ARTICLE

Approach Bias Modification as an Add-On to Smoking Cessation Treatment: A Randomized Controlled Trial

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Objective: Smoking is associated with an approach bias toward smoking-related stimuli. Approach bias modification (ApBM), a computerized training specifically designed to modify this approach bias, has shown positive effects in patients with alcohol use disorder; however, its efficacy as an add-on in smoking cessation treatment is inconclusive. The aim of this clinical trial was to investigate whether ApBM as an add-on to smoking cessation treatment results in higher 6-month prolonged abstinence rates compared to two control conditions.

Methods: In this randomized, controlled, double-blind, single-center superiority trial, 351 participants received a 1-day cognitive-behavioral smoking cessation treatment (treatment as usual [TAU]) and were subsequently randomized to either TAU+ApBM (N=119), TAU+sham training (N=115), or TAU only (N=117). Training sessions were conducted over 7 days. The primary outcome was prolonged abstinence at 6-month follow-up. Participants were classified as either nonsmoking (continuous abstinence for 6 months, ≤5 cigarettes since quit attempt, and breath CO level ≤9 ppm) or relapsed (no objective verification of smoking status, breath CO level ≥10 ppm, >5 cigarettes since quit attempt).

Results: In the intention-to-treat analyses, abstinence rates at 6 months were 19.3% (95% CI=12.13, 26.53) for TAU+ApBM, 17.4% (95% CI=10.36, 24.42) for TAU+sham training, and 16.2% (95% CI=9.46, 23.02) for TAU only, with no significant differences between groups.

Conclusions: This large-scale clinical trial demonstrates that TAU+ApBM is not significantly superior to TAU+sham training or TAU only. ApBM has been included in Australian and German alcohol use disorder treatment guidelines, but this randomized controlled trial shows that positive effects do not apply to tobacco use disorder.

Am J Psychiatry 2026; 183:240–250; doi: 10.1176/appi.ajp.20250189

Worldwide, approximately 1.14 billion individuals are current smokers. Smoking is one of the leading risk factors for premature mortality, accounting for more than 7.6 million deaths in 2019 alone (1). Quitting smoking yields substantial health benefits (2). However, quit attempts are often unsuccessful, with high relapse rates even among individuals receiving evidence-based treatments (3). Given the severe health consequences and high societal costs associated with smoking (4, 5), developing new cessation strategies to increase long-term abstinence is essential.

One potential, yet underexplored approach in current first-line smoking cessation treatments is to modify automatic cognitive biases, which are thought to play an important role in the development and maintenance of substance use disorders (6). In particular, pathological substance consumption is believed to be driven by strong, appetitive responses to drug-related cues, such as approach biases toward smoking-related cues, that individuals cannot sufficiently inhibit through controlled processes (7, 8). A core assumption of dual-process models is that individual differences in impulsivity and executive functioning moderate the impact of appetitive responses on behavior (7). Specifically, individuals with higher impulsivity and weaker executive functioning should exhibit stronger biases toward drug-related cues, a notion that is supported by empirical evidence (9–11).

Computerized interventions, such as approach-bias modification (ApBM), aim to directly reduce approach biases by training individuals to consistently avoid drug-related stimuli (12). The rationale behind ApBM is that reductions in approach biases toward smoking-related stimuli mediate the positive effects of the intervention on substance use behaviors (13). In alcohol use disorder, ApBM has been shown to significantly reduce long-term (14, 15) and early relapse (16, 17) when added to treatment as usual (TAU).

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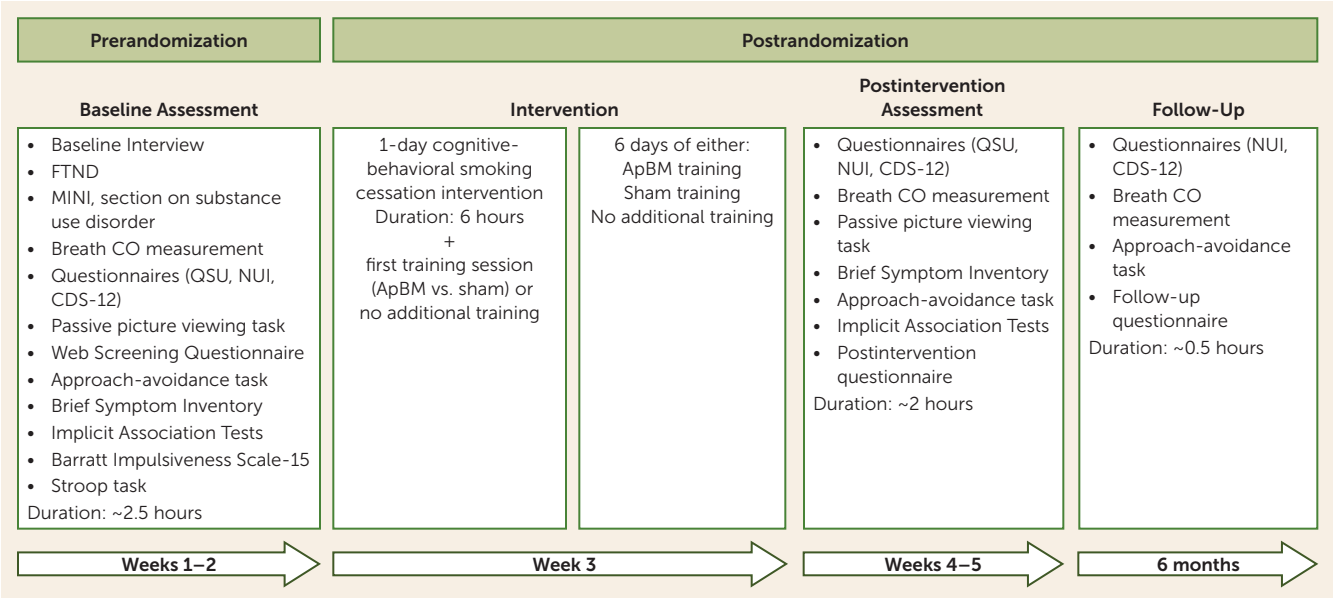
FIGURE 1. Study procedure



