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Approach-avoidance modification as an add-on in smoking cessation: A randomized-controlled study

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ABSTRACT

Biases in information processing are attributed an important role in the maintenance of tobacco dependence. As these biases are not sufficiently taken into account in current treatments, the aim of the present study was to investigate whether clinical outcome can be improved by combining treatment-as-usual (TAU) with Approach-Avoidance Modification Training (AAMT). A two group parallel (1:1) randomized-controlled single-blind study with adult smokers (N = 105) was conducted (DRKS00011406). Participants received three sessions of TAU and either six sessions of AAMT or Sham training. During AAMT, participants were trained to implicitly avoid all smoking-related and to approach all smoking-unrelated pictures, while the contingency was 50:50 in Sham training. Participants were assessed after the intervention and 6 months later. Primary outcome was daily cigarette consumption at follow-up. Participants receiving TAU + AAMT did not show a significantly greater reduction of daily cigarette consumption at follow-up compared to TAU + Sham (per-protocol: 95% CI: -2.56–4.89, p = .608; intention-to-treat: 95% CI: -3.11–2.96, p = .968). Using an implicit AAMT (vs. Sham) as an add-on to TAU did not improve clinical outcome. However, no consistent evidence for a change of bias was found. It is important for future research to explore the effectiveness of optimized training versions (e.g., explicit instructions).

Pre-registration: German Clinical Trials Register (DRKS00011406).

1. Introduction

Despite negative long-term consequences and although the majority of tobacco dependent smokers report a desire to quit (Centers for Disease Control and Prevention, 2016), long-term abstinence is the exception rather than the norm (e.g., Garcia-Rodriguez et al., 2013; Hughes, Keely, & Naud, 2004). Dual-process theories propose that this is due to addiction-related behavior being mainly driven by automatic types of information processing rather than strategic processes (Bechara, 2005; Deutsch & Strack, 2006). This is thought to result from a sensitization of mesolimbic dopaminergic systems so that reward-related stimuli (e.g., smoking-related cues) gain *incentive salience* resulting in hypersensitivity towards these cues (Berridge & Robinson, 2016; Robinson & Berridge, 1993). It has indeed been shown that smoking is associated with attentional biases (Cox, Fadardi, & Pothos, 2006) and implicit approach tendencies (Machulska, Zlomuzica, Adolph, Rinck, & Margraf, 2015; Wiers et al., 2013) for smoking-related stimuli. The latter are typically assessed using the Approach-Avoidance Task (AAT, Rinck & Becker, 2007), where participants are shown smoking-related vs. -unrelated pictures and instructed to respond to these pictures by either pulling or pushing a joystick or computer mouse; the response direction depends on a non-affective dimension (e.g., picture format). Implicit approach tendencies are inferred from faster pulling than pushing, whereas the opposite is true for avoidance tendencies.

If approach biases for substance-related stimuli play an important role in the maintenance of addictive disorders, their direct manipulation via an Approach-Avoidance Modification Training [AAMT] should reduce the substance use behavior. In AAMT, participants are instructed to respond to smoking-related stimuli with pushing, and to smoking-unrelated stimuli with pulling. The AAMT is usually compared to a Sham training with 50% pull and push instructions for each picture category (Wiers, Eberl, Rinck, Becker, & Lindenmeyer, 2011). The combination of treatment-as-usual (TAU) and AAMT has been shown to increase abstinence rates after one year in abstinent inpatients with alcohol dependency (Eberl et al., 2013: TAU + AAMT: 51% abstinence vs. TAU + Sham: 43%; Wiers et al., 2011: TAU + AAMT: 54%

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abstinence vs. TAU + Sham: 41% abstinence). In another study, patients undergoing detoxification from alcohol received either four sessions of AAMT or four sessions of Sham training (Manning et al., 2016). Continuous abstinence two weeks after discharge was higher in the AAMT (69%) compared to the Sham group (47%, intention-to-treat analysis). Evidence for the efficacy of AAMT in smoking is mixed. Promising results were found for AAMT as a stand-alone training (Baird et al., 2017; Wittekind, Feist, Schneider, Moritz, & Fritzsche, 2015) or in combination with a low-threshold intervention (i.e., three sessions of psychoeducation and motivational interviewing; Machulska, Zlomuzica, Rinck, Assion, & Margraf, 2016). However, the combination of AAMT with a strong CBT intervention in adolescent smokers (Kong et al., 2015) failed to show long term effects. In addition, in these earlier studies the AAMT did not reduce approach biases to smoking-related pictures (Kong et al., 2015; Machulska et al., 2016).

1.1. The present study

The present study aimed to examine the efficacy of AAMT as an add-on to a well-established smoking cessation intervention (smoke-free program, Gradl, Kröger, Floeter, & Piontek, 2009; IFT-Gesundheitsförderung, 2013) in a sample of adult smokers. Participants receiving the AAMT were trained to consistently avoid smoking-related and approach smoking-unrelated pictures while participants in the Sham training had to approach 50% of each category. We hypothesized that daily cigarette consumption after six months (primary outcome) would be significantly reduced in the TAU + AAMT group and abstinence rates would be significantly higher compared to the TAU + Sham group. Furthermore, we expected that only the AAMT would lead to a reduction of the approach bias and that the intervention effect on substance use behavior would be mediated by a change in bias.

2. Method

2.1. Participants

Inclusion criteria were: age 18 to 70y; a score of ≥3 in the Fagerström Test of Nicotine Dependence (FTND, Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991); ≥10 daily cigarettes in the last year; ≥10 ppm carbon monoxide (CO) in exhaled air; and agreement not to use e-cigarettes, nicotine replacement therapy (NRT) or any other smoking cessation aid during study participation. Exclusion criteria were: any substance dependence (except tobacco) within the last year; usage of NRT or pharmacological treatment for smoking cessation within the last three months; usage of e-cigarettes or smoke-free tobacco products; severe cardiovascular or psychiatric disorder; acute suicidality; pregnancy or lactation; severe neurological disorders; or insufficient language skills. All participants received the smoking cessation intervention (value: €250) free of charge.

