifically allocated freezer space as part of the University of Nottingham BRU tissues samples database, in accordance with HTA requirements, in the Clinical Sciences Building, Nottingham City Hospital. A database for the current study has already been established (as part of the feasibility trial, see background section for further information) as part of the BRU tissue samples database.

Samples will be stored in linked anonymised format and labelled using the participant's unique trial identity code number and the visit number (1, 2 or 3) to permit accurate linkage to consent forms. All samples are stored in a swab storage tube at -20 degrees centigrade in a box clearly labelled with the study title, ethical reference numbers and contact details of the research team. The master database will be held by the BRU in a password encrypted file.

The analysis of samples will take place at an external laboratory: Advanced Bioanalytical Service Laboratories also known as ABS Laboratories Ltd. BioPark, Broadwater Road, Welwyn Garden City Hertfordshire. Samples will be transferred from the University of Nottingham to ABS laboratories in

batch shipments by courier as frequently as required. All shipments will contain a complete inventory of all samples, along with the name of the person responsible for sending the samples. Once analysis has taken place, all samples will be will be destroyed by ABS in accordance with the Human Tissue Act, 2004.

**LABORATORY ANALYSES**

Saliva samples (three from each index child in total) will be sent to ABS Laboratories for cotinine (the primary metabolite of nicotine and used to assess exposure to SHS) analysis. ABS use a fully quantitative assay using liquid chromatography tandem mass spectrometry with the assay being validated to 0.1ng/mL (19). All samples received from the study will be booked in at ABS and then stored under a unique ABS Reference No. in sealed polypropylene bags at a nominal temperature of -20 degrees C until analysis when they will be thawed for a minimum of 1 hour at room temperature and then returned to -20 degrees C. All temperatures are monitored continually. After approximately 6 weeks after all the samples have been analysed and the cotinine results reported in a particular year, the University of Nottingham will be formally requested for permission to dispose of the samples by incineration as biological waste by a registered waste disposal company. ABS Laboratories is a MHRA GLP and GCP accredited company who can provide a complete audit trail from receipt, storage to disposal of all the samples.

**STATISTICS**

**Methods**

RCT

Data capture, cleaning and analysis will be conducted using SPSS and/or STATA software. Analysis will be led by Elena Ratschen and Magdalena Opazo Breton and overseen by Professor Sarah Lewis. All analyses will be conducted on UoN computers/laptops that are regularly backed up to UoN servers.

Primary outcome

- The primary outcome will be the change in average home air quality ($PM_{2.5}$) between baseline and the end of the study (12 weeks), which will be compared between treatment groups (intervention vs. usual care).

Secondary outcomes

- Changes in home air quality including 24h average concentration of PM2.5, the peak concentration of PM2.5, the percentage of time when household PM2.5 concentrations exceeded a health-based threshold of 25 mg/m3 between baseline, week 7 and week 12 between and within treatment groups
- Changes in salivary cotinine levels from the index child between baseline and week 12, between baseline, week 7 and week 12, between and within treatment groups
- Changes in self-reported child SHS exposure in the home, home smoking rules, overall cigarette consumption, mental health, SHS risk knowledge, and motivation to quit between treatment groups
- The number of quit attempts and referrals to New Leaf cessation services overall and between treatment groups
- The number of caregivers who are quit at 12 weeks between groups
- We will assess the use of any stop smoking medications including NRT

We will describe and compare (descriptively) the baseline characteristics of the two groups. For our primary outcome, we will compare the change in average $PM_{2.5}$ between baseline and the end of the study between intervention and usual care groups, using linear regression. We will also compare change in maximum $PM_{2.5}$ and the percentage of time during 24 hour measurement period that is spent greater than 25µg/$m^3$ (WHO reported safe level for 24 hours of exposure) using similar methods. In all cases, $PM_{2.5}$ measurements will be log transformed if appropriate for analysis. Other continuous outcomes will be analysed similarly and binary and rates outcomes using logistic and Poisson regression respectively. Mixed models will be used for analysis of repeated measurements to deal with correlation of repeated measurements within individuals.

