Psychiatry Research 363 (2026) 117223



Contents lists available at ScienceDirect

Psychiatry Research

journal homepage: www.elsevier.com/locate/psychres



Original article

Transcranial direct current stimulation (tDCS) as an additional treatment to cognitive behavior group therapy in adults with tobacco dependence - a double-blind, randomized, sham-controlled pilot trial

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ARTICLE INFO

Keywords:
Tobacco
tDCS
Non-Invasive brain stimulation
Cognitive behavioral therapy
Transcranial magnetic stimulation
Electroencephalography

ABSTRACT

Transcranial direct current stimulation (tDCS) targeting the dorsolateral prefrontal cortex (DLPFC) has been proposed as a safe, accessible intervention for tobacco dependence. However, existing evidence is mixed and primarily limited to short-term outcomes.

This study investigated the efficacy and safety of prefrontal tDCS as an adjunct to standardized cognitive behavioral group therapy (CBT) for tobacco dependence.

In this double-blind, randomized, sham-controlled pilot trial conducted in Germany, adults with tobacco dependence defined by an Fagerström Test of Nicotine Dependence score >4 and CO levels >10 ppm were randomized to receive either active or sham tDCS alongside standardized group CBT. Participants underwent seven tDCS sessions followed by CBT over seven weeks. Active stimulation was delivered at 2 mA for 30 minutes over the left DLPFC (anode) and right supraorbital region (cathode). The primary outcome was abstinence at 6-month follow-up, analyzed in the modified intention-to-treat population.

Of 190 individuals assessed for eligibility between July 2012 and November 2013, 54 were randomized (27 active, 27 sham), and 49 were included in the final analysis (23 male, 26 female; mean age 50.7 years, SD 12.3). At 6 months, the probability of abstinence was significantly higher in the active tDCS group (OR = 1.66, 95% CI = 1.02 to 2.70), with 50% abstinent vs. 26% in the sham group. No serious adverse events were reported.

This pilot trial provides initial evidence supporting the safety and efficacy of combining prefrontal tDCS with group CBT for smoking cessation. Further research should explore mechanisms and long-term outcomes.

Trial Registration: clinicaltrials.gov Identifier: NCT01729507.

1. Introduction

Tobacco dependence is a prevalent but preventable cause of morbidity, disability, and premature mortality (World Health Organization, 2023; Ng et al., 2014). Up to half of all lifetime smokers eventually die from tobacco-related diseases, including cancer,

Abbreviations: : CBT, Cognitive behavioral therapy; NIBS, Non-invasive brain stimulation; TMS, Transcranial magnetic stimulation; tDCS, Transcranial direct current stimulation; DLPFC, Dorsolateral prefrontal cortex; CO, Carbon monoxide; Cig/day, Cigarettes smoked per day; FTND, Fagerström test of Nicotine dependence; IFT, Institut für Therapieforschung; EEG, Electroencephalography.

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https://doi.org/10.1016/j.psychres.2026.117223
Received 4 March 2026; Received in revised form 8 May 2026; Accepted 10 May 2026
Available online 13 May 2026
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cardiovascular disease, and chronic obstructive pulmonary diseases, with half of these deaths occurring before the age of 70 (Doll et al., 2004). Thus, successful smoking cessation effectively reduces health risks and improves life expectancy (Doll et al., 2004; Pirie et al., 2013). Evidence-based guidelines recommend psychotherapeutic interventions (e.g., cognitive behavioral therapy, CBT) and medication (e.g., nicotine replacement therapy, varenicline or bupropion) for smoking cessation (National Institute for Health and Care Excellence, 2021; World Health Organization, 2024), but even in combination, these treatments have moderate success rates, and relapses are common (Chaiton et al., 2016; Hartmann-Boyce et al., 2019). Therefore, effective and tolerable new treatment approaches are urgently needed to improve abstinence rates in individuals with tobacco dependence.

Non-invasive brain stimulation (NIBS) of the prefrontal cortex (PFC) and connected areas has emerged as a promising treatment for substance-use disorders (Nardone et al., 2012; Wing et al., 2013). A recent multicenter randomised controlled trial (RCT) confirmed the efficacy of bilateral repetitive transcranial magnetic stimulation (rTMS) followed by a brief motivational intervention in increasing smoking cessation rates, leading to U.S. Food and Drug Administration (FDA) clearance for rTMS as a smoking cessation aid (Zangen et al., 2021). Transcranial direct current stimulation (tDCS), which has a favorable safety profile and is suitable for home use (Burkhardt et al., 2023; Woodham et al., 2025), has also been proposed as a potential NIBS treatment for tobacco dependence, with early evidence indicating reductions of nicotine craving and consumption after single or multiple tDCS sessions (Boggio et al., 2009; Fregni et al., 2008). However, except for a single 12 week RCT that showed abstinence rates comparable to bupropion treatment after 6 months (Ghorbani Behnam et al., 2019), most RCTs to date have focused on improving short-term outcomes with tDCS monotherapy and yielded highly variable results (Mehta et al., 2024).

