ISRCTN81701383 https://doi.org/10.1186/ISRCTN81701383

An intervention to reduce childrens exposure to secondhand smoke in the home

Submission date
25/01/2013

Recruitment status
No longer recruiting

Registration date
29/01/2013

Overall study status
Completed

Last Edited
15/11/2018

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Secondhand smoke (SHS), also known as passive smoke or environmental tobacco smoke, is made up of two components: mainstream smoke, which the smoker exhales, and side-stream smoke which comes from the burning end of the cigarette. While both forms of smoke are harmful, side-stream smoke is more toxic than mainstream smoke. 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 linked with a number of childhood illnesses including chest and ear infections, asthma and meningitis. Children are at greater risk from exposure to SHS compared with adults as they breathe more quickly and have less well-developed airways, lungs, and immune system. The home is the main source of SHS exposure for children. Although exposure in England has gone down over the last ten years or so, over half (52%) of children who live with one or more smokers are still regularly exposed to SHS in the home. It is difficult to reduce or prevent smoking in the home but the best way is to encourage parents to stop smoking altogether. However, for those parents who cannot or will not stop, the next best option is to encourage parents to make their homes completely smoke-free, even if they continue to smoke outside. Having said this, some parents find it very difficult to create and maintain a smoke-free home, and at present there is no clear evidence for the best way to help them. To try and learn how to best support parents to protect their children from SHS exposure at home, we have carried out preliminary work with parents to develop a feasible and acceptable intervention and this study aims to test whether this intervention works.

Who can participate?
The trial will recruit parents and caregivers who smoke in the home and have at least one child under five years of age living with them.

What does the study involve?
Parents who are recruited into the study will be randomly allocated into one of two treatment groups: usual care or intervention. Usual care group participants will be registered with the local smoke-free homes scheme, which encourages parents/carers/adults to introduce a ban or restriction on smoking within their home and provides them with the resources to help. In the intervention group caregivers and other adult smokers who live in the same household will be asked to make their homes completely smoke-free, without necessarily stopping smoking

altogether and will be offered the following support package:
(i) Behavioural support will be offered 24-48 hours after enrolment, and then three, seven and 12 weeks later. It will be delivered by a specialist smoke-free homes advisor who will also telephone twice during the study period, at one and five weeks following enrolment.
(ii) Nicotine Replacement Therapy all parents/caregivers will be offered up to 12 weeks supply for use instead of smoking, or to reduce the number of cigarettes smoked inside the home.
(iii) Air quality feedback home air quality samples will be collected from the participants home at enrolment and then seven and 12 weeks afterwards. These will give participants an indication of how much SHS their children are being exposed to in the home.
At the end of 12 weeks, those in the usual care group will also receive advice from the smoke-free homes advisor, one months supply of nicotine replacement therapy, and will receive information about how much SHS their children are being exposed to in the home.

What are the possible benefits and risks of participating?
The main benefit of taking part is that participants will receive support to help them reduce their childrens exposure to SHS in the home and free nicotine replacement therapy, the timing and amount of this support depending on whether they are in the intervention or usual care group. In addition, by taking part in this research they will help the study team to test ways of supporting people to protect their children from SHS, by making their homes completely smoke-free. The main disadvantage is the inconvenience of being visited at home on up to five separate occasions, for up to two hours, over a 12 week period. In addition, those who take up the offer of nicotine replacement therapy will only have this for a maximum of 12 weeks.

Where is the study run from?
The study researchers are based at the University of Nottingham. Participants are recruited from several locations, including Sure Start childrens centres, health visitor clinics, the Nottingham smoke-free homes project (run by the local stop smoking service) and childrens services teams. All the research visits will take place in the participants home.

When is the study starting and how long is it expected to run for?
November 2012 to September 2016

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Graeme Docherty
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13619

Study information

Scientific Title
An exploratory randomised controlled trial of an intervention to reduce childrens exposure to secondhand smoke in the home

Acronym
SFH Trial

Study objectives
The study aims to test the effectiveness and cost effectiveness of new ways of helping parents /carers to abstain from smoking inside their homes in order to reduce their children's exposure to secondhand smoke (SHS), by supportingthem to make their homes completely smokefree.