2.2. Recruitment and setting

Participants were recruited via announcements in the local press, the department homepage and intranet, posters and flyers distributed at university buildings, the university hospital and medical practices, via social media channels (e.g., Facebook), and online marketing tools (Google AdWords). Assessments and interventions were carried out at an outpatient center specialized in tobacco dependence (November 2016 to January 2018).

3. Measures

3.1. Clinical assessments and ratings

Table 1 shows sociodemographic and smoking-related variables assessed at baseline. CO concentration in expired air was evaluated at baseline and posttest (Micro + Smokerlyzer Bedfont Scientific Ltd., Maidstone, England). The Nicotine Use Inventory (NUI; for items see Supplementary Material 1) and the FTND were conducted at all assessments. Abstinence was defined as 7-day point prevalence and was assessed with item #1 of the NUI (*"Did you smoke during the last 7 days?"*). At t1, abstinence was also verified biochemically by means of the CO concentration (cut-off: CO < 10 ppm, e.g., Benowitz et al., 2002). If participants indicated that they were not smoking within the last 7 day at the post- or follow-up assessment, the FTND was considered to be zero. To assess participants' commitment to abstinence, the Thoughts about Abstinence Scale (TAAS, Hall, Havassy, & Wasserman, 1990) was administered. In order to screen for mental disorders, each participant completed the Web Screening Questionnaire for Common Mental Disorders (WSQ, Donker, van Straten, Marks, & Cuijpers, 2009). During posttest participants evaluated the intervention and indicated whether they thought they had received AAMT or Sham. Besides the sociodemographic information, all assessments were conducted computer-based via Unipark® (www.unipark.de).

3.2. Experimental tasks

All experimental tasks were programmed and administered using the Software Inquisit® (www.millisecond.com).

3.2.1. Approach-Avoidance Task: assessment

The AAT was administered to assess implicit behavioral tendencies. Twenty-four smoking-related and 24 smoking-unrelated pictures were selected from prior studies (Luijten, Littel, & Franken, 2011; Luijten, Veltman, et al., 2011; Stippekohl et al., 2010; Wiers et al., 2013) (for further information, e.g., on picture ratings, see Supplementary Material 1 & 2). The color of the picture frame (blue vs. yellow) was used to indicate instructions to either push or pull a computer mouse. Response direction was linked to a "zoom"-function, i.e., pictures became smaller when pushed and bigger when pulled.

Participants first rated their urge to smoke (visual analogue scale from 0 to 100) and completed 10 practice trials with blue- and yellow-framed checkered patterns. During the following experimental task, each picture was presented four times (total: 192 fully randomized trials; total duration: 10–15min). In each trial, a fixation cross (500 ms) was followed by a picture (smoking-related or smoking-unrelated). Depending on the frame color, the picture had to be pushed or pulled. If the mouse was moved in the correct direction, the picture disappeared. If the mouse was moved in the wrong direction, error feedback was given. To initiate the next trial, a red cross centrally located on the screen had to be clicked moving the mouse back to its initial position. Upon completion of the task, the current urge to smoke was rated again. Half of the participants were instructed to pull blue and to push yellow framed pictures, the other half received the reversed instruction.

3.2.2. Implicit association task

In order to assess the associative strength between smoking- and approach-related concepts in memory, an approach-avoid Implicit Association Test (IAT, Palfai & Ostafin, 2003) was administered (for detailed description see Supplementary Material 1). For the target categories, 10 smoking-related and 10 smoking-unrelated pictures were presented. For the attribute categories, the German translations of five approach- and five avoidance-related words were selected from a prior study (Wiers et al., 2011). Both target stimuli and attribute words had to be categorized using one of two response keys ("E" and "I"). In the combined compatible blocks, smoking- and approach-related stimuli shared one key (i.e., "E") while smoke-unrelated- and avoidance-related stimuli shared the other key ("I"). For the combined incompatible blocks, the key assignment was reversed so that smoking- and avoidance-related stimuli share one key ("I") and smoke-unrelated- and approach-related stimuli share the other key ("E"). The order of the blocks (compatible vs. incompatible) was counterbalanced.

Table 1
Sociodemographic, psychopathological, and smoking-related information for both the ITT- and the PP-sample: means (SD), percent and frequencies.