A more promising approach may be to combine tDCS with other treatment modalities like psychotherapy (Bajbouj and Padberg, 2014). tDCS has been shown to positively modulate cognitive processes, including emotional regulation (Feeser et al., 2014), cognitive and inhibitory control (Wolkenstein and Plewnia, 2013), and working memory-core mechanisms addressed by CBT (Begemann et al., 2020). A recent study demonstrated that even a single session of prefrontal tDCS (2 mA for 25 min, with the anode placed over the left DLPFC using the Beam F3 algorithm and the cathode over the right ventromedial PFC) can modulate cognitive dysfunction associated with nicotine withdrawal (Fischell et al., 2020). We recently investigated the effects of an intervention combining five sessions of active tDCS with a subsequent brief individual CBT intervention for smoking cessation over nine days (Palm et al., 2024). While active tDCS did not significantly improve abstinence rates, it had positive effects on craving outcomes. To our knowledge, no RCTs have yet tested longer treatment protocols with combinations of tDCS with group psychotherapy. Given that CBT group therapy is more scalable than individual therapy and has proven effective in smoking cessation (Gradl et al., 2009), we conducted a double-blind, randomized, sham-controlled pilot trial to evaluate the efficacy and safety of active tDCS versus sham tDCS as an additional treatment to group CBT in individuals with tobacco dependence seeking to quit smoking.

2. Methods

2.1. Study design

This double-blind, randomized, sham-controlled pilot trial was conducted at the Tobacco Dependence Outpatient Clinic within the Department of Psychiatry and Psychotherapy at LMU University Hospital, Munich, Germany. The trial was registered on ClinicalTrials.gov (Identifier: NCT01729507) and adhered to the Declaration of Helsinki. Ethical approval was obtained from the Ethics Committee of the Medical Faculty at LMU Munich.

2.2. Participants

We recruited female and male adults with tobacco dependence, defined by an Fagerström Test of Nicotine Dependence (FTND) (Heatherton et al., 1991) score >4 and CO levels >10 ppm (West et al., 2005) measured with a Micro Smokerlyzer (Bedfont Scientific Ltd., Maidstone, England). Eligible participants had smoked for at least one year, consuming more than 10 cigarettes daily, and had not attempted smoking cessation or used related pharmacological treatments for at least three months prior to enrollment. All were tDCS-naïve. Exclusion criteria were acute or severe psychiatric disorders according to ICD-10/DSM-IV, dementia, acute suicidality, substance abuse, history of severe craniocerebral trauma, structural damage to the basal ganglia or the brain stem, severe neurological and medical disorders, electronic implants, pregnancy, and use of contraception methods with a Pearl Index >1. Participants were recruited via local press and the department's website. After an initial telephone pre-screening for eligibility and availability, suitable candidates underwent detailed on-site screening assessments. All participants provided written informed consent before inclusion and received 60€ financial compensation.

2.3. Randomization and blinding

Eligible participants were randomized (1:1) to active tDCS or sham tDCS using alpha-numeric codes provided by the device manufacturer (neuroConn, Ilmenau, Germany). These codes were integrated into a computer-generated randomization list prepared by an independent clinician. After screening assessments, clinical raters received a unique code for each participant and entered it into the tDCS devices (DC-Stimulator Mobile, neuroConn, Ilmenau, Germany). The devices were pre-programmed to deliver active or sham tDCS without displaying any information about the treatment condition. Thus, study raters and participants were blinded to the treatment condition. Unblinding occurred after the last follow-up visit of the last patient. To assess blinding integrity, participants were asked to guess treatment assignments after the last tDCS session.

2.4. Procedures

The treatment protocol encompassed one stimulation session per week over seven consecutive weeks (Fig. 2). Each stimulation session was immediately followed by a 90-minute group CBT session focused on smoking cessation (Killen and Fortmann, 1997).

Active tDCS was administered with an intensity of 2 mA using two 35 cm^2 saline-soaked, sponge-covered rubber electrodes. Every stimulation session included a 15-second ramp-up phase, a stable 20-minute period of 2 mA direct current stimulation, and a 15-second ramp-down phase. Electrodes were positioned according to the international 10–20 EEG system, with the anode placed over F3 (targeting the left DLPFC) and the cathode over Fp2 (targeting the right supraorbital cortex). Sham tDCS comprised an initial 30-second ramp-up/ramp-down phase, a subsequent 20-minute interval without active stimulation, and a final 30-second ramp-up/ramp-down phase. The ramp-up/ramp-down phases were designed to generate similar sensory effects as active tDCS, thus maintaining participant blinding. Up to 12 participants-the maximum group size for CBT sessions-were simultaneously stimulated. Participants were explicitly instructed not to discuss physical sensations or potential side effects experienced during sessions with one another.

Group CBT was performed according to the standardized "Smoke-free programme" manual developed by the Institute for Therapy Research (Institut für Therapieforschung, IFT) and the German Federal Centre for Health Education (BZgA), aligning with international smoking cessation guidelines (Fiore et al., 2008). The program is well evaluated for feasibility and efficacy with approximately 50,000 participants in Germany since 1973 (Kröger and Gradl, 2010). All CBT instructors were formally trained and certified by the IFT and BZgA. The CBT

intervention consisted of seven weekly group sessions, each lasting 90 min. The four pillars of cognitive-behavioral therapy constitute the core mechanisms of action of the program: therapeutic clarification/motivational clarification, resource activation, problem activation, and active support for problem solving. Participants were encouraged to smoke a "collective last cigarette" during the fourth session (designated quit day) and to maintain abstinence thereafter. Participants were reminded at each study visit not to use any pharmacological aids for smoking cessation, including nicotine replacement therapy, varenicline, or bupropion. Additionally, participants received two supportive telephone consultations of 10 min each-one following the quit day and another after the final group session.

Clinical raters collected sociodemographic data, medical history, handedness assessed with the Edinburgh Handedness Test (Oldfield, 2013, 1971), smoking history, and the FTND at baseline. Self-reported smoking status (smoker/non-smoker) and the number of cigarettes smoked daily were assessed at the fifth course session (immediately after the quit day), the final (seventh) course session, and at follow-ups conducted after three and six months. For participants unable to attend follow-up visits in person, these data were collected via telephone interviews.

Expired carbon monoxide (CO) levels were measured using a Micro Smokerlyzer (Bedfont Scientific Ltd., Maidstone, England) at baseline, after the fifth session, and at six-month follow-up. During the treatment phase, CO measurements were obtained at a standardized time of day (sessions took place between 17:30 and 19:30). At the 6-month follow-up, measurement timing was not standardized. Cigarette craving was assessed after each treatment session with the Questionnaire of Smoking Urges (QSU) (Tiffany and Drobes, 1991). Following each tDCS session, adverse events (AEs) experienced during and after stimulation were recorded using the Comfort Rating Questionnaire (CRQ) (Palm et al., 2014).

Follow-up assessments were initially planned for 4 weeks post-treatment but were revised to take place after 3 and 6 months before the trial started, aiming to better capture clinically relevant outcomes. Unfortunately, this change was not updated in the trial registration.

2.5. Outcomes

The primary outcome was self-reported abstinence at the 6-month follow-up. This outcome was modified during the trial due to significant participant attrition at on-site follow-up visits, which impeded CO measurements. However, this adjustment was unintentionally omitted from the trial registry. Secondary outcomes were the number of cigarettes smoked daily and expired CO levels at the 6-month follow-up. Additionally, we examined cigarette craving in two dimensions of the QSU (factor 1: intention and desire to smoke, anticipation of pleasure from smoking; factor 2: anticipation of relief from negative affect and nicotine withdrawal, urgent and overwhelming desire to smoke) as well as the time until relapse (smoking after quit day, i.e. 4th session).

2.6. Statistical analysis

As a pilot study, the sample size was pragmatically determined based on resources and recruitment capacity. Post-hoc power analysis showed that a total of $N = 54$ participants would adequately power ($1\text{-}\beta = 0.83$) a comparison of proportions (abstinent/not abstinent) between the treatment groups, assuming a significance level of α=0.05 and a medium to large effect size ($w = 0.40$).

All analyses of primary and secondary outcomes were conducted with the modified intention-to-treat (mITT) sample (ie, all participants who initiated treatment).

For the primary outcome (abstinence), a mixed effects logistic regression with binomial distribution (GLMM) was calculated. This model takes all measurements into account to compensate for attrition across groups. Repeated measurements were considered as nested within patients. Fixed effects included log-transformed weeks since randomization as a continuous level-1 predictor, treatment as a categorical level-2 predictor, and their cross-level interaction. A sensitivity analysis was conducted to examine the robustness of the main findings by adjusting for baseline differences in sex distribution.

Continuous secondary outcomes (CO, QSU) were analyzed using linear mixed effects models (LMM). Count data on cigarettes smoked daily were analyzed using GLMM with negative binomial distribution, after checking for overdispersion (Gelman & Hill, 2006). LMM and GLMM for count data included an identical fixed and random effects structure as the primary outcome analysis. Time until relapse was modeled in a survival analysis framework using failure (to account for events increasing over time). An accelerated failure time model (AFT) was used to determine the capacity of each treatment to delay the time until relapse, assuming a log-logistic distribution (Kalbfleisch and Prentice, 2011). Models were adjusted for baseline severity by including the number of daily smoked cigarettes at baseline as a covariate. Significance of model factors was determined using χ^2-likelihood-ratio-tests for GLMM and AFT models and using type-III analysis of variance with Satterthwaite's approximation to degrees of freedom for LMM models. Model parameters were determined using maximum likelihood estimation (ML) with Laplace approximation for discrete outcomes and count data and using restricted maximum likelihood estimation (REML) for continuous outcomes.

Adverse-event frequency was compared between treatment groups using independent samples *t*-tests. Blinding integrity was evaluated by comparing patients' guessing rates between groups using Fisher's exact test or χ^2-test, as appropriate. We assessed correct guesses as a function of both smoking status at week seven and of actual group membership.

For all analyses the significance level was set at α=0.05. P values were not adjusted for multiple testing across outcomes; thus, results for outcomes other than the primary outcome should be considered exploratory. Statistical analyses were carried out using the *lme4* package for LMM and binomial GLMM models (Bates et al., 2014), the *glmmTMB* package for GLMM models for count data (Magnusson et al., 2017) and the *survival* package for AFT modeling (Therneau and Lumley, 2015) in R (version 4.4.3). Anonymized data, R scripts and a codebook are available at doi: 10.5281/zenodo.18461572.

3. Results

3.1. Participants

From July 2012 to November 2013, 190 individuals were prescreened for this study. Of these, 54 participants were enrolled and randomly assigned to treatment (27 to active tDCS and 27 to sham tDCS; see Fig. 1). Since five participants withdrew consent prior to the first treatment session, a total of 49 participants were included in the mITT analysis (25 to active tDCS and 24 to sham tDCS). Participants consisted of 23 females (47%) and 26 males (53%), with a mean age of 50.7 years (SD 12.3) and an average smoking history of 32.4 years (SD 12.0; for further baseline characteristics see Table 1). Two (8%) participants in the active tDCS group and 5 (21%) participants in the sham tDCS group discontinued the study before the end of the treatment phase. At the 6-month follow-up, 10 (40%) participants from the active tDCS group and 14 (58%) participants from the sham tDCS group were unavailable for assessment via on-site or telephone visits.

3.2. Primary outcome

At the 6-month follow-up, abstinence rates were 50% in the active tDCS group and 26% in the sham tDCS group (see Supplementary Table 1). Mixed effects logistic regression (GLMM) showed significant main effects for time ($\chi^2_{(1)}$=19.12, p<0.001) and a significant interaction between time and treatment ($\chi^2_{(1)}$=4.18, p=0.041). These results indicate a significant reduction in the odds of being a smoker over time

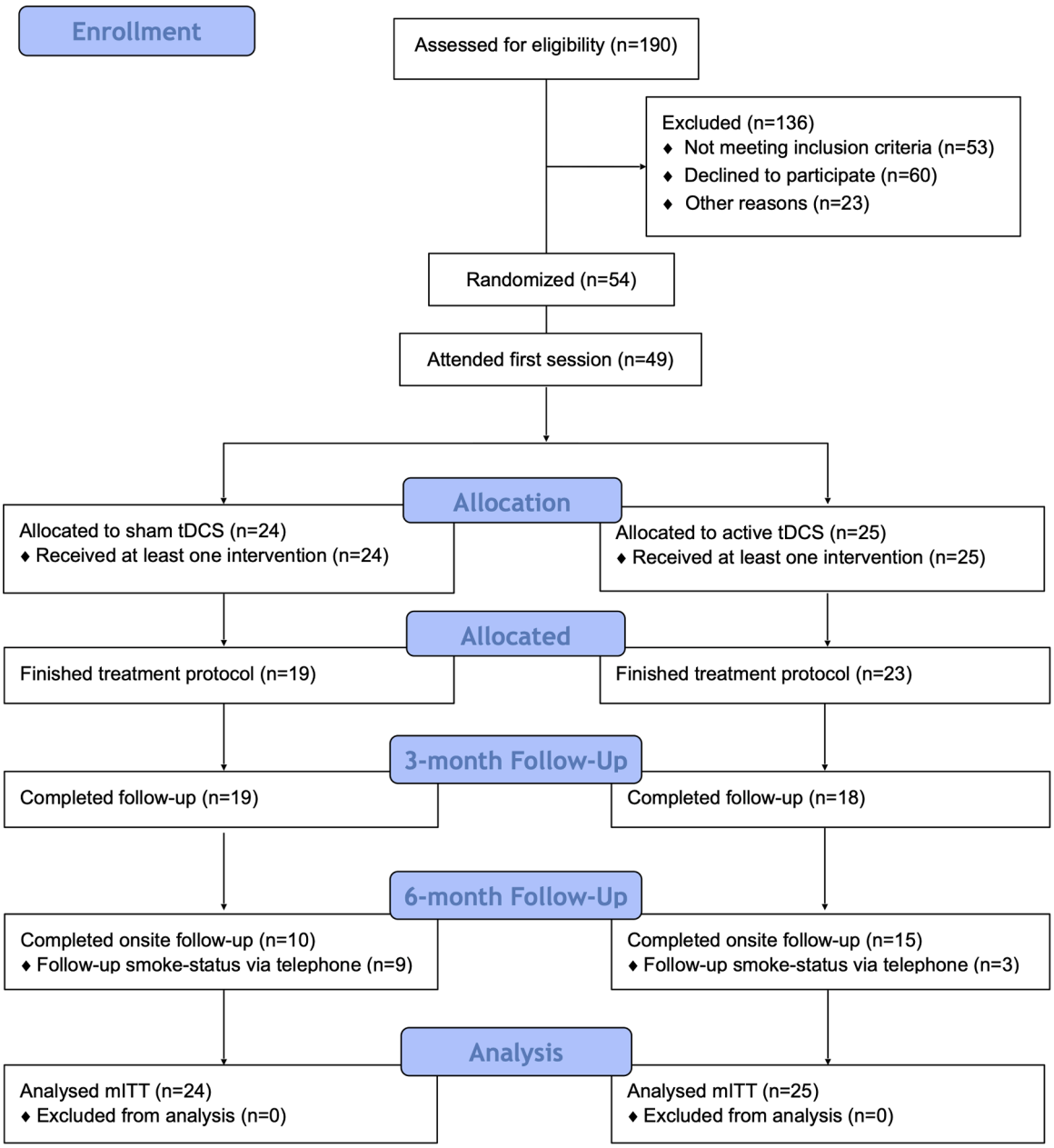


Fig. 1. Patient flow chart *Note: n* = number of subjects.

across both groups (see Fig. 3A and Table 2) and a significantly higher proportion of non-smokers over time in the active tDCS group compared to the sham tDCS group (OR_{Δ}=1.60 $CI_{95\%}$=1.02 to 2.70). Time (weeks) was log-transformed (base 2), so ORs represent the proportional change in odds of being a smoker for every doubling of weeks since randomisation. In the sensitivity analysis, the time × treatment interaction remained robust after adjusting for sex ($\chi^2_{(1)}$=4.18, p=0.041), and no significant main effect of sex was observed ($\chi^2_{(1)}$=2.46, p=0.117).

3.3. Secondary outcome measures

Participants showed significant improvements over time in all secondary outcomes (Table 2; Fig. 3B). However, no significant differences in trajectories of cigarettes smoked daily and expired CO levels were observed between treatment groups. Although participants who relapsed in the active tDCS group smoked numerically more cigarettes (7th session: M = 6.00±1.87; 6-month follow-up: M = 14.11±8.46) compared to those in the sham tDCS group (7th session: M = 4.50±2.00; 6-month follow-up: M = 12.07±6.66), these differences did not reach statistical significance at either the final session (p=0.075; *IRR*=1.80) or at the 6-month follow-up (p=0.528; *IRR*=1.17). Similarly, among participants who relapsed, expired CO levels at the 6-month follow-up did not differ significantly between groups ($t_{(10.20)}$=0.88; p=0.398; d=0.48 $CI_{95\%}$ −0.71 to 1.68).

Regarding craving, participants in the active tDCS group showed a significantly greater reduction in QSU scale 2 scores from sessions 1 to 7 compared to the sham tDCS group (β=−0.09, $F_{(1292)}$,=8.64, p=0.004, d=−0.54 $CI_{95\%}$ −1.17 to 0.1), while no significant difference was found for reductions in QSU scale 1 scores. AFT modeling showed a numerically longer time until relapse in the active tDCS group, though this was not statistically significant (β=1.13, $\chi^2_{(1)}$=3.02, p=0.082, TR=3.10 $CI_{95\%}$=0.87 to 11.04). The time ratios indicate that participants receiving active tDCS experienced relapse at approximately 32% of the speed (1/TR x 100) of those receiving sham tDCS (Fig. 3C).

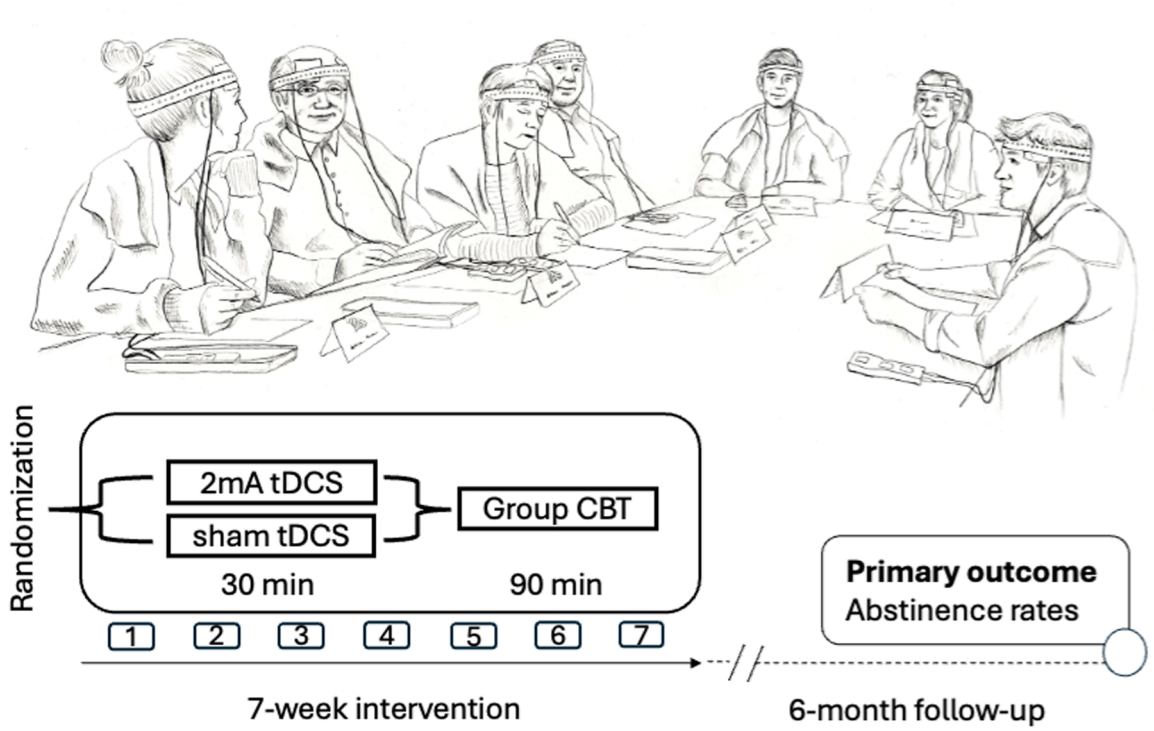


Fig. 2. Outline of study design *Note:* The treatment protocol encompassed one stimulation session per week over seven consecutive weeks. Each stimulation session was immediately followed by a 90-minute group CBT session focused on smoking cessation. The illustration above was manually redrawn from a photograph to anonymize the depicted individuals.

Table 1
Modified Intention-to-treat (mITT) sample baseline characteristics.

	Total (N = 49)	Sham tDCS (n = 24)	Active tDCS (n = 25)
Female, n (%)	26 (53)	10 (42)	16 (64)
Age (years)	50.7 (12.3)	53.4 (10.7)	48.0 (13.2)
Handedness (right), n (%)	37 (76)	21 (88)	16 (64)
Education, n (%)			
High	18 (37)	8 (33)	10 (40)
Medium	16 (33)	8 (33)	8 (32)
Low	15 (31)	8 (33)	7 (28)
Education (years), mean (SD)	10.8 (1.8)	10.6 (1.8)	11.0 (1.8)
Family status, n (%)			
Married	24 (49.0)	14 (70.0)	10 (43)
Not married	19 (38.8)	6 (30.0)	13 (57)
Other	6 (12.2)		
Cigarettes/day, mean (SD)	21.7 (7.0)	21.8 (7.6)	21.7 (6.4)
FTND, mean (SD)	5.4 (1.7)	5.3 (1.8)	5.6 (1.7)
Quit attempts, mean (SD)	3.9 (3.5)	2.9 (2.8)	4.9 (3.8)
Smoking years, mean (SD)	32.4 (12.0)	34.4 (10.9)	30.5 (12.7)
CO [ppm], mean (SD)	19.2 (9.9)	19.1 (9.6)	19.3 (10.3)

Note: N = number of subjects; SD = standard deviation; FTND = Fagerström Test of Nicotine Dependence; CO = concentration of carbon monoxide (CO) in expired air.

