ISRCTN22526020 https://doi.org/10.1186/ISRCTN22526020

Rapid reduction versus abrupt quitting for smokers who want to stop soon

Submission date	Recruitment status	[X] Prospectively registered
14/10/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/10/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/03/2016	Mental and Behavioural Disorders	

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
2008-006433-28

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RG_08_082

Study information

Scientific Title
Rapid reduction versus abrupt quitting for smokers who want to stop soon: a randomised controlled non-inferiority trial

Study objectives
The trial will investigate the abstinence success rates of participants reducing cigarette smoking by 50% for two weeks prior to smoking quit date whilst using nicotine replacement therapy (NRT), when compared with abrupt cessation with no cutting down, whilst also utilising NRT for two weeks prior to quitting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Nottingham Research Ethics Committee 2, 20/01/2009, ref: 08/H0408/213
2. Medicines and Healthcare products Regulatory Agency (MHRA), 12/12/2008, ref: 21761/0222 /001-0001

Study design
Randomised controlled unblinded non-inferiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Smoking cessation in response to nicotine addiction

Interventions
Participants will be seen at an assessment session, similar to that used by the stop smoking services. Here they will be randomised 1:1 to reduction or abrupt cessation arm of the trial.

In the rapid reduction arm participants will decide on a quit date in two weeks time, and in the two weeks leading up to this will reduce smoking consumption by 50%, whilst using nicotine patches (Niquitin, Nicotinell, Nicorette), usually 21 mg, and replacing missing cigarettes with an acute form of nicotine replacement therapy (for example nicotine gum). Participants will be

asked to complete a daily diary (explained at the assessment visit). The target number of cigarettes will be completed for each day, and at the end of each day participants will be asked to put aside the next day's cigarettes into a separate pack to encourage adherence to target.

In the abrupt cessation arm participants will also decide on a quit date in two weeks time and be given homework to identify critical cigarettes, which will be the basis for the pre-quit discussion the next week. During the two-week period leading up to the quit date participants will also use patches (usually 21 mg), but will not utilise acute NRT.

Both arms will then go on to have five weekly sessions on quit week and weekly thereafter, following the typical seven-session UK withdrawal-orientated therapy programme. Follow-up will also be carried out eight weeks and six months after quit day. All NRT used will have the brand name Niquitin, Nicotinell or Nicorette, and participants will be able to have some input in the type(s) of NRT and dosage that they use.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Nicotine (Niquitin, Nicotinell, Nicorette)

Primary outcome measure
Abstinence at four weeks in all treatment arms, measured according to the Russell standard (allows a two-week grace period from quit day for slips).

Secondary outcome measures
Point prevalence at each follow-up and prolonged abstinence at eight weeks and six months (according to the Russell standard). Throughout the trial and at follow-up, the following will be monitored:
1. Urges and withdrawal (using the Mood and Physical Symptoms Scale [MPSS])
2. Self-efficacy
3. Exhaled carbon monoxide (using a CO monitor)
4. Salivary continine levels
5. Daily smoking and NRT use (using written diaries)
6. Satisfaction from smoking particular cigarettes (using the Cigarette Evaluation Scale)

Overall study start date
01/10/2008

Completion date
17/09/2012

Eligibility

Key inclusion criteria
Participants will be recruited by writing to patients on GP practice lists recorded as smokers, writing to people on the stop smoking service's database who have tried and failed to stop, and

by offering the treatment to those booking with the stop smoking service. Any participants will be eligible if they are:
1. Prepared to stop either abruptly in two weeks or cut down and stop over two weeks
2. Aged 18 or over, either sex
3. Willing and able to complete data collection

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
686 (343 participants in each arm).

Key exclusion criteria
Pregnancy will be the only exclusion for insurance purposes

Date of first enrolment
26/06/2009

Date of final enrolment
13/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
c/o Brian Berry
Research and Enterprise Services
Edgbaston
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Sponsor type
University/education

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

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (BHF) (UK) (ref: PG/08/047/25082)

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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?
Protocol article	protocol	14/08/2009		Yes	No
Results article	results	03/05/2016		Yes	No
HRA research summary			28/06/2023	No	No