[a] ApBM, approach bias modification; CDS-12, Cigarette Dependence Scale; FTND, Fagerström Test for Nicotine Dependence; MINI, Mini-International Neuropsychiatric Interview; NUI, Nicotine Use Inventory; QSU, Brief Questionnaire of Smoking Urges.

Evidence regarding the efficacy of ApBM for smoking cessation is less consistent. Some studies report that ApBM has positive effects on daily cigarette consumption (18, 19) as well as on short-term (20) and 3-month abstinence rates (21). Also, there is evidence that ApBM is associated with a higher likelihood of abstinence among more impulsive individuals who smoke (22). However, a recent efficacy trial on ApBM as an add-on to TAU in individuals who smoke found no significant effects compared to a sham training condition (23). Importantly, this trial had several key limitations, which point to the need for further investigation. First, the trial did not include a TAU-only condition, leaving unanswered whether TAU+ApBM or TAU+sham training is more effective than TAU alone. Second, three of the six ApBM or sham training sessions took place before the quit attempt, which may have compromised the efficacy of the intervention. Third, with 105 participants, the trial was underpowered, as 243 participants would have been required to adequately detect differences in abstinence rates at follow-up, increasing the risk of type II error.

The present study addresses these limitations by conducting a large-scale, sufficiently powered, randomized trial that included two control conditions: TAU+sham training and TAU only. Following the rationale of ApBM, we hypothesized that TAU+ApBM would lead to higher long-term abstinence (i.e., 6-month follow-up [primary outcome]) compared to TAU+sham training and TAU only. Additionally, we posited that the effects of the intervention on abstinence would be mediated by a reduction in approach biases toward smoking-related stimuli. Lastly, we hypothesized that the efficacy of ApBM would be moderated by individual differences in executive functioning and impulsivity, with greater efficacy expected in individuals with lower executive functioning and higher levels of impulsivity.

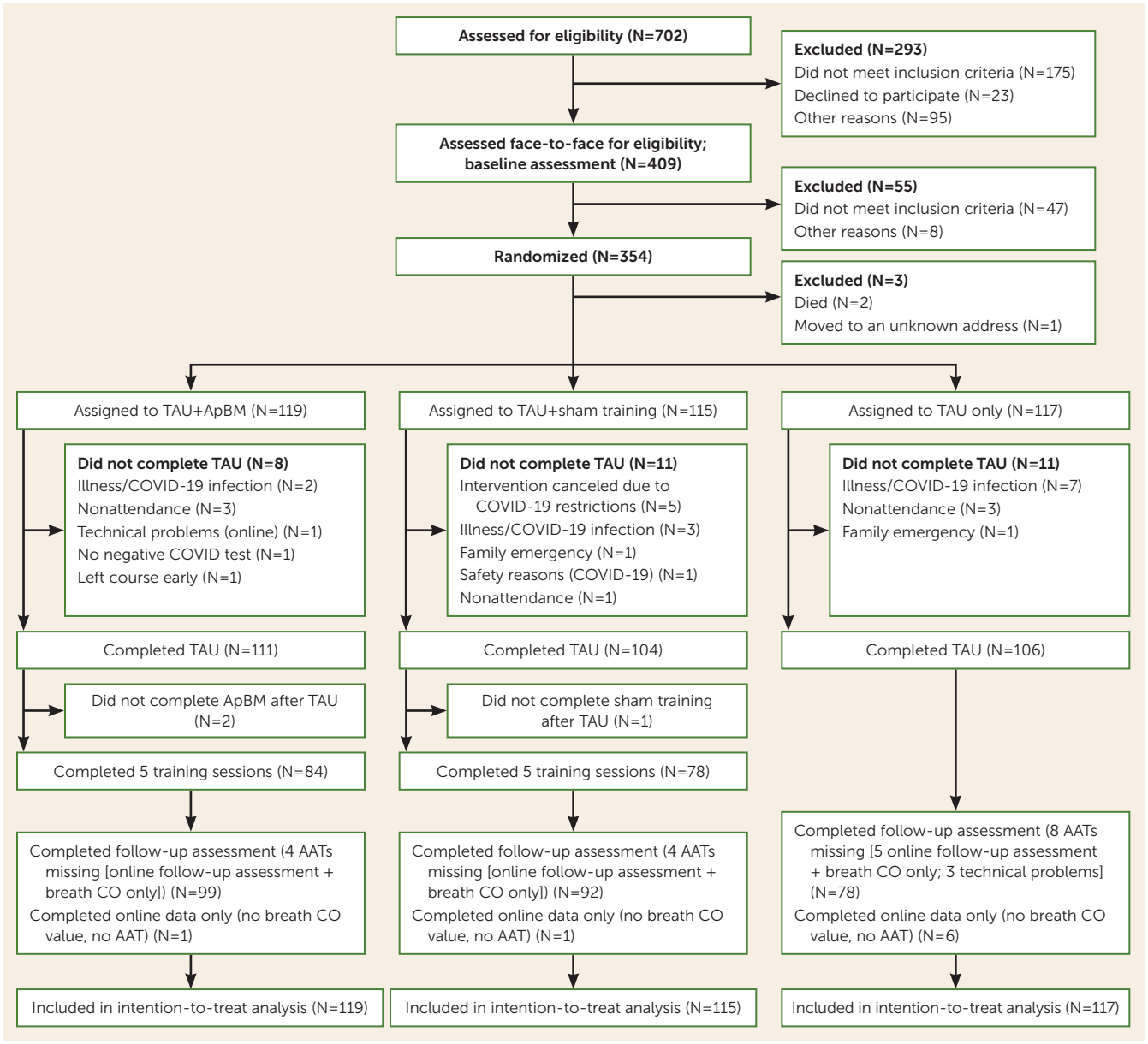
METHODS

Trial Design and Procedures

This study was a randomized, controlled, double-blind, single-center, parallel-group superiority trial. The study was conducted at the Department of Psychology, LMU Munich, and the outpatient treatment center for tobacco dependence at LMU University Hospital Munich. Data were collected between November 2019 and March 2023, with follow-up assessments continuing until October 2023. Enrollment was stopped once the minimum number of participants had been recruited. Participants were reimbursed for taking part in the assessments either financially (€8/hour) or with course credit (N=2), and the intervention itself was provided free of charge. The study was registered with the German Clinical Trials Register (https://www.drks.de/DRKS00019221) and approved by the Ethics Committee of the Department of Psychology, LMU Munich (23_Wittekind_c_2019). All procedures adhered to the CONSORT guidelines (24).

The study procedure is depicted in Figure 1. Individuals who expressed interest in the study underwent an initial telephone screening to determine preliminary eligibility. For those deemed potentially eligible, a baseline appointment was scheduled, during which written informed consent was obtained and inclusion and exclusion criteria were verified. An interview was conducted to confirm eligibility and to collect sociodemographic and smoking-related information (see the supplementary methods section in the

FIGURE 2. Flow of participants in the study



[a] AAT, approach-avoidance task; ApBM, approach bias modification; CDS-12, Cigarette Dependence Scale; FTND, Fagerström Test for Nicotine Dependence; MINI, Mini-International Neuropsychiatric Interview; NUI, Nicotine Use Inventory; QSU, Brief Questionnaire of Smoking Urges.

online supplement). Additionally, participants completed the substance use disorder section of the Mini-International Neuropsychiatric Interview (MINI) (25) as well as the Fagerström Test for Nicotine Dependence (FTND) (26). The assessment continued only if the participant met all eligibility criteria. Participants also completed the Web Screening Questionnaire for common mental disorders (27) to screen for mental health disorders.

For each 1-day smoking cessation intervention, up to 14 participants were recruited. Participants completed the baseline assessment in the 2 weeks before attending the course. Randomization took place upon completion of the baseline assessments of all participants scheduled for a specific smoking cessation intervention. Participants randomized to one of the training conditions completed their first training session immediately after the smoking cessation intervention at the Department of Psychology. Subsequent training sessions were completed at home over the following 6 days, using joysticks provided for the duration of the training. Participants who missed training sessions received e-mail reminders from a staff member not involved in the assessments. Participants who did not attend the smoking cessation intervention did not receive any training (eight participants randomized to TAU+ApBM and 11 participants randomized to TAU+sham training) (Figure 2). One week after the intervention, participants received

an individual telephone coaching session and completed the postintervention assessment. The follow-up assessment took place 6 months after the date of the intervention. We refrained from including more frequent assessments, as established guidelines and standard criteria for reporting long-term abstinence (28) recommend follow-up assessments at 6 or 12 months. Shorter follow-up periods are considered inadequate for reliably predicting long-term cessation and are unlikely to lead to meaningful health benefits (28). Modifications to the study procedures during the COVID-19 pandemic are described in the supplemental methods section in the online supplement.

Participants and Sample Size

Participants were included if they met the following inclusion criteria: age between 18 and 70 years, a total score ≥3 on the FTND (26), a breath CO level ≥10 ppm, smoking ≥10 cigarettes daily within the past 12 months, no use of nicotine replacement therapy (NRT) or pharmacological smoking cessation therapy within 3 months before study participation, willingness to abstain from NRT, e-cigarettes, and any other smoking cessation interventions during the study period, and interest in participating in the smoking cessation program. Exclusion criteria were presence of a severe psychiatric disorder (e.g., bipolar disorder, psychosis) or neurological disorder (e.g., multiple sclerosis, Parkinson's disease); acute suicidality; moderate substance dependence within the past year (i.e., ≥4 criteria according to *DSM-5* [29]), except tobacco dependence; pregnancy or breastfeeding; and insufficient knowledge of German. Participants were recruited from the community through various strategies (e.g., social media, distribution of flyers at pharmacies, medical practices, residents' registration office, media advertisements, notices in public spaces). Based on a power analysis (see reference 30 and the supplementary methods section in the online supplement) and a power curve, the minimum required sample size to achieve a power of 0.78 was estimated at 268 participants. Accounting for an expected dropout rate of 20%, the final target sample size was set at 336 participants.

Interventions

TAU smoking cessation intervention. The 1-day version of the TAU smoking cessation intervention is an intensive cognitive-behavioral group intervention (total duration: 6 hours), not including pharmacological treatment. All interventions were delivered by certified trainers who had been extensively trained. The intervention follows a highly structured manual describing the procedure in detail and includes various methods, such as psychoeducation, motivational interviewing, cognitive strategies, and strategies of goal orientation (31). The intervention consists of four sections. The first section aims to increase motivation by reinforcing ambivalence and to improve participants' knowledge of their own smoking behavior (e.g., psychoeducation on the development of chronic smoking behavior; self-monitoring of smoking behavior with registration cards; collection of arguments for smoking and nonsmoking). The second section aims to strengthen motivation by reducing anxiety (e.g., sharing experiences of previous quit attempts; psychoeducation on withdrawal symptoms and positive effects of smoking cessation) and to build confidence in the skills to remain abstinent, and it includes the implementation of the quit attempt. During the third section, participants plan their first 24 hours after the quit attempt, receive psychoeducation regarding high-risk situations, craving, and relapse prevention. Additionally, participants are taught a set of strategies (skills) to manage high levels of craving (e.g., strong sensory input, such as smelling ammonia, eating spicy food). The fourth section aims to support participants to develop an identity as a nonsmoker and to strengthen their confidence. Participants are offered a telephone counseling session that takes place 1 week after the intervention. In total, 35 smoking cessation interventions with an average of nine participants were conducted.

ApBM and sham training. Participants assigned to the ApBM or sham training sessions received content-irrelevant instructions, that is, to push or pull a joystick based on the tilt of the images presented (5° to the left or right). The direction of movement (push or pull) was counterbalanced across participants to control for individual differences. The ApBM training used a modified version of the assessment approach–avoidance task (32). In the ApBM condition, 100% of smoking-related pictures were tilted in the direction associated with pushing, whereas 100% of positive, non-smoking-related pictures were tilted in the direction associated with pulling. In contrast, the sham training presented a neutral task structure in which 50% of each image category (smoking-related images or positive images) had to be pushed or pulled.

To simulate the impression of approach or avoidance, images increased in size when pulled and decreased in size when pushed. Of the 40 smoking-related and 40 positive images used in the assessment approach–avoidance task, half of each category (20 smoking-related, 20 positive) were used during the training to allow for testing of generalization effects to untrained stimuli. Each training session consisted of 10 practice trials followed by 240 training trials. Training sessions were programmed using Inquisit (https://www.millisecond.com).

TAU. Participants randomized to the TAU-only group did not receive any additional training.

Outcomes

The primary outcome was prolonged abstinence (from the quit date) at the 6-month follow-up, defined by the Russell Standard (28). Criteria of the Russell Standard are (1) smoking a maximum number of five cigarettes over the whole follow-up period, (2) biochemical verification, (3) application of an intention-to-treat approach, (4) inclusion of

participants with protocol violations in all analyses, and (5) blind collection of follow-up data. Secondary outcomes assessed pre- and postintervention comprised current craving (Brief Questionnaire of Smoking Urges) (33) and psychological distress (the Global Severity Index of the Brief Symptom Inventory) (34). Secondary outcomes assessed at all assessment time points comprised smoking behavior (e.g., cigarettes per day), tobacco dependence (Cigarette Dependence Scale) (35), and breath CO levels (Smokerlyzer, Micro+Smokerlyzer, Bedfont Scientific Ltd., Maidstone, UK). At postintervention, participants were also asked about their beliefs regarding the group to which they had been allocated and their perceptions of the working mechanisms of the training (see the supplementary methods section in the online supplement). To investigate whether the effects of the training were mediated by changes in approach biases toward smoking-related stimuli, the joystick approach–avoidance task was administered preintervention, postintervention, and at follow-up. Additionally, participants completed two versions of a Single-Target Implicit Association Test (Wigboldus et al., unpublished 2006 manuscript) designed to assess associations between smoking and approach/avoidance, as well as valence (positive/negative). Individual differences in inhibitory control were measured using the Stroop task (36) (for a detailed description of all tasks, see the supplementary methods section in the online supplement).

Randomization

The randomization sequence (block-wise, 1:1:1 allocation ratio) was generated by an external study center (Munich Center of Clinical Trials). The randomization list, which consisted of varying block sizes, was inaccessible to the project staff responsible for assessments and study organization. Staff members involved in recruitment, enrollment, and assessments, as well as trial participants and the smoking cessation intervention trainers, were blind to forthcoming assignments and group allocation. On completion of the baseline assessments of all participants scheduled for a specific smoking cessation intervention, an individual not involved in recruitment, enrollment, or assessments retrieved the forthcoming group assignment using an online tool programmed by the Munich Center of Clinical Trials. This staff member informed participants of their group allocation at the end of the smoking cessation intervention, conducted the first training session, monitored training adherence, and sent training reminders. Participants in the training groups were blind as to the specific nature of their assigned training; however, it was not possible to blind participants assigned to the TAU-only condition.

