Investigating a personalized smoking cessation treatment based on neurocognitive profile: an innovative deep cTBS study

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

Summary

ID

NL-OMON57086

Source
ToetsingOnline

Brief title
Insula inhibition for smoking cessation

Condition

- Psychiatric disorders NEC

Synonym
smoking addiction, Tobacco use disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universiteiten

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: cTBS, deep TMS, insula, smoking cessation

Outcome measures

Primary outcome

Days untill relapse, number of smoked cigarettes and craving

Secondary outcome

Abstinence (yes/no), number of abstinent days, degree of tobacco dependence, withdrawal symptoms, cognitive control, craving, goal-directed behavior, neurobiological measures (brain network activity, brain activity involved in cognitive control and craving, dACC glutamate concentrations), craving after cTBS session.

Study description

Background summary

Tobacco use disorder is associated with deviating cognitive functions, including cognitive control and craving. A brain area that is associated with these addiction-related cognitive functions is the insula, but there appears to be a functional lateralization. These neurocognitive deviations give rise to the development of novel treatment strategies. One promising strategy is transcranial magnetic stimulation (TMS), by which specific (cortical) brain areas can be targeted to either increase or decrease neural activity and thereby normalize cognitive functioning. Recently a novel approach has been developed by which deeper brain areas can be targeted; deep TMS. It has been suggested that inhibiting, rather than stimulating the insula, might have stronger clinical potential. Continuous theta burst stimulation (cTBS), a form of TMS, results in neural inhibition and can be targeted at the insula with the use of an innovative H8 TMS coil.
It is expected that inhibition of left and right insula will show differential effectiveness on outcomes and that there will be sex differences.

Study objective

The aim of the study is to investigate whether inhibition of the left or right insula has differential effects with regard to clinical outcomes (i.e. smoking cessation/reduction), cognitive processes (i.e. cognitive control, craving and goal-directed action) and underlying neurobiological processes (i.e. brain network activity, activity associated with cognitive control and craving, and glutamate concentrations in the dorsal ACC). Sex-related differences in the outcomes will also be investigated.

Study design

double-blind RCT

Intervention

Participants are randomized to 1 of 3 conditions; 1) active cTBS of the left insula, 2) active cTBS of the right insula, or 3) sham stimulation of the left or right insula. All participants will receive additional motivational interviewing.

Study burden and risks

Potential negative side effects of cTBS, including headaches and facial twitching, will only be temporary for participants. The results of this research can be used for a better understanding of tobacco addiction and for further development and improvement of the treatment of tobacco addiction. The benefits of this study outweigh the small risks associated with participating in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Age 25-55 years
Smoking at least 10 filter cigarettes per day
Smoking for at least 10 years
Fagerstrom Test for Nicotine Dependence score of at least 3
Primarily smoking filter cigarettes and nog any other form of tobacco
Desire to quit smoking
Having at least one quit attempt using an evidence-based treatment

Exclusion criteria

Previous experience with TMS
Primarily smoking tobacco products other than filter cigarettes, such as shag, cigars, e-cigarettes and cannabis
Currently undergoing other treatment to quit smoking
Current diagnosis or last year treatment for a psychiatric disorder
Suffering from a neurological disorder
Heavy use or possible dependence on alcohol
Heavy use or possible dependence on substances other than tobacco
TMS and MRI contraindications, including:
o Cardiac demand pacemakers, implanted defibrillators, or other electronic implants.
o History of seizure or heat convulsion.
o History of epilepsy or seizure in first degree relatives; Receiving or requiring antiepileptic drugs.
o History of head injury.
o History of metal implants in the head (except dental fillings).
o Known history of any metallic particles in the eye, implanted cardiac pacemakers or any intracardiac lines, implanted neurostimulators, surgical

clips or any medical pumps.
o Hearing loss or history of hearing loss.
o Known history of cochlear implants
o Known or possible pregnancy
o Systemic and metabolic disorders.
o Any known factor that lowers the threshold for epileptic seizures (e.g. psychotropic medications, sleep deprivation, caffeine, substance abuse, etc.).
o Irremovable prosthesis.
o Irremovable piercings.
o Irremovable medicine patches
o IUDs placed within 6 weeks or material other than copper.
o Irremovable dentures.
o Implanted lenses in the eye.
o Bone screws or plates.
o Metal particles in the eye or they body.
o Tinnitus
o Inadequate communication with the patient

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	112
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO Date:	22-10-2024
Application type:	First submission
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	NL86870.018.24