3.4. Safety

Both treatment groups experienced only mild and transient AEs during and after stimulation (Supplementary Table 2). Participants in the active tDCS group reported significantly more phosphenes compared to those in the sham tDCS group ($t_{(45.8)}$=2.12, p=0.039); no other significant differences were observed. No participant discontinued treatment due to AEs.

3.5. Blinding integrity

Out of 49 patients, 33 (67%; active tDCS: 17 [68%]; sham tDCS: 16 [67%]) answered a blinding integrity assessment after the last treatment session. 76.5% of participants in the active tDCS group and 56.3% in the sham tDCS group correctly guessed their treatment (see Supplementary Table 3). Fisher's exact test showed significant differences regarding relapse (p=0.018), but no significant differences in blinding integrity between the two groups (p=0.280).

4. Discussion

In this pilot study, a sequentially combined 7-week active tDCS-CBT group intervention for individuals with tobacco dependence was safe and significantly improved abstinence rates until 6-month follow-up compared to sham tDCS-CBT treatment. Moreover, secondary outcomes during acute treatment indicated that tDCS specifically reduced smoking urges driven by negative reinforcement processes (e.g., relief from negative affect and withdrawal), while urges related to positive reinforcement (e.g., desire to smoke and anticipated pleasure) did not differ between groups. No serious adverse events occurred, and aside from more frequently reported phosphenes in the active tDCS group, the safety profile was consistent with previous findings on tDCS applications (Brunoni et al., 2017, 2013; Burkhardt et al., 2023). To our knowledge, this is the first trial providing initial evidence for the added benefit of tDCS when combined with group CBT for smoking cessation.

With a 50% abstinence rate in the active tDCS group, outcomes were notably higher than those reported for other neuromodulation approaches, including a 12-week, 20-session bifrontal tDCS monotherapy (25.7%) (Ghorbani Behnam et al., 2019) and high-frequency deep transcranial magnetic stimulation (dTMS) of the PFC and insula following smoking cues (33% at 6 months; 28% at 4 months when followed by a 2-minute motivational talk) (Dinur-Klein et al., 2014), (Zangen et al., 2021). These results further support recent meta-analytic evidence on the efficacy of non-invasive brain stimulation for smoking