Statistical Analysis

Details of the data preprocessing and multiple imputation procedure are provided in the supplementary methods section in the online supplement. Analyses adhered to the analysis plan described in the study protocol (30). Analyses were conducted using R (37) and SPSS 29.0. All randomized participants were analyzed using an intention-to-treat approach except for those who died during the study (N=2) or moved to an unknown address (N=1) (28).

A logistic regression analysis was performed to assess the association between group allocation and abstinence at the 6-month follow-up (primary outcome) using the *glm* function in R. Secondary outcomes were analyzed with linear mixed-effects models using the *lmerTest* package in R (38) (see the supplementary methods section in the online supplement).

The main generalized linear model and linear mixed-effects model analyses were repeated in the per-protocol sample, which consisted of participants who completed all three assessments and at least five training sessions (excluding the TAU-only group). The results of the per-protocol analyses were consistent with those of the intention-to-treat analyses (see Tables S15–S23 in the online supplement).

Mediation analyses were conducted in the per-protocol sample using change scores from the experimental tasks (postintervention assessment minus baseline assessment) as mediators, group assignment as the predictor (reference category: TAU only), and abstinence at follow-up as the outcome. These analyses were performed using structural equation modeling using a weighted least square mean and variance-adjusted estimator.

Moderation analyses examined whether participants in the TAU+ApBM group with lower levels of executive functioning, specifically inhibitory control (measured by the Stroop task), and higher self-reported impulsivity (measured by the Barratt Impulsiveness Scale–short form) benefited more from the training. In planned exploratory analyses, relapse status was tested as a potential moderator of treatment effects on the secondary outcomes, namely, cigarettes per day and tobacco dependence.

Descriptive statistics at each time point are reported as marginal means with 95% confidence intervals. Reliability for each measure was calculated (see the supplementary methods section and Table S1 in the online supplement). The results of the additional analyses are presented in the supplementary results section in the online supplement.

RESULTS

Sample Characteristics and Adherence

The flow of participants is depicted in Figure 2. Baseline characteristics, smoking-related information, psychopathological, and additional measures are summarized in Table 1. The final sample of 351 participants comprised 168 men and 183 women with a mean age of 42.21 years (SD=12.46). On average, participants smoked 18.74 cigarettes per day (SD=6.54) and had been smoking for 23.50 years (SD=12.14). At baseline, no significant group differences were observed in any characteristics. Dropout rates were approximately 20%, as anticipated (for more details,

TABLE 1. Baseline characteristics and treatment adherence in the intention-to-treat sample[a]

Variable	Whole sample (N=351)		TAU+ApBM (N=119)		TAU+sham training (N=115)		TAU only (N=117)		Comparison	
	N	%	N	%	N	%	N	%	χ^2	p
Sex										
Male	168	48	58	49	53	46	57	49	0.22	0.898
Female	183	52	61	51	62	54	60	51		
German university entrance qualification (Abitur)										
No	123	35	33	28	46	40	44	38	4.19	0.123
Yes	224	65	84	72	68	60	72	62		
Depressive disorder										
No	344	98	115	98	114	99	115	98	0.97	0.617
Yes	6	2	3	2	1	1	2	2		
Anxiety disorder[b]										
No	157	45	58	49	50	44	49	42	1.23	0.540
Yes	194	55	61	51	65	56	68	58		
OCD										
No	288	82	97	82	94	82	97	83	0.06	0.973
Yes	62	18	21	18	21	18	20	17		
PTSD										
No	163	47	56	48	56	49	51	44	0.66	0.718
Yes	187	53	62	52	59	51	66	56		
SUD										
No	316	90	107	90	105	91	104	89	0.38	0.827
Yes	35	10	12	10	10	9	13	11		
Completed TAU										
No	30	8	8	7	11	10	11	9	0.77	0.681
Yes	321	92	111	93	104	90	106	91		

	Mean	SD	Mean	SD	Mean	SD	Mean	SD	F	p	η^2
Age (years)	42.21	12.46	42.21	12.43	43.57	12.50	40.87	12.42	1.36	0.259	0.008
Average number of participants in TAU	9.23	2.89	9.58	2.91	9.45	2.79	8.83	3.21	0.22	0.804	0.014
Cigarettes per day	18.74	6.54	18.37	5.49	19.43	7.81	18.45	6.16	0.94	0.394	0.005
Breath CO level (ppm)	26.89	12.53	28.42	13.13	27.30	12.58	24.93	11.69	2.40	0.093	0.014
Smoking duration (years)	23.50	12.14	23.47	12.02	24.52	12.30	22.55	12.15	0.75	0.472	0.004
Previous quit attempts	3.86	5.69	3.32	4.06	3.92	6.37	4.36	6.37	0.98	0.378	0.006
FTND	5.35	1.61	5.32	1.40	5.56	1.77	5.18	1.64	1.43	0.241	0.009
BIS-15	32.30	5.95	32.24	5.75	31.45	6.05	33.20	5.97	2.52	0.082	0.014
Stroop interference score (ms)	272.02	234.69	245.10	210.54	286.54	254.43	284.08	236.59	1.10	0.333	0.007

									t	p	Cohen's d
Number of training sessions	6.73	3.31	6.96	3.38	6.48[c]	3.23	—	—	1.07	0.284	0.15

[a] Although for most variables data were available for all participants, Ns for the data in the table range from 339 to 351 for the whole sample, from 109 to 119 for the TAU+ApBM group, from 103 to 115 for the TAU+sham training group, and from 114 to 117 for the TAU-only group. ApBM, approach bias modification; BIS-15, Barratt Impulsiveness Scale–short form; FTND, Fagerström Test for Nicotine Dependence; OCD, obsessive-compulsive disorder; PTSD, posttraumatic stress disorder; SUD, substance use disorder; TAU, treatment as usual.

[b] All anxiety-related disorders assessed with the Web Screening Questionnaire for common mental disorders were combined.

[c] N=103 (212 of 215 participants attending the smoking cessation intervention took part in the training [see Figure 2; 111 participants in the TAU+ApBM group and 104 participants in the TAU+sham training group]; data from the training sessions of three participants who took part in the training online during the COVID pandemic could not be verified as completed; therefore, the training data for these participants were considered missing).

see the supplementary results section and Table S2 in the online supplement).

Outcome Measures

For the primary outcome, 19.3% (95% CI=12.13, 26.53) of participants in the TAU+ApBM group were abstinent at follow-up, compared to 17.4% (95% CI=10.36, 24.42) in the TAU+sham training group and 16.2% (95% CI=9.46, 23.02) in the TAU-only group. Logistic regression analyses showed no significant group differences in abstinence rates at follow-up (see Table 2).

Results for the secondary outcomes are presented in Table 3. Cigarette dependence (Cigarette Dependence Scale), craving (Brief Questionnaire of Smoking Urges), daily cigarette consumption, and approach biases toward untrained smoking-related stimuli significantly decreased over time (p values <0.008). Reductions did not significantly differ between groups (p values >0.20). Breath CO levels also showed significant reductions over time across groups (p values <0.001); however, this decline was significantly greater in the TAU+ApBM group at postintervention (p=0.002) and follow-up compared to the TAU-only group

TABLE 2. Results of the logistic regression analysis for the primary outcome: abstinence[a]

	Log odds ratio	SE	z statistic	p	95% CI
TAU+sham training	1.09	0.35	0.23	0.815	0.54, 2.17
TAU+ApBM	1.24	0.34	0.62	0.536	0.63, 2.42

[a] ApBM, approach bias modification; TAU, treatment as usual.

(p=0.003). For all other secondary outcomes, no significant effects were found for time or time-by-group interactions (p values >0.10) (for details, see Tables S3–S11 in the online supplement; effect sizes for secondary outcomes are presented in Table S12).

Mediation and Moderation

The mediation analyses did not provide conclusive evidence that changes in approach biases toward untrained smoking-related stimuli mediated the effects of the intervention on outcomes. The indirect effects were nonsignificant for both the TAU+ApBM group (β=−0.004, p=0.613) and the TAU+sham training group (β=−0.005, p=0.600). Similarly, none of the indirect effects for the alternative working mechanisms were significant (see Table S13 the online supplement). The direct effects of group assignment on abstinence were also nonsignificant (TAU+ApBM: β=−0.03, p=0.772; TAU+sham training: β=0.02, p=0.864). Individual differences in inhibitory control and impulsivity did not moderate the effects of the training on the outcomes, regardless of whether both moderators were analyzed jointly within a single model or considered separately (see Table S14 the online supplement for results).

DISCUSSION

This randomized controlled trial investigated the efficacy of ApBM as an add-on to smoking cessation treatment in a large sample of adults with chronic tobacco dependence. In line with findings from an earlier small-scale randomized controlled trial (23), this study found no evidence that TAU+ApBM was superior to the control conditions for either the primary or secondary outcomes. Significant reductions

TABLE 3. Summary statistics from linear mixed-effects models for secondary outcomes[a]

