

Can a brief cognitive intervention assist smokers in giving up?

Submission date 17/03/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/04/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/04/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

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
N/A

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.

Study design

Single-centre two-group cluster-randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

02/06/2008

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

Age group

Adult

Sex

Both

Target number of participants

140

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

England

United Kingdom

Study participating centre
King's College London
London
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Sponsor information

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

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Sponsor type
University/education

Website
<http://www.iop.kcl.ac.uk>

ROR
<https://ror.org/0220mzb33>

Funder(s)

Funder type
Charity

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/02/2012	17/04/2019	Yes	No