Study Protocol

A study to test the feasibility of an intervention to reduce children's exposure to second hand smoke in the home

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Background

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 [1-3]. A recent report by the Royal College of Physicians [3] 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 [6, 7]. The home is the primary source of SHS exposure in children [4, 5] 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 [7]. Exposure is highest for the most deprived children because their caregivers are more likely to smoke and smoke more heavily [6, 8].

Children's exposure to SHS is therefore an ongoing 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 [9], 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 [10-14]. 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 [13, 14].

In a recent systematic review of 36 intervention studies for reducing SHS exposure in children, Priest el al. [15] 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 two previous qualitative interview studies conducted by the applicants (REC references: A/5/2009 & 10/H0403/18) which together have explored the views of 36 smoking caregivers as to what health care professionals can do to help them to initiate and maintain a smoke-free home. The findings from these two studies indicate 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 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.

Aim

To test the feasibility and acceptability of a complex multi-component intervention to help caregivers protect their children from second hand smoke exposure in Nottingham, in preparation for a controlled efficacy trial of the intervention for which separate ethical permission will be sought.

Methods

Study design

This is a mixed methods feasibility study in which the proposed intervention will be delivered to families to assess the feasibility and acceptability of the intervention, and of the methods proposed for the subsequent efficacy trial. The study will use an iterative approach to refine the details of the components of this complex intervention and their delivery (Figure 1). The intervention will initially be delivered to eight families, and once this first intake of families have all completed baseline interventions and data collection, the intervention will be refined to improve its acceptability and adequacy if required and a further eight families will be recruited and delivered the refined intervention. After this first intake of families have completed the intervention period and have been interviewed (after 12 weeks), any further refinements to the intervention or its delivery will be made and a final intake of eight families will be recruited and delivered the intervention. We envisage that the feasibility study will involve a maximum of 24 families. Quantitative data will be collected via interviewer administered questionnaires at four time points (baseline, four weeks, eight weeks and 12 weeks). Qualitative data will be collected via one to one semi-structured interviews at two time points (weeks one to two after enrolment and at the 12 week home visit).

Recruitment

Potential participants will be identified via Children's Centres within the Nottingham City area. The staff within each of these Children's Centres will have been informed of the aims

of the current study through a presentation given by members of the research team. Posters will then be distributed to each Children's Centre and will be placed in prominent positions to attract attention. The posters will state that interested caregivers can contact a member of the Children's Centre staff or Dr Laura Jones for further information about the study. In addition, contact detail forms will be left with the posters, so that interested caregivers, who wish to be contacted directly by the research team, can complete them and return them via freepost. Staff will also promote the study as part of their routine interaction with families. Children's Centre staff and members of the research team will also advertise and promote the study at specific Children's Centre sessions such a "New Parent" and "Fun for Toddlers".

The eligibility of each interested caregiver will be assessed to ensure that they meet the inclusion criteria (see below). If so, they will be given an information pack (which includes an invitation letter and a participant information sheet) about the study and a time for the baseline appointment will be arranged. All five appointments (baseline, one to two week interview, four weeks, eight weeks, 12 weeks/interview) will be held in the caregiver's home. During the baseline home visit, written informed consent will be gained from this caregiver, prior to the commencement of any data collection and the use of digital audio recording equipment, by Dr Laura Jones or Miss Sarah Field-Richards.

At the baseline appointment, each caregiver will be asked if there are any other smokers living in the household over the age of 18 years. If yes, the caregiver will be asked if they would like the other smoking adult/s to be offered support from the smoke-free homes advisors and NRT throughout the intervention period. Should the caregiver consent to other smoking adult members of the household being offered support, an invitation pack (including an invitation letter, participant information sheet, contact detail form and a freepost envelope) will be offered to these individuals if they are present at the baseline visit or otherwise left with the caregiver for these individuals. Smoking adults within the household will be asked to return the contact detail form using the freepost envelope if they wish to participate. Participation for these individuals will involve completing a short quantitative questionnaire at the 4, 8 and 12 week visits and receiving smoke-free homes and NRT. Consent to participate in the study will be taken from the other smoking adults at the next home visit to the caregiver (4 weeks). It will be made clear that participation of both the caregiver and the other smoking adults in the household is voluntary and that the caregiver will not be excluded if other smoking adults in the household do not wish to participate.

Eligibility criteria

Inclusion:

- 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 attends one of the Children's Centres in which recruitment is taking place and report smoking in the home
- Caregivers and other smoking adults who live within the household who have provided informed consent to participate in the trial and in an interview
- Caregivers who consent to their children having urine and/or saliva samples taken at each time point
- All participants will be over the age of 18 years
- All participants will have good spoken English

Exclusion:

- Caregivers who report their home to be smoke-free i.e., they do not smoke anywhere in the house
- Caregivers who do not consent to their children having urine and/or saliva samples taken at each time point
- Women who are pregnant or planning a pregnancy during the intervention period
- Caregivers who are planning to quit smoking in the next three months
- Caregivers who are already using nicotine replacement therapy

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 four component intervention:

Smoke-free homes

Smoke-free homes to help caregivers to stop smoking in the home will be offered on three occasions (baseline, four weeks and eight weeks) for up to an hour in the home by an experienced and appropriately trained specialist smoking advisor. The smoke-free homes advisors 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 three home based support sessions, caregivers will be informed that they can contact the smoke-free homes advisors 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 session 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, whilst not asking them to quit smoking.

Education and information

In addition to the support offered by the smoke-free homes advisors, all participants will receive an education and information pack at the baseline appointment. This pack will contain a smoke-free homes support pack and diary that provides advice on how to make your home smoke-free and information on the harms of tobacco smoking and second hand smoke exposure to children and other non-smoking adults living within the household and provides space to record smoking and NRT use within the home for the duration of the 12 week intervention period. In addition, the pack will contain a DVD of three short films commissioned by the Children and Young People's Smoking and Tobacco Control Group (Nottingham County Council and BANG productions) which aims to raise awareness of the benefits of going smoke-free in a non-confrontational way from two different perspectives. The first film is from the perspective of a child of a smoking caregiver and the second is from the perspective of the smoking caregiver. The third film provides an integration of the key messages around going smoke-free from the two films. The DVD will be supported by a caregiver resource pack which aims to answer questions raised as a result of watching the films and will signpost to other appropriate resources and services.

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 prescribed (following New Leaf General Sales License (GSL) protocols) for one of three different uses: (1) temporary abstinence from smoking whilst in the home, (2) cutting down the number of cigarettes smoked with no intention to quit smoking, or (3) cutting down the number of cigarettes smoked with an intention to quit smoking at some point in the future. Caregivers will be able to move between these groups as it is envisaged that participating in the study may trigger quit attempts, even if this was not planned at the outset. At the baseline appointment, each participant will be offered a sample of each of the NRT products that are available to them, before they make a decision as to which product/s may work best for them. Mixed-therapy (a combination of two different NRT products such as gum and the inhalator) will be offered to those who request it. Once a mutual decision has been made between the caregiver and the smoke-free homes advisors, four weeks of NRT will be prescribed to the caregiver. The caregiver's use of NRT will be reviewed at each home visit and a further four weeks prescribed if appropriate. Up to a maximum of 12 weeks of free NRT will be prescribed. Caregivers will be able to contact the smoke-free homes advisors 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.

Biochemical feedback

At each time point, urine and saliva samples will be collected from the youngest child (under the age of five years) who lives (the majority of the time) in the household with the smoking caregiver. Urine will be collected using either a clean catch method (for children who are toilet trained) or via cotton pads in nappies (for children who are not toilet trained) and saliva will be collected using a children's swab (recommended for children under the age of six years). Caregivers will receive detailed information of how to prepare the child's nappy (for those children who are not toilet trained) ahead of the visit from the research/smoke-free homes team and then a member of the team will extract the sample from the cotton pads during the home visit. For children who are toilet trained, then the research/smoke-free homes advisors will ask the caregiver to collect a sample during the visit. The salvia sample will also be collected during the home visit by the caregiver in the presence of a member of the research/smoke-free homes staff. If the caregivers are unable to obtain a sample, the smoke-free homes advisors or the research staff will attempt to collect a sample during the home visit (all staff will have completed appropriate safeguarding and infection control training etc). The urine and 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). A letter providing cotinine feedback will be sent to the caregiver after each home visit with the contact number of the smoke-free homes advisors should they wish to discuss their results immediately. In addition, they will be advised that there will be an opportunity to discuss the results at the following home visit.

Data collection from study participants (see Figure 1)

Quantitative data will be collected at baseline, four week, eight week and 12 week home visits via interviewer administered questionnaires, and qualitative data will be collected via caregiver interviews at one to two weeks after enrolment and at the 12 weeks home visit. Informed consent will be gained by a member of the research team (Dr Laura Jones or Miss Sarah Field-Richards) at the baseline appointment. The interviewer administered questionnaires will be conducted by a member of the research team (Dr Laura Jones and/or Miss Sarah Field-Richards) at baseline and 12 weeks home visits, and at 4 and 8 weeks by the smoke-free homes advisors (Ms Jane Hassall or Ms Julie Greenwood), and each visit will be audio-taped if acceptable to the participant. In addition, a member of the research team (Dr Laura Jones or Miss Sarah Field- Richards) will conduct the caregiver interviews at one to two weeks after enrolment and at the 12 week home visit. The caregivers will be seen by a member of the research team at these specific time points to allow open and frank discussion about each component of the intervention, in particular, the support received from the smoke-free homes staff. In addition to the interviews, with the written permission of the caregivers, each of the home visits will be digitally audio recorded to allow the research team to assess the adequacy and effectiveness of the smoke-free homes offered to each of the caregivers.

Data collection at the baseline home visit

At baseline, the interviewer administered questionnaire will cover topics including demographics, family and household dynamics, characteristics of the home, home smoking behaviour and beliefs, and general health. A urine and saliva sample will also be collected from the youngest child (under the age of five years) who lives within the household. Each caregiver will also be given a diary to complete, that will record their daily smoking habits, smoking in the home and NRT use.

Data collection at the one to two week interview

These one to one semi-structured interviews will explore with each caregiver their thoughts on the recruitment process, the baseline home visit and the support offered at the first visit by the smoke-free homes staff.

Data collection at four and eight week home visits

The interviewer administered questionnaire for the caregiver at these time points 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 urine and saliva sample will also be collected from the youngest child (under the age of five years) who lives within the household. Each caregiver will be given an opportunity to discuss the content of their previous four week smoking, smoking in the home and NRT use diary. An interviewer administered questionnaire, for the other adult smokers in the household who have consented to participate, will also be administered and will cover topics including: demographics, family and household dynamics, characteristics of the home, home smoking behaviour and beliefs, and general health. Each other smoking adults will also be given a diary to complete, that will record their daily smoking habits, smoking in the home and NRT use. An opportunity to discuss the content of their previous four week smoking, smoking in the home and NRT use diary will be given at the subsequent home visit (8 weeks) for the other adult smokers.

Data collection at 12 week home visit

Data will be collected via an interviewer administered questionnaire which 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. This questionnaire will also be administered to any other adult smokers living in the house who have received support during the intervention period. Feedback on their child's cotinine levels assessed at the previous visit will be offered and an opportunity for discussion provided. A urine and saliva sample will also be collected from the youngest child (under the age of five years) who lives within the household. Each caregiver and other adult smoker will be given an opportunity to discuss the content of their

previous four week smoking, smoking in the home and NRT use diary. In addition, once the quantitative data have been collected, a one to one semi structured interview will be undertaken to explore with the caregiver (and the other smoking adults should they wish to participate) their thoughts on each of the home visits and will discuss each component of the intervention and how it might be improved to help support caregivers to stop smoking in the home.

Informed consent

All subjects (including both the caregiver and other smoking adults within the household who agree to participate) will provide written informed consent prior to participation. A participant information sheet will explain the details of the study and time will be given for the participant to read the information and to decide if they will to participate or not. Each participant will be given an opportunity to ask questions prior to the commencement of data collection. The Informed Consent Form will then be signed and dated by both the participant and the researcher. A copy of the participant information sheet and the informed consent form will be given to each participant for their records and one will be kept by the researcher.

