ABC-training: a new, personalized cognitive training for smoking cessation

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CONFIRMATORY HYPOTHESIS Our novel cognitive training incorporates several aspects that are expected to increase its effectiveness when compared to traditional Cognitive Bias Modification (CBM). As a confirmatory hypothesis we expect that, as an add...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25519

Bron
Nationaal Trial Register

Verkorte titel
ABC-training

Aandoening

Smoking

Ondersteuning

Primaire sponsor: NWO (016.Veni.195.016)
Overige ondersteuning: NWO (016.Veni.195.016)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of days that participants stay abstinent after their initial quit attempt (continuous).

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND

Smoking remains a common cause of premature disease and death, with 25.4% of Dutch men and 18.1% of women smoking in 2019. While most smokers want to quit, quitting attempts are generally unsuccessful. Cognitive Bias Modification (CBM) training has been tested as a method to increase quitting rates, but results have been mixed (1,2). We will combine features that have individually shown promise to increase the effectiveness of CBM in a novel training. We will test its effectiveness in a randomized controlled trial, with the training being added to smoking cessation therapy sessions for smokers seeking help to quit.

The novel training incorporates personally relevant risk contexts, or antecedents (A), and requires participants to make behavioural choices (B) that are in accordance with their personal (health) goals, in light of their consequences (C). The theoretical concept of the ABC training was recently published (3). The rationale behind the approach is that inferential processes may underlie CBM training effects. That is, having participants repeatedly make behavioural choices with certain consequences (smoking is bad, alternative behaviour is good) will lead to the formulation of inferences about the evaluative properties of these choices. Notably, the antecedents, the alternative behavioural choices and the consequences will be personalized. For instance; a smoker may be most tempted to smoke at home after dinner and they would like to choose exercise as an alternative behaviour in order to reach their goal of becoming healthier (consequence). The contexts, behaviours and goals will be simulated in a virtual environment with an ‘avatar’ representing the participant.

While the complete ABC training is as-yet untested, there is tentative evidence that its components are effective. A proof-of-principle study showed that when CBM to reduce unhealthy eating was performed in a simulated real-life context (standing in front of a fridge of food), with direct (health) consequences to unhealthy eating, its effectiveness improved (4). In a separate study, personalized, alternative behavioural choices increased the effectiveness of CBM training for smoking (5).

METHODS

The ABC training will be added to smoking cessation therapy provided by ‘WeQuit’, a stop smoking service. WeQuit provides Cognitive Behavioural Therapy (CBT) by trained psychologists via video-chat group sessions to help smokers who want to quit smoking (www.wequit.nl).

We will randomize participants, per therapy group, over 4 conditions. Condition I: ABC-training, incorporating personalized antecedents (A), alternative behavioural choices (B) and consequences (C) which trains participants to learn the consequences of both smoking (e.g., poorer health) and alternative behaviours (e.g. improved health). Condition II: Standard CBM training (100% alternative behaviour 0% smoking), which trains participants to always

choose the alternative behaviour over smoking, based on an irrelevant feature (a frame around the stimuli). It incorporates A and B, but not C. Condition III: Standard CBM sham-training (50% alternative behaviour, 50% smoking), which trains participants to choose the alternative behaviour or smoking, based on an irrelevant feature. It incorporates A and B, but not C. Condition IV: Passive control condition, no computerized cognitive training (only treatment as usual: WeQuit smoking cessation therapy).

Aligned with the timeline of WeQuit (6 CBT consultations over 6 weeks), we will offer weekly sessions of ABC training during the 6 weeks that WeQuit therapy takes place. We ask / encourage participants to perform ABC training 2 times a week, during the training period of 6 weeks, totaling 12 training sessions. Participants are required to perform ABC training at least once a week (6 in total).

