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Retraining automatic action tendencies for smoking using mobile phone-based approach-avoidance bias training

Submission date
20/11/2018

Recruitment status
No longer recruiting

Registration date
24/01/2019

Overall study status
Completed

Last Edited
09/12/2020

Condition category
Mental and Behavioural Disorders

[X] 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
Tobacco smoking remains a major public health problem. The World Health Organization (WHO) states that smoking cigarettes is the largest preventable risk factor for morbidity and mortality worldwide, with smoking-related deaths being estimated at over five million people per year. Even following regular, gold-standard smoking cessation interventions, only about 25 percent will achieve sustained abstinence. This might be the case because contemporary interventions often fail to target automatic processes associated with smoking. One such process involves automatic tendencies to approach smoking-related stimuli that have been implicated in smoking intensity. The Approach-Avoidance-Task (AAT) has proven valuable in both measuring and modifying smoking-related approach tendencies. During the training version of the task, smokers are instructed to make an avoidance movement in response to all smoking-related images using a joystick attached to the computer. Although recent literature shows that the AAT-training has merit in modifying smoking-related approach biases or reducing nicotine consumption, accessibility of the training is impaired by the fact that trainings are carried out in the lab on desktop PCs. To facilitate access to the training and to increase training efficiency, the present study provides mobile phone-based AAT training (app-AAT), which can be completed outside the laboratory context (i.e., at home). The main goal is to investigate the effectiveness of the app-AAT in reducing smoking behavior or facilitating abstinence. The results of this study can inform future research in the optimization and advancement of treatment for nicotine addiction.

Who can participate?
People who have smoked at least six cigarettes per day for at least six months, 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 randomly allocated to the app-AAT group are given access to the mobile-phone based training. Participants in this group are instructed to perform the training on a daily basis. Training effects on automatic approach tendencies and smoking behavior are measured immediately after

training and at a four-week follow-up. Participants who do not receive the training (waitlist control group) are then given access to the training app.

What are the possible benefits and risks of participating?
A possible benefit is that the app-AAT may help smokers to reduce or stop smoking. There are no significant risks of participating in the study.

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?
Ministerium für Kultur und Wissenschaft, NRW (Germany)

Who is the main contact?
Dr Alla Machulska

Contact information

Type(s)
Scientific

Contact name
Dr Alla Machulska

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Retraining automatic action tendencies for smoking using mobile phone-based approach-avoidance bias training: a randomized controlled study

Study objectives
It is expected that participants in the intervention condition will show reduced smoking behavior, increased abstinence rates and diminished cognitive biases than participants in the 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 therapy effects on clinical outcomes such as smoking behavior, attitudes towards smoking and motivation to quit smoking.

It is expected that the training intervention will decrease or reverse cognitive biases and that these changes can possibly mediate the effects on the clinical outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University of Siegen

Study design
Single-centre randomised trial, 2(condition)x3(time) factorial design

Primary study design
Interventional

Study type(s)
Treatment

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

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

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: app-AAT training at home for 14 consecutive days
4. Post-test (Second lab session): post-test two weeks after the baseline assessment.
5. Follow-up (Third lab session): after 4 weeks.

Prior to randomization, participants receive psychoeducation containing information on nicotine addiction and maintenance and short and long-term effects associated with cigarette smoking (TAU; about 60 minutes). Afterwards, smokers will be handed over a self-help book (“The Easy Way to Stop Smoking” by Allen Carr) to aid smoking cessation. Participants allocated to the experimental condition are then given access to the AAT-training app and are instructed to train at least once per day for 14 consecutive days. Participants perform a practice training with the researchers to ensure that the training handling and concepts have been fully understood. To ensure compliance, participants will receive daily reminders via short message service (SMS) to complete the training. After competition of the study (at the end of the four-week follow-up session), the waitlist-control condition will receive access to the training app.

Intervention Type

Behavioural

Primary outcome(s)
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
follow-up. 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)

Key secondary outcome(s))
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

Completion date
31/05/2020

Eligibility

Key inclusion criteria
Smokers are included if they had smoked for at least six months at least six cigarettes per day, are active smokers at study entry and are motivated to quit smoking.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Exclusion criteria are current alcohol or drug misuse or dependency, psychiatric illness, insufficient German language skills or uncorrected visual or auditory impairment.

Date of first enrolment

01/03/2019

Date of final enrolment
01/03/2020

Locations

Countries of recruitment
Germany

Study participating centre
University of Siegen
Adolf-Reichwein-Str. 2a
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Sponsor information

Organisation
University of Siegen

ROR
https://ror.org/02azyry73

Funder(s)

Funder type
Government

Funder Name
Ministerium für Kultur und Wissenschaft, NRW, Germany

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Alla Machulska (Alla.machulska@uni-siegen.de).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/12/2019	09/12/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes