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Effects of varenicline and cognitive bias modification on responses to smoking cues

Submission date
09/07/2012

Recruitment status
No longer recruiting

Registration date
30/01/2014

Overall study status
Completed

Last Edited
18/01/2019

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many smokers find quitting smoking extremely difficult and failure rates are high. It has been shown that cues associated with smoking (e.g., cigarette packets, smell of smoke) can lead to cigarette cravings. Also, smokers may find that their attention is drawn to smoking cues significantly more than other objects or cues in the environment. This capturing of attention by smoking-related cues is an example of what is known as a 'cognitive bias'. Cognitive biases for smoking cues may lead to increased craving for cigarettes and interfere with attempts to stop smoking. Given this link between cognitive bias and smoking, programmes aimed at reducing cognitive bias are considered promising targets for quitting smoking. Recent research indicates that it is possible to 'train' attention away from drug cues using a computer-based programme known as cognitive bias modification (CBM). Therefore in this study we propose to find out the impact of a CBM procedure on the brain's responses to smoking-related cues. Additionally, a licenced smoking cessation drug, varenicline, has also been proposed to change responses to smoking-related cues. Varenicline may therefore increase the effects of CBM on responses to smoking cues.

Who can participate?
The study will enrol regular daily smokers (at least 10 cigarettes or 15 roll-ups per day), who smoke within one hour of waking in the morning.

What does the study involve?
The participants will be randomly allocated to either a training group or a drug group. Participants in the drug group will be randomly allocated to receive either varenicline or a placebo (dummy) tablet. Participants in the training group will be randomly allocated to receive either CBM to induce cognitive bias away from smoking-related cues, CBM to induce cognitive bias towards smoking-related cues, or a treatment designed to induce no change in cognitive bias. They will undergo a brain scan to find out the responses to smoking-related cues and cognitive bias towards smoking-related cues. Cigarette craving and nicotine withdrawal will also be analysed.

What are the potential benefits and risks of participation?
Information we get from this study may help us to understand and treat cigarette smokers who

have difficulty stopping in the future. The study medication (varenicline) is a licensed smoking cessation aid. It has been associated with some side effects. The more common side effects are fatigue, sleeplessness/abnormal dreams and vomiting, which may cause discomfort but are not considered dangerous or life-threatening.

Where will the study be run from?
The study will be run from Clinical Research and Imaging Centre (CRICBristol), University of Bristol, Bristol, UK.

When is the study starting and how long will it be expected to run for?
The study ran from August 2012 to February 2013.

Who is funding the study?
The study funded by Pfizer Inc. (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
UoB:1407

Study information

Scientific Title
Effects of varenicline and cognitive bias modification on neural response to smoking-related cues

Study objectives
1. We hypothesise that experimental procedures designed to induce cognitive bias towards smoking-relates cues will lead to an increase in neural response to smoking-related cues, in brain

regions previously implicated in cue reactivity in cigarette smokers.
2. We hypothesise that experimental procedures designed to induce cognitive bias away from smoking-relates cues will lead to a decrease in neural response to smoking-related cues, in brain regions previously implicated in cue reactivity in cigarette smokers.
3. We hypothesise that experimental procedures designed to induce cognitive bias away from smoking-relates cues will lead to a decrease in cognitive bias from pre-training to post-training.
4. We hypothesise that experimental procedures designed to induce cognitive bias towards smoking-relates cues will lead to an increase in cognitive bias from pre-training to post-training
5. We hypothesise that changes in the neural response to smoking-related cues relative to neutral cues, and changes in attentional bias, will be greatest in those trained to attend away from smoking-related cues and treated with varenicline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Brent, London, 07/02/2012, ref: 11/LO/1726

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Interventions
Participants are randomised to the training group or the drug group

Drug group:
Participants would receive either varenicline or placebo in tablet form. Varenicline would be taken as 0.5 mg once daily for days 1-3, and 0.5 mg twice daily for days 4-6, and 0.5 mg once daily for day 7, consistent with standard dosing regimen for smoking cessation. All outcome measures would be assessed on day 7.

Training group:
Participants are randomised to three groups:
1. An experimental condition designed to induce cognitive bias away from smoking-related cues
2. An experimental condition designed to induce cognitive bias towards smoking-related cues
3. A control condition designed to induce no change in cognitive bias

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Varenicline

Primary outcome(s)
1. Neural responses to smoking-related cues
2. Cognitive bias

Key secondary outcome(s)
1. Questionnaire of Smoking Urges
2. Minnesota Nicotine Withdrawal Scale (MNWS)

Completion date
28/02/2013

Eligibility

Key inclusion criteria
1. Smokes > 10 manufactured cigarettes or > 15 roll up cigarettes per day
2. Smokes within one hour of waking
3. Aged between 18 and 40 years
4. Able to attend all of the study session
5. English as first language or equivalent level of fluency

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Female volunteers who are pregnant or breast feeding
2. Female volunteers not using adequate contraception
3. Volunteers who do not currently have a GP
4. Current or previous substance or alcohol misuse or dependence [other than nicotine]
5. Alcohol use in excess of 35 Units/week if female or 50 Units/week if male
6. Caffeine use ≥ 8 cups per day
7. Significant current or past psychiatric illness (Axis 1 or 2 psychiatric diagnoses) as diagnosed by a psychiatrist
8. Clinically significant abnormality including cardiology risk factors and history of arrhythmia (as assessed by self-report)
9. Ongoing use of medication (i.e. intake of any medication within 8 weeks of study, with

exception of local treatment and occasional paracetamol or non-steroidal anti-inflammatory drugs, e.g., aspirin or ibuprofen)
10. Smokers actively trying to give up smoking during the study period
11. Uncorrected visual impairment (including colour-blindness)
12. Uncorrected auditory impairment
13. Condition that makes MRI scanning unsafe (e.g. metallic implants; history of metal-working)
14. Unable to tolerate scanning environment (as established during a short anatomical MRI scan on day 0)
15. Hypersensitivity to Champix

Date of first enrolment
23/07/2012

Date of final enrolment
28/02/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Bristol
Bristol
United Kingdom
BS8 1TU

Sponsor information

Organisation
University of Bristol (UK)

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Industry

Funder Name
Pfizer

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
University of Bristol (UK)

Alternative Name(s)
Universitas Bristolliensis, bristoluniversity, bristoluni

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/10/2014	18/01/2019	Yes	No
Protocol article	protocol	07/10/2014		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes