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Investigation to explore whether there is a synergistic effect between nicotine replacement therapy and guided bodyscanning on cigarette cravings and withdrawal symptoms

Submission date
15/10/2008

Recruitment status
No longer recruiting

Registration date
27/10/2008

Overall study status
Completed

Last Edited
10/05/2016

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EC/3008/21/FHS

Study information

Scientific Title
Investigation to explore whether there is a synergistic effect between nicotine replacement therapy and guided bodyscanning on cigarette cravings and withdrawal symptoms

Study objectives
The research aims to determine whether there is a synergistic effect between the relaxation technique of guided bodyscanning and nicotine replacement therapy (NRT) in reducing cigarette cravings and withdrawal symptoms in temporarily abstinent smokers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Surrey Ethics Committee gave approval on the 1st May 2008. An application is also being prepared for submission to the National Research Ethics Service (NRES) for ethical review before the end of October 2008.

Study design
A randomised single-blind placebo-controlled, single-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

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

Interventions
Participants will be randomly allocated to receive either
1. Active nicotine patch plus:
1.1. Guided bodyscanning audio
1.2. Passive control audio (a natural history text reading)
2. Placebo patch plus:

2.1. Guided bodyscanning audio
2.2. Passive control audio (a natural history text reading)

Those who are assigned to the active nicotine patch conditions will complete a Fagerström Test for Nicotine Dependence (FTND) and depending on their individual level of dependence will be administered with either a 14 mg or 21 mg transdermal NiQuitin nicotine replacment patch at the beginning of the trial to be kept on for a maximum of 7 hours.

Participation in all potential arms of the trial will last for a maximum of 7 hours. There will be no follow up period as the study is a brief lab-based intervention.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Nicotene replacement therapy

Primary outcome measure
Strength of desire to smoke and tobacco withdrawal symptoms will be measured using the self-report 7-point Mood and Physical Symptoms Scale (MPSS), whereby 1 = 'not at all', 4 = 'somewhat' and 7 = 'extremely'.

All ratings will be made on a pre-programmed palmtop computer which will prompt participants to ratings at:
1. 10 am: Single set of ratings in the presence of the researcher
2. 11 am: Single set of ratings in your natural environment
3. 12 pm: Multiple rating at the intervals detailed below
4. Between 1 pm and 4 pm (if necessary): Multiple ratings at the intervals detailed below:
Rating 1 (just before audio)
Audio (10 minutes)
Rating 2 (just after audio)
Rating 3 (5 minutes after audio)
Rating 4 (20 minutes after audio)
Rating 5 (30 minutes after audio)

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2009

Completion date
30/09/2009

Eligibility

Key inclusion criteria

1. Smokers
2. Aged 18 to 65 years, either sex
3. Consume at least 10 cigarettes a day, and have done for at least the last three consecutive years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72

Key exclusion criteria
1. Receiving treatment for mental health problems
2. Pregnant
3. Currently trying to conceive

Date of first enrolment
01/01/2009

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Surrey
Guildford
United Kingdom
GU2 7XH

Sponsor information

Organisation
University of Surrey (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.som.surrey.ac.uk/profile/details.aspx?id=368

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
University/education

Funder Name
University of Surrey (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

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