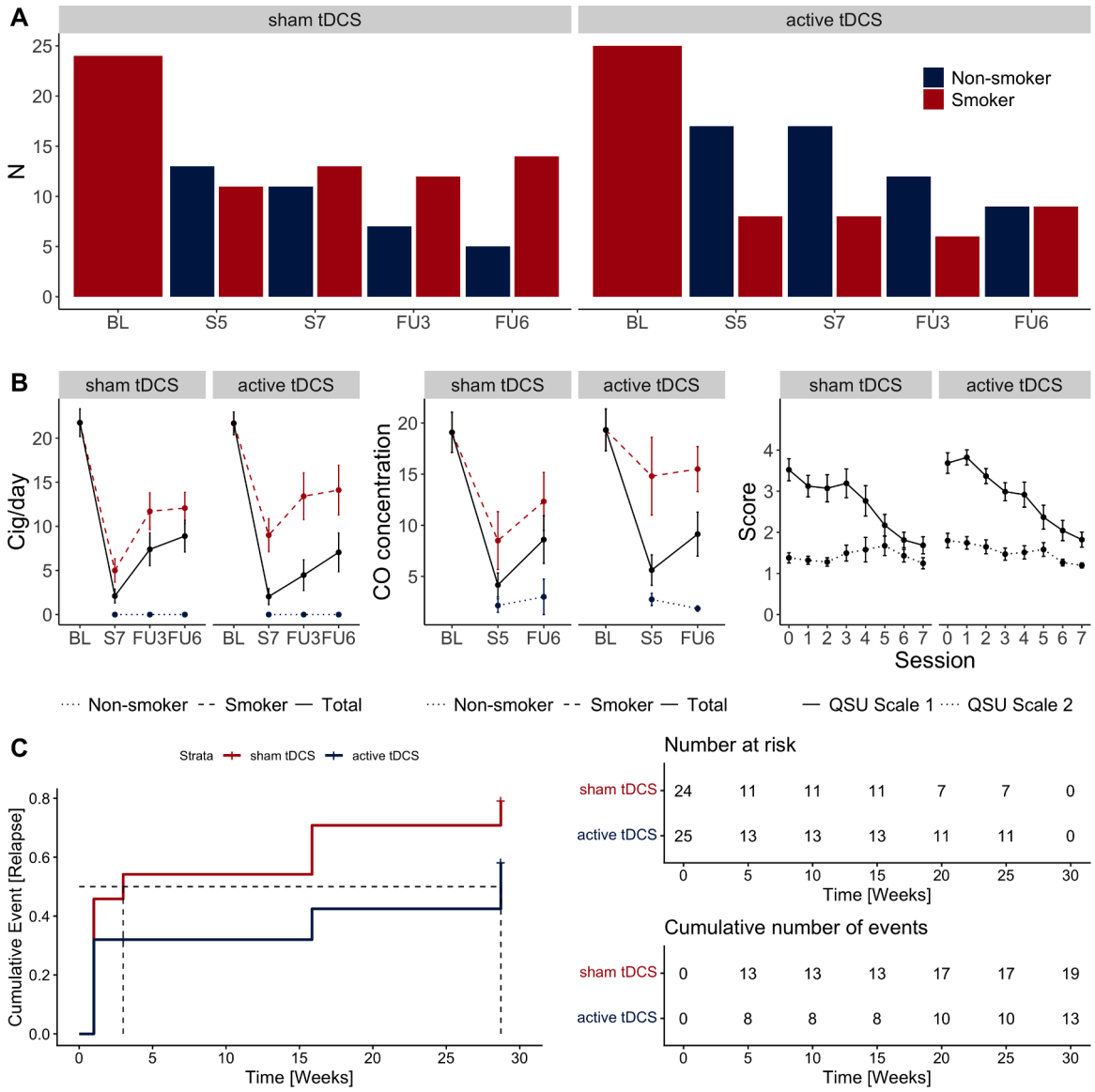


Fig. 3. Outcomes after CBT for smoking cessation with and without tDCS augmentation *Note:* (A) Primary outcome: Smoking status within each treatment group; N number of participants; BL baseline, S5 5th session, S7 7th session, FU3 3-month follow-up, FU6 6-month follow-up (B) Trajectories of secondary outcomes; error bars represent ± 1 standard error; CO = concentration of carbon monoxide (CO) in expired air; QSU = Questionnaire of Smoking Urges. (C) Survival curves representing time until relapse; dashed lines represent group-specific median time until event; cumulative number of events indicate the number of relapsed participants up until the given time interval.

Table 2
Omnibus tests on change in outcomes until primary study endpoint after CBT for smoking cessation with and without tDCS augmentation.

	Time		Group		Time x Group		
Characteristic	F or χ^2(df)	P-value	F or χ^2(df)	P-value	F or χ^2(df)	P-value	ES
Smoking status[a]	19.12 (1)	<0.001***	3.49 (1)	0.062	4.18 (1)	0.041*	1.66 (1.02 to 2.70)
Time until relapse[a]			3.02 (1)	0.082			3.1 (0.87 to 11.04)
Cig/day[a]	19.65 (1)	<0.001***	0.82 (1)	0.365	0.44 (1)	0.505	0.93 (0.76 to 1.15)
CO concentration[b]	33.96 (1,80.84)	<0.001***	0.01 (1,105.85)	0.94	0.05 (1,80.53)	0.825	−0.18 (−1.03 to 0.66)
QSU scale 1[b]	158.94 (1,292)	<0.001***	1.11 (1103.33)	0.295	0.42 (1,292)	0.515	−0.02 (−0.64 to 0.61)
QSU scale 2[b]	5.06 (1,292)	0.025*	6.49 (1103.33)	0.012*	8.64 (1,292)	0.004**	−0.54 (−1.17 to 0.1)

Note: [a] significance of model factor determined using χ^2-likelihood-ratio-tests; [b] significance of model factor determined using type III analysis of variance with Satterthwaite's method; ES = Effect size; 95 % confidence interval presented in parentheses; ES for smoking status is expressed as group difference in change in odds ratio (OR, e^{β}) over time. As time was measured in log-transformed weeks (logarithm to the base of 2) ES represents the group difference in proportional increase of odds to be a smoker with a doubling in weeks since randomization; ES for time until relapse is expressed as time ratio (TR, e^{β}), representing the deceleration effect associated with active tDCS treatment; ES for Cig/day is expressed as incidence rate ratio (IRR, e^{β}) representing risk to smoke an additional cigarette associated with receiving active tDCS; ES for CO concentration and QSU scales is expressed in Cohen's d; (*) $p < 0.05$ (**) $p < 0.01$ (***) $p < 0.001$.

cessation (Petit et al., 2022) and underscore the importance of the DLPFC as a stimulation target for this indication. The DLPFC has recently been identified as a key component of a connectivity map derived from brain lesions associated with spontaneous smoking cessation (Joutsa et al., 2022) and is hypothesized to play a critical role in the preoccupation/anticipation stage following drug cessation in neurocircuitry models of addiction (Koob and Volkow, 2016). Moreover, a recent meta-analysis across neuropsychiatric disorders indicated that rTMS of the DLPFC effectively reduces craving with a large effect size (Kan et al., 2023). Post-cessation craving is a well-established predictor of early relapse (Killen and Fortmann, 1997) and has therefore been a primary target of pharmacological treatments for tobacco dependence (West et al., 2008). Our finding that active tDCS specifically reduces cravings associated with negative reinforcement processes suggests a potential mechanism underlying its long-term effects on abstinence. These effects on craving may be mediated by previously reported-albeit heterogenous-direct effects of prefrontal tDCS on negative affect (Razza et al., 2020) or by improvements in cognitive control (Wolkenstein and Plewnia, 2013), though the relative contribution of these processes during drug withdrawal remains a subject of ongoing debate (Baker et al., 2004). The selective effect of tDCS on negative reinforcement craving (QSU factor 2) in our trial, in the absence of between-group differences in positive reinforcement craving (QSU factor 1), cigarettes per day, and CO levels, is compatible with an interpretation in which prefrontal tDCS facilitates abstinence by attenuating the urge to relapse in response to negative affect and withdrawal rather than by reducing consumption or smoking motivation directly. However, this interpretation is post-hoc and should be tested in future trials with formal mediation analyses. Alternatively, tDCS might indirectly facilitate the acquisition of coping strategies during CBT sessions. Unlike a previous RCT from our group, which combined prefrontal tDCS with brief individual CBT interventions over 9 days (Palm et al., 2024), we applied a standardized 7-week group therapy program incorporating multiple CBT components, including psychoeducation, motivation building, cognitive restructuring, behavioral activation, and relapse prevention. The relatively high abstinence rate of 30% in the sham tDCS group suggests that this comprehensive therapeutic approach yields more robust effects and should be favored in future trials. Pharmacological cessation aids were excluded in the present study to isolate the added benefit of tDCS over CBT alone, without the potential confound of concurrent pharmacotherapy. However, the present findings should not be interpreted as positioning tDCS as a replacement for pharmacological treatment. Rather, tDCS may represent a promising adjunctive component that could be integrated into multimodal treatment approaches combining CBT and pharmacotherapy.