Variable/time	ITT		Statistics	PP		Statistics
	AAMT (n = 54)	Sham (n = 51)		AAMT (n = 33)	Sham (n = 34)	
Age (in years)	41.67 (11.17)	42.78 (10.75)	$t(103) < 1$, $p = .603$	42.56 (10.80)	42.53 (12.08)	$t(64) < 1$, $p = .987$
Education (% high school graduation)	52%	55%	$\chi(1) < 1$, $p = .754$	46%	50%	$\chi(1) < 1$, $p = .710$
Gender (m/f)	24/30	20/31	$\chi(1) < 1$, $p = .587$	13/20	13/21	$\chi(1) < 1$, $p = .922$
Tobacco dependence (FTND)	5.41 (2.06)	5.65 (1.80)	$t(103) < 1$, $p = .528$	5.21 (1.73)	5.71 (1.45)	$t(64) = 1.27$, $p = .209$
CO value	17.56 (7.04)	16.20 (4.98)	$t(103) = \|1.14\|$, $p = .258$	16.03 (4.79)	16.97 (5.46)	$t(64) < 1$, $p = .457$
Abstinent days	0.11 (0.50)	0.04 (0.28)	$t(103) < 1$, $p = .370$	0.12 (0.55)	0.06 (0.34)	$t(64) < 1$, $p = .576$
Daily cigarettes (n)	17.09 (6.24)	17.43 (7.76)	$t(103) < 1$, $p = .805$	15.67 (5.83)	18.35 (7.26)	$t(64) = 1.67$, $p = .10$
Smoking duration (in years)	23.07 (11.49)	24.06 (10.29)	$t(103) < 1$, $p = .645$	24.06 (10.76)	24.09 (10.74)	$t(64) < 1$, $p = .992$
Prior quit attempts	3.48 (3.14)	5.53 (7.18)	$t(103) = 1.91$, $p = .059$	2.82 (2.39)	4.35 (3.32)	$t(64) = 2.17$, $p = .034$
Living with smoker (%)	39%	33%	$\chi(1) < 1$, $p = .554$	46%	29%	$\chi(1) = 1.84$, $p = .175$
TAAS abstinence goal[a]	2.00 (1.18)	1.73 (0.67)	$t(103) = \|1.46\|$, $p = .149$	2.12 (1.34)	1.71 (0.68)	$t(64) = \|1.61\|$, $p = .113$
TAAS desire to quit[b]	9.26 (1.17)	9.02 (1.50)	$t(103) < 1$, $p = .362$	9.06 (1.35)	9.29 (0.87)	$t(64) < 1$, $p = .401$
TAAS expected success in quitting[b]	6.50 (1.80)	6.45 (1.96)	$t(103) < 1$, $p = .894$	6.55 (1.99)	6.41 (1.99)	$t(64) < 1$, $p = .784$
TAAS expected difficulty of quitting[b]	8.11 (1.70)	8.43 (1.69)	$t(103) < 1$, $p = .335$	8.09 (1.86)	8.26 (1.81)	$t(64) < 1$, $p = .700$
Psychiatric disorders (yes/no)	34/20	32/19	$\chi(1) = 1$, $p = .982$	18/15	19/15	$\chi(1) < 1$, $p = .912$
Mean number of smoking cessation sessions (n) and number of sessions attended (3/2/1/0)	2.57 (0.82) 39/10/2/3	2.67 (0.71) 39/9/1/2	$t(103) < 1$, $p = .826$	2.85 (0.44) 29/3/1/0	2.88 (0.33) 30/4/0/0	$t(64) < 1$, $p = .722$
Mean number of training sessions (n) and number of training sessions attended (6/5/4/3/2/1/0)	4.83 (1.67) 27/11/7/3/2/2	4.90 (1.51) 24/14/5/5/0/1/2	$t(103) < 1$, $p = .338$	5.36 (1.14) 22/5/4/1/0/1/0	5.24 (1.10) 20/7/2/5/0/0/0	$t(64) < 1$, $p = .641$

Note. AAMT = Approach-Avoidance Modification Training; FTND = Fagerström Test for Nicotine Dependence; TAAS = Thoughts about Abstinence Scale.
[a] 1 = total abstinence, never use again, 2 = total abstinence but realize a slip is possible, 3 = occasional use when urges strongly felt, 4 = temporary abstinence, 5 = controlled use, 6 = no goal; [b] 0–10.

3.3. Treatment conditions

3.3.1. Treatment-as-usual: smoke-free program

As TAU both groups received the smoking cessation intervention *smoke-free* (IFT-Gesundheitsförderung, 2013). The program is a manualized CBT-based smoking cessation program that is supported by the German Federal Centre for Health Education, follows current clinical guidelines and has been updated regularly. The *smoke-free* program was superior to a cessation program following a reduction procedure in a quasi-experimental study (Gradl et al., 2009) and is the most widely used group program in Germany (Wenig, Erfurt, Kröger, & Nowak, 2013). The program is evaluated on an annual basis with a mandatory participation of all trainers. Abstinence rates after six months vary between 34 and 38% (Kröger & Braun, 2017). The program consists of three weekly group sessions (à 180min) and two individual telephone consultations (à 15min) after the second and the third group session. It includes a fixed Quit Smoking date, which takes place during the second group session, and several behavior modification methods: cognitive strategies, motivational interviewing, psycho-education, goal orientation, imagination rehearsals, and coping skills. The program was conducted by three certified smoke-free trainers.

3.3.2. AAMT and sham training

Based on the principle of the AAT (Rinck & Becker, 2007), in the AAMT condition all smoking-related pictures were framed in the color that had to be pushed and all smoking-unrelated pictures in the color that had to be pulled. In the Sham training, 50% of smoking-related and 50% of smoking-unrelated pictures had to be pushed and pulled, respectively. Thus, the only difference between AAMT and Sham training was the contingency. In total, 48 pictures were presented (24 smoking-related, 24 smoking-unrelated) of which 24 pictures (12 smoking-related, 12 smoking-unrelated) had already been used in the diagnostic AAT and 24 pictures (12 smoking-related, 12 smoking-unrelated) had not been presented in order to assess whether the training would generalize to untrained stimuli. However, due to a mistake, 14 pictures of assessment AAT were used during the trainings such that 10 instead of 12 pictures were untrained. For analyses, all pictures used during the AAMT were classified as trained (n = 14) and all other pictures as untrained (n = 10). The design was generally the same as in the assessment AAT, except that participants conducted more trials (n = 384). Participants were blinded to training condition and were given the same instruction (i.e., pull yellow – push blue; pull blue – push yellow) as in the diagnostic AAT. Participants conducted the trainings twice per week: once per week the training was conducted directly before the smoking cessation intervention started and the second time at their home computer in between smoking cessation sessions. As the quit attempt was conducted during the second group session, three trainings were administered before and three sessions after the quit date yielding a maximum number of six training sessions.

3.4. Power analysis

As no previous trial investigating the efficacy of AAMT as an add-on to an evidence-based cessation intervention was available, sample size calculation was based on a small effect obtained in a previous study for a repeated-measures design (Machulska et al., 2016). Power analysis using G*Power® (Faul, Erdfelder, Lang, & Buchner, 2007) revealed that a sample size of 82 participants was required to find a significant small effect of $f = 0.143$ (with $\alpha = 0.05$, ß = 0.8, three assessments). As a drop-out of 20% was expected (Kiss et al., 2016), a total sample of 102 participants was necessary to obtain sufficient power. The trial was closed after the necessary sample size had been recruited.

3.5. Design and procedure

A randomized-controlled, single-blind, parallel group study was conducted comparing the efficacy of two trainings (AAMT, Sham) in addition to a smoking cessation intervention. After the baseline assessment (t0), participants were randomized to one of the training conditions following a computer-generated randomization plan (www.randomizer.org) with a 1:1 allocation ratio. The randomization sequence was generated by the first author and concealed from the staff enrolling and assessing participants; i.e., raters were blind to forthcoming assignments. If a participant was included after t0, group allocation was mailed to the staff conducting the trainings so that participants were blinded whereas study personal was not after t0. After t0,

the intervention was conducted and participants were re-assessed upon its completion (4w after baseline, t1) and at follow-up (6 m after posttest, t2). If participants did not show up at t1, they were invited to complete the posttest online (via Unipark and Inquisit), which was done by three participants. The study was registered at German Clinical Trials Register (DRKS00011406) and approved by the Ethics Committee of the Medical Center, LMU Munich (project number 598–16). All patients gave written informed consent prior to participation. The study was performed in accordance with Declaration of Helsinki.

3.6. Data reduction

For the diagnostic AAT, RTs of incorrect trials were excluded (i.e., mouse movement in wrong direction, change of direction within trial). Second, RTs faster than 200 ms and slower than 2.5SD above the group mean were excluded. In total, 10% of the trials (t0) were excluded with no differences between groups, $t(103) < 1.00$, $p = .609$. Two participants had an excessive number of missing trials (> 35%) and were not included for AAT-analyses. Post-AAT data of one participant was mistakenly not recorded. For each combination of picture type, response direction and familiarity median RTs were calculated yielding eight median RTs per participant (cf. Wiers et al., 2011). For analyses, AAT effects were calculated by subtracting the mean of the pull RTs from the mean of the respective push RTs separately for pictures presented during both assessment and training (i.e., push smoking trained–pull smoking trained) and assessment only (i.e., push smoking untrained–pull smoking untrained). Positive scores reflect an approach while negative scores reflect an avoidance tendency. To analyze split-half reliabilities two data sets were created (even, odd trials) for baseline data (ITT sample). Split-half reliability was computed by correlating AAT effects for smoking-unrelated and smoking-related pictures of each data set. Split-half reliability of the AAT effect was $r = .462$, $p < .01$, for smoking-related and $r = .282$, $p < .01$, for smoking-unrelated pictures. AAT effects of both data frames were correlated using Spearman-Brown; the Spearman-Brown correction was not applied as the reliability of the AAT might not increase by adding more trials (Reinecke, Becker, & Rinck, 2010). If applied, split-half reliability increased: AAT effect smoking: $r = .632$; AAT effect smoking-unrelated: $r = .440$. IAT data were analyzed using the D2 scoring algorithm (Greenwald, Nosek, & Banaji, 2003). Two participants of the Sham group doing the posttest online did not complete the IAT.

3.7. Strategy of data analysis

Data were analyzed using R Language for Statistical Computing (R Core Team, 2017) and SPSS24. Baseline differences were analyzed using independent t-tests for continuous and chi-square tests for categorical variables. To test whether smoking-related and smoking-unrelated pictures were rated differently, paired t-tests were used.

Main analyses were conducted using linear mixed effects models (MEM, lme4 package in R, Bates, Maechler, Bolker, & Walker, 2015). MEMs are an intention-to-treat approach and include all available data (and therefore all participants), thus, randomly missing data do not present a problem (Gueorguieva & Krystal, 2004) and are not imputed for analyses.

An outcome variable was predicted by dummy codes of time, group allocation, and their interactions. The time dummies were created to reflect the differences between the baseline and post-training (t1, coded as 0, 1, 0 for the baseline, post-training, and follow-up) and between the baseline and follow-up (t2, coded as 0, 0, 1). Group allocation was also dummy-coded (1 = AAMT; 0 = sham control). Time effects were assumed to vary across the group (i.e., cross-level interaction) and participants (i.e., random effects). Primary outcome was daily cigarette consumption at follow-up. Secondary outcomes were changes in implicit biases at post-assessment (AAT; IAT), abstinence rates, abstinent days (past week), and severity of tobacco dependence (FTND) at post-intervention and follow-up. Both per-protocol (PP) and intention-to-treat (ITT) analyses were performed. Participants who completed all assessments, attended at least one session of the smoke-free program, and used the training at least once were included in the PP sample (i.e., completer). The ITT sample comprised all randomized participants. When no information regarding smoking status was available, participants were considered to be smoking.

4. Results

4.1. Sample characteristics

Groups did not differ as to demographic, smoking-related and psychopathological information, with one exception (see Table 1). The Sham group had a higher number of prior quit attempts compared to the AAMT group (ITT: $p = .059$; PP: $p = .034$). The overall sample smoked on average 17.26 cigarettes per day ($SD = 16.99$), for 23.55 years ($SD = 10.88$), and had tried to quit 4.48 times ($SD = 5.56$). Participants showed a moderate to strong tobacco dependence (FTND: $M = 5.52$; $SD = 1.93$; CO: $M = 16.90$; $SD = 6.17$). Participants did not show an approach-bias for smoking-related stimuli at baseline ($M = 0.97$, $SD = 50.09$, $t(102) < 1$, $p = .844$).