A novel, multi-component intervention to help smokers to protect their children from SHS exposure in the home will be delivered to households across Nottingham where parents/carers of at least one child under five years smoke inside the house.

A parallel group exploratory randomised controlled trial design will be used, with participants randomised to one or two treatment arms by computer based random generation created by Nottingham Clinical Trials Unit. The treatments are:
1. Usual care, where participants are signed up to, and follow the local Smokefree homes initiative.
2. Intervention, which is delivered via both face to face and telephone over 12 weeks, and will comprise of 3 components:
2.1. Behavioural support incorporating educational information provided by an experienced smokefree homes advisor
2.2. Nicotine replacement therapy for temporary abstinence or cutting down smoking in the home provided for up to 12 weeks
2.3. Air quality feedback and biochemical feedback provided by the smokefree advisor to the parents/carers as part of a novel personalised motivational approach in initiating smoking behaviour change in the home

Quantitative data will be collected at baseline, seven and 12 week home visits via interviewer-administered questionnaire. These questionnaires will be administered by a member of the research team.

There will also be an evaluative qualitative component in which a purposive sample of intervention arm participants will be invited to take part in an audio-recorded evaluative telephone interview that will cover topics such as the importance of the different components of the intervention and how the intervention might be improved.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Solihull REC, 25/09/2012, ref: 12/WM/0286

Study design
Parallel-group exploratory randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England / second hand smoke

Interventions
The intervention group
Following informed consent and randomisation to the intervention treatment arm, caregivers will receive a multi-component intervention involving five face to face contacts (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) up to 12 weeks supply will be offered.
3. Air quality feedback and biochemical feedback provided by the smoke-free advisor to the parents/carers as part of a novel personalised motivational approach in initiating smoking behaviour change in the home

The usual care group
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. At the end of 12 weeks, those in the usual care group will also receive advice from the smoke-free homes advisor, one months supply of nicotine replacement therapy, and will receive information about how much SHS their children are being exposed to in the home.

Follow Up Length: 3 month(s); Study Entry: Single Randomisation only

Intervention Type
Behavioural

Primary outcome measure
Change in average home air quality (PM2.5) between baseline and the end of the study (12 weeks), which will be compared between treatment groups (intervention vs. usual care)

Secondary outcome measures
1. 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
2. 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
3. The number of quit attempts and referrals to New Leaf cessation services overall and between treatment groups
4. The number of caregivers who are quit at 12 weeks between groups
5. Use of any stop smoking medications including NRT

Overall study start date
12/11/2012

Completion date
01/09/2016

Eligibility

Key inclusion criteria
1. Caregivers male and female, over the age of 18 years who are smokers and who report smoking in their home
2. Caregivers who have at least one child under the age of five years living with them
3. Other smoking adult household members who cohabit with a caregiver who consents to participate and admits to smoking inside the home

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200; Description: 100 smoking families in each treatment group, 200 in total.

Key exclusion criteria
1. Caregivers who live in refuges, sheltered or supported housing
2. Caregivers who are currently signed up to the local stop smoking service
3. Caregivers who have been signed up to the local smoke-free homes project within the last three months
4. Caregivers who are planning to move residence during the intervention period
5. Women who are pregnant, planning a pregnancy or breast feeding during the intervention period
6. Caregivers who are contraindicated for the prescription of nicotine replacement therapy (NRT)

Date of first enrolment
15/03/2013

Date of final enrolment
09/06/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham University Hospitals NHS Trust
Nottingham
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NG5 1PB

Study participating centre
NHS Nottingham Clinical Commissioning Group
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Sponsor type
University/education

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ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research - Central Commissioning Facility (CCF)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan
The main trial findings have been written up as a research paper and submitted for publication.

Intention to publish date
01/01/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mrs Rebecca Thorley (Rebecca.thorley@nottingham.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2018		Yes	No
Results article	results	13/11/2018		Yes	No