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ORIGINAL ARTICLE

Mobile phone-based approach bias retraining for smokers seeking abstinence: a randomized-controlled study

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Abstract
Approach bias modification (ApBM) has shown promise in addiction treatment, but effects are small and ecological validity suffers from completing trainings in the laboratory. Providing app-based trainings via mobile phones could increase training efficacy. One-hundred-and-thirty-one smokers seeking abstinence attended a smoking cessation intervention and were thereafter randomized to one of three conditions: (a) app-based ApBM-training; (b) app-based sham training; (c) no training. App trainings were performed on 14 consecutive days at home. Behavioral and self-report data was assessed at pretest, posttest, and a 6-week follow-up. App-based ApBM led to stronger reductions in cigarette smoking as compared to no training. However, both training variants led to stronger declines in nicotine dependence and the sham training was superior in reducing alcohol consumption. Although approach biases for positive cues increased following ApBM training, this effect did not mediate treatment outcome. Other smoking-related cognitive biases did not change after training. Our results can inform future research in the optimization and advancement of ApBM treatment for addiction.
Trial registration Registered with Current Controlled Trials: study ID ISRCTN15690771. Registered on 20 November 2018; http://www.isrctn.com/ISRCTN15690771.

Keywords Approach bias · Approach bias modification · Cogitive bias modification · Cigarette smoking · Nicotine addiction · Internet- and mobile-based intervention

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Despite devastating health effects, cigarette smoking is extremely common and nicotine addiction continues to represent one of the most frequent substance-use disorders worldwide. Consistently, a central hallmark of addiction is the persistent drug use despite experiencing substantial harm and adverse consequences (American Psychiatric Association 2013). Accordingly, dual process models are centered upon the notion that addiction arises from an imbalance between reflective and impulsive processes, with the latter becoming a more important determinant of actual behavior (Deutsch and Strack 2006; Wiers et al. 2007). Recent research could indeed provide support for the model's central assumptions. For instance, it has been shown that as addiction progresses, information processing is biased in favor of drug-related cues (Rooke et al. 2008). From this perspective, interventions for substance-use disorders should not merely address rational decision making but also biased information processing, as both factors are likely to contribute to drug taking and the inability to cease. Indeed, a wide array of research has begun to focus on feasible ways to target such biases. Known as cognitive bias modification (CBM), several attempts have been undertaken to experimentally modify existing biases for smoking (Kakoschke et al. 2017; Mühlig et al. 2016). In this regard, approach bias modification (ApBM) aimed at changing maladaptive approach biases, may be considered a special type of CBM, and has been proven most successful in recent years (Baird et al. 2017; Machulska et al. 2016). For this purpose, the approach avoidance task (AAT; Rinck and Becker 2007) that was initially designed to assess biased approach and avoidance behavior by pull and push joystick movements has been adapted to a training variant by adjusting contingencies between picture content and arm movements. Most encouraging results have been reported in the domain of alcohol addiction (Wiers et al. 2011). However, for other substance-use behaviors, including nicotine addiction, effects on behavior are mixed (Machulska et al. 2021, 2022; Wittekind et al. 2019). Reasons that may account for heterogeneous outcomes include different trial designs, training dosage and context, or the conceptualization of control groups. While research into the precise working mechanisms underlying ApBM is still at its infancy, there is evidence that ApBM should be embedded into a comprehensive intervention, which targets conscious beliefs and motivation (see dual process account; Wiers et al. 2007). Furthermore, ApBM should be applied multiple times to produce stable effects over time (Eberl et al. 2014). Finally, training sessions should be performed in multiple contexts, which ideally resemble real-world consumption conditions (Wiers et al. 2020). The main objective of the present study was to address these critical demands to contribute to the optimal utilization of ApBM. While these requirements are difficult to reconcile when trainings are provided in the laboratory, a promising and feasible approach to address these challenges lies in providing trainings via smartphone applications (apps). Due to a rapid spread of smartphones, combined with lower acquisition costs, the number of users is high (i.e., 89% in Germany; Tenzer 2022) and is expected to increase further in the near term. The major advantage of app-based training is that most mobile phone owners keep their devices with them all day. Hence, trainings can be carried out whenever convenient. This circumstance does not only allow adhering to a daily training routine without time-consuming expenditure but also perform individual ad-hoc trainings in situations which otherwise trigger action tendencies to consume cigarettes. Therefore, transferring ApBM-principles to mobile phones can facilitate high-dosage treatment, advance a widespread and cost-effective dissemination, and improve ecological validity and training generalization in an efficient manner.

Research on internet- and mobile-based interventions (IMI) has grown considerably over the past decade. In this context, several recent studies adopted the objective of delivering psychological interventions via smartphone-apps, including CBM paradigms (Zhang et al.

2018). Applying the ApBM rationale, Berking and colleagues created app-based AAT-trainings to reduce body dissatisfaction (Kollei et al. 2017) or procrastination (Lukas and Berking 2017). However, these studies are not without limitations. For instance, only healthy participants have been included and sample sizes were usually low, leading to serious power issues (Kakoschke et al. 2018). Apart from this, ubiquitous training dissemination was sometimes impeded by the fact that trainings were only possible for certain smartphone models. Finally, critical conditions of comparison comprised passive waitlist control groups, rendering an investigation of training-specific effects unfeasible.

The present study is the first to deliver app-based ApBM as an add-on to a brief behavioral counseling for smoking cessation to a group of heavy smokers motivated to quit. By doing so, former shortcomings in the literature were addressed by (a) employing an adequately powered sample size; (b) using both an active (sham-training) and passive (no-training) control group to disentangle specific from unspecific mechanisms of action; and (c) promoting broad and unbiased participation by enabling maximum compatibility with various mobile phone models. Adopting a preregistered randomized controlled trial (RCT) design, we hypothesized that our newly developed ApBM app will reduce nicotine consumption as well as smoking-related approach biases over and above the sham training and waitlist control conditions.

Methods

Trial Design and Sample Size Calculation

This trial was preregistered (study-ID ISRCTN15690771) and the study protocol was published prior to the start of data collection (Machulska et al. 2019). Please note that we deviated from the protocol in one aspect: Rather than employing a two-group design (app-based ApBM training vs. no training) as reported in Machulska et al. (2019), we decided to include a third group (app-based sham-training) in order to aid interpretation of results. Hence, after attending a brief smoking cessation intervention, smokers were randomly allocated to one of three conditions: (a) app-based ApBM; (b) app-based sham training; (c) no training. Behavioral, biochemical, and self-report data was assessed at baseline, post-intervention, and at 6-week follow-up (FU).

Data collection took place between March 2020 and November 2021. Prior to the start of the data collection, we updated the power analysis reported in Machulska et al. (2019) to determine the minimum sample size required for a three-group design (G*Power 3.1; Faul et al. 2009). Based on previous research, a small-to-moderate effect size (Cohen's $d = 0.30$, $\alpha = 0.05$) for the interaction between experimental condition and time was estimated. A power of 0.80 and a correlation between the repeated measures of $r = 0.5$ were assumed. Results indicated that 93 participants in total would be needed. Due to an expected attrition rate of approximately 25% (defined as dropout at any time point after completing the baseline assessment), we decided to include a minimum of 120 participants, which is 40 per condition.

