Effects of cTBS at left and right insula using deep TMS on cue-induced nicotine craving and cognitive control

Published: 24-07-2023
Last updated: 09-11-2024

To evaluate whether cue-induced nicotine craving and cognitive control in smoking individuals can be modulated with cTBS at left or right insula using deep TMS.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON56171

Source
ToetsingOnline

Brief title
Inhibit smoke memory

Condition

- Psychiatric disorders NEC

Synonym
smoking addiction, Tobacco use disorder

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Deep rTMS, Insula, Nicotine craving, Smoking

Outcome measures

Primary outcome

Subjective cue-induced nicotine craving, measured by the Questionnaire on Smoking Urges score after a smoking cue-exposure task, and behavioural cognitive control, measured by the stop signal reaction time on the stop signal task.

Secondary outcome

Physiological cue-induced nicotine craving and cognitive control, measured by heart rate variability and skin conductance level.

Study description

Background summary

Tobacco use disorder is a mental health disorder characterized by the compulsive urge to smoke, and smoking is the leading global risk factor for premature death and disabilities. A brain area crucially involved in smoking addiction is the insula, and the left and right insula appear to have opposite roles in addictive processes. High frequency (HF) repetitive transcranial magnetic stimulation (rTMS) is a non-invasive brain stimulation method found to be effective in reducing nicotine craving and tobacco consumption, with promising results of the novel techniques deep rTMS and theta burst stimulation (TBS). Unfortunately, quit rates after deep HF rTMS at the bilateral frontal cortex and insula in chronic smokers dropped to 19% after 4.5 month follow-up. In our study, continuous TBS (cTBS) is used as a rTMS protocol in combination with a deep TMS system that allows for unilateral stimulation, to investigate the effect of inhibiting the insula on addictive processes, and the differential role that the left and right insula play in this.

Study objective

To evaluate whether cue-induced nicotine craving and cognitive control in

smoking individuals can be modulated with cTBS at left or right insula using deep TMS.

Study design

This study is a single-blind randomized sham-controlled intervention trial using a single-session, mixed factorial, cross-over design.

Intervention

One group receives cTBS at the left insula, and the other group receives cTBS at the right insula. Participants from both groups receive active and sham cTBS for 20s each.

Study burden and risks

All participants will attend only a two hour single session. Possible negative AEs of cTBS, including headaches and facial muscle twitching, as well as possible beneficial effects of cTBS on cue-induced craving and cognitive control, for the participants will only be transient. Results from this study could be used for the better understanding of tobacco use disorder and further development and improvement for the treatment of tobacco use disorder. Thus, benefits of this study outweigh the low risks associated with study participation.

Contacts

Public
Amsterdam UMC

De Boelelaan 1108
Amsterdam 1081 HZ
NL
Scientific
Amsterdam UMC

De Boelelaan 1108
Amsterdam 1081 HZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Age of 18-30 year
Females: use of a medically accepted form of hormonal birth control
Smoking on average at least 10 filter cigarettes per day
Smoking for at least one year
Primarily smoking filter cigarettes and not any other form of tobacco

Exclusion criteria

Previous experience with (deep) rTMS
No reliable communication with the investigator or coping with the requirements of the experiment possible
Last year or current psychiatric disorder diagnosis or treatment
Suffering from a neurological disorder
Possible alcohol dependence or drug (other than tobacco) use disorder diagnosis
TMS contraindications

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2023
Enrollment:	54
Type:	Actual

Medical products/devices used

Generic name:	Deep TMS system (model 102)
Registration:	No

Ethics review

Approved WMO Date:	24-07-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-10-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL83625.018.23