

# The efficacy of group hypnosis and relaxation in smoking cessation

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/09/2014	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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

**Contact name**  
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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](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**

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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?
<a href="#">Results article</a>	results	23/12/2013		Yes	No