Ethical Approval

The study protocol was approved by the local Ethics Committee of the University of Siegen and was conducted in accordance with the Declaration of Helsinki.

Participants

One-hundred-and-thirty-one current smokers were recruited via advertisements on websites and flyers, radio broadcasts, television, and newspaper reports. Interested participants were screened for eligibility during a telephone interview. Inclusion criteria were (i) at least 18 years of age, (ii) smoking at least six cigarettes per day during the last 6 months, and (iii) a self-reported motivation to quit smoking within the next 6 months. Exclusion criteria were (i) current alcohol or drug abuse disorder, (ii) current psychiatric illness, (iii) insufficient German language skills, (iv) uncorrected visual or auditory impairment, or (v) dyschromatopsia. Full written informed consent was obtained from each participant at study entry.

Primary and Secondary Outcome Measures

Primary outcome measures were reductions in self-reported daily cigarette consumption and changes in approach biases as assessed via the standard (joystick-based) AAT. Secondary outcome measures were changes in other cognitive biases (attentional and association biases), expired carbon monoxide (CO), cigarette craving, explicit attitudes toward smoking, motivation to stop smoking, and thoughts about abstinence. To account for potential risks and/or symptoms shifting, psychological wellbeing, alcohol consumption, sports activities, and eating habits have also been assessed throughout the trial.

Procedure

The first appointment started with a brief smoking cessation intervention (duration: 90–120 min). Subsequently, a baseline laboratory assessment was carried out, including a CO breath test, cognitive bias assessments, and questionnaire measures. Finally, smokers were randomized and were instructed to download the smartphone app from the app store. While participants randomized to the active training groups could initiate the app trainings immediately, the training was unlocked after completion of the final laboratory assessment for participants in the no-training group. Smokers were instructed to perform app trainings daily and preferable in high-craving or high-risk smoking situations within a 14-day training interval. Afterward, all participants were invited to a posttest and 6-week FU laboratory session to perform the laboratory assessment once again (see above).

Interventions

Brief Smoking Cessation Intervention

A trained psychologist provided a brief smoking cessation intervention based on psychoeducation and motivational interviewing, which was carried out in groups of up to four participants (see Machulska et al. 2019, 2021). Afterward, smokers received a self-help book (a German copy of *The easy way to stop smoking* by Allen Carr) to aid smoking cessation and were instructed to self-monitor daily smoking by means of an additional app feature. The intervention should target more controlled, goal-directed, and reflective processes associated with smoking.

Approach Bias Modification

Smartphone Application The app training was programmed in-house and was thoroughly piloted prior to the start of the current trial (Eiler et al. 2020). During training, smoking-related (i.e., smoking individuals) or positive pictures (i.e., positive social interactions or nature scenes) appeared at the center of the mobile screen. Baird et al. (2017) kindly provided all pictures. Images were rotated either 3° to the left or 3° to the right. The training instructed participants to ignore image content and to respond to image orientation by making a swipe-up gesture to pictures rotated to the right and making a swipe-down gesture to picture rotated to the left. Thus, an indirect task instruction was employed. Training contingency awareness, which has been shown to be a critical parameter for ApBM efficacy (MacLeod and Clarke 2015; van Dessel et al. 2016), was assessed after training and was accounted for in the final analyses. Swiping up decreased the picture in size, whereas swiping down increased the picture size, creating a sense of avoiding vs. approaching the image. Each of the picture categories contained 25 images, which were shown twice, resulting in 100 training trials per training. Training sessions took approximately 5 min to complete.

Training compliance was inferred from the number of completed training sessions. In addition, a training evaluation questionnaire was applied at posttest to ensure that trainings were perceived as equally effective in both groups.

App-Based ApBM Training Each training started with 12 test trials, which lacked the contingency between swiping movement and picture content. Unbeknown to the participants, a contingency was introduced thereafter: Smoking-related pictures were always rotated to the right and had to be swiped up, whereas positive pictures were always rotated to the left and had to be swiped down. As a result, the ApBM training constitutes both a smoking avoidance as well as a positive-approach training.

App-Based Sham Training The sham training included the same stimulus material and instructions but did not introduce a contingency between swiping movement and picture content. That is, smoking-related and positive control pictures were presented both in swipe-up and swipe-down format. In addition, we strived to preclude other training mechanisms that could lead to an unintended training effect (i.e., cue exposure). Therefore, different from the app-based ApBM training, the presentation of smoking-related pictures was reduced to a minimum (meaning that in total, only three smoking-related pictures in swipe-up and swipe-down format were presented over the course of a training session).

Assessments

Cognitive Bias Assessment

A brief description of experimental paradigms for cognitive bias assessment will be given in the following. Please refer to Machulska et al. (2019) for detailed task descriptions. All tasks were performed on a personal computer using Inquisit Lab Software, except for the AAT, which was programmed with Microsoft Visual Basic. Estimates of reliability were calculated for each task and measurement point and can be obtained from the Supplemental Material Appendix (SMA; Table S1).

Approach Bias Assessment Automatic approach biases were measured by the means of the standard AAT (Rinck and Becker 2007). The task was comparable to the app training but was performed on a personal computer using a joystick (Logitech Extreme 3D). Similarly, 25 smoking-related and 25 positive images provided by Baird et al. (2017) appeared consecutively on a computer screen and were tilted either 3° to the left or 3° to the right. Participants were told to push images rotated to the right and to pull images rotated to the left by means of the joystick. Each picture was shown once in push-away format und once in pull-closer format, resulting in 100 assessment trials.

Following Rinck and Becker (2007), an approach bias score was calculated by subtracting median reaction times (RT) for pulling an image from median RTs for pushing the exact same image.

Attentional Bias Assessment Attentional biases were measured by the visual dot-probe task (Miller and Fillmore 2010). A smoking-related and a control picture appeared side by side on the left and right side of the screen. After a 1000 ms time interval, both pictures disappeared and a probe stimulus (“X”) appeared in the location of one of the pictures. Participants were instructed to indicate probe location via a response pad (Cedrus Response Pad RB844).

The stimulus material was provided by Stippekohl et al. (2010) and comprised 10 smoking-related and 10 color- and form-matched tooth-cleaning control images. Each image pair was presented four times, resulting in 40 test trials. To minimize habituation effects, 40 filler trials (10 pairs of neutral images) were also embedded, but not included in the final analyses.

To calculate an attention bias score, median RTs for probes replacing smoking pictures were subtracted from median RTs for probes replacing tooth-cleaning pictures (see Becker et al. 2015).

Association Bias Assessment Association biases for smoking were assessed by two different versions of the implicit association test (IAT): The standard IAT to assess positive or negative associations with smoking (Kahler et al. 2007) and the single-target IAT to assess automatic approach associations with smoking (Woud et al. 2016).

During the positive-negative IAT, participants were instructed to categorize positive and negative attributes and target items via response pad button presses. The crucial test blocks (comprising 64 trials) asked participants to sort items into combined categories (e.g., “positive attributes OR smoking targets” vs. “negative attributes OR neutral targets”). Pairings were reversed for a second test block. As such, a total of 128 trials were included into the final analysis. Association biases were calculated by using the improved scoring algorithm (d-score) as recommended by Greenwald et al. (2003).

During the approach-avoid IAT, participants had to categorize six approach- or avoidance-related words via response pad button presses. The first combined block (24 practice + 72 test block trials) added six different smoking words. During the compatible block assignment, smoking and approach-related words shared a response key, while in the incompatible block (24 practice + 72 test block trials), smoking and avoidance-related words shared the same response key. Approach associations were calculated by subtracting the median RT of the compatible block from the median RT of the incompatible block as outlined by Woud et al. (2016).

Biochemical and Self-Report Measures

Expired CO (piCO™ Smokerlyzer®; Bedfont Scientific Ltd) was measured at each of the three laboratory sessions. In addition, participants completed an extensive set of questionnaires concerning (1) cigarettes smoked daily; (2) cigarette craving (ranging from 0 ["not at all"] to 5 ["very high"]); (3) degree of nicotine dependence (Fagerström Test for Nicotine Dependence; FTND ranging between 0 and 10; Heatherton et al. 1991; German version: Bleich et al. 2002); (4) attitude toward smoking (ranging between − 3 and + 3; Swanson et al. 2001); (5) the Stages of Change Scale based on the transactional model of change by Prochaska et al. (1991; SoC; ranging from 0 [pre-contemplation] to 4 [maintenance]; German version: Jäkle et al. 1999); (6) the Thoughts About Abstinence Scale (TAA; Hall et al. 1990), consisting of four scales: abstinence goal (scale: 0–5), desire to quit smoking (scale: 1–10), anticipated success (scale: 1–10), anticipated difficulties in quitting (scale: 1–10); (7) the Barratt Impulsiveness Scale (BIS; Patton et al. 1995); (8) Positive Mental Health ranging between 0 and 27 (PMH; Lukat et al. 2016); (9) alcohol use (Alcohol Use Disorders Identification Test; AUDIT, Saunders et al. 1993); and (10) a health behavior checklist, including questions regarding sports activities and eating habits. All questionnaire measures were administered at baseline, posttest, and follow-up (except for the BIS, which is supposed to be a measure of traits and was therefore only filled out at baseline). Please note that questionnaires 8–10 were included to account for possible adverse effects or symptom shifting and to gain a broader understanding of possible therapeutic effects. To obtain a comprehensive measure of treatment compliance, participants indicated whether they have engaged in reading the self-help book to aid smoking cessation and evaluated the app training at posttest. In addition, they indicated their awareness about training contingencies. Finally, the number of completed training sessions was assessed by means of the training app.

Data Preparation and Planned Analyses

Missing values were replaced through multiple imputation and the intention-to-treat (ITT) principles (Fergusson et al. 2002). Missing data were assumed to be missing at random in the sense of Rubin (1976). To prevent loss of data and subsequently statistical power due to exclusion of cases, missing data regarding the mixed ANOVA models were multiply imputed (m = 100 times) by R package jomo (Quartagno and Carpenter 2019). Imputation models were compatible to the subsequent analysis models, i.e., so-called substantive-model compatible multiple imputation (Carpenter and Kenward 2013; Goldstein et al. 2009, 2014). F statistics for the ANOVA models were combined as outlined in Enders (2010). Estimates for the exploratory analyses (see below for details) were full information maximum likelihood estimates (Enders 2010).

Prior to computing cognitive bias scores, error trials were excluded. As outlined above, participants that failed to become aware of training contingencies were excluded from further analyses. Results including all participants can be found in the SMA. Changes in approach, attentional, and association biases, as well as secondary therapy effects were analyzed by mixed ANOVA models. The Greenhouse-Geisser method was used to correct for violations of the sphericity assumption.

To explore working mechanisms underlying the app training, a mediation analysis with a multicategorical independent variable was conducted as outlined in Hayes and Preacher (2014). We regressed the target variable (changes in cigarettes smoked daily from pre- to posttest) on the respective mediator (changes in AAT biases for smoking-related vs. positive images, respectively) and the multicategorical independent variable (experimental condition), where the no-training control group was defined as the reference category. Indirect effects regarding the other two experimental conditions were interpreted relative to the reference group. Standard errors and confidence intervals were obtained by a bias corrected and accelerated bootstrap with 10,000 bootstrap replications.

Results

Sample Characteristics and Treatment Compliance

A flowchart of the study participants is shown in Fig. 1. As can be seen, attrition was rather high, especially for the FU measurement. This was due to the fact that the complete data collection took place during the Covid-19 pandemic (March 2020–November 2021). This period was characterized by several lockdowns, increased cases of illness, and quarantine times. To prevent extreme loss of data, participants had the chance to complete posttest and follow-up self-report measures online in case of an inability to appear in person. However, this could not be done for reaction-time measures, which had to be performed in the laboratory setting only. Therefore, missing values are more frequent for this type of measurement. Because of its extent, missing data could not be replaced adequately for the follow-up time point for this type of data. Hence, results based on cognitive bias assessment only comprise the pre- and posttest measurements.

Six participants in the app-based ApBM condition failed to become aware of the training contingencies and were therefore excluded from the final analyses.

Smokers were on average 46.4 (SD = 11.5) years old, 52% indicated to be female, while 48% indicated to be male. Participants smoked 19.6 (SD = 8.5) cigarettes per day and had a mean FTND score of 5.1 (SD = 2.1). According to the classification by Heatherton et al. (1991), those scores are indicative of a moderate nicotine dependence.

As shown in Table 1, groups did not differ on any demographic characteristics, smoking- or health-related measures at baseline (ps > 0.05), indicating that randomization was successful. Treatment compliance was high and comparable for both groups, as participants who received the app training (both ApBM and sham) completed an average of 11 sessions within the 14-day training period (see Table 1). However, at posttest, the app-based ApBM training was evaluated more positively than the app-sham training ($F(1,56) = 4.69$, $p = 0.013$).