The actual training (for conditions I, II and III) takes place in a virtual environment in which an avatar represents the participant. At the start of the training the participant can choose an avatar that fits them best, based on their gender and complexion. The virtual environment will be made up of a series of mp4. video and PNG Image files, portraying the avatar in risk situations and acting out alternative behaviours. These videos will be animated in iClone version 7, a type of 3D animation software. The software allows for the creation of a 3D scene with props inside, personalized avatars and having them act out any required movement. The .mp4 video files will be combined within lab.js – a free, open, online study builder (https://lab.js.org/) – to create an interactive user-friendly virtual environment for the participant to navigate. Lab.js builder works to combine a series of screens to present choice on relevant antecedent, alternative behaviours and consequences. Dependent on these choices it will present a series of sequences, each consistent of a risk situation, a choice of two alternative action portrayals, and the respective action feedback.

REFERENCES

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2. Boffo, M. et al. Cognitive Bias Modification for Behavior Change in Alcohol and Smoking Addiction: Bayesian Meta-Analysis of Individual Participant Data. Neuropsychol. Rev. 29, 52–78 (2019).
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4. Van Dessel, P., Hughes, S. & De Houwer, J. Consequence-Based Approach-Avoidance Training: A New and Improved Method for Changing Behavior. Psychol. Sci. 29, 1899–1910 (2018).
5. Kopetz, C., MacPherson, L., Mitchell, A. D., Houston-Ludlam, A. N. & Wiers, R. W. A novel training approach to activate alternative behaviors for smoking in depressed smokers. Exp. Clin. Psychopharmacol. 25, 50–60 (2017).

Doel van het onderzoek

CONFIRMATORY HYPOTHESIS

Our novel cognitive training incorporates several aspects that are expected to increase its effectiveness when compared to traditional Cognitive Bias Modification (CBM). As a confirmatory hypothesis we expect that, as an add-on to video-chat cognitive behavioural therapy sessions, active CBM training (condition I + condition II) will decrease smoking when compared to a non- or minimally effective sham-control condition or treatment as usual (condition III + condition IV).

EXPLORATORY HYPOTHESES

- Full ABC-training (condition I) will decrease smoking more when compared to training which is similar to a more traditional CBM scheme (condition II; forced-choice for alternative behaviour 100% smoking 0%, without consequences)

- The sham-control condition (condition III; forced-choice for alternative behaviour 50% smoking 50%, without consequences) will have some effect on smoking when compared to the passive control, TAU group (condition IV).

CONFIRMATORY PREDICTORS / MODERATORS

Predictor = experimental condition. Moderator = a composite measure of smoking behaviour at baseline, incorporating the number of cigarettes smoked per day, number of years regular smoking, age at first cigarette, and Fagerström Test for Nicotine Dependence (FTND).

EXPLORATORY MODERATORS

- Implicit associations towards smoking (as measured by the single target - implicit association task (ST-IAT)) as a moderator for the main effect. The task instructs participants to categorize a series of words to one of three categories, approach, avoid or smoking, by pressing the “E” and the “I” keys as quickly as possible, without making too many errors. The task takes ~5 minutes to complete. The task assesses the relative strength of sorting together cigarettes with approach vs. cigarettes with avoidance.
- Automatic evaluation of beliefs related to outcome expectancies of, and self-efficacy towards smoking (cessation) (as measured with a propositional evaluation paradigm using mouse-tracking – PEP-MT) as a moderator for the main effect. The task consists of ‘probe trials’, where participants see a sentence, and then either the word ‘true’ or ‘false’, and have to respond based on this latter word, ignoring the truth value of the preceding sentence, and ‘catch trials’ where participants see a sentence and must respond to the truth value of that sentence. The task takes ~5 minutes to complete.
- Degree to which the personalized goals (consequences; only in condition I) are reached (whether or not they manage to get healthier, become happier, etc.) as a moderator for the main effect. For this, we will compute an average sum score that reflects how much each participant reached their goals across all blocks and trials.
- Mental health problems as measured with a composite score from the K6 screening scale as a moderator for the main effect.