	TAU+ApBM (N=119)		TAU+sham training (N=115)		TAU only (N=117)	
Assessment	Marginal mean	95% CI	Marginal mean	95% CI	Marginal mean	95% CI
Craving (QSU-Brief)						
Baseline	26.50	24.64, 28.36	27.10	25.20, 28.99	26.47	24.59, 28.35
Postintervention	18.99	17.03, 20.95	19.44	17.37, 21.52	19.54	17.53, 21.55
Psychological distress (GSI)						
Baseline	0.54	0.46, 0.62	0.48	0.39, 0.56	0.63	0.55, 0.71
Postintervention	0.50	0.41, 0.59	0.48	0.39, 0.57	0.58	0.49, 0.67
Approach ST-IAT effect score						
Baseline	0.01	−0.06, 0.07	−0.10	−0.17, −0.03	−0.01	−0.08, 0.05
Postintervention	−0.07	−0.14, 0.00	−0.07	−0.14, 0.00	−0.06	−0.14, 0.02
Valence ST-IAT effect score						
Baseline	−0.29	−0.36, −0.22	−0.28	−0.35, −0.21	−0.25	−0.32, −0.18
Postintervention	−0.32	−0.39, −0.25	−0.31	−0.38, −0.24	−0.22	−0.30, −0.15
Tobacco dependence (CDS-12)						
Baseline	47.82	46.81, 48.84	47.71	46.68, 48.75	47.70	46.68, 48.73
Postintervention	30.23	27.78, 32.68	31.55	29.04, 34.05	31.40	28.93, 33.88
Follow-up	35.34	32.64, 38.05	35.36	32.40, 38.33	34.08	31.33, 36.83
Cigarettes per day						
Baseline	18.37	17.16, 19.58	19.43	18.19, 20.66	18.45	17.23, 19.67
Postintervention	7.08	5.42, 8.74	7.33	5.51, 9.14	6.80	5.05, 8.56
Follow-up	10.01	8.15, 11.86	10.91	9.14, 12.69	9.48	7.63, 11.34
Breath CO level (ppm)						
Baseline	28.42	26.13, 30.71	27.30	24.96, 29.63	24.93	22.62, 27.24
Postintervention	13.76	11.18, 16.34	15.31	12.43, 18.19	14.50	11.68, 17.31
Follow-up	16.68	14.04, 19.33	18.33	15.57, 21.10	17.68	14.86, 20.51
AAT bias score smoking pictures						
Baseline	−6.72	−16.05, 2.62	−4.57	−13.88, 4.73	−1.41	−10.71, 7.89
Postintervention	−19.24	−28.57, −9.91	−5.33	−15.26, 4.60	−12.64	−22.67, −2.61
Follow-up	−13.99	−23.99, −3.98	−2.98	−13.10, 7.14	−15.78	−27.36, −4.20
AAT bias score positive pictures						
Baseline	−4.37	−14.38, 5.65	4.96	−4.99, 14.91	−2.82	−12.75, 7.10
Postintervention	15.63	4.64, 26.63	−5.16	−16.16, 5.84	−0.72	−11.05, 9.62
Follow-up	3.55	−7.15, 14.25	−7.32	−18.81, 4.17	−4.16	−16.01, 7.69

[a] AAT, approach-avoidance task; ApBM, approach bias modification; CDS-12, Cigarette Dependence Scale; GSI, Global Severity Index of the Brief Symptom Inventory; QSU-Brief, Brief Questionnaire of Smoking Urges; ST-IAT, Single-Target Implicit Association Test; TAU, treatment as usual.

in smoking-related variables were observed over time across groups. Overall, these results contrast with the established efficacy of ApBM in alcohol use disorder (AUD), despite the assumption that tobacco and alcohol use disorder share similar mechanisms at the level of information processing (6). Several possible explanations for these discrepant findings warrant consideration.

First, the theory behind ApBM, which is based on dual-process (7) and incentive-motivation models of substance use disorder (8), might not be applicable to all individuals who smoke or to smoking behavior at all (8, 39, 40). These models posit that substance-related stimuli acquire motivational significance through associative learning processes linking substance use and its rewarding effects. However, other models of substance use disorder, such as habit-based models (41, 42), propose that incentive salience drives drug-seeking behavior mainly in the early stages of pathological substance use. Later stages should be dominated by stimulus-response associations (i.e., habits). This alternative theoretical account might be particularly relevant in tobacco use disorder, where smoking behavior may not be driven by strong appetitive responses toward smoking-related cues but rather by difficulties in controlling habitual behavior. This notion is also supported by neurobiological findings (43), which indicate that smoking may involve a stronger habitual component than AUD. Specifically, nicotine receptors have been shown to play a role in the neurobiological mechanisms underlying habit formation. As a result, smoking cues may have reduced incentive value and be less responsive to devaluation through ApBM.

Second, tobacco use disorder and alcohol use disorder differ in their behavioral patterns. Smoking typically involves a highly regular consumption pattern, with hundreds of nicotine inhalations per day, whereas alcohol use tends to occur less frequently. Moreover, smoking typically takes place in highly varied stimulus conditions. Consequently, future studies should examine whether delivering ApBM more frequently and across diverse smoking-related contexts could enhance its effectiveness.

Third, person-specific factors, such as abstinence motivation, might affect the processing of substance-related stimuli. It has been shown that cue reactivity was attenuated in abstinence-motivated compared to non-abstinence-motivated individuals who smoke, both at the neural (40) and psychophysiological level (39). Thus, while the strong motivational significance of smoking-related cues may drive smoking behavior in non-abstinence-motivated individuals who smoke, different processes may maintain smoking in abstinence-motivated smokers. Future studies should systematically investigate how smoking-related stimuli are processed in individuals with early versus chronic smoking behavior and with varying levels of abstinence motivation.

Fourth, some researchers have proposed that inferential (44) rather than associative mechanisms may explain the effectiveness of ApBM. This perspective suggests that participants draw conscious inferences based on the cues presented during training and the actions associated with them. For example, if participants are instructed to consistently avoid smoking-related cues, they might (automatically) infer that they are able to avoid smoking, which in turn might increase their ability to abstain from smoking in real life. According to this account, ApBM is expected to be more effective when a personally relevant outcome is approached, rather than an arbitrary, experimenter-chosen contrast category (45). More specifically, although a natural contrast category—namely, nonalcoholic drinks—is available in AUD, no such readily available alternative exists for smoking. This might explain the limited efficacy of ApBM observed in smoking. Future studies should therefore aim to include behavioral choices that are linked to individual cessation goals (45).