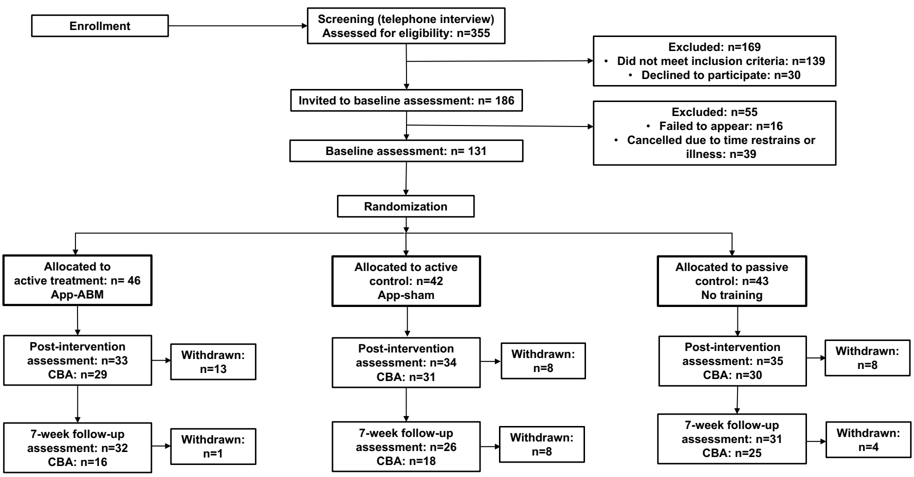

Fig. 1 A flowchart of the study participants. *Note*. CBA = cognitive bias assessment

Table 1 Participants' characteristics

Variable	Overall (n = 125)	App-ApBM (n = 40)	App-sham training (n = 42)	No training (n = 43)	p
Age (years)	46.42 (11.54)	44.60 (12.68)	48.83 (11.14)	45.77 (10.64)	0.228
Gender (% female)	52	52	43	60	0.271
Impulsivity (BIS)	30.72 (5.93)	31.88 (6.09)	31.05 (5.86)	29.33 (5.71)	0.134
Duration of cigarette consumption (years)	27.65 (11.31)	26.38 (12.09)	29.43 (10.59)	27.08 (11.31)	0.452
Number of daily smoked cigarettes	19.64 (8.53)	21.65 (10.08)	19.60 (7.77)	17.81 (7.37)	0.123
CO-level	18.93 (11.83)	19.85 (14.32)	16.90 (8.57)	20.21 (12.06)	0.387
Number of prior quit attempts	4.16 (4.24)	3.25 (2.20)	4.92 (4.75)	4.26 (5.09)	0.236
Cigarette craving	1.84 (1.49)	1.53 (1.43)	2.19 (1.44)	1.79 (1.55)	0.124
Nicotine dependence (FTND)	5.08 (2.14)	5.40 (2.24)	5.07 (2.02)	4.79 (2.18)	0.436
Smoking attitude	− 0.83 (0.81)	− 0.74 (0.90)	− 0.88 (0.79)	− 0.86 (0.75)	0.722
Stages of change	1.28 (0.87)	1.37 (0.87)	1.43 (0.80)	1.05 (0.90)	0.088
Thoughts about abstinence					
Abstinence goal	4.15 (0.78)	4.10 (0.78)	4.10 (0.79)	4.26 (0.79)	0.566
Desire to quit	8.35 (2.24)	8.05 (2.52)	8.40 (2.25)	8.58 (1.94)	0.551
Anticipated success	5.98 (2.00)	6.00 (2.05)	5.83 (2.00)	6.12 (1.99)	0.809
Anticipated difficulties	8.00 (2.14)	7.90 (2.32)	7.83 (2.25)	8.26 (1.87)	0.624
Wellbeing (PMH)	19.81 (5.15)	20.00 (5.46)	19.12 (5.19)	20.30 (4.84)	0.551
Alcohol use (AUDIT)	5.62 (3.59)	5.56 (3.97)	6.35 (4.26)	5.00 (2.30)	0.256
Activity level	8.68 (3.00)	8.70 (3.38)	8.52 (2.67)	8.81 (2.99)	0.906
Eating habits					
Healthy food	22.53 (4.59)	21.88 (4.63)	21.81 (4.71)	23.84 (4.25)	0.069
Diet food	15.78 (5.86)	14.83 (6.63)	15.69 (4.81)	16.74 (6.01)	0.329
Hearty food	26.91 (6.01)	26.05 (7.46)	26.67 (5.22)	27.53 (5.25)	0.701
Treatment compliance					
Attendance of smoking counseling (%)	100	100	100	100	1
Reading the book (%)	48	50	51	42	0.725
Number of completed App-sessions	10.37 (7.93)	9.78 (8.60)	10.95 (7.26)	-	0.504
App-training evaluation	5.76 (1.86)	6.40 (1.63)	5.39 (1.83)	-	*0.013*

Demographic, smoking, and health-related variables were assessed at baseline, treatment compliance and VR-training evaluation were assessed at posttest. BIS (scale: 15–60); cigarette craving (scale: 0–5); FTND (scale: 0–10); smoking attitudes (scale: − 3 to +3); stages of change (scale: 0–4); abstinence goal (scale: 0–5), desire to quit (scale: 1–10); anticipated success (scale: 1–10); anticipated difficulties (scale: 0–10); PMH (scale: 0–27); AUDIT (scale: 0–40); activity level (scale: 0–28); healthy food (scale: 0–50); diet food (scale: 0–40); hearty food (scale: 0–70); VR-training evaluation (scale: 0–10). Variables were analyzed using univariate ANOVAs, $F(2,122)$. All p-values are two-tailed. Standard deviations are given in parentheses

Primary Outcomes

Changes in Daily Cigarette Consumption

The 3 (condition) × 3 (time: pre, post, follow-up) ANOVA revealed a significant main effect for time ($F(1.851\ 1096.797) = 64.50$; $p < 0.001$; partial $\eta^2 = 0.430$), and a significant condition by time interaction ($F(3.702, 2014.192) = 2.85$; $p = 0.026$, partial $\eta^2 = 0.060$). Results indicate a steep decrease in cigarettes smoked daily in all conditions over time. However, a significantly

