

Erasing smoking memories using a retrieval-distractor protocol

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Proof-of-principle that a 3-day intervention protocol, during which smoking memories are being retrieved and desensitised, will lead to a reduced ability of nicotine-associated stimuli to induce cigarette craving.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55689

Source

ToetsingOnline

Brief title

erasing smoking memories

Condition

- Other condition

Synonym

nicotine addiction, tobacco use disorder

Health condition

tabakverslaving

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cue exposure, EMDR, memories, smoking

Outcome measures

Primary outcome

1 day before and 1 day after the intervention cue-induced cigarette craving will be assessed with questionnaires. At the 2 week and 3 month follow-up nicotine-dependence will be assessed with a questionnaire.

Secondary outcome

Before the first and second exposure-test: the Questionnaire of smoking urges (QSU)

Study description

Background summary

Smoking is the leading risk factor for premature death and disabilities. The latest global report on addictive behaviour shows that the harm to society from legal drugs far outweighs the harm from illicit drugs: 240 million people have an alcohol use disorder and more than 1 billion people smoke tobacco with 6 million annual deaths from smoking, and approximately 600,000 premature deaths from exposure to second hand cigarette smoke. Tobacco use disorder is a chronically relapsing condition. During abstinence, memories of smoking, typically triggered by exposure to smoking-associated stimuli in the environment, elicit craving and precipitate relapse and are associated with brain activation/connectivity abnormalities. Therefore, this brain-related disease can be viewed as the result of maladaptive processes of Pavlovian and instrumental learning and memory. Manipulating the maladaptive memories may thus open new venues to reduce the impact of smoking-related cues on craving and relapse behaviour. Pharmacological and behavioural disruption of reconsolidation of drug memories has been repeatedly demonstrated in

well-established animal models of addiction and resulted in long-lasting reductions in cue-reactivity and relapse probability. Now is the time to translate these promising findings to clinical applications and to cure the most prevalent brain-related disorder in our society. Based on our own preclinical data and recent clinical observations it is our goal to establish a novel behavioural intervention in smokers aimed at reducing smoking-cue reactivity and the probability to relapse by reframing the nicotine-occupied mind. To that end, we have developed a modified Eye Movement Desensitization and Reprocessing (EMDR) protocol in which distractor stimuli will be used to blur nicotine memories.

Study objective

Proof-of-principle that a 3-day intervention protocol, during which smoking memories are being retrieved and desensitised, will lead to a reduced ability of nicotine-associated stimuli to induce cigarette craving.

Study design

Doubleblind placebo controled intervention study with a 2 week and 3 months follow-up. The primary outcome measures (cue-induced craving) will be collected on day 1 (baseline), day 5 (after the intervention) and during the follow-up by a research assistant blind for the experimental condition. The experimenter guides the intervention itself and has (of necessity) knowledge of the experimental condition.

Intervention

Intervention includes 3 sessions of 45 minutes on 3 consecutive days during which the experimental group (n=40) walks in a virtual surrounding and is alternately exposed to visual smoking cues and distractor stimuli. The control group (n=40) receives neutral stimuli instead of the distractor stimuli.

Study burden and risks

Participants are asked to stop smoking during the 5 day study. The financial reward is €20 per day. This will be assessed by self-report and daily CO breath tests. There is a risk that craving induced during the exposure tests and the intervention will provoke a relapse. Given the fact that these cues are also present in daily life, the additional risk is considered small. There is, in fact, no extra risk as participants will then return to their previous (smoking) condition. There is a chance that the intervention will reduce the risk to relapse, which obviously is a positive outcome. The intervention itself does not cause health risks. After the study, participants will be provided with information from Rookstopoli Beverwijk on support for smoking cessation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- 1) between 25 and 55
- 2) history of smoking of >10 year
- 3) >=10 cigarettes a day

Exclusion criteria

- 1) neurological disorders
- 2) lifetime diagnosis or treatment of psychosis or mania
- 3) other psychiatric diagnosis or treatment in the past 4 years
- 4) current use of psychoactive drugs
- 5) current drug dependence, except for nicotine
- 6) physical impairment
- 7) inability to understand study procedures

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-07-2020
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Multi-Modular Motion-assisted Memory Desensitization and Reconsolidation (3MDR)
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	26-07-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	12-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	21-08-2020
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	09-02-2021
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

ID: 27225

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL63887.029.18
OMON	NL-OMON27225