Lastly, the setting in which the cognitive bias modification training is delivered may influence its effectiveness. Evidence suggests that cognitive bias modification interventions are more effective when delivered in the clinic than when delivered at home (46). In AUD, the positive effects of TAU+ApBM on abstinence have been consistently observed in abstinent inpatients (15), whereas in one study with outpatients, ApBM was not superior to a sham intervention (47). The same pattern has been found for smoking: Smits et al. (21) found positive effects on abstinence when ApBM was administered in a clinical setting, whereas in the Wittekind et al. study (23), in which 50% of the training sessions were conducted at home, no effects on abstinence were observed.

To our knowledge, this is the first adequately powered trial to investigate ApBM as an add-on to smoking cessation treatment. An important strength of the trial is its sound methodology, including the blinding of participants, assessors, and care providers, as well as its strict abstinence criteria, with biochemical verification to minimize the risk of bias. Other strengths are the inclusion of two control conditions and the assessment of approach biases as the proposed working mechanism. However, there are several important limitations. First, attrition rates differed between groups, with the TAU-only group experiencing the highest dropout rate. The higher attrition rate in the TAU-only group may reflect reduced motivation, likely because patients did not receive additional training. It is conceivable that the combination of TAU and supplementary training represented the preferred treatment option. A recent meta-analysis supports this notion, showing that not receiving one's preferred treatment is significantly associated with higher dropout rates (48). Because participants without follow-up data were classified as having relapsed, relapse rates may have been overestimated in this group. Second, the assessment schedule may have been too sparse to detect changes in smoking behavior. A denser assessment schedule, particularly with more frequent measurements early in the follow-up period, might have been more sensitive to treatment effects, as these might occur early on. Third, the study excluded participants who used NRT or engaged in dual use of smoking and e-cigarettes during the trial. These restrictions may limit the generalizability of the findings, as a substantial proportion

of individuals who smoke use additional nicotine products (49). Fourth, the fidelity of TAU was not monitored, so it cannot be assured that all sessions were delivered at an acceptable level of fidelity. Fifth, breath CO measurement captures past 18- to 24-hour abstinence, and no repeated measures of breath CO were conducted during the follow-up period, so classification of prolonged abstinence relied on self-report.

In summary, this randomized controlled trial in a large sample of adults does not provide evidence that ApBM, when used as an add-on to smoking cessation treatment, improves long-term abstinence rates. This finding is consistent with previous research on ApBM in smoking cessation. ApBM as an add-on treatment has been included in different guidelines for AUD (50, 51). Notably, the results of this trial emphasize that results from interventions designed to treat one substance use disorder (e.g., AUD) cannot be directly generalized to another (e.g., tobacco use disorder). To improve smoking cessation treatments, future research should investigate the role of contextual and person-specific factors in greater detail and systematically test the assumptions of alternative theoretical frameworks.

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Presented in part at the 3rd German Psychotherapy Conference, Berlin, June 12–15, 2024.

This study was supported by a grant from the German Research Foundation (Deutsche Forschungsgemeinschaft) (WI4856/3-1 to Dr. Wittekind).

Dr. Rüther has served as a consultant for, received grants, research support, or honoraria from, served as a speaker for, or served on advisory board of Johnson & Johnson and Pfizer, and he has been a principal investigator in clinical studies sponsored by Kenvue and Pfizer. The other authors report no financial relationships with commercial interests.

German Clinical Trials Register identifier: DRKS00019221.

Received February 20, 2025; revisions received July 11 and August 20, 2025; accepted September 9, 2025; published online February 4, 2026.

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Examination Questions for "Approach Bias Modification as an Add-On to Smoking Cessation Treatment: A Randomized Controlled Trial"

1. **What was the primary outcome of the randomized controlled trial investigating ApBM as an add-on to smoking cessation treatment?**
   - A. Biochemically verified 7-day point-prevalence abstinence at 6-month follow-up
   - B. Prolonged abstinence from the quit date to 6-month follow-up according to the Russell Standard
   - C. Continuous abstinence for 12 months with biochemical verification
   - D. Reduction in cigarette consumption of at least 50% at 6-month follow-up
2. **Which conclusion regarding the efficacy of approach bias modification (ApBM) as an add-on to smoking cessation treatment is best supported by the findings of this randomized controlled trial?**
   - A. ApBM significantly enhanced long-term abstinence, but only after adjusting for baseline differences in nicotine dependence
   - B. ApBM showed small but statistically significant benefits only among participants with high impulsivity
   - C. ApBM was not significantly superior to treatment as usual (TAU) plus sham training or TAU alone in improving long-term abstinence
   - D. All three groups achieved abstinence rates above 20%
3. **Did changes in approach biases toward smoking-related stimuli mediate the effect of ApBM on long-term abstinence?**
   - A. Yes; significant indirect effects indicated that reductions in approach bias statistically accounted for the effect of ApBM on abstinence
   - B. No; mediation analyses yielded nonsignificant indirect effects, and direct effects of group assignment on abstinence were also nonsignificant
   - C. Yes; mediation effects emerged only in the per-protocol sample but not in the intention-to-treat analyses
   - D. No; although approach biases changed over time, mediation was not tested because abstinence rates did not differ descriptively between groups