Sample size and justification

As this is a small feasibility study to test the acceptability and feasibility of the proposed intervention and the methods of evaluation that will be used in the subsequent trial, only a small number of families ("families" will include as many smoking adults over the age of 18 years who live within the same household and who consent to participate) will be recruited to allow detailed data collection via both qualitative and quantitative methods. The aim of the study is to assess the acceptability, feasibility and adequacy of the intervention and so the families will be recruited using a phased approach, with the components of the intervention refined iteratively with each wave of recruitment. Eight families will initially be recruited (intake 1), with a further eight families recruited (intake 2) after intake 1 have completed their four week follow up appointments. If the intervention still requires refinement after the first intake have completed their 12 week follow up and the subsequent qualitative interview, then a further eight families will be recruited (intake 3). Therefore, up to a total of 24 families may be recruited, however, this will remain flexible to ensure that the intervention is refined appropriately for it to be acceptable, feasible and adequate.

Study duration, participant involvement and reimbursement

The total time available for this study is twelve months, starting 1st April 2011 and ending 31st March 2012. The baseline and 12 weeks appointments will last no longer than two hours. The four and eight week appointments will last no longer than one hour. Interviews will last no longer than 60 minutes with caregivers (and other smoking adults if they choose to participate). At the end of the study, each household (irrespective of how many smoking

adults took part in the study) will be reimbursed with a £50 retail voucher if they have completed each data collection wave.

Data analysis

Quantitative data

Quantitative data will be entered in PASW Statistics 18 and/or Stata 11. Since the aim of this work is to just assess the feasibility and acceptability of the intervention and the methods of evaluation, including the collection of quantitative data, the quantitative analysis will involve simply assessing whether questionnaires have been completed successfully, identifying questions that were ambiguous or otherwise not well completed by participants, and then basic descriptive analysis to describe whether and how components of the intervention worked as planned, for example looking at the use of NRT by both the caregiver and other smoking adults in the household. We will also assess the adequacy of our proposed outcomes for the main trial, including assessment of how many families provide useable urine and saliva samples for cotinine measurement.

Qualitative data

Each audio file will be transcribed verbatim, with the interviewee identified by their unique study identifier code. Audio files will be transcribed by experienced transcriptionists who specialise in transcribing research interviews and focus groups. The transcription company will sign a Confidentiality Agreement agreeing not to disclose any information to third parties. All files sent between the research team and the transcription company will be SSL 128 encrypted ensuring only the intended recipient can access the files. The transcription company's upload and file transfer system is also HIPAA compliant. Following receipt of the transcripts from the transcription company, Dr Laura Jones or Miss Sarah Field-Richards will go through each transcript and anonomise any identifiable references (which will be highlighted by the transcriptionists) made during the discussion such as children's names and places. The anonomysed transcripts from each interview and home visit will then be systematically analysed to identify emergent main and sub themes. These data will then be used as part of the iterative process of intervention development.

Primary outcome and study end point

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.