Notably, among participants who relapsed, those in the active tDCS group smoked numerically - though not significantly - more cigarettes than those in the sham group. Given the very small subgroup sizes, this likely represents a chance finding, but we cannot exclude adverse effects of active stimulation in a subgroup of non-responders, consistent with non-linear dose-response relationships increasingly recognized in transcranial brain stimulation (Soleimani et al., 2026).

Our trial has some limitations. First, the primary outcome was based on self-reported abstinence without consistent biochemical verification. Although expired CO levels were collected, they were available only for a subgroup and showed no significant group differences. CO's short half-life (~4 hours) inherently limits its ability to verify sustained abstinence months after treatment (Benowitz et al., 2020), and biomarkers better suited to confirm long-term abstinence, such as cotinine or urinary NNAL, were not feasible within the resources of this pilot trial. While comparable attrition rates are common in smoking cessation trials with long-term follow-up (Hartmann-Boyce et al., 2021) and disengagement from study contact is a well-documented pattern among participants who relapse, future confirmatory trials should incorporate biomarkers with longer detection windows alongside dedicated funding for incentivized follow-up assessments to maximize retention. Despite the anticipated attrition, we retained the 6-month endpoint because short-term abstinence rates immediately after treatment substantially overestimate lasting cessation. Second, our trial included only individuals without psychiatric comorbidities, which may limit the generalizability of the findings to clinical populations with high smoking prevalence, such as individuals with schizophrenia. While smoking cessation interventions can be equally effective in psychiatric populations (Prochaska, 2011), interactions with psychotropic medications and social-environmental factors may modulate the response to brain stimulation, warranting specific inclusion of these patients in future trials. Third, although we applied a tDCS protocol consistent with recent consensus guidelines for brain stimulation in addiction medicine-targeting the left DLPFC-we did not acquire imaging data to calculate individual electric field distributions. Since tDCS likely results in a diffuse current flow under and between electrodes (Karabanov et al., 2019), modulation of adjacent regions, such as the frontopolar cortex - recently proposed as a promising target for addiction treatments (Mehta et al., 2024) - may have contributed to the observed effects. Fourth, the statistical model for the evaluation of the primary outcome was chosen to minimize the effect of high attrition rates and to capture the temporal dynamics of treatment effects across the full study trajectory rather than relying solely on the 6-month endpoint without a priori statistical analysis plan preregistered. Fifth, although sensitivity analyses controlling for sex as a covariate yielded robust findings, the baseline imbalance in sex distribution between groups (64% vs. 42% female) should be acknowledged as a limitation, as the sample size was insufficient to formally test a treatment × sex interaction and therefore sex-specific treatment responses cannot be excluded. Lastly, we employed a parallel-group design to evaluate a specific implementation of combined tDCS/CBT. As such, the study does not allow for conclusions regarding the optimal tDCS parameters, the most effective CBT components, or their interaction. Given the high rates of false-positive findings in pilot studies, future research may benefit from employing innovative designs-such as adaptive platform trials-to systematically refine and optimize tDCS interventions for smoking cessation before proceeding to large-scale confirmatory trials (Burkhardt et al., 2024).

Our exploratory findings indicate that combining tDCS with subsequent group-based CBT is a safe, feasible, and potentially effective approach for enhancing long-term abstinence, supporting its further evaluation and development in larger trials.

Funding

GB was supported by the Medical Faculty of LMU Munich (grant number CS063).

Data sharing statement

Anonymized data, R scripts and a codebook are available at https://zenodo.org/records/18461573 (doi:10.5281/zenodo.18461572).

CRediT authorship contribution statement

Stephan Goerigk: Methodology, Formal analysis, Writing – original draft, Visualization. **Gerrit Burkhardt:** Investigation, Methodology, Writing – original draft, Visualization. **Frank Padberg:** Supervision, Conceptualization, Project administration, Writing – review & editing. **Anna Zeren:** Investigation, Data curation, Writing – review & editing. **Heike Ludwig:** Investigation, Data curation. **Andrea Rabenstein:** Investigation, Data curation. **Christoph Kröger:** Writing – review & editing, Supervision. **Sara Vragolic:** Writing – review & editing. **Ulrich Palm:** Writing – review & editing, Supervision. **Oliver Pogarell:** Writing – review & editing. **Daniel Keeser:** Methodology, Writing – review & editing. **Andre R. Brunoni:** Writing – review & editing. **Alkomiet Hasan:** Writing – review & editing. **Tobias Rüther:** Supervision, Conceptualization, Project administration, Writing – review &

editing.

Declaration of competing interest

TR has been a consultant for, received grant/research support and honoraria from and been a speaker for or on the advisory board of AstraZeneca, Johnson & Johnson, Janssen-Cilag, Lundbeck, and Pfizer. FP received speaker honorarium from Mag & More and technical support for research projects by Brainsway Inc. and neuroConn GmbH.A. Hasan has been invited to scientific meetings by Lundbeck, Janssen-Cilag, and Pfizer, and he received a paid speakership from Desitin, Otsuka and Lundbeck. He was a member of an advisory board of Roche. SG, GB, AZ, HL, AR, CK, SV, UP, OP, DK, AB, and AH declare no conflict of interest.

Acknowledgements

We are grateful to all the patients who agreed to participate in the study, the study staff delivering the intervention, and the clinicians who helped with patient recruitment.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.psychres.2026.117223.

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