Eighty percent of the sample completed the post-test (AAT: 78%; Sham: 82%), 88% the follow-up assessment (AAT: 89%; Sham: 86%), and 77% all assessments (AAT: 76%; Sham: 78%, see Fig. 1), thus, there were no significant differences in the attrition rate between groups, all $ps > .5$. Completers and non-completers differed on the FTND, $t(103) = 2.39$, $p = .019$ (completers: $M = 5.28$; $SD = 1.96$; non-completers: $M = 6.33$; $SD = 1.63$), estimated difficulty to quit, $t(103) = 2.33$, $p = .022$ (completers: $M = 8.06$; $SD = 1.78$; non-completers: $M = 8.96$; $SD = 1.12$), attendance of intervention, $t(24.65) = |4.34|$, $p < .001$ (completers: $M = 2.85$; $SD = 0.39$; non-completers: $M = 1.83$; $SD = 1.13$), and training, $t(26.81) = |4.74|$, $p < .001$ (completers: $M = 5.33$; $SD = 1.06$; non-completers: $M = 3.29$; $SD = 2.03$). Non-significant differences emerged for gender, $\chi(1) = 3.45$, $p = .063$, with women showing higher completion rates (84% of women completed all assessments compared to 68% of men) and presence of mental disorder, $\chi(1) = 3.55$, $p = .060$, with participants without mental disorders showing higher completion rates (87% vs. 71%). For all other variables assessed at t0, completers and non-completers did not differ, all $ps > .09$. Training compliance can be considered excellent (see Table 1), as more than 80% of the AAMT and the Sham group completed five or more training sessions and 80% of both groups attended all sessions of the smoking cessation program.

5. Outcome analyses

5.1. Clinical outcome

For the primary outcome (daily cigarette consumption at t2), no significant differences between the AAMT and the Sham group emerged, both groups showed a significant reduction in the number of daily smoked cigarettes from pre to follow-up (see Tables 2 and 3). The same pattern emerged for secondary outcomes (severity of tobacco dependence, number of abstinent days, CO value), i.e., there were significant reductions across time in both groups, with no differences between groups. Both groups showed high, almost identical abstinence rates at t1: PP: AAT: 25 of 33 (76%), Sham: 25 of 34 (74%); ITT: AAT: 33 out of 54 (61%), Sham: 31 out of 51 (61%). At follow-up, abstinence rates were substantially lower and

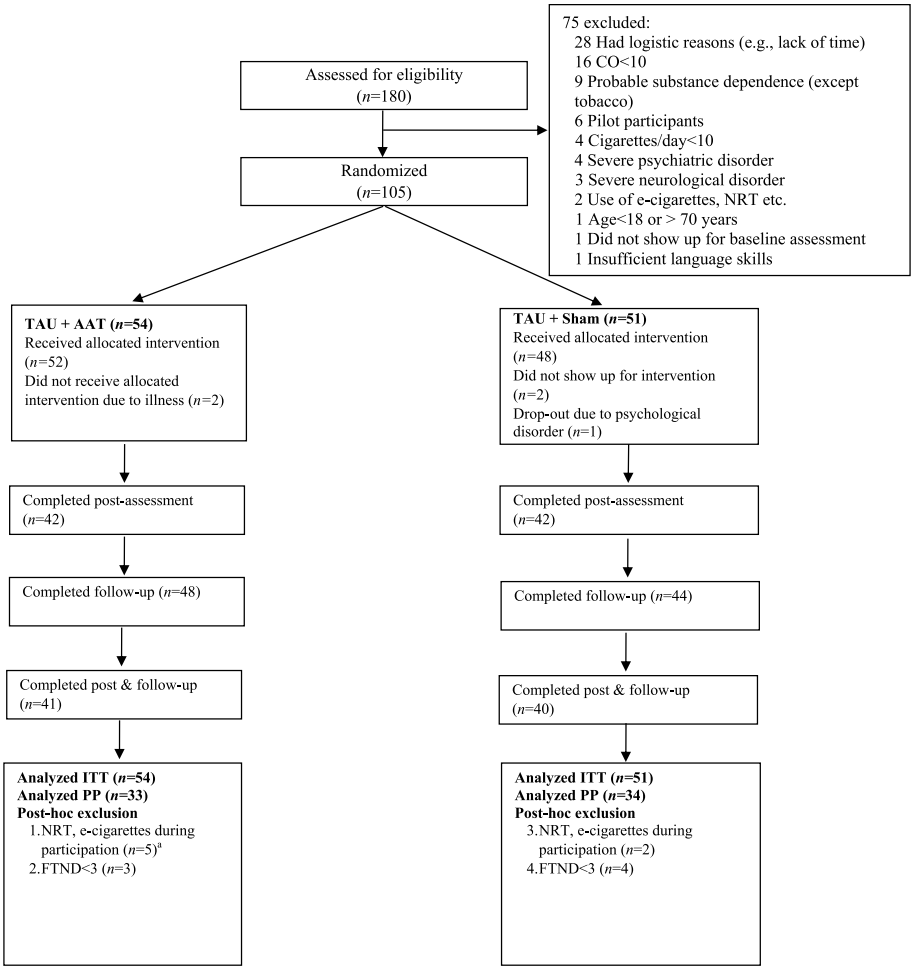

Fig. 1. Flow of participants. Several participants who did not show up for the post assessment completed the follow-up. For PP analyses, only participants with complete assessments and fulfilling inclusion criteria were considered.
[a] Across both groups (AAT: $n = 54$ and Sham: $n = 51$), there were participants deviating from the protocol. Within the AAT group, five participants used NRT, e-cigarettes or other smokeless tobacco products and three participants had a FTND < 3 at baseline. In the Sham group, three participants used NRT, e-cigarettes or other smokeless tobacco products and four participants had a FTND < 3 at baseline.

Table 2
Smoking-related information of the post- and follow-up assessment for both the intention-to-treat- (ITT) and the per-protocol- (PP) samples: means (SD).

	ITT				PP			
	AAMT		Sham		AAMT		Sham	
Variable/time	Post (n = 42)	Follow-up (n = 48)	Post (n = 42)	Follow-up (n = 44)	Post (n = 33)	Follow-up (n = 33)	Post (n = 34)	Follow-up (n = 34)
Cigarettes per day	1.50 (4.46)	8.27 (7.91)	1.93 (4.60)	8.75 (8.86)	1.91 (4.97)	7.27 (7.38)	1.94 (4.84)	8.79 (9.38)
FTND	0.60 (1.82)	2.42 (2.67)	0.67 (1.63)	2.75 (2.89)	0.76 (2.03)	2.03 (2.46)	0.74 (1.78)	2.76 (2.94)
Abstinent days	6.29 (1.97)	2.63 (3.21)	6.17 (2.23)	2.98 (3.37)	6.09 (2.19)	2.70 (3.20)	6.29 (2.17)	3.44 (3.38)
CO value	5.88 (6.09)[a]	–	6.15 (7.69)[b]	–	6.30 (6.59)	–	6.31 (8.25) [c]	–

Note. AAMT = Approach-Avoidance Modification Training.
[a] n = 41.
[b] n = 40.
[c] n = 32.

did not significantly differ between groups: PP: AAT: 10 of 33 (30%), Sham: 14 of 34 (41%), $\chi(1) < 1$, $p = .353$; ITT: AAT: 15 out of 54 (28%), Sham: 16 out of 51 (31%), $\chi(1) < 1$, $p = .687$.[1]

[1] PP analyses were repeated with a strict PP sample that included participants who completed all smoking cessation and training sessions (n = 42). However, results remained unchanged (see Table 5 in the Supplementary Material 2).

5.2. Implicit measures

5.2.1. Pre-post change in AAT effect

To examine the effect of AAMT on implicit behavioral tendencies, we estimated a mixed model in which the AAT effect at t1 was predicted by stimulus type (smoking-related, smoking-unrelated), familiarity (trained, untrained), time (baseline, post), condition (AAMT, Sham), and their interactions. Our data had a three-level nested structure; the stimulus type and familiarity (2x2 experimental design)

Table 3
Results of the linear mixed effects model for all dependent variables, PP- and ITT sample.

Fixed parts	Cigarettes per day			FTND			Abstinent days			CO value		
	B	*CI*[a]	*p*	*B*	*CI*	*p*	*B*	*CI*	*p*	*B*	*CI*	*p*
Per Protocol												
Intercept	18.35	16.68–20.02	< .001	5.71	5.24–6.17	< .001	0.06	−0.07 – 0.19	.454	16.97	15.52–18.42	< .001
Group	−2.69	−5.07–−0.30	.066	−0.49	−1.15 – 0.16	.222	0.06	−0.12 – 0.25	.577	−0.94	−3.01 – 1.13	.457
Time (t1)	−16.41	−18.51–−14.32	< .001	−4.97	−5.56–−4.38	< .001	6.24	5.62–6.85	< .001	−10.89	−12.98–−8.81	< .001
Time (t2)	−9.56	−12.17–−6.95	< .001	−2.94	−3.66–−2.23	< .001	3.38	2.45–4.31	< .001	–	–	–
Group x t1	2.65	−0.33 – 5.64	.147	0.52	−0.32 – 1.35	.312	−0.27	−1.14 – 0.61	.621	1.16	−1.76 – 4.09	.515
Group x t2	1.16	−2.56 – 4.89	.608	−0.24	−1.26 – 0.78	.699	−0.81	−2.13 – 0.52	.321	–	–	–
ITT	17.43	16.00–18.86	< .001	5.65	5.20–6.09	< .001	0.04	−0.06 – 0.13	.496	16.20	14.78–17.61	< .001
Intercept												
Group	−0.34	−2.33 – 1.66	.780	−0.24	−0.86 – 0.38	.526	0.07	−0.06 – 0.20	.371	1.36	−0.61 – 3.33	.258
Time (t1)	−15.65	−17.49–−13.81	< .001	−4.91	−5.44–−4.38	< .001	6.12	5.59–6.66	< .001	−10.39	−12.23–−8.54	< .001
Time (t2)	−8.69	−10.88–−6.50	< .001	−2.82	−3.48–−2.16	< .001	2.94	2.12–3.75	< .001	–	–	–
Group x t1	0.49	−2.10 – 3.08	.755	0.20	−0.55 – 0.96	.654	0.04	−0.72 – 0.80	.930	−0.75	−3.34 – 1.84	.634
Group x t2	−0.07	−3.11 – 2.96	.968	−0.17	−1.09 – 0.75	.761	−0.43	−1.56 – 0.70	.536	–	–	–

Note. CI = 95% confidence interval. FNTD = Fagerström Test for Nicotine Dependence.
When number of prior quit attempts was included as predictor, results remained unchanged.

Table 4
AAT effects for each combination of Picture Type, Familiarity, and Group and IAT effects: means (SD).

	Familiarity	PP				ITT			
		AAMT		Sham		AAMT		Sham	
		pre[a]	post[a]	pre[b]	post[b]	pre[c]	post[d]	pre[e]	post[f]
AAT effect									
Smoking	Trained	−7.45 (51.08)	−6.00 (45.89)	−6.84 (56.06)	−7.79 (51.29)	−5.13 (50.11)	−3.36 (47.68)	−0.55 (52.84)	−6.95 (51.40)
	Untrained	20.80 (50.10)	−7.50 (43.68)	−15.81 (85.05)	−1.32 (52.82)	19.08 (52.92)	2.27 (50.12)	−9.74 (73.81)	−10.06 (55.45)
Smoking-unrelated	Trained	3.67 (49.12)	−6.30 (57.59)	−10.43 (51.33)	−13.35 (48.67)	6.54 (48.71)	1.59 (65.56)	−7.26 (54.43)	−12.48 (46.01)
	Untrained	−9.47 (76.73)	−7.30 (58.84)	−9.13 (54.01)	−5.53 (42.63)	−4.34 (63.74)	−17.23 (62.22)	−5.23 (54.56)	−6.39 (43.25)
		pre[g]	post	pre[h]	post[i]	pre[j]	post[k]	pre[l]	post[m]
IAT effect		−0.24 (0.71)	−0.36 (0.59)	−0.09 (0.71)	−0.16 (0.61)	−0.10 (0.69)	−0.33 (0.58)	−0.13 (0.76)	−0.17 (0.64)

Note: [a] $n = 30$; [b] $n = 34$; [c] $n = 52$; [d] $n = 39$; [e] $n = 51$; [f] $n = 42$; [g] $n = 33$; [h] $n = 34$; [i] $n = 32$; [j] $n = 54$; [k] $n = 42$; [l] $n = 51$; [m] $n = 41$.

were nested to each assessment occasion, which was further nested to condition. The effects of stimulus type and familiarity were assumed to vary across time (level-2 random effects), and the effect of time was assumed to vary across participants (level-3 random effect). In the PP sample, the four-way interaction was statistically significant, indicating that the training effect varied across condition, stimulus types, and familiarity (Table 4). To simplify the model, we estimated a multi-level model with condition, time, and their interaction for the smoke-related and untrained stimuli. The results showed a significant condition-time interaction, $B = -42.79$, $SE = 20.52$, 95% CI [-83.00, -2.57], $p = .04$, which was qualified by a marginally significant reduction in AAT effect for AAMT, $B = -28.3$, $SE = 14.95$, $t = 1.89$, $p = .06$, but not in Sham condition, $B = 14.49$, $SE = 14.05$, $t = 1.03$, $p = .31$. Note that the significant reduction in the AAMT condition was due to the higher baseline AAT effect compared to Sham (see Table 4). We repeated the same analyses for the other three conditions, smoking-trained, smoking-unrelated-untrained, and smoking-unrelated-trained stimuli. There were no significant group-time interactions in these conditions. In the ITT sample, however, the significant four-way interaction was not replicated, which suggests that the pre-post changes in AAT effect did not vary between condition and stimuli in this sample.

5.2.2. IAT effect

We also estimated a mixed model where the IAT score was predicted by time, condition, and their interaction. The expected two-way interaction of condition x time was not significant, PP: $B = -0.05$ (95% CI: -0.26 – 0.15), $p = .660$; ITT: $B = -0.16$ (95% CI: -0.34 – 0.02), $p = .146$ (see Table 4).

5.3. Mediation

Although the training effects on clinical outcomes and implicit behavioral tendencies were not established in the current data, we performed mediation analyses to test the indirect effect of AAMT on clinical outcomes via changes in AAT effects. The traditional approach to test mediation (e.g., Baron & Kenny, 1986) requires a significant bivariate association between a predictor (X) and outcome (Y) as a first step, before the indirect effect via a mediator (M) is investigated. However, a more recent study (Shrout & Bolger, 2002) suggests relaxing this requirement; specifically, they argue the bivariate association between predictor and outcome often has limited power due to its distal relationship. It also demonstrates that an appropriate mediation model can improve the power to detect such a distal effect over the power to test the simple bivariate association (Shrout & Bolger, 2002). Therefore, we followed this recommendation to test the indirect effect. Following Machulska et al. (2016), we estimated two regression models on the PP sample (a) with condition predicting pre-post changes in the AAT effect for smoking-related pictures, $B = -42.79$, $SE = 20.52$, $t = 2.09$, $p = .04$, and (b) with the AAT-bias changes predicting pre-follow-up changes in daily cigarette consumption, $B = -0.01$, $SE = 0.01$, $t = 0.36$, $p = .72$, after controlling for condition. The indirect effect, defined by (a)*(b) effects, was 0.22, 95% CI [-1.15, 1.73], bootstrapped with 1000

iterations. As the 95% CI included zero, this indirect effect is not statistically significant. The same mediation analyses were repeated for tobacco dependence, also showing a non-significant indirect effect, which was estimated 0.22, 95% CI [-0.03, 0.73].

5.4. Blinding

At t1, 22 participants (out of 42 [52%]) in the Sham group thought that they received the general training, while this was true for 11 (out of 42 [26%]) participants of the AAMT group, $\chi(1) = 6.04$, $p = .014$. Thus, blinding was successful in the Sham, but not in the AAMT group.[2]

6. Discussion

The main aim of the present study was to test whether effects of standard treatment for smoking cessation can be increased by adding AAMT. Results do not show a superiority of TAU + AAMT compared to TAU + Sham on any clinical outcome. This is at odds with earlier findings in inpatients with alcohol dependency (Eberl et al., 2013; Manning et al., 2016; Wiers et al., 2011), but adds to earlier inconsistent evidence in the smoking literature.

Given that AAMT training has shown promising results in patients with alcohol dependence (Eberl et al., 2013; Wiers et al., 2011), the question arises whether reward processing differs in alcohol and tobacco use. In this regard, studies investigating biased information processing towards substance-related cues have found similar patterns in tobacco and alcohol use as both are associated with attentional biases (e.g., Cox et al., 2006), biased memory associations (e.g., De Houwer, Custers, & De Clercq, 2006; Palfai & Ostafin, 2003), and approach biases (e.g., Machulska et al., 2015; Wiers et al., 2013; Wiers, Rinck, Dictus, & Van Den Wildenberg, 2009) towards substance-related stimuli. Therefore, inconsistent findings between alcohol and tobacco use seem not to be explained by unique patterns of information processing. Rather, the following explanations for the null findings are conceivable. Results could be due to the overall failure of the AAMT to consistently change the approach-bias, as a reduction of the bias is regarded a prerequisite for change in problem behavior (Grafton et al., 2017; MacLeod & Clarke, 2015, for a critical discussion see Cristea, Kok, & Cuijpers, 2017). In this regard, two findings are noteworthy in the present study: First, there was no significant approach-bias for smoking-related stimuli at baseline. However, although the approach-bias at baseline was small (R. W. Wiers et al., 2011) or even absent (Eberl et al., 2013) in other studies as well, effects on clinical outcome emerged. Importantly, however, in both earlier studies the AAMT produced a change in bias in that participants of the active condition showed an avoidance bias for alcohol-related stimuli after training. This leads over to the second problem of our study, namely, that no consistent evidence for a change of bias was found. Following the rationale of CBM, this might explain the absence of evidence for an impact of AAMT on clinical outcome in our study. It is noteworthy that in mediation analyses changes in bias were not associated with clinical outcome. Although the rationale for CBM predicts that a change in biases should mediate intervention effects, empirical evidence regarding this issue is not clear. For example, Machulska et al. (2016) found significant training effects at follow-up even though they failed to induce a positive change in bias. These contradictory findings raise the question which mechanisms mediate the effect of the training on outcome. As previous studies in inpatients with alcohol dependency also provided inconsistent evidence as to mediation effects (Eberl et al., 2013; Wiers et al., 2011), it might be the case that AAMT achieves positive effects by the modification of another cognitive process. It is important to address this question in future research, for example, by assessing not only behavioral tendencies pre- and post-intervention, but also other cognitive processes such as response inhibition.

Alternatively, the smoke-free program is already a highly effective intervention, thus, the add-on training with six sessions might not have been intensive enough to improve outcome or delivery of training needs to be improved. For example, it has been shown that contingency awareness is an important moderator of training effects (Nishiguchi, Takano, & Tanno, 2015; Van Dessel, De Houwer, & Gast, 2016). Not only were training effects increased using explicit instructions, but effects on symptoms were only found in the explicit (vs. implicit) instruction (Krebs, Hirsch, & Mathews, 2010). When explicit instructions are used, participants are explicitly instructed to push smoking-related and to pull smoking-unrelated stimuli. In contrast, in the case of implicit instructions responses depend on a dimension which is independent of picture content, for example, the color of frames. Therefore, future studies should investigate whether clinical outcome can be improved by combining TAU with an explicit AAMT. Beyond, it remains unresolved how many training sessions are needed (Eberl et al., 2014) and it is conceivable that more than six training sessions are required to obtain additional effects. However, the number of trainings ($n = 6$) and trials per session ($n = 384$) in the present study was higher compared to studies revealing positive effects on clinical outcome. In most successful studies, four training sessions were administered (Baird et al., 2017; Machulska et al., 2016; Manning et al., 2016; Wiers et al., 2011) and trial number ranged from 120 (Manning et al., 2016) to 250 (Machulska et al., 2016). One “outlier” is the study by Eberl et al. (2013) in which 12 training sessions were administered (with 160 trials each). The study in adolescent smokers (Kong et al., 2015) in which no group differences emerged in the long-term also used four training sessions with 300 trials per session. Therefore, the explanation that more training sessions are needed seems rather unlikely. Alternatively, null findings could result from a lack of adherence to the intervention; however, adherence was excellent in both groups rendering this explanation improbable. Lastly, the technical set-up differed from previous studies and the usage of a different response device might have affected training effects, thus, future studies should use the original design (i.e., joystick).

Important avenues for future studies can be inferred from the study. One inherent problem of implicit measures is their low reliability constraining the possibility to assess implicit biases reliably and to perform mediation analyses (Rodebaugh et al., 2016). Split-half reliabilities for AAT effects in our study were inadequate and lower compared to the study of Rinck and Becker (2007). Poor reliability can result when variability between participants is small compared to the overall error variance. Due to the setup of the study (i.e., use of a mouse) it is likely that measurement error was relatively high and higher than in studies using a joystick as indicated by the number or errors. In line with this interpretation, the mean number of errors (i.e., mouse was moved in the wrong direction, change of direction within the trial) was higher in the present study (PP sample, baseline: 11%; post-test: 7%) than in previous AAT studies (e.g., Rinck & Becker [2007] had an average error rate of < 2%). This could indicate that participants attended to the content and not the frame of the pictures; however, this interpretation is speculative and we cannot verify whether participants indeed attended to picture content. One means to assess attendance to picture content would be the inclusion of a recognition task. Another possibility is to use the relevant pictorial stimuli as primes, not as targets (as done in Experiment #3 in the study by Rotteveel & Phaf, 2004). If picture content is processed automatically, then the valence of the prime should affect RTs for arm flexion and extension when responding to a neutral target. One means to improve reliability of AAT effects is to use an explicit instruction: One study revealed that, regardless of type of measures, when explicit instructions were used, AAT effects showed satisfactory reliability whereas poor reliability emerged with implicit instructions (Kersbergen, Woud, & Field, 2015).

[2] In order to test whether blinding impacted results, all analyses regarding smoking-related outcome were repeated with blinding (successful yes vs. no) as an additional predictor; however, results remained unchanged.

7. Limitations

Results of the present study need to be interpreted against the background of several limitations. Split-half reliabilities of AAT effects were unsatisfactory and consequently, it was not possible to reliably assess biases pre- and post-treatment and findings regarding AAT effects should be interpreted with caution. Future research should focus more strongly on the development of experimental paradigms that reliably assess and change the bias of interest. As discussed above, contingency awareness is important with regard to training effects; however, we did not explicitly inquire whether participants were aware of training contingencies which represents a limitation. A threat to internal validity is that a single-instead of a double-blind design was used (data collectors not blinded). However, assessments were computer-based and smoking status was objectively verified reducing the risk of bias.

8. Conclusion

This is the first study that investigated whether long-term clinical outcome can be improved by combining TAU + AAMT (vs. TAU + Sham) in a sample of adult smokers. Contrary to studies in abstinent patients with alcohol dependency, expected clinical effects could not be established. Future studies should investigate the effectiveness of optimized training version (e.g., explicit instructions).

Declaration of interest

Dr. Rüther has been a consultant for, received grant/research support and honoraria from and been a speaker for or on the advisory board of Johnson & Johnson and Pfizer (both manufacturer of medication for smoking cessation). All other authors declare no conflicts of interest.

Ethical standards

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

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Appendix A. Supplementary data

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