ISRCTN10774163 https://doi.org/10.1186/ISRCTN10774163

Hospital to home: smokers support study

Submission date
31/05/2016

Recruitment status
No longer recruiting

Registration date
31/05/2016

Overall study status
Completed

Last Edited
16/09/2022

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Tobacco smoking is the largest avoidable cause of premature death and disability in the UK. Half of all lifelong smokers die as a consequence of their smoking, typically from lung cancer, chronic obstructive pulmonary disease (lung disease) or cardiovascular disease (heart and blood vessel disease). Average life expectancy among smokers is 10 years less than those who have never smoked, which is equivalent to nearly 3 months of life lost for every year smoked after the age of 35. A previous study found that identifying smokers admitted to hospital and delivering support to help them quit smoking as a default service can help increase the amount of smokers who want to quit. However, it was also found that many patients started smoking again (relapsed) when they were discharged from hospital. This study is looking at whether providing outpatient support after an inpatient stop smoking service can help to reduce relapse rates. The aim of this study is to test the effectiveness of this program at helping prevent patients from relapsing to smoking after they are discharged from hospital.

Who can participate?
All adult patients admitted for at least 24 hours to any participating inpatient ward at Nottingham City Hospital who are current smokers or have smoked within the seven days before admission to hospital.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive usual care, which involves being given advice from a trained councilor at their bedside about stopping smoking. Those in the second group are offered advice at their bedside but are also offered a home visit within 24 hours of being discharged from hospital in order to receive a face-to-face behavioural support program designed to help stop them from starting smoking again. For all participants, whilst on the ward, the amount of carbon monoxide (a harmful gas present in cigarettes) in their body measured by breathing into a special monitor. This test is then repeated four weeks later.

What are the possible benefits and risks of participating?
The main benefit of taking part for study participants is help to stop smoking, reducing illness and improving quality of life and life expectancy. There are no risks to participants in the trial,

although some people may have an adverse reaction to nicotine replacement products. However, all participants will be supported by a fully trained smoking cessation practitioner and so any adverse reaction to therapies will be quickly rectified.

Where is the study run from?
Nottingham City Hospital (UK)

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

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

Who is the main contact?
Dr Rebecca Thorley
rebecca.thorley@nottingham.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Rebecca Thorley

Contact details
Room B125 Clinical Sciences
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB
+44 115 8231361
rebecca.thorley@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
199599

ClinicalTrials.gov number
NCT02767908

Secondary identifying numbers
20835, NIHR grant RP-PG-0608-10020

Study information

Scientific Title
Randomised controlled trial to test the effectiveness of an intensive home support intervention for newly abstinent smokers leaving hospital

Study objectives
The aim of this study is to investigate the effectiveness of a multi-component intervention to prevent relapse to smoking after hospital discharge.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Nottingham 2 Research Ethics Committee, 06/04/2016, ref: 16/EM/0088

Study design
Randomised; Interventional; Design type: Treatment, Complex Intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Specialty: Health services and delivery research, Primary sub-specialty: Health services and delivery research; UKCRC code/ Disease: Other/ Symptoms and signs involving the circulatory and respiratory systems, Other/ General symptoms and signs

Interventions
Patients will be informed of the study during their period of inpatient stay. If they are a smoker, during the last 24 hours of their stay they will be asked if they would like to take part in the research. Patients will then be individually randomised into either the usual care arm or the intervention arm of the trial.

Usual care arm: Patients will receive smoking cessation advice in hospital and at home according to the recommendations set out in NICE (PH48) guidance, including pharmacotherapy and behavioural support before leaving hospital, referral to NHS Stop Smoking Service for continued care after discharge, and ascertainment of smoking status at 4 weeks; participants will also be asked to consent to smoking status ascertainment at three months.

