

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	☒ Prospectively registered
Registration date 27/10/2008	Overall study status Completed	☐ Protocol
Last Edited 10/05/2016	Condition category Mental and Behavioural Disorders	☐ 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

Protocol serial number
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.

Primary study design

Interventional

Study design

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

Study type(s)

Prevention

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 replacement 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(s)

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)

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre

University of Surrey

Guildford

United Kingdom

GU2 7XH

Sponsor information**Organisation**

University of Surrey (UK)

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

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration