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Stoke-on-Trent smokefree homes service evaluation

Submission date	Recruitment status
12/09/2016	No longer recruiting
Registration date	**Overall study status**
09/12/2016	Completed
Last Edited	**Condition category**
26/04/2021	Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
It has been understood for some time now that environmental tobacco smoke (ETS) is harmful to the health of those breathing it in, particularly so in the case of young children. Children often breathe in ETS because their parents smoke and they are at particular risk of ETS if their mother smokes. It is not clear at the moment whether programmes (or interventions) developed to reduce the amount of ETS that children breathe in actually work. This study is testing a programme called the Smokefree Homes Service that will shortly be made available across the city of Stoke-on-Trent and that uniquely consists of telephone support, self-help materials and Nicotine Replacement Therapy (NRT)

Who can participate?
Households that agree to participate in the Smokefree Homes Service.

What does the study involve?
Potential participants/households are identified and , as long as they are happy to take part, they are randomly allocated a “time to intervention” by the researcher. This means that the time at which they start the Smokefree Homes Service during the study period will be at random. All participants do receive the Smokefree Homes Service at some point, however. This includes support via telephone, being provided with self-help materials and being given NRT. They are also given access to various training and support from a number of organisations. The programme runs for a total of 12 weeks.

What are the possible benefits and risks of participating?
Potential benefits to participants include being able to share their experience of the service and whether it has helped them to make their home smoke free. There are no risks beyond the inconvenience of organizing home visits during the study.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
August 2016 to May 2017

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

Who is the main contact?
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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
Protocol number 1

Study information

Scientific Title
Stoke-on-Trent Smokefree Homes Service Evaluation: a stepped-wedge cluster randomised controlled trial

Acronym
SSHSE

Study objectives

Participation in the service leads to statistically significant reduction in indoor smoking, measured by:
1. Self-reported behavioural change
2. Indoor smoking-related particulate matter concentrations

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Bristol Health Sciences Faculty Research Ethics Committee, 05/08/2016, ref: 39241

Study design
Single-centre stepped-wedge cluster randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Self-reported home indoor tobacco smoking, 24hr indoor air pollution (PM2.5) concentration, and carbon monoxide concentration in exhaled air (all family members aged 16 years or older).

Interventions
Receiving/participating in Smokefree Homes Service:
1. Telephone behavioural support
2 Self-help materials for 12 weeks plus Nicotine Replacement Therapy (NRT), sent by post to support temporary abstinence from smoking
3. Training and support for frontline staff from a range of organisations

Every participant will receive the intervention, but time-to-start will be randomized (randomization done by PI)

Intervention Type
Behavioural

Primary outcome measure
Successful smokefree home at the end of follow-up (8 month maximum). The a priori cut-off to define “smokefree” is based on:
1.1. Self-reported cessation of smoking of all family members, assessed by a questionnaire

OR
1.2. Self-reported cessation of indoor smoking (with or without use of nicotine patches), assessed by a questionnaire
AND
2. Average 24-hr average PM2.5 indoor concentration <50% of pre-intervention measurement, measured using the air quality monitor Dylos DC1700

Secondary outcome measures
1. Pre/post intervention difference in 24-hr average indoor PM2.5 concentration, measured using the air quality monitor Dylos DC1700
2. Amount of carbon monoxide (CO) in exhaled air (as a measure of individual health benefit and to confirm self-reported smoking cessation. CO in exhaled air of family members will be measured using the Bedfont Micro+ Smokerlyzer

Measured pre/post intervention.

Overall study start date
20/08/2016

Completion date
01/05/2017

Eligibility

Key inclusion criteria
1. Every household that has agreed to participate in the Smokefree Homes Service
2. Household members aged 16 years or older

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
80 households

Total final enrolment
0

Key exclusion criteria
1. Not participating in Smokefree Homes Service
2. Younger than 16 years of age

Date of first enrolment
01/09/2016

Date of final enrolment
01/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bristol
School of Social and Community Medicine
Canynge Hall
39 Whatley Road
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BS8 2PS

Sponsor information

Organisation
University of Bristol

Sponsor details
Senate House
Tyndall Avenue
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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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

Funder Name
Public Health England

Alternative Name(s)
PHE

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The researchers anticipate five deliverables of the PHES by the end of the project (2018):
1. A final report will be prepared for dissemination for peer-review to NIHR
2. A distilled version of the final report will be written as a journal article to be submitted to an international peer-review journal in open access format
3. For fast dissemination and knowledge transfer to the academic community, we anticipate a presentation at an appropriate conference (to be determined)
4. We further aim to present at an even or events (conference/regional meeting) for local authority (to be determined)
5. A summary briefing paper will be made available for knowledge transfer to local authorities

Intention to publish date
30/03/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		26/04/2021	26/04/2021	No	No