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Assessing the feasibility of using nicotine replacement therapy (NRT) to enable disadvantaged parents to create a smoke-free home

Submission date
22/05/2025

Recruitment status
No longer recruiting

Registration date
23/05/2025

Overall study status
Ongoing

Last Edited
22/08/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The harmful health effects of children's exposure to second-hand smoke are well established. Most second-hand smoke exposure now occurs in the home, in low-income households. This is because smoking rates are higher in more disadvantaged groups, who may find it harder to create a smoke-free home because of challenges including limited access to private outdoor space or being a sole parent.

Who can participate?
Parents, and carers and relatives who are at least 18 years old, smoke in the home, and care for one or more children aged 5 or over in the home, at least 1 day per week, will be eligible to participate. Multiple family members can participate in the study. The study is based in Lanarkshire in Scotland, and those who participate should live here.

What does the study involve?
Previous research suggests that using nicotine replacement therapy (NRT) in the home could help to reduce the amount of smoking indoors. We want to build on this work and test in the future if using NRT works for people who smoke and their families as a way to reduce children's exposure to second-hand smoke. First, we need to conduct a smaller version of this study to test whether we can deliver it as planned. Some people who smoke will get free NRT posted to their home alongside telephone support for 12 weeks to reduce children's exposure to second-hand smoke. We will compare this with other people who smoke who receive current Scottish Government advice on reducing children's exposure to second-hand smoke in the home. We will check whether enough people who smoke want to be involved in the study, how acceptable (or not) the study is with people who smoke and look at the potential costs of this approach. If results are promising, we will seek funding for a larger trial to tell us whether using free NRT in the home to reduce children's exposure to second-hand smoke improves child health outcomes and is effective for the NHS.

Where is the study run from?
The study is led by the University of Stirling, with recruitment led by our study partner NHS Lanarkshire (UK)

When is the study starting and how long is it expected to run for?
The study started in June 2023 and it will run until May 2026.

Who is funding the study?
The Chief Scientist Office, which is part of the Scottish Government Health Directorates (UK)

Who is the main contact?
Dr Rachel O'Donnell, at the Institute for Social Marketing and Health, University of Stirling, Scotland. Email: r.c.odonnell@stir.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
329222

Study information

Scientific Title
A pilot randomised control trial of an intervention to reduce children’s exposure to second-hand smoke in the home in disadvantaged communities in Scotland

Study objectives
Principal Research Question: Is the intervention feasible in terms of participation and retention rates, NRT adherence, andthe practicalities of intervention delivery within an established NHS service?

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 15/12/2023, West of Scotland Research Ethics Service 3 (Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 141 314 0212; WoSREC3@ggc.scot.nhs.uk), ref: 23/WS/0153

Study design
Pilot randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Children's exposure to second-hand smoke in the home

Interventions
Intervention arm (Group A): Fifty participants are being randomly allocated to Group A. They receive a free, 12-week supply of nicotine replacement therapy posted to home, an information sheet on how to use NRT effectively, plus fortnightly telephone support to aid effective use of NRT for temporary abstinence in the home.

Control group (Group B): Fifty participants are being randomly allocated to Group B. Group B participants are signposted to the Scottish Government's 'Take it Right Outside' advice by email. This NHS Inform website provides tailored interactive advice on creating a smoke-free home. On completion of the study at week 12, all participants in the control arm are being offered the NRT information sheet and a 12 week's supply of free NRT products posted-to-home fortnightly.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment, randomisation and retention:
1.1. Number of participants screened, eligible and successfully recruited into the study, and the characteristics of non-consenting and ineligible participants (measured using a baseline data collection tool and Excel recruitment tracker)
1.2. Number of participants enrolled in the allocated recruitment time (measured using an Excel recruitment tracker)
1.3. Retention of participants in their trial arms following randomisation, the proportion engaging in 12 week follow ups, and number/reasons for dropping out (measured using an Excel recruitment tracker).
2. Intervention delivery:
2.1. The proportion of participants (a) receiving NRT and demonstrating their adherence to NRT at fortnightly follow ups; and (b) engaging in fortnightly telephone support calls (all monitored by Excel participant tracker).
3. Data collection methods: Proportion of completed baseline and follow up assessments in each arm; Number of participants successfully providing child saliva samples and measuring air quality at baseline and 12 week follow up.

Key secondary outcome(s))
1. Number of cigarettes smoked per day (in general and in the home) (measured by baseline and follow up questionnaires)
2. Home smoking practices (measured by baseline and follow up questionnaires)
3. Self-reported quit attempts (measured by follow up questionnaire)
4. Nicotine dependence (measured at baseline and 12 week follow up using the Heaviness of Smoking Index).
5. We are also testing the feasibility of participants collecting saliva samples from their youngest child (age 5 or over) for cotinine analysis, and collection of resource use and economic data prior to a future definitive trial.

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. Parents, and carers and relatives
2. Aged at least 18 years old
3. Smokes in the home
4. Cares for one or more children aged or over in the home, at least 1 day per week, most days.
5. Multiple family members can participate in the study.
6. Individuals who are interested to take part but live with another adult smoker who does not wish to, are able to participate.

Participant type(s)
Healthy volunteer, Resident

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. Individuals who are not able to understand or speak English as their primary language are excluded given we do not have a budget to recruit, train and pay bilingual staff.
2. Individuals who use Warfarin, Theophylline or Aminophylline, Clozapine, Erlotinib, Olanzapine, Riociguat, Chlorpromazine, Flecainide, Methadone or Warfarin are excluded as NRT use would require GP monitoring.
3. Pregnant and breastfeeding women are excluded from participation as the NRT products

offered are only licensed for this group of people who are making a quit attempt.
4. Participants who have a hypersensitivity to nicotine or any components of the nicotine replacement products offered in this study and listed in the product literature are excluded from taking part – we establish this by asking specific questions regarding any previous use of NRT and whether participants have any allergies.

Date of first enrolment
01/01/2024

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Lanarkshire
14 Beckford Street
Hamilton
United Kingdom
ML3 0TA

Sponsor information

Organisation
University of Stirling

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Rachel O'Donnell - r.c.odonnell@stir.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		21/08/2025	22/08/2025	Yes	No
Participant information sheet	version 1.3	11/12/2024	23/05/2025	No	Yes