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The efficacy of group hypnosis and relaxation in smoking cessation

Submission date
15/08/2011

Recruitment status
No longer recruiting

Registration date
26/08/2011

Overall study status
Completed

Last Edited
04/09/2014

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Scientists believe that hypnosis may help people stop smoking, but studies show unclear results. At the same time, people who want to give up smoking are not always able and willing to attend several sessions of therapy or to use medication. Therefore, we are investigating whether a single hypnosis session helps smokers quit smoking.

Who can participate?
You are invited to participate in the study if you are older than 18 years, if you smoke at least five cigarettes per day, if you want to quit and if you are not trying to give up smoking in any other way.

What does the study involve?
You will attend a 40-minutes session of motivational training then you will be randomly allocated to attend a 40-minute group session of either hypnosis or relaxation. You will attend the session together with 10-15 other people. A trained hypnotherapist and relaxation instructor will lead the session.

What are the possible benefits and risks of participating?
There are no risks for you because hypnosis has hardly any side effects in healthy people. The results will provide information to tobacco prevention organisations in Switzerland on whether or not to recommend hypnosis as a method to stop smoking.

Where is the study run from?
Institut für Sucht- und Gesundheitsforschung (ISGF) (Switzerland).

When is the study starting and how long is it expected to run for?
The study ran from April 2011 to June 2012.

Who is funding the study?
Tobacco Control Fund (Switzerland).

Who is the main contact?
Dr Michael Schaub
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10.005768

Study information

Scientific Title
Smoking cessation through group hypnosis: a randomised controlled trial

Study objectives
A one-time session consisting of mental preparation followed by hypnosis or relaxation in a group setting helps smokers quit smoking. We hypothesise that 6 months following the intervention, at least 30% of participants in the hypnosis group and at least 18% of participants in the relaxation group will be abstinent.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cantonal Ethical Committee of Zurich, 25/08/2010

Study design
Single-centre randomised controlled double-blind study with repeated measurements

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Patient information can be found at http://www.isgf.ch/index.php?id=94&no_cache=1&tx_ttnews[tt_news]=27&tx_ttnews[backPid]=9&cHash=859b89b6fa6ac5bd25fa181c4e58ae97%20 [German]

Health condition(s) or problem(s) studied
Public health, smoking, hypnosis, smoking cessation

Interventions
Two groups to be compared:
1. Participants receive 40 minutes of motivational training followed by 40 minutes of hypnosis in a group session (8 to 15 participants)
2. Participants receive 40 minutes of motivational training followed by 40 minutes of relaxation in a group session (8 to 15 participants)

Motivational training: the intention of the participants to quit smoking is reinforced in an oral presentation given by a trained instructor. The presentation focuses on participants life after smoking cessation.

Group hypnosis: deep relaxation is induced through repetitive statements and soft background music. During the hypnosis, suggestions reinforcing cigarette abstinence are made by a trained instructor.

Group relaxation: relaxation is induced through soft music. During the relaxation, suggestions reinforcing cigarette abstinence are made by a trained instructor.

All participants are contacted 2 weeks and 6 months following the intervention in order to check their smoking status, mental and physical health.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Number of participants smoking 2 weeks after each intervention (smoking defined as 5 or more cigarettes per day) (inter-subject design)

2. Number of participants smoking 6 months after each intervention (inter-subject design)
3. Changes in the number of daily cigarettes smoked from baseline to 2 weeks after the intervention (intra-subject design)
4. Changes in the number of daily cigarettes smoked from baseline to 6 months after the intervention (intra-subject design)
5. Changes in salivary cotinine levels from baseline to 6 months after the intervention (intra-subject design)

Secondary outcome measures
1. Depression (BDI-V, Schmitt et al. 2003; 2006) at baseline, 2 weeks and 6 months after the intervention
2. Anxiety (BAI, Beck et al. 1988, German version by Margraf & Ehlers) at baseline, 2 weeks and 6 months after the intervention
3. Expected self-efficacy in situations of high smoking temptation (Tönjes et al., 2007) at baseline and 2 weeks after the intervention
4. Adverse events (headache, insomnia, gastrointestinal problems etc.) 2 weeks and 6 months after the intervention

Overall study start date
20/04/2011

Completion date
01/06/2012

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. Smoking five or more cigarettes per day
3. Not taking any medication or following another program for smoking cessation
4. Willing to stop smoking
5. Not suffering from alcohol dependence or psychotic disorders
6. No intake of stimulating medication such as methylphenidate (Ritalin) or venlafaxine (Effexor®)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
172

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
20/04/2011

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
Switzerland

Study participating centre
Konradstrasse 32
Zurich
Switzerland
8031

Sponsor information

Organisation
Tobacco Control Fund (Switzerland)

Sponsor details
c/o Mr Peter Blatter
Hessstrasse 27E
Bern
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3003

Sponsor type
Government

ROR
https://ror.org/01qtc5416

Funder(s)

Funder type
Government

Funder Name
Tobacco Control Fund (Switzerland)

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	23/12/2013		Yes	No