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Can a brief cognitive intervention assist smokers in giving up?

Submission date	Recruitment status	[X] Prospectively registered
17/03/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/04/2019	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

Study information

Scientific Title
Evaluation of the effectiveness of acceptance of the negative reinforcement explanation for smoking in facilitating smoking cessation: A cluster-randomised controlled trial

Study objectives

Primary hypothesis:
Successful communication of the negative reinforcement explanation for smoking reduces the urge to smoke (thereby facilitating smoking cessation) (Hypothesis I).

Secondary hypotheses:
Three possible mechanisms for this effect are hypothesised:

Acceptance of the negative reinforcement explanation for smoking reduces the urge to smoke via:
1. Decreased negative outcome expectations about remaining abstinent from smoking (Hypothesis II)
2. Increased positive outcome expectations about remaining abstinent from smoking (Hypothesis III)
3. Increased self-efficacy to abstain from smoking (Hypothesis IV)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Application will be submitted to the East London and the City Research Ethics Committee 1 for their May 2008 meeting.

Primary study design
Interventional

Study design
Single-centre two-group cluster-randomised controlled trial

Study type(s)
Not Specified

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

Interventions
Interventions:
Both experimental and control interventions will be delivered as the last part of the pre-quit group session (week two of a seven-week course). They will consist either of a 15-20 minute didactic presentation for the experimental intervention, or a 20 minute video for the control intervention. Both will be followed by ten minutes of discussion. One week later, again at the end of the standard group treatment session, this will be followed up by a 15-minute discussion of the previous week's session.

Experimental intervention:
The intervention communicates a set of ideas aimed at changing the way patients perceive the benefits of smoking and the post-quit withdrawal discomfort. It attempts to explain that in dependent smokers chronic smoking creates adaptation to nicotine. Withdrawal discomfort ensues in the absence of smoking. Smoking behaviour is largely driven by the desire to remove or avoid this unpleasant state. The apparently positive effects of smoking upon perceived stress, mood and concentration are primarily misattribution of the relief of withdrawal discomfort experienced immediately after smoking a cigarette. The withdrawal discomfort and urges to

smoke which follow smoking cessation weaken after a few weeks. However, complete abstinence is necessary to achieve this, as even a single cigarette can reinstate the need to carry on smoking.

In a task to be completed as homework before the second treatment session, participants would be asked to monitor their urge to smoke over a three-hour period of abstinence and complete a task card to record the increase in urge to smoke relative to the increasing period of abstinence, and the abrupt alleviation of the resulting tension after smoking.

Control intervention:
Participants will view a 19-minute DVD entitled Smoking and Human Physiology (AIMS Multimedia). The DVD details the adverse health consequences of smoking and will be followed by a discussion. The video does not cover any aspect of the cognitive intervention.

Intervention Type
Behavioural

Primary outcome(s)
Urges to smoke and withdrawal symptoms, assessed using the Mood & Physical Symptoms Scale (T2 and T3)

Timepoints:
T0: At baseline, immediately prior to the first intervention session
T1: Immediately following the first intervention session
T2: One week later, immediately following the second intervention session
T3: At follow-up one week following the second session

Key secondary outcome(s)
The following will be assessed by a 12-item questionnaire developed for the current research:
1. Participants' cognitions regarding the positive outcome expectations of smoking (T0, T1, T2, T3)
2. Expectations of the quitting process (T0, T1, T2, T3)
3. Self-efficacy (T0, T1, T2, T3)

Timepoints:
T0: At baseline, immediately prior to the first intervention session
T1: Immediately following the first intervention session
T2: One week later, immediately following the second intervention session
T3: At follow-up one week following the second session

Completion date
29/05/2009

Eligibility

Key inclusion criteria
Participants must be attending for treatment at the NHS specialist smoking cessation clinic (SSCC) at The Royal London Hospital in East London. All clinic clients who provide informed consent and are able to fill in the study forms in English will be eligible.

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
145

Key exclusion criteria
Unable to fill in the study forms in English.

Date of first enrolment
02/06/2008

Date of final enrolment
29/05/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Institute of Psychiatry, King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK PhD studentship (ref: C4770/A7173)

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	21/02/2012	17/04/2019	Yes	No