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Promoting smoking abstinence through Virtual Reality (VR) - Approach Bias Training

Submission date
12/02/2019

Recruitment status
No longer recruiting

Registration date
28/03/2019

Overall study status
Completed

Last Edited
06/01/2021

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Treatment programs for addictive behaviors, including cigarette smoking, still face the problem of low response rates, comparatively high dropouts and high relapse rates. One possible explanation for poor treatment outcomes might be that contemporary interventions fail to target implicit cognitive processes that might maintain addictive behavior. Automatic processes to approach smoking-related cues have been repeatedly linked to smoking status, intensity of smoking and cigarette craving. Moreover, recent findings suggest that targeting those tendencies directly by means of approach-bias modification has merit in changing maladaptive approach tendencies for drug cues and reducing drug consumption. However, findings have not always been clear-cut and the effects tend to be rather small to moderate in size. Thus, there is a growing need to improve training efficacy. Embedding the training into virtual reality (VR) technology could be a promising new way to improve ecological validity, realism and immersion and thereby increase training effects. The main goal of the present study is to investigate the effectiveness of a newly developed VR approach-bias retraining in reducing smoking behavior or facilitating abstinence in smokers motivated to quit smoking.

Who can participate?
People who have smoked at least six cigarettes per day for at least six months, who are active smokers at study entry and are motivated to quit smoking

What does the study involve?
Participants take part in a brief behavioral support for smoking. Afterwards, smokers are randomly allocated either to the experimental (VR-avoidance training) or the placebo (VR-placebo training) group. Smokers allocated to the experimental group are implicitly instructed to make an avoidance movement in response to smoking-related objects (i.e., cigarettes) and an approach movement in response to alternative objects (i.e., healthy food). Smokers allocated to the placebo group respond to smoking-related and alternative objects without making any approach or avoidance movements. Smokers in both conditions complete six training sessions within two weeks. Training effects on automatic approach tendencies and smoking behavior are measured immediately after training and at a four-week follow-up.

What are the possible benefits and risks of participating?
A possible benefit is that the VR-avoidance training may help smokers to reduce or stop smoking. Some individuals might experience short-term symptoms such as sensations of nausea or vertigo during or after VR exposure (i.e., “cybersickness”).

Where is the study run from?
University of Siegen (Germany)

When is the study starting and how long is it expected to run for?
July 2018 to May 2020

Who is funding the study?
Ministry of Culture and Science of North Rhine-Westphalia

Who is the main contact?
Dr Alla Machulska
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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
N/A

Study information

Scientific Title
Virtual approach-bias retraining for smokers seeking to quit smoking: a randomized controlled trial

Study objectives
It is expected that participants in the experimental condition will show reduced smoking behavior, increased abstinence rates and diminished cognitive biases than participants in the placebo control condition. Close (diminished approach bias for untrained pictures in the assessment version of the AAT) and broad (diminished attentional and association biases) generalization of training is explored, as well as therapy effects on clinical outcomes such as smoking behavior, attitudes towards smoking and motivation to quit smoking. Since the VR-training does not only require participants to avoid health-damaging, smoking cues (i.e., cigarettes, cigarette lighter), but simultaneously to approach health-promoting items (i.e., fruits and vegetables, sports devices), training effects on health-promoting behaviors are also a target of investigation.

It is expected that the VR-avoidance training will decrease or reverse cognitive biases and that these changes can possibly mediate the effects on the clinical outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/01/2019, Ethics Committee of the University of Siegen (Adolf-Reichwein-Str. 2, 57076 Siegen; ethikrat@uni-siegen.de), ref: ER_18_2018.

Study design
Single-center randomized trial, 2(condition) x 3(time) factorial design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Nicotine addiction

Interventions

Participants will be randomly assigned to the experimental or placebo control group, according to an externally constructed randomization plan.
1. TAU (brief behavioral support for smoking) + VR-avoidance training
2. TAU + VR-placebo training

Research Flow for the treatment and control group:
1. Recruitment
2. Brief behavioral support for smoking (TAU) + Baseline assessment (First lab session): After the first session, participants are randomly allocated to one of two conditions
3. Training: six sessions of VR-training (avoidance training or placebo) within two weeks
4. Post-test (Second lab session): Post-test two weeks after the baseline assessment.
5. Follow-up (Third lab session): Four weeks after post-test.

Prior to randomization, participants receive psychoeducation containing information on nicotine addiction (initiation and maintenance) and short and long-term effects attributed to smoking (TAU; about 60 minutes). Afterwards, smokers receive a self-help book ("The Easy Way to Stop Smoking" by Allen Carr) to aid smoking cessation. Smokers in both groups perform six VR-training sessions within two weeks. The VR scenario takes place in an office. A simplified virtual male or female hand (depending on participant's gender) displays the interaction hand. Prior to the first training session, participants are introduced to grasping and warding interactions using neutral objects. During training, red or blue-framed objects appear successively on a desk in front of the participants. Participants allocated to the VR-avoidance training are instructed to make an avoidance (push) or an approach (pull) hand movement depending on the frame color. Most importantly, all smoking-related objects are presented in a push away/avoidance format while alternative objects are presented in a pull closer/approach format. Participants allocated to the placebo training had to move the smoking-related and alternative objects to the left or to the right depending on frame color. Thus, the placebo control condition did not include any approach or avoidance movements.

Intervention Type
Behavioural

Primary outcome measure
Measured at baseline, post-training and at a 4-week follow-up:
1. Approach bias measured by the assessment version of the Approach-Avoidance Task
2. Self-reported nicotine consumption measured via a questionnaire.
In addition, participants will be instructed to log smoked cigarettes when smoking by using a smartphone-based cigarette-tracking app. The logging period will cover 6 weeks, which is the study duration for each participant
3. Abstinence from smoking determined through self-report and biochemically-verified expired CO (Smokerlyzer)

Secondary outcome measures
Measured at baseline, post-training and at a 4-week follow-up:
1. Cognitive biases measured by a visual dot-probe task and the Implicit Association Task
2. Smoking behavior assessed using Fagerström Test for Nicotine Dependence (FTND; Heatherton et al., 1991)
3. Motivation to stop smoking assessed using Stages of Change Scale; Prochaska et al., 1991; Thoughts About Abstinence Scale; Hall et al., 1990
4. Cigarette craving assessed using single item craving rating ranging from: 0 = not at all, to 5 = very much

5. Explicit attitudes toward smoking assessed using semantic differential based on Swanson et al., 2001

Overall study start date
01/07/2018

Completion date
31/05/2020

Eligibility

Key inclusion criteria
1. Smoked for at least six months at least six cigarettes per day
2. Active smokers at study entry
3. Motivated to quit smoking.

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Current alcohol or drug misuse or dependency
2. Psychiatric illness
3. Insufficient German language skills
4. Uncorrected visual or auditory impairment.

Date of first enrolment
01/03/2019

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Germany

Study participating centre
University of Siegen
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Sponsor information

Organisation
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Sponsor type
University/education

Website
https://www.uni-siegen.de/start/

ROR
https://ror.org/02azyry73

Funder(s)

Funder type
Government

Funder Name
Ministerium für Kultur und Wissenschaft, NRW, Germany

Results and Publications

Publication and dissemination plan
Planned publication of the study protocol in Trials,
planned publication of the study results in a high-impact peer reviewed journal, intention to publish date: 01/03/2021

Intention to publish date
01/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the corresponding author (Dr. Alla Machulska; alla.machulska@uni-siegen.de). The data will be available after the overall trial end (31.5.2020).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/02/2020	06/01/2021	Yes	No