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Attentional bias retraining in cigarette smokers attempting smoking cessation

Submission date	Recruitment status	[X] Prospectively registered
24/02/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/02/2015	Mental and Behavioural Disorders	

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
RG_09-156

Study information

Scientific Title
A randomised controlled trial of attentional bias retraining in cigarette smokers attempting smoking cessation

Acronym
ARTS

Study objectives
Smokers often attend differentially to objects in their environment by exhibiting an 'attentional bias' or readiness to process cues related to smoking over other types of cues. There is evidence that attentional bias can alter processes like craving, which may increase the risk of relapse in smokers who are trying to quit. A translational study is proposed here to examine the effectiveness of computerised attentional bias retraining to change the way smokers respond to smoking-related cues. The trial will examine the strength of association between attentional bias and urges to smoke, whether attentional bias is associated with an increased probability of relapse and the effects of attentional bias retraining in cigarette smokers attempting cessation.

The trial will randomise smokers to either an intervention group who will receive attentional retraining or a control group who will receive a placebo procedure completed in a clinic on a laptop computer, while standard smoking cessation medication and NHS behavioural support is provided.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Staffordshire Research Ethics Committee (REC) – approval pending as of 25/02/2010

Study design
Single-centre feasibility double-blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
Participants attending a seven-session weekly NHS stop smoking clinic will be randomised to either an intervention group receiving a modified visual probe task consisting of attentional retraining (AR) or a control group who receive a modified visual probe task of placebo training (PT). Both groups will undergo 6 weekly sessions of either AR or PT, starting one week prior to quit day and then be given on quit day and at weeks 1, 2, 3 and 4. Attentional bias will be assessed during test trials of the visual probe task, two weeks and one week prior to quit day, on quit day and at weeks 1, 2, 3, 4 and again at follow-up at 8 weeks, 3 months and 6 months post-quit. The procedure that assesses attentional bias and trains smokers runs off a computer and will take between 20 - 30 minutes to complete.

Participants in both the intervention group and control group will use 21 mg/24 hour transdermal nicotine patches, starting one week prior to quit day and lasting 8 - 12 weeks following quit day. Nicotine patch dose will be adjusted accordingly for light smokers, based on exhaled carbon monoxide and nicotine dependence measured using the Fagerstrom Test of

Nicotine Dependence (FTND). Behavioural support starts 2 weeks before quit day and lasts 4 weeks following quit day, which follows the typical 7-session UK withdrawal orientated therapy programme.

Both groups will be given a cue exposure procedure to test subjective craving immediately after completion of the visual probe tasks at 4 weeks and follow-up sessions at 8 weeks, 3 months and 6 months. They will be instructed to handle an unlit cigarette and provide ratings of urges to smoke.

Participants will also be trained to use a hand-held electronic diary to capture withdrawal and behaviour as it happens on a day-by-day basis. Participants will use the diaries from two weeks prior to their designated quit date to 6 weeks post-quit.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Assessment of attentional bias during test trials of the visual probe task, as measured by reaction time data. This will be assessed in abstinent smokers at 4 weeks post-quit.
2. Strength of urge to smoke and withdrawal symptoms measured using the Mood and Physical Symptoms Scale (MPSS) measured prior to and at the end of the cue-exposure task at 4 weeks, 8 weeks, 3 months and 6 months in abstinent smokers and using the electronic diaries from baseline to 6 weeks post-quit

Key secondary outcome(s))
Prolonged abstinence measured and biochemically validated at 4 weeks, 8 weeks, 3 months and 6 months post-quit, using the Russell standard (allows a two week grace period from quit day for slips). Abstinence will be assessed by means of expired carbon monoxide reading, with a cut-off point of less than 10 ppm.

Completion date
31/03/2012

Eligibility

Key inclusion criteria
1. Aged 18 years or over, either sex
2. Smokes at least 10 cigarettes per day or blows greater than or equal to 10 on carbon monoxide (CO) monitor
3. Have normal or corrected-to-normal vision
4. Be able and willing to complete all study procedures

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Participants will be excluded if they present with any of the following:
1. A medical condition that prevents them seeing the computerised images properly, attending to the task, or pressing the keyboard buttons on the computer accurately, or completing any other study procedures
2. Are currently using other nicotene replacement therapy (NRT), bupropion, nortriptyline, mecamylamine, reserpine, or varenicline, or undergoing any treatment for tobacco dependence (e.g. acupuncture)
3. Unstable angina pectoris, myocardial infarction, or cerebrovascular accident during the last 3 weeks
4. Severe cardiac arrhythmia
5. Currently uncontrolled hyperthyroidism
6. Active phaeocromocytoma
7. Suspected alcohol or drug abuse
8. Are taking part in other medicinal trials during study participation
9. Have previously had severe skin reactions to nicotine patches or severe eczema or other skin diseases that make patch use hazardous or undesirable
10. Severe acute or chronic medical or psychiatric condition or previously diagnosed clinically important renal or hepatic disease, which may increase the risk associated with study participation or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the participant inappropriate for entry into this study

Date of first enrolment
01/07/2010

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UK Centre for Tobacco Control Studies
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Doctoral Research Fellowship (DRF) (ref: DRF-2009-02-15)

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	01/04/2015		Yes	No
Protocol article	protocol	13/12/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes