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

Submission date
20/03/2006

Registration date
17/05/2006

Last Edited
14/02/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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 prevalance 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

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

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