**Cost effectiveness analysis**

Cost effectiveness analysis will be carried out by a health economist, Steve Parrott at University of York. The economic analysis will project the cost savings that may result from the measured reductions in parental smoking and consequently passive smoking. Nationally published costs can be applied to the reduction in cases of disease as a result of passive smoking to estimate the potential cost savings as a result of the programme. Programme costs will also be calculated using local cost estimates to calculate the net financial impact of the programme, and whether the health care cost savings can offset programme costs to generate net financial savings. Service costs will also be used to conduct a cost-effectiveness analysis, by combining primary outcomes with the cost of provision. Uncertainty around the cost-effectiveness ratio will be explored using cost-effectiveness acceptability curves. Cost-effectiveness will be assessed using age, gender and other client specific characteristics to identify variations in the cost-effectiveness of providing programmes for different client groups.

<u>Evaluative qualitative telephone interviews</u>

Interviews will be audio recorded and then transcribed verbatim by an external specialist transcription company. Following receipt of the interview transcripts, the researchers will ensure all personal identifiers are removed and that transcripts are accurate. Data will be analysed using the framework approach. This approach will allow the research team to understand differences in views of the intervention according to those who were successful in making their home smoke-free and those who were unsuccessful. As an initial step and to aid familiarisation, data for each interview will be summarised into a framework matrix (using NVivo 10) which will provide a visual representation of the dataset. Transcripts will be read several times and will be annotated where emerging themes and sub-themes will be identified, resulting in an analytical framework of key themes and sub-themes. Themes and sub-themes will then be discussed between the research team which will allow clarification of the final framework. Data will then be charted according to each theme to synthesise the data and aid interpretation, where particular attention will be given to highlighting the similarities and differences according to successful and unsuccessful participants. Extracts from interview transcripts will be included in the charts.

**Sample size and justification**

<u>RCT</u>

The power calculation is based on the primary outcome of change in average home air quality ($PM_{2.5}$) between baseline and the end of the study (12 weeks), which will be compared between treatment groups (intervention vs. usual care). We have used preliminary data from the REFRESH study (1), using average $PM_{2.5}$ at baseline and week 4, to inform our power calculation. Average $PM_{2.5}$ was

skewed and was log transformed (log 10) for analysis. Using log transformed values, the standard deviation for change over time in the REFRESH study was 0.419 (the maximum of that for the intervention and usual care groups). We have powered the study to detect a 33% reduction in average $PM_{2.5}$ in the intervention compared to the usual care group (similar but slightly greater than that reported for the REFESH study – we would expect our effect to be greater than this as our intervention is more intensive), that is a difference in log10 transformed values of -0.187. With 100 families per treatment group, we will be able to detect an effect of this size with 88% power assuming alpha of 0.05.

Evaluative qualitative telephone interviews

The formal sample size calculations used in quantitative research are not applicable for this type of qualitative study. We will aim to interview up to 20 successful and 20 unsuccessful intervention arm participants. The numbers will however remain flexible to ensure that we collect sufficiently rich data to effectively evaluate the SFH intervention.

**Procedures for missing, unused and spurious data**

We will follow the approaches recommended by the MRC biostatistics unit (Handling missing outcome data in randomised trial – a short course 2012, White et al). Analysis will use an intention to treat approach; we will aim to collect all outcome data on all randomised individuals including those who withdraw from the intervention. However, there will inevitably be missing data from individuals who refuse consent for follow-up. In our primary analysis, we will assume that the data are missing at random (MAR) and deal with missing data by multiple imputation using chained equations in Stata, and including in the model baseline covariates and the outcome at other time points. We will then carry out sensitivity analysis to explore alternative missing not at random (MNAR) assumptions about the missing data, including using a last one carried forward approach, and by including a "sensitivity" parameter in the model which specifies the degree of departure from MAR, firstly assuming this is the same in both treatment arms, and then assuming that bias differs between randomised groups.

