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Exploring ways to help hospital patients stop smoking

Submission date	Recruitment status	[_] Prospectively registered
28/10/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/07/2013	Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8974

Study information

Scientific Title
Evaluation of the impact of systematic delivery of cessation interventions on delivery of smoking cessation in secondary care

Study objectives
To develop and test the effectiveness and cost-effectiveness of a systematic smoking intervention service that offers treatment to all smokers admitted to the medical wards of an acute NHS Trust who want to quit smoking.

A service is currently offered to relevant patients and we now wish to test the delivery of a new service by randomising certain wards to receive the new service. The study is therefore not a service evaluation and should be categorised as research.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee 1 approved on the 30th April 2010 (ref: 10/H0403/34)

Study design
Single centre randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Public Health Research

Interventions
For participants in the active intervention group, a cessation practitioner will deliver a brief cessation intervention and offer Nicotine Replacement Therapy and further 1:1 counselling. If accepted and not contraindicated, NRT will be prescribed according to service protocol and where appropriate. Participants who decline NRT will be offered varenicline or bupropion, and if accepted, their clinician requested to confirm that no contra-indications apply and to prescribe

the treatment. Carbon monoxide validation will be performed at one and six months post discharge on participants from both groups to ascertain smoking status. Behavioural support will continue to be given by the counsellor on repeated occasions as appropriate and as acceptable to the patient during admission. Follow-up behavioural support after discharge will be arranged with the appropriate local Stop Smoking Service (SSS).

Follow up length: 6 months
Study entry: registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Number of smokers with validated cessation, measured at one month post-discharge

Secondary outcome measures
1. Smokers abstinent from smoking at discharge (CO validated), measured at discharge
2. Smokers abstinent from smoking, with CO validation, at 6 months post-discharge
3. Smokers discharged on cessation therapy and have post-discharge support arranged, measured at discharge
4. Smokers offered cessation counselling and pharmacotherapy as an inpatient, measured up to one month
5. Smokers who accept cessation counselling and pharmacotherapy as an inpatient, measured up to one month
6. Smokers who leave hospital with an active prescription for a smoking cessation therapy, measured at discharge
7. Smokers who receive post-discharge support from Stop Smoking Services (e.g. New Leaf), measured at 1 and 6 months following discharge

Overall study start date
11/10/2010

Completion date
10/03/2011

Eligibility

Key inclusion criteria
1. Adult patients 16 years and older, either sex
2. Admitted to one of eighteen medical wards at the Nottingham City Hospital for a medical condition or illness
3. Current smokers, or have smoked regularly within 28 days of admission or the onset of the illness causing admission

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned sample size: 1300; UK sample size: 1300

Key exclusion criteria
1. Do not consent to participate
2. Too ill to understand the information and consent forms

All other smokers will be eligible for inclusion. Decisions to prescribe nicotine replacement therapy will be made in discussion with supervising clinicians. The default will however be to prescribe NRT if it seems otherwise more likely than not that the patient will smoke.

Date of first enrolment
11/10/2010

Date of final enrolment
10/03/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Epidemiology & Public Health
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details

Research Innovation Services
Kings Meadow Campus
Lenton Lane
Nottingham
England
United Kingdom
NG7 2NR

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/07/2013		Yes	No