

# Using genotype to tailor prescribing of Nicotine Replacement Therapy (NRT): a randomised controlled trial assessing impact upon medication adherence

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<b>Registration date</b> 17/05/2006	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 14/02/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr David Armstrong

### Contact details

King's College London  
5 Lambeth Walk  
London  
United Kingdom  
SE1 6SP

## Additional identifiers

### EudraCT/CTIS number

2006-000106-24

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

G0500274 (MRC ref no)

## Study information

### Scientific Title

Using genotype to tailor prescribing of Nicotine Replacement Therapy (NRT): a randomised controlled trial assessing impact upon medication adherence

### Study objectives

Adherence to NRT is greater when given feedback that NRT is tailored to genotype as opposed to heaviness of smoking.

The trial is 1 of 3 studies that make up an MRC-funded programme of research: GRAB (Genetic Risk And Behaviour change)

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Added as of 03/08/2007:

Hertfordshire 1 Research Ethics Committee, approved in June 2006 (ref: 06/Q0201/21; Protocol No.1)

### Study design

Open-label, parallel group, randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Smoking

### Interventions

Participants will be divided into two groups of equal size by randomisation. One group will be informed that prescribing for NRT is based upon DNA information and addiction, and the other group informed that it is based on addiction alone.

### Intervention Type

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Nicotine replacement therapy

**Primary outcome measure**

The proportion of all NRT consumed in the first 4 weeks of quitting or to the point of relapse, whichever is the sooner. This will be measured by self-report daily diary, backed up by 'pill count reconciliation' with the diary at the clinic. If pill counts are discrepant with the diary, this will be discussed and reconciled at the clinic visit.

**Secondary outcome measures**

1. Responses to the Mood and Physical Symptoms Scale, a measure of nicotine withdrawal symptoms
2. Point prevalence of 14-day complete abstinence measured at 28 days after smoking cessation
3. Response efficacy of NRT
4. State anxiety

**Overall study start date**

21/05/2006

**Completion date**

21/05/2009

## Eligibility

**Key inclusion criteria**

Eligible participants are:

1. Motivated quitters attending the participating NHS smoking cessation clinics
2. Participants must be smokers smoking 10 or more cigarettes per day over the last 12 months
3. Aged 18 and over
4. Living in the British Isles

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

630

**Key exclusion criteria**

1. Non-smokers
2. Smokers smoking less than 10 cigarettes daily over the last 12 months
3. Aged under 18
4. Living outside the British Isles
5. Cigar/pipe smokers
6. NRT contraindications (e.g. pregnant or lactating women)
7. Those with previous severe adverse reactions to NRT
8. Currently taking medication for smoking cessation that they are unwilling to cease taking or medication with a known influence on smoking cessation that they cannot stop

**Date of first enrolment**

21/05/2006

**Date of final enrolment**

21/05/2009

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

King's College London

London

United Kingdom

SE1 6SP

## Sponsor information

**Organisation**

King's College London (UK)

**Sponsor details**

Institute of Psychiatry

De Crespigny Park

London

England

United Kingdom

SE5 8AF

**Sponsor type**

University/education

ROR

## Funder(s)

### Funder type

Research council

### Funder Name

Medical Research Council (UK) (ref: G0500274)

### Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### 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	09/11/2010		Yes	No
<a href="#">Results article</a>	results	01/11/2012		Yes	No
<a href="#">Results article</a>	results	01/09/2013		Yes	No
<a href="#">Results article</a>	results	29/01/2018		Yes	No