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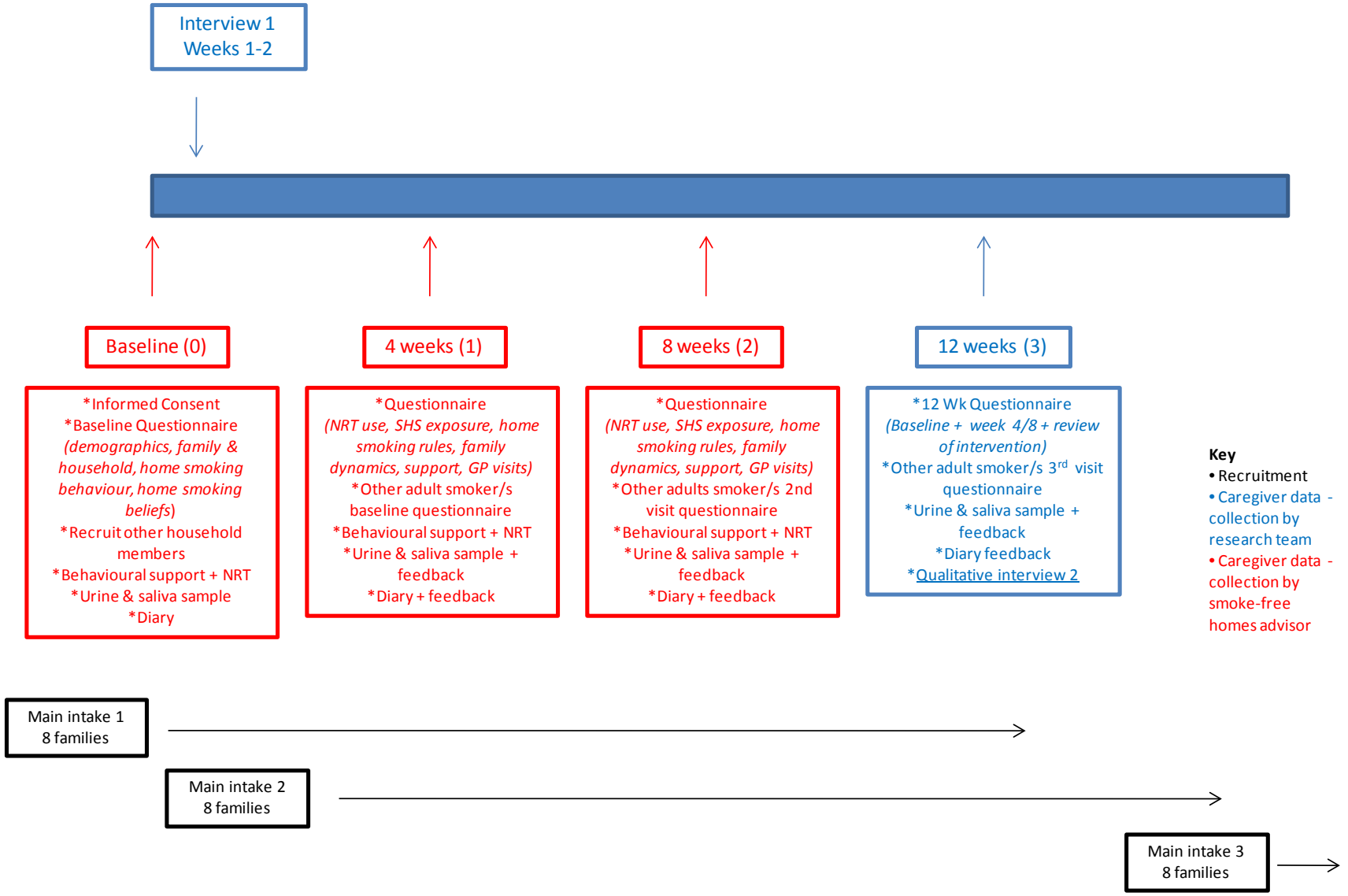
Interview 1
Weeks 1-2
Baseline (0)
4 weeks (1)
8 weeks (2)
12 weeks (3)
*Informed Consent
*Baseline Questionnaire
(demographics, family & household, home smoking behaviour, home smoking beliefs)
*Recruit other household members
*Behavioural support + NRT
*Urine & saliva sample
*Diary
*Questionnaire
(NRT use, SHS exposure, home smoking rules, family dynamics, support, GP visits)
*Other adult smoker/s baseline questionnaire
*Behavioural support + NRT
*Urine & saliva sample + feedback
*Diary + feedback
*Questionnaire
(NRT use, SHS exposure, home smoking rules, family dynamics, support, GP visits)
*Other adults smoker/s 2nd visit questionnaire
*Behavioural support + NRT
*Urine & saliva sample + feedback
*Diary + feedback
*12 Wk Questionnaire
(Baseline + week 4/8 + review of intervention)
*Other adult smoker/s 3rd visit questionnaire
*Urine & saliva sample + feedback
*Diary feedback
*Qualitative interview 2
Key
• Recruitment
• Caregiver data - collection by research team
• Caregiver data - collection by smoke-free homes advisor
Main intake 1
8 families
Main intake 2
8 families
Main intake 3
8 families

Figure 1