**Definition of populations analysed**

Since this is a pragmatic study our primary and only analysis will be of the intention to treat population, that is all randomised participants, regardless of drop outs after randomisation.

**ADVERSE EVENTS**

It is unlikely that there will be any adverse events as a result of participating in this trial and therefore no adverse event data will be collected.

**ETHICAL AND REGULATORY ASPECTS**

**ETHICS COMMITTEE AND REGULATORY APPROVALS**

The trial will not be initiated before the protocol, informed consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), and the respective National Health Service (NHS) Research & Development (R&D) department. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent

immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005.

**INFORMED CONSENT AND PARTICIPANT INFORMATION**

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant shall both sign and date the Informed Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms and the original will be retained in the Trial Master File.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future access to services, or loss of benefits to which the participant is otherwise entitled. No trial-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Informed Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for on-going participants).

**RECORDS**

Each participant will be assigned a unique study identification code (in the form of SFHXXX), allocated at the point of informed consent, for use on all trial documents and the electronic database.

Contact detail forms will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's name, date of birth and Participant Trial Number (the Trial Recruitment Log), to permit identification of all participants enrolled in the trial, in accordance with regulatory requirements and for follow-up as required. Contact detail forms shall be restricted to those personnel approved by the Chief or local Principal Investigator and recorded on the 'Trial Delegation Log.'

All paper forms shall be filled in using ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated. The Chief or local Principal Investigator shall sign a declaration ensuring accuracy of data recorded in the contact detail forms.

**Sample Labelling**

Each participant will be assigned a unique study identification code (in the form of SFHXXX) for use on the samples, consent forms and other study documents and the electronic database.

**Source documents**
Source documents shall be filed at the investigator's site and may include but are not limited to, consent forms, laboratory results and records. A contact detail form may also completely serve as its own source data. Only trial staff as listed on the Delegation Log shall have access to trial documentation other than the regulatory requirements listed below.

**Direct access to source data / documents**
The contact detail form and all source documents, including progress notes and copies of laboratory results shall made be available at all times for review by the Chief Investigator, Sponsor's designee and inspection by relevant regulatory authorities (e.g. DH, Human Tissue Authority).

**DATA PROTECTION**
All trial staff and investigators will endeavour to protect the rights of the trial's participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. The contact detail form will only collect the minimum required information for the purposes of the trial. Contact detail forms will be held securely in a locked cupboard or cabinet in a locked room. Access to the information will be limited to the trial staff and investigators and relevant regulatory authorities (see above). Computer held data including the trial database will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method). Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

**QUALITY ASSURANCE & AUDIT**
**INSURANCE AND INDEMNITY**
Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

**TRIAL CONDUCT**
Trial conduct will be subject to systems audit of the Trial Master File for inclusion of essential documents; permissions to conduct the trial; Trial Delegation Log; CVs of trial staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, correct randomisation, timeliness of visits); adverse event recording and reporting; accountability of trial materials and equipment calibration logs.

**TRIAL DATA**

Monitoring of trial data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation.

Entries on contact detail forms will be verified by inspection against the source data. A sample of contact detail forms (10% or as per the study risk assessment) will be checked on a regular basis for verification of all entries made. In addition the subsequent capture of the data on the trial database will be checked. Where corrections are required these will carry a full audit trail and justification.

Trial data and evidence of monitoring and systems audits will be made available for inspection by REC as required.

**RECORD RETENTION AND ARCHIVING**

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The Trial Master File and trial documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all trial databases and associated meta-data encryption codes.

**DISCONTINUATION OF THE TRIAL BY THE SPONSOR**

The Sponsor reserves the right to discontinue this trial at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice from the Trial Steering Committee and Data Monitoring Committee as appropriate in making this decision.

**STATEMENT OF CONFIDENTIALITY**

Individual participant medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above. Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files. Data generated as a result of this trial will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

**PUBLICATION AND DISSEMINATION POLICY**

The scope of this study includes time for the preparation and critical revision of high quality manuscripts for submission to peer reviewed journals and the dissemination of information through seminars and conferences at the national and international level. Participants will not be identified in any presentation or publication relating to these data.

**USER AND PUBLIC INVOLVEMENT**

As part of the larger National Institute for Health Research (NIHR) funded programme of research, of which this study forms one work stream, we have three lay people working with us in developing, implementing and disseminating all aspects of this research; Wayne Sherwood, a co-applicant on the NIHR grant, recent ex-smoker and member of the British Lung Foundation's Breathe Easy group and two additional smokers. The Trent Local Children's Research Network has also offered to support the work.

**STUDY FINANCES**

**Funding source**

This study is funded by a National Institute for Health Research programme grant (RP-PG-0608-10020)

**Participant stipends and payments**

Participants will receive a £50 inconvenience allowance in the form of a high street gift voucher upon successful completion of all data collection touch points. This allowance remains fixed irrespective of treatment group, the number of adults within the household who participate in the intervention, and success or failure in making their home smoke-free.

**SIGNATURE PAGES**

Signatories to Protocol:

**Chief Investigator:** Dr Elena Ratschen

Signature:_____

Date: _____

**Co- investigator**: Dr Laura Jones

Signature:_____

Date: _____

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**USUAL CARE ARM**

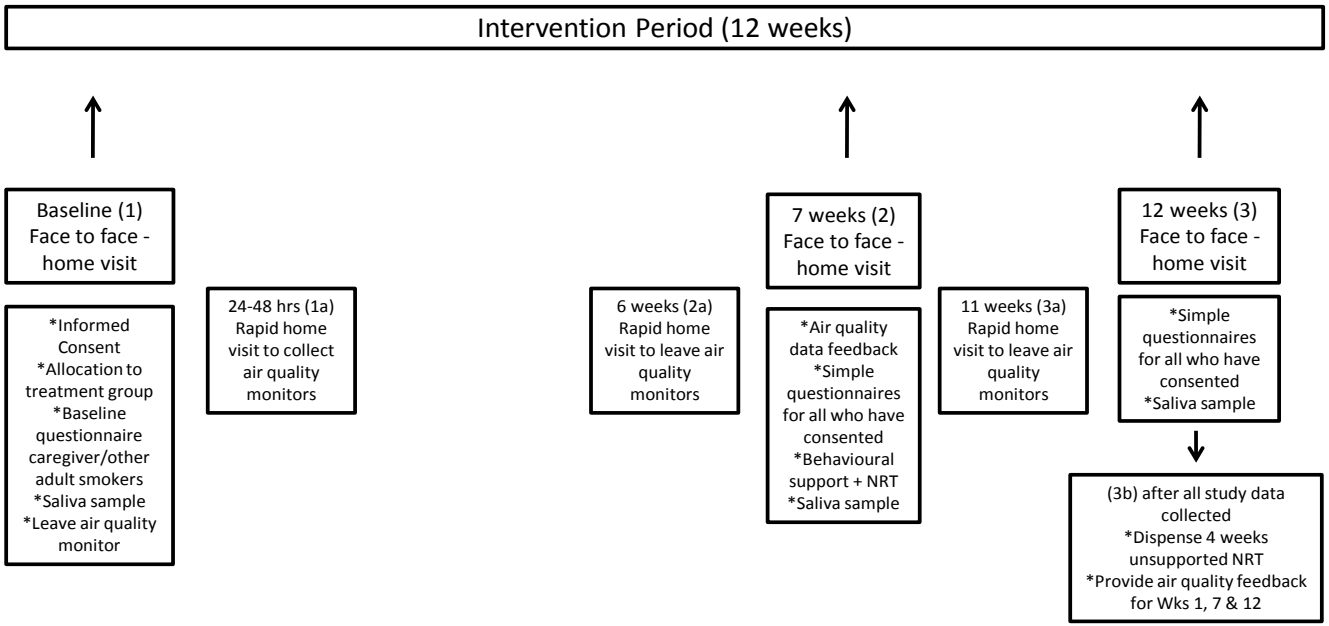

**Figure 2**