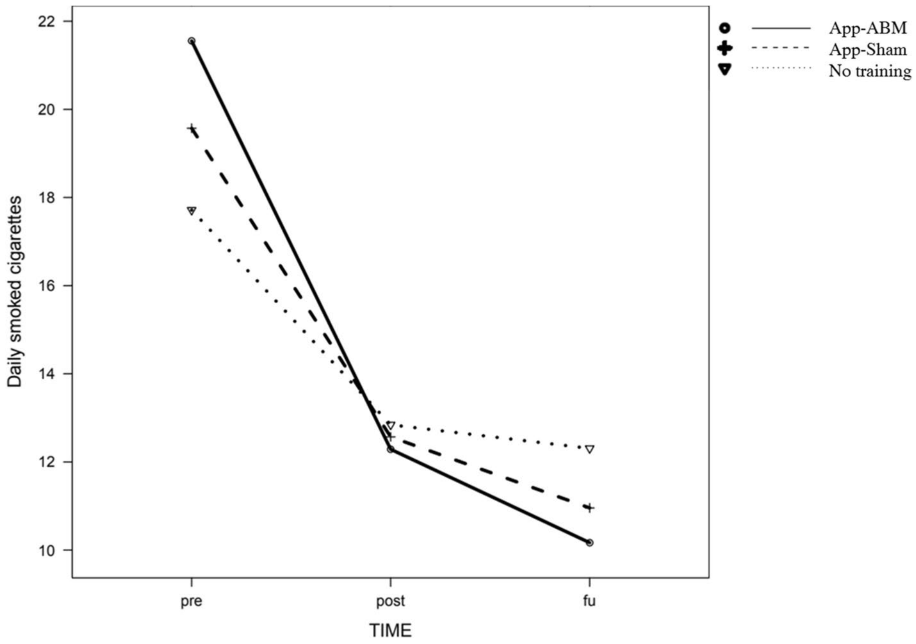

Fig. 2 Changes in daily cigarette consumption

stronger decrease could be observed in the app-based ApBM group as compared to the no-training condition from pre- to posttest ($F(1, 2088.210) = 5.52$; $p = 0.019$) and from pretest to follow-up ($F(1, 2001.344) = 8.33$; $p = 0.004$). In particular, while smokers in the ApBM condition halved their cigarette consumption throughout the curse of the study ($M_{\text{pre}} = 20.85$; $M_{\text{fu}} = 10.31$), smokers in the no-training condition reported only a 30% decrease in cigarette smoking from pretest to follow-up ($M_{\text{pre}} = 17.81$; $M_{\text{fu}} = 12.39$). In the sham training group, observed reductions were in between ($M_{\text{pre}} = 19.60$; $M_{\text{fu}} = 10.84$). Detailed results are illustrated in Fig. 2.

Approach Bias Change

The 3 (condition) × 2 (time: pre vs. post) × 2 (picture category: smoking-related vs. positive) ANOVA revealed a main effect for picture category: $F(1, 2287.714) = 9.76$; $p = 0.002$; partial $\eta^2 = 0.100$. As can be seen in Fig. 3, participants displayed stronger approach tendencies for smoking-related ($M = 15.23$) than for positive images ($M = -7.91$), replicating a smoking-related approach bias. Furthermore, there was a significant two-way interaction between condition and picture category ($F(2,1281.930) = 4.06$; $p = 0.018$; partial $\eta^2 = 0.096$) and a marginal significant interaction between condition, picture category, and time ($F(2,1198.871) = 2.86$; $p = 0.057$; partial $\eta^2 = 0.072$). Follow-up comparisons revealed that the stronger approach bias for smoking pictures at pretest was more pronounced in the two control groups (app-based sham training: $M_{\text{smoke}} = 26.17$ vs. $M_{\text{positiv}} = -30.57$; no-training: $M_{\text{smoke}} = 22.11$ vs. $M_{\text{positiv}} = -10.16$) than in the app-based ApBM group ($M_{\text{smoke}} = 17.89$ vs. $M_{\text{positiv}} = -0.69$). Furthermore, participants' approach bias for positive pictures increased after training in the ApBM condition, but not in the remaining conditions ($F(1,903.938) = 5.57$; $p = 0.018$). No group-specific effects were found for smoking-related pictures.

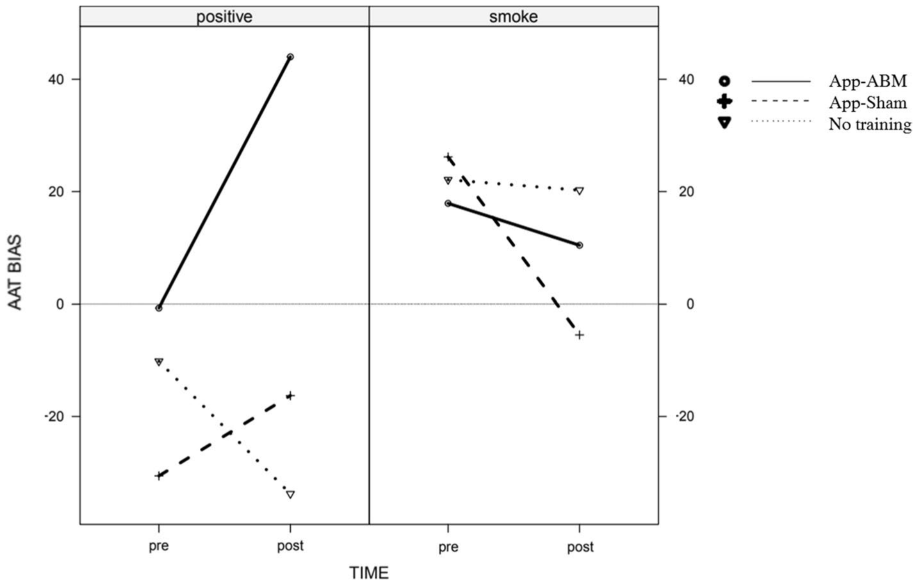

Fig. 3 Changes in approach biases

Secondary Outcomes

Secondary Therapy Effects

Smoking-Related Variables Regarding nicotine dependence, there was a significant main effect for time ($F(1.923,950.838) = 45.77$; $p < 0.001$; partial $\eta^2 = 0.358$) and a significant time × condition interaction ($F(3.846,1523.164) = 2.58$; $p = 0.038$; partial $\eta^2 = 0.058$). Follow-up analyses revealed a comparable decrease in nicotine dependence in all groups from pre- to posttest (*ps* > 0.172). With regard to the entire measurement period (pretest-FU), both training groups were characterized by an overall stronger decrease in FTND scores as compared to the no-training group (*ps* < 0.048).

Regarding other smoking-related variables (expired CO, cigarette craving, smoking attitudes, and desire to quit), there were significant main effects for time (*ps* < 0.05), but no significant two-way interactions between condition and time (see Table 2, for detailed results). Hence, there were improvements in several smoking-related outcomes over time, but no specific group differences could be established.

Other Consumption Behavior For alcohol drinking patterns, there was a significant main effect of time ($F(1.842,1367.300) = 10.42$; $p < 0.001$; partial $\eta^2 = 0.106$) and a significant condition × time interaction ($F(3.684,872.581) = 3.05$; $p = 0.019$; partial $\eta^2 = 0.076$). Results indicated reduced self-reported alcohol intake in all groups. However, the app-sham training condition was characterized by a stronger reduction from pretest to FU than the app-based ApBM ($F(1,1239.349) = 8.15$; $p = 0.004$) or the no-training condition ($F(1,1823.257) = 6.22$; $p = 0.013$).

Table 2 Secondary outcome measures. Means (standard errors) and inference statistics

Variables	App-ApBM			App-Sham			No training			Statistics
	Pre	*Post*	*FU*	*Pre*	*Post*	*FU*	*Pre*	*Post*	*FU*	
CO-level	19.58 (1.84)	13.34 (2.03)	12.18 (2.09)	16.92 (1.81)	18.25 (2.00)	13.33 (2.06)	19.98 (1.79)	17.67 (1.98)	20.93 (2.04)	Condition: $F(2, 1647.178) = 2.04$; $p = 0.130$ Time: $F(1.969, 725.138) = 2.57$; $p = 0.078$ Interaction: $F(3.939, 570.380) = 2.17$; $p = 0.072$
Craving	1.50 (0.23)	1.37 (0.22)	1.48 (0.23)	2.19 (0.23)	1.23 (0.21)	1.20 (0.23)	1.78 (0.23)	1.55 (0.21)	1.78 (0.22)	Condition: $F(2, 4135.062) = 0.52$; $p = 0.593$ **Time: $F(1.979\ 3247.685) = 3.85$; $p = 0.022$** Interaction: $F(3.958\ 2545.561) = 2.09$; $p = 0.081$
Nicotine dependence (FTND)	5.36 (0.34)	3.70 (0.39)	2.67 (0.38)	5.07 (0.33)	3.61 (0.38)	2.89 (0.37)	4.78 (0.33)	3.75 (0.37)	3.65 (0.36)	Condition: $F(2, 35798.660) = 0.11$; $p = 0.894$ **Time: $F(1.923, 950.838) = 45.77$; $p < 0.001$** **Interaction: $F(3.846, 1523.164) = 2.58$; $p = 0.038$**
Smoking attitudes	− 0.75 (0.12)	− 1.35 (0.14)	− 1.29 (0.13)	− 0.87 (0.12)	− 1.32 (0.14)	− 1.77 (0.12)	− 0.83 (0.12)	− 1.32 (0.14)	− 1.75 (0.12)	Condition: $F(2, 9047.996) = 0.77$; $p = 0.464$ **Time: $F(1.869, 1106.558) = 42.75$; $p < 0.001$** Interaction: $F(3.738, 862.269) = 1.63$; $p = 0.170$
Stages of change	1.35 (0.14)	1.55 (0.16)	1.44 (0.15)	1.43 (0.13)	1.37 (0.16)	1.44 (0.15)	1.04 (0.13)	1.17 (0.16)	1.30 (0.15)	Condition: $F(2, 6345.875) = 1.52$; $p = 0.218$ Time: $F(1.968, 2196.685) = 0.71$; $p = 0.489$ Interaction: $F(3.936, 2224.935) = 0.55$; $p = 0.697$
Thoughts about abstinence:										
Abstinence goal	4.10 (0.12)	4.19 (0.13)	3.83 (0.14)	4.09 (0.12)	4.31 (0.12)	4.31 (0.14)	4.25 (0.12)	4.17 (0.11)	4.17 (0.14)	Condition: $F(2, 8083.791) = 0.88$; $p = 0.417$ Time: $F(1.829, 1796.901) = 1.02$; $p = 0.355$ Interaction: $F(3.657, 1246.423) = 1.84$; $p = 0.125$
Desire to quit	8.45 (0.33)	8.01 (0.33)	8.23 (0.26)	8.45 (0.34)	8.98 (0.34)	9.51 (0.27)	8.45 (0.34)	8.22 (0.34)	8.90 (0.27)	**Condition: $F(2.000, 1949.648) = 5.45$; $p = 0.004$** **Time: $F(1.646, 2382.074) = 3.84$; $p = 0.029$** Interaction: $F(3.292, 4919.080) = 2.03$; $p = 0.101$
Anticipated success	6.03 (0.30)	6.15 (0.39)	6.10 (0.35)	5.81 (0.29)	6.21 (0.39)	6.74 (0.35)	6.04 (0.29)	6.26 (0.31)	6.51 (0.34)	Condition: $F(2, 11618.069) = 0.14$; $p = 0.870$ Time: $F(1.982, 1392.955) = 2.05$; $p = 0.129$ Interaction: $F(3.964, 1262.969) = 0.52$; $p = 0.721$

Table 2 (Continued)

Variables	App-ApBM			App-Sham			No training			Statistics
	Pre	*Post*	*FU*	*Pre*	*Post*	*FU*	*Pre*	*Post*	*FU*	
Anticipated difficulties	7.98 (0.33)	7.52 (0.35)	7.29 (0.35)	7.82 (0.32)	7.91 (0.35)	8.18 (0.34)	8.20 (0.32)	7.83 (0.34)	7.93 (0.34)	Condition: $F(2, 5778.689) = 0.63; p = 0.535$ Time: $F(1.895, 3000.904) = 0.66; p = 0.511$ Interaction: $F(3.789, 1598.358) = 0.77; p = 0.454$
Wellbeing (PMH)	19.79 (0.82)	20.24 (0.79)	19.81 (0.85)	19.12 (0.81)	19.58 (0.78)	20.43 (0.84)	20.29 (0.80)	19.83 (0.77)	19.78 (0.83)	Condition: $F(2, 97990.799) = 0.05; p = 0.956$ Time: $F(1.944, 1966.531) = 0.40; p = 0.667$ Interaction: $F(3.888, 1085.075) = 1.33; p = 0.258$
Alcohol use (AUDIT)	5.41 (0.55)	4.72 (0.53)	5.13 (0.57)	6.12 (0.54)	4.93 (0.53)	3.99 (0.56)	4.71 (0.54)	4.31 (0.53)	4.12 (0.55)	Condition: $F(2, 35016.254) = 0.58; p = 0.5759$ **Time: $F(1.842, 1367.300) = 10.42; p < 0.001$** **Interaction: $F(3.684, 872.581) = 3.05; p = 0.019$**
Activity level	8.67 (0.47)	9.08 (0.52)	9.52 (0.49)	8.53 (0.46)	8.66 (0.51)	9.13 (0.49)	8.84 (0.46)	8.85 (0.50)	8.93 (0.48)	Condition: $F(2, 42301.761) = 0.13; p = 0.877$ Time: $F(1.984, 1034.175) = 2.46; p = 0.086$ Interaction: $F(3.968, 1377.220) = 0.55; p = 0.696$
Eating habits										
Healthy food	21.82 (0.71)	16.83 (0.71)	18.32 (0.75)	21.81 (0.70)	16.83 (0.70)	17.10 (0.74)	23.84 (0.69)	18.14 (0.69)	18.88 (0.73)	Condition: $F(2, 19705.979) = 1.90; p = 0.150$ **Time: $F(1.960, 733.832) = 113.36; p < 0.001$** Interaction: $F(3.920, 1206.080) = 1.02; p = 0.397$
Diet food	14.71 (0.92)	15.00 (0.85)	15.13 (0.85)	15.69 (0.90)	15.01 (0.84)	15.00 (0.83)	16.76 (0.90)	16.03 (0.83)	17.36 (0.85)	Condition: $F(2, 27897.720) = 1.35; p = 0.260$ Time: $F(1.969, 1026.138) = 0.85; p = 0.428$ Interaction: $F(3.938, 1892.073) = 1.17; p = 0.209$
Hearty food	26.25 (0.92)	15.54 (0.73)	15.20 (0.74)	26.70 (0.91)	16.01 (0.62)	15.97 (0.73)	27.68 (0.90)	16.78 (0.71)	16.51 (0.72)	Condition: $F(2, 21318.085) = 0.88; p = 0.414$ **Time: $F(1.865, 315.322) = 274.39; p < 0.001$** Interaction: $F(3.730, 3588.160) = 0.22; p = 0.472$
Cognitive biases										
Attention bias	− 0.46 (4.24)	7.80 (3.42)	-	1.48 (4.02)	7.13 (3.25)	-	6.82 (3.93)	1.00 (3.17)	-	Condition: $F(2, 4934.642) = 0.15; p = 0.861$ Time: $F(1, 2883.444) = 0.31; p = 0.576$ Interaction: $F(2, 1598.240) = 1.63; p = 0.197$

Table 2 (Continued)

Variables	App-ApBM			App-Sham			No training			Statistics
	Pre	*Post*	*FU*	*Pre*	*Post*	*FU*	*Pre*	*Post*	*FU*	
Association bias (standard IAT)	0.24 (0.07)	0.31 (0.07)	-	0.28 (0.07)	0.41 (0.07)	-	0.32 (0.07)	0.33 (0.07)	-	Condition: $F(1, 5909.280) = 0.35$; $p = 0.703$ Time: $F(1, 941.600) = 2.04$; $p = 0.153$ Interaction: $F(2, 1180.510) = 0.57$; $p = 0.567$
Association bias (st-IAT)	− 41.14 (14.48)	− 27.65 (11.91)	-	− 40.81 (15.46)	− 24.57 (12.72)	-	−23.57 (13.96)	− 16.06 (11.48)	-	Condition: $F(2, 2600.025) = 0.53$; $p = 0.588$ Time: $F(1, 1859.454) = 1.04$; $p = 0.307$ Interaction: $F(2, 5959.735) = 0.14$; $p = 0.868$

Means bias scores (standard errors are given in parentheses). Inference statistics (3 × 3 ANOVAS) are based on multiple imputation of missing data. Post-assessments were carried out 2 weeks after baseline, follow-up assessments 6 weeks after baseline. p-values ≤ 0.05 are bolded

For eating habits, there was a significant main effect for time ($ps < 0.001$), indicating that participants in all conditions consumed less healthy and less hearty food from pre- to posttest.

Wellbeing and Behavioral Habits With regard to mental health and activity levels, no main effects or interactions could be established ($ps > 0.086$; see Table 2).

Secondary Training Effects

Attentional and association biases as assessed by means of the dot probe task, the IAT, and the st-IAT did not change as a function of time and/or group, as the 3 (experimental condition) × 2 (time) ANOVAs did not reveal any significant main effects or interactions (for attentional biases: $F_{condition}(2, 4934.642) = 0.15$; $p = 0.861$; $F_{time}(1, 2883.444) = 0.31$; $p = 0.576$; $F_{condition\times time}(2, 1598.240) = 1.63$; $p = 0.197$; for positive-negative association biases: $F_{condition}(1, 5909.280) = 0.35$; $p = 0.703$; $F_{time}(1, 941.600) = 2.04$; $p = 0.153$; $F_{condition\times time}(2, 1180.510) = 0.57$; $p = 0.567$; for approach-avoid association biases: $F_{condition}(2, 2600.025) = 0.53$; $p = 0.588$; $F_{time}(1, 1859.454) = 1.04$; $p = 0.307$; $F_{condition\times time}(2, 5959.735) = 0.14$; $p = 0.868$). Detailed results are presented in Table 2.

Exploratory Analyses

Mediation

It was hypothesized that AAT bias change (i.e., a reduction in smoking-related approach biases and/or an increase in approach bias for positive pictures) would mediate the primary treatment outcome. We performed two different mediation analyses (once with changes in smoking approach biases from pre- to posttest as the mediator and once with changes in positive approach biases from pre- to posttest as the mediator). In both analyses, three different pathways were analyzed. Path "a" tested whether the experimental condition predicted change in approach biases. In both cases, this path failed to become significant (for smoking biases: $B_{\text{ApBM vs. no-training}} = 36.88$ (38.03), $p = 0.332$; $B_{\text{sham vs. no-training}} = 23.74$ (35.42), $p = 0.503$; for positive biases: $B_{\text{ApBM vs. no-training}} = -46.36$ (40.90), $p = 0.257$; $B_{\text{sham vs. no-training}} = -0.92$ (40.62), $p = 0.982$). Path "b" tested whether changes in approach biases predicted therapy outcome. Again, this path was not significant (for smoking biases: $B = -0.004$ (.01), $p = 0.535$; for positive biases: $B = -0.001$ (0.01), $p = 0.836$). Path "c" tested whether experimental condition predicted treatment outcome. In both mediation analyses, this path was significant for the ApBM–no-training contrast (for smoking biases: $B = 5.07$ (1.86), $p = 0.006$; for positive biases: $B = 3.55$ (1.74), $p = 0.041$), but not for the sham–no-training contrast ($ps > 0.122$). Finally, the indirect path (c′) via change in AAT biases was non-significant in both analyses (for smoking biases: $B_{\text{ApBM vs. no-training}} = -0.16$ (0.38), $p = 0.675$; $B_{\text{sham vs. no-training}} = -0.10$ (0.31), $p = .739$; for positive biases: $B_{\text{ApBM vs. no-training}} = 0.06$ (0.43), $p = 0.891$; $B_{\text{sham vs. no-training}} = 0.01$ (0.26), $p = 0.996$). Hence, participants who received the app-based ApBM training had a stronger reduction in the number of cigarettes smoked daily than participants in the no-training group, which is in line with the primary outcome (see above). However, changes in AAT biases did not seem to be a mediating factor here.

Discussion

The present RCT is the first to investigate the efficacy of an app-based approach bias modification training as an add-on to a brief smoking cessation intervention. To broaden the understanding about crucial working mechanisms, we applied a three-group design: Next to the experimental group, which received the app-based ApBM, an active and a passive control condition were employed. Consequently, observed effects can be either attributed to the smoking cessation intervention, which was attended by all participants, to the execution of a nonspecific app training, or to a specific training to constantly avoid smoking cues (and to approach positive ones).

Regarding the primary treatment outcome, the ApBM was superior to the no-training group in reducing cigarettes smoked daily. Our results confirm the notion that applying app-based ApBM as an add-on to regular counseling may be indeed helpful in the context of cigarette smoking. However, it appears that the sham training also expired some beneficial effects. Both training variants led to a stronger decline in nicotine dependence than the no-training group and the sham training was superior in reducing alcohol consumption. Our findings are in line with previous research that found sham trainings to be sometimes as effective as "real" trainings, being indicative of a digital placebo effect (Adams et al. 2017; Kong et al. 2015; Machulska et al. 2022, 2021; Wittekind et al. 2019). Reasons for this may include aspects concerning the design of control conditions and unspecific working mechanisms. For example, most sham conditions apply 50/50 contingencies between image content and reaction. While such approaches can be regarded as continued bias assessments, some authors speculate that 50/50 control conditions may constitute a low-dose or diluted ApBM intervention (McNally 2018). That is, if smokers approach smoking cues in 100% of the time due to their smoking habits, a condition whereby 50% of smoking cues must be pushed might also be potent in some way and does not guarantee a neutral outcome (Chan et al. 2015). In line with this, there is some evidence for the fact that a 90/10 contingency (i.e., avoid 90% + approach 10% of substance-related cues) might be even more effective than a 100% contingency (Wiers et al. 2015). Finally, in the context of attention bias modification, a surprising outcome by Badura-Brack et al. (2015) showed that a 50/50 control condition was even more effective in reducing symptoms than a bias modification intervention using a 100% contingency (i.e., training attention away from threat-related cues). Apart from specific proportions of contingencies, it is conceivable that control trainings might exert their influence by simply exposing participants to drug cues without providing the possibility to consume (i.e., cue exposure; Mogg et al. 2017). Because of that, we opted to create an active control condition that should avoid additional (unspecific) training ingredients as much as possible (low-dose training, cue exposure), while—at the same time—providing a reasonable paradigm for participants randomized to this condition. For this purpose, we decided to keep the presentation of smoking-related stimuli to the minimum (i.e., showing only three smoking pictures in push and pull format). Despite this and although the sham training was evaluated as less positive than the ApBM training, we were unable to find a clear superiority of the ApBM training over sham training. Future studies with systematic variations of specific training ingredients (i.e., contingencies between stimulus content and reaction) and their underlying (neurocognitive) mechanisms are clearly warranted.

Regarding reaction-time data, we were able to replicate a smoking-related approach bias (Machulska et al. 2015). Surprisingly, the bias was less pronounced in the ApBM group. It might be that the non-existence of a clear smoking-related approach bias in this group is accountable for some inconclusive results in this study. Although still a matter of scientific debate, some authors argue that there has to be a cognitive bias to begin with for a CBM procedure to be effective (Gober et al. 2021). In addition, we did not find changes in other smoking-related biases (attentional or association biases) following training. Reasons that might account for this include specific characteristics in task design and methodological issues (i.e., limited psychometric properties; Machulska et al. 2022). In line with prevailing literature, we employed indirect task instructions, which led to the advantage that task instructions do not need to be changed throughout the task. In addition, irrelevant feature tasks are less prone to the influence of response strategies, which might constitute a confound to actual information processing patterns that are supposed to be measured (Rinck and Becker 2007; Woud et al. 2016). However, some recent work points to the fact that direct task instructions might be more reliable (Kersbergen et al. 2015). Indeed, an inspection of reliability indices for the present tasks (see Table S1) confirms that psychometric properties might have been insufficient, especially for the dot-probe task.

However, there were some indications for a training effect regarding positive pictures, which were constantly trained to be approached in the ApBM. Although our focus was on smoking pictures, it is obvious that the AAT works in two directions. Thus, training-specific effects for positive pictures are in line with dual process accounts (Wiers et al. 2007) as well as the literature (Hahn et al. 2019). For one part, this underlines the importance of using meaningful alternative categories for the AAT (Wiers et al. 2020). On the downside, we were unable to show that training effects were related to clinical outcomes, as the explorative mediation analysis was non-significant. Hence, more research into the precise working mechanisms and/or optimal task designs for reliable bias assessment is warranted.

The present study has clear strengths in that it incorporated both an active and a passive control group to aid interpretation of results. Moreover, our trial surpasses prior shortcomings in the literature by combining ApBM procedures to existing interventions and providing multiple training sessions in meaningful real-life situations. In addition, although our trial is innovative regarding training administration, the training design was carefully matched to existing ApBM interventions for greater comparability. Most importantly, the use of indirect task instructions led to the fact that a small amount of participants failed to become aware of the training contingencies. Additional analyses comprising all participants (see SMA) showed that effect sizes were smaller when including contingency-unaware participants. This finding points to a potential working mechanism underlying ApBM and raises the question as to whether forthcoming CBM interventions should implement explicit task/training instructions.

However, an important limiting factor concerns the final sample size. Due to the Covid-19 pandemic, attendance in person was difficult to achieve, leading to immense difficulties in recruitment as well as adherence after inclusion (see flowchart in Fig. 1). As a result, drop-out rates were unfortunately high. This had an impact on both the data analysis and achieved power.

Taken together, the present study was the first to combine ApBM for smoking with a mobile phone-based application as an adjunct to a brief behavioral counseling for smoking cessation. In doing so, we aimed to build upon and expand previous research on internet- and mobile-based interventions (IMI) for CBM (Kollei et al. 2017; Lukas and Berking 2021; Meule et al. 2020) by including a sample of heavy smokers motivated to quit. Our findings indicated that an app-based ApBM in the realm of cigarette smoking is a feasible tool to contribute to less smoking. This is in line with most recent research, which points to the utility of incorporating mental health apps into clinical practice and thereby contributing to improved health care (Firth et al. 2017; Forman et al. 2018). In the upcoming years, the implementation of evidence-based health apps in clinical work will be both a challenge and an opportunity for policymaking. On the one hand, it is conceivable that continued technological advances will lead to the advancement of digital treatments for mental health problems, including smoking. On the other hand, given the large number of already available health apps, which will certainly continue to grow, it is important to keep track of existing digital interventions. Thus, a major task for both policy makers and clinical researchers will be to evaluate the digital offer, to elaborate important mechanisms of action, and to provide scientifically sound criteria by which available digital interventions will be evaluated. This study is intended as an important contribution in this direction.

An avenue for future research on digital CBM interventions would lie in focusing on design components that encourage perceived meaningfulness and increase engagement and self-efficacy to contribute to an optimization in training efficacy (in this context, see the “Effort-optimized intervention model” by Baumel and Muench (2021)). This could be achieved by including individualized stimulus material, expanding the training by simultaneously addressing different senses and/or cognitive processes (i.e., next to motor movements and visual feedback, providing auditory feedback and encouraging participants to apply imagination techniques; Moritz et al. 2020) or by linking training execution to specific moods (i.e., immediately following a craving induction; Wen et al. 2022). Our results concerning training-specific ingredients were rather inconclusive, as both trainings (ApBM and sham) led to improved clinical outcomes compared to no training. Hence, research into the precise working mechanisms attributed to the training is warranted. Notwithstanding, the present trial provided first evidence that an app-based ApBM for nicotine addiction may constitute a cost-effective and easy to access intervention that could be used as an add-on to more traditional treatments.

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Author Contributions Conceptualization: AM, TK, TJE, BH, KJ, RB, and BN; methodology: AM and KK; software: AM, TJE, and BH; formal analysis: AM and KK; investigation: AM; data curation: the and BH; writing—original draft: AM; writing—review and editing: TK, TJE, KJ, RB, and BN; visualization: AM and KK; project administration: AM; supervision and funding acquisition: TK, RB, and BN. All authors read and approved the final manuscript.

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Data, Materials, and Code Availability We report all data exclusions, all manipulations, and all measures in the study. The dataset used and analyzed during the current study is available for download on the link below: https://osf.io/87d2z/. Supplemental Material includes further information on psychometric properties of cognitive bias assessment tasks and additional analyses for primary and secondary outcome measures.

Declarations

Ethics Approval The study protocol was approved by the local Ethics Committee of the University of Siegen. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

Consent to Participate Informed consent was obtained from all individual participants included in the study.

Conflict of Interest The authors declare no competing interests.

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