

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

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| <b>Submission date</b><br>14/10/2008   | <b>Recruitment status</b><br>No longer recruiting             | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>22/10/2008 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>16/03/2016       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data   |

**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 cotinine 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

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**Sponsor information**

**Organisation**

University of Birmingham (UK)

**Sponsor details**

c/o Brian Berry  
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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? |
|--------------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a>     | protocol | 14/08/2009   |            | Yes            | No              |
| <a href="#">Results article</a>      | results  | 03/05/2016   |            | Yes            | No              |
| <a href="#">HRA research summary</a> |          |              | 28/06/2023 | No             | No              |