EXPLORATORY MEDIATORS

- Implicit associations towards smoking (as measured by the single target - implicit association task (ST-IAT)) as a mediator for the main effect. Particularly, condition II is expected to change ST-IAT associations.
- Automatic evaluation of beliefs related to outcome expectancies of, and self-efficacy towards smoking (cessation) (as measured with a propositional evaluation paradigm using mouse-tracking – PEP-MT) as a mediator for the main effect. Particularly, condition I is expected to change such beliefs.

CONTROL VARIABLES

Mental health (Kessler Screening Scale for Psychological Distress), number of ABC training sessions completed, number of WeQuit therapy sessions completed.

Onderzoeksopzet

TIME-LINE

After participants have registered at WeQuit and indicated their interest to participate in the ABC study, they will be assigned to therapy groups of 3 individuals in total. Per therapy group, randomization across the 4 conditions will occur. Note that it is not necessary for all participants within a therapy group to participate in the ABC study, but if they do, they are assigned the same experimental condition to avoid problems with blinding of the participants to the condition they are in. Per therapy group a date for the first therapy session will be set: day 1. From that date on, the time-line is:

Week 1
Day 1: First therapy session
Day 1 - 3: First ABC training session + Baseline measurements (surveys and cognitive tasks)
Day 4 - 7: Second ABC training session (+ Baseline measurements if not completed at day 1 - 3)
Week 2
Day 1: Second therapy session
Day 1 - 3: Third ABC training session
Day 4 - 7: Fourth ABC training session
Week 3
Day 1: Third therapy session
Day 1 - 3: Fifth ABC training session + Mid-training measurements (surveys and cognitive tasks)
Day 4 - 7: Sixth ABC training session (+ Mid-training measurements if not completed at day 1 - 3)
Week 4
Day 1: Fourth therapy session

Day 1 - 3: Seventh ABC training session
Day 4 - 7: Eight ABC training session
Week 5
Day 1: Fifth therapy session
Day 1 - 3: Ninth ABC training session
Day 4 - 7: Tenth ABC training session
Week 6
Day 1: Sixth therapy session
Day 1 - 3: Eleventh ABC training session + Post-training measurements (surveys and cognitive tasks)
Day 4 - 7: Twelfth ABC training session (+ Post-training measurements if not completed at day 1 - 3)

Follow-up:
3 months after quit date (data collected by University of Amsterdam)
6 months after quit date (data collected by WeQuit)
12 months after quit date (data collected by WeQuit)

MEASUREMENTS

- At baseline there are questions on demographics, smoking, other substance use, readiness for change and mental health (K6 screening scale).
- Two cognitive tasks will be performed at baseline, mid-training and post-training; a propositional evaluation paradigm to measure outcome expectancies of, and self-efficacy towards smoking, and a paradigm that measures implicit smoking associations.
- During each session there are questions on smoking and visual analogue scales to indicate craving and motivation.
- Post-training and at 3 months follow-up, smoking behaviour will be assessed with survey questions and cessation will be verified by asking a collateral informant.
- At 3 months follow-up, there are questions on awareness of the intervention and training enjoyment.

Onderzoeksproduct en/of interventie

A novel, computerized cognitive training: ABC training

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Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible participants are smokers who want to quit smoking and who enrolled to receive smoking cessation help at WeQuit stop smoking service.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

There are no specific exclusion criteria for participation in the study, other than not being enrolled at WeQuit.

Participants will be removed before analysis when they took part in fewer than 6 of the 12 ABC training sessions and/or when they took part in fewer than 5 of the 6 WeQuit therapy sessions. In addition, based on the 4 training blocks (of 12 trials each) in the training that have a response window we will remove participants who did not comply to the required response window in more than half of the trials.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	13-12-2020
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	10-11-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9024
Ander register	Ethics Review Board of the Faculty of Social and Behavioural Sciences, University of Amsterdam : 2020-DP-12361

Resultaten