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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered	
20/03/2006		[X] Protocol	
Registration date 17/05/2006	Overall study status Completed	Statistical analysis plan	
		[X] Results	
<b>Last Edited</b> 14/02/2018	<b>Condition category</b> Mental and Behavioural Disorders	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

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# Additional identifiers

Clinical Trials Information System (CTIS) 2006-000106-24

## Protocol serial number

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

### Study type(s)

Treatment

#### 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(s)

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.

#### Key secondary outcome(s))

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

#### Completion date

21/05/2009

# Eligibility

#### Key inclusion criteria

Eligible participants are:

- 1. Motivated guitters 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

#### Healthy volunteers allowed

No

## Age group

Adult

#### Lower age limit

18 years

#### Sex

Αll

#### 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

**United Kingdom** 

England

Study participating centre King's College London London United Kingdom SE1 6SP

# **Sponsor information**

#### Organisation

King's College London (UK)

#### **ROR**

https://ror.org/0220mzb33

# 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**

# 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	01/11/2012		Yes	No
Results article	results	01/09/2013		Yes	No
Results article	results	29/01/2018		Yes	No
Protocol article	protocol	09/11/2010		Yes	No