Intervention arm: Patients will be offered cessation advice at their bedside but will also be offered a home visit in the 24 hours post discharge to deliver face-to-face behavioural support designed to reduce the risk of relapse. This will include advice on changing routines to avoid smoking cues when in the home; help with strategies to deal with cravings and high risk situations; help to remove physical smoking cues (e.g. cigarettes, ashtrays, other paraphernalia) from the home; ensuring continuity of supply and advice on optimal use of pharmacotherapy; engagement with and provision (if accepted) of nicotine replacement therapy to promote smoking cessation or at least temporary abstinence in the home by family or other household members or regular visitors who smoke; the offer of 24-hour indoor air quality monitoring, using a using a battery-operated Sidepak Aerosol Monitor AM510 (TSI Instruments Ltd, High Wycombe UK) positioned in the main living area, in the first week after discharge from hospital and again at 12 weeks, as motivation to sustain a smoke-free home; and a range of other support aimed at supporting smoking cessation. For participants who decline a home visit, the above support options will be offered as far as possible through telephone contact and delivered to the extent accepted by the participant. Ascertainment of smoking status will be undertaken at both 4 and 12 weeks.

Both intervention and usual care participants will be asked, as part of the study, to undergo a carbon monoxide (CO) measure (breath test) while on the ward and will be contacted at 4 weeks and 12 weeks after leaving hospital to ask about the patients smoking status and (if appropriate) take further CO measures.

Intervention Type
Other

Primary outcome measure
Continuous abstinence from smoking assessed by measuring carbon monoxide levels (<6ppm) at baseline and 4 weeks post discharge from hospital.

Secondary outcome measures
Current secondary outcome measures as of 08/05/2019:
1. Continuous abstinence from smoking assessed by measuring carbon monoxide levels (<6ppm) at 3 months post discharge from hospital
2. Continuous abstinence from smoking, self-report by participant at baseline, 4 weeks and 3 months post-discharge from hospital
3. Self- reported reduction in cigarette consumption assed by recording the difference in the number of cigarettes smoked per day at baseline and 4 weeks post discharge from hospital
4. Self-reported presence of a smoke free home, assessed by asking participant if anyone smokes inside the home at baseline 4 weeks and 3 months post-discharge from hospital
5. Utilisation of each component of the complex intervention measured through participant self-reporting at 4 weeks and 3 months post-discharge from hospital

Previous secondary outcome measures:
1. Continuous abstinence from smoking assessed by measuring carbon monoxide levels (<6ppm) at 3 months post discharge from hospital
2. Continuous abstinence from smoking, self-report by participant at baseline, 4 weeks and 3 months post-discharge from hospital
3. Self- reported reduction in cigarette consumption assed by recording the difference in the number of cigarettes smoked per day at baseline and 4 weeks post discharge from hospital
4. Self-reported presence of a smoke free home, assessed by asking participant if anyone smokes inside the home at baseline 4 weeks and 3 months post-discharge from hospital

5. Changes in maximum concentrations of P.M2.5 and the proportion of time PM2.5 concentrations exceed WHO recommended safe levels of maximum exposure of 25 µg/m3 per 24-hour period, measured using an AM510 Sidepak aerosol monitor 24 to 48 hours, 4 weeks and 3 months post-discharge from hospital
6. Utilisation of each component of the complex intervention measured through participant self-reporting at 4 weeks and 3 months post-discharge from hospital

Overall study start date
11/01/2016

Completion date
28/02/2018

Eligibility

Key inclusion criteria
1. All patients aged 18 and over
2. Have been admitted for 24 hours or more to any participating inpatient ward at Nottingham City Hospital
3. Who report that they are current smokers, or had smoked within 7 days before the current admission
4. Are capable of understanding and consenting to the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 400; UK Sample Size: 400

Total final enrolment
404

Key exclusion criteria
1. Pregnancy. Pregnant smokers (of whom very few are admitted to medical wards) will be offered cessation advice in line with NICE PH48 guidance.
2. Those who do not provide consent to participate
3. Those who are are too ill or otherwise lack capacity to understand the information and consent forms
4. Living more than 50 miles from the City Hospital (these patients will be referred to their local community cessation services, in line with NICE recommendations)

Date of first enrolment
28/06/2016

Date of final enrolment
28/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham

Sponsor details
-
Nottingham
England
United Kingdom
NG7 2RD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ee9ar58

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

Results and Publications

Publication and dissemination plan
The results of the study will be presented at appropriate conferences and submitted for publication in a peer-reviewed journal.

Intention to publish date
30/11/2018

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		08/05/2019	08/05/2019	No	No
Results article	results	01/11/2019	15/01/2020	Yes	No
Protocol file	version 2.0	03/05/2017	16/09/2022	No	No
HRA research summary			28/06/2023	No	No