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Supervised vigorous-intensity exercise intervention as an add-on to group cognitive behavioral therapy in smoking cessation: a randomized controlled trial

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Abstract

Physical exercise has been considered to be a promising adjunct to smoking cessation, yet the findings are inconsistent. This randomized controlled trial examined whether adding a supervised vigorous-intensity exercise intervention, initiated before the quitting date, would enhance outcomes when combined with group cognitive behavioral therapy (CBT). Participants with tobacco use disorder were randomized to CBT alone or CBT + exercise. CBT consisted of six weekly sessions; the exercise intervention included 36 supervised cycling sessions over 12 weeks. The primary outcome was the number of abstinent days; secondary outcomes were craving, withdrawal, depressive symptoms, and physical activity. Linear mixed models were used for group comparisons, and exploratory correlations examined associations within the exercise group. In total, 132 participants were randomized. No significant group differences emerged for abstinent days or secondary outcomes post-intervention or at follow-up. However, within the CBT + exercise group, higher session adherence correlated with more abstinent days (post-intervention: $r = 0.62$; follow-up: $r = 0.53$; both $p \leq 0.001$) and lower craving ($r = -0.40$; $p = 0.001$). Adding supervised vigorous-intensity exercise did not enhance cessation outcomes at the group level. Nevertheless, the identified dose–response relationship indicates that individuals who adhere to exercise may experience meaningful benefits, underscoring the relevance of engagement with the intervention.

Keywords: Smoking cessation, Group cognitive behavioral therapy, Exercise intervention, Randomized controlled trial

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Introduction

Tobacco use continues to represent a major contributor to preventable morbidity and premature mortality worldwide[1]. Despite the well-documented health risks, most smokers find it difficult to achieve and sustain abstinence[2]. Although the majority express a strong desire to quit and many attempt cessation each year, long-term success rates remain low[2], with relapses frequently occurring within the first weeks following an attempt to quit[3,4]. This difficulty is driven by a range of psychological and physiological processes, including nicotine craving, withdrawal symptoms, and challenges in regulating negative affect[5,6].

Multiple interventions have demonstrated efficacy in promoting smoking cessation, including pharmacological approaches such as nicotine replacement therapy and bupropion[7], as well as psychological interventions like cognitive behavioral therapy (CBT) and behavioral counseling[8,9]. Nevertheless, long-term cessation rates remain suboptimal[1,2], highlighting a critical need for adjunctive or alternative strategies that can support individuals through the cessation process.

Exercise has emerged as a promising complementary intervention. Previous research indicates that even short bouts of exercise may transiently reduce craving and withdrawal symptoms[10–13]. Moreover, regular exercise may improve mood, increase self-regulation, and mitigate post-cessation weight gain—factors known to influence relapse[14–16]. In randomized controlled trials and observational studies, exercise has also been associated with higher treatment adherence and improved abstinence outcomes in certain subgroups[17,18].

Despite these findings, the overall evidence remains inconsistent. Meta-analyses such as that by Ussher et al.[19] found no conclusive evidence that adding exercise to standard smoking cessation treatment improves abstinence rates. These inconclusive findings may be explained by the substantial heterogeneity in study designs and exercise protocols. Key variables such as the intensity, frequency, and type of exercise, as well as its timing relative to the quitting date, vary substantially among studies. For example, some interventions start exercise on or after the quitting date, which may overload participants with simultaneous behavioral demands[20–22]. Others started exercise after a period of smoking abstinence, where the potential for exercise to moderate withdrawal symptoms during this period was lost[12,13], suggesting that an exercise intervention should ideally start before the quitting date and continue after the period of abstinence. Other exercise-based interventions have often applied moderate-intensity exercise or lower levels of supervision, which may limit physiological benefits and engagement compared with more intensive supervised programs[23,24].

Importantly, several reviews and empirical studies point to specific parameters that might moderate the effectiveness of exercise as an adjunct treatment. In particular, initiating exercise

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before the quitting date, ensuring vigorous intensity, providing frequent supervision, and achieving a sufficient exercise dose (e.g., 110 min/week) appear to be critical[25–27]. These elements may enhance both physiological and psychological resilience during cessation and help bridge critical periods of vulnerability.

However, these recommendations have rarely been tested in combination within a single controlled trial. The present study aims to address this gap by integrating several evidence-based parameters within a randomized controlled design. To this end, our exercise intervention was structured to reflect key aspects identified in prior research, including the timing of exercise relative to the quitting date[20–22], vigorous-intensity training based on individualized physiological thresholds[23,24], high-frequency sessions (three times per week) to ensure a sufficient exercise dose[25–27], and close supervision to enhance adherence and ensure adequate training stimulus[23]. By systematically integrating these components, the study aimed to provide a more comprehensive approach to evaluate the potential of exercise as an adjunct to CBT for smoking cessation.

Building on this framework, we examined whether the addition of a supervised vigorous-intensity exercise intervention to standard group CBT improves smoking cessation outcomes. Specifically, we hypothesized that participants receiving the combined intervention would report more abstinent days post-treatment and at follow-up compared with participants receiving CBT alone. Additionally, we expected greater improvements in secondary outcomes, including craving, withdrawal, depressive symptoms, and physical activity levels. Finally, we explored whether adherence to the exercise program—measured by the number of completed sessions—was associated with improved outcomes.

Materials and methods

Study design

This study had a two-arm, parallel-group randomized controlled design examining the effects of a supervised vigorous-intensity exercise intervention as an adjunct to group CBT for smoking cessation. The exercise intervention was designed to reflect empirical evidence on exercise parameters relevant for smoking cessation[25–27] and recommendations by the World Health Organization (WHO) for physical activity[28]. Further details on the intervention's components are provided below. The study was conducted at the Department of Psychiatry and Psychotherapy, Charité–Universitätsmedizin Berlin, within the framework of the Collaborative Research Center TRR 265: "Losing and Regaining Control over Drug Intake," funded by the German Research Foundation (DFG). Ethical approval was obtained from the institutional ethics committee, and all participants provided written informed consent. The study was preregistered on ClinicalTrials.gov (identifier: NCT04251936).

Participants

Participants were recruited in Berlin through flyers, social media, and public transportation advertisements between December 2019 and April 2022. Recruitment was interrupted for a total of four months during the COVID-19 lockdowns.

Participants were eligible if they met the following criteria: (a) A current Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR) diagnosis of tobacco use disorder (TUD), verified via the structured clinical interview for DSM-5-TR (SCID-5-CV) and (b) age between 18 and 65 years. Exclusion criteria were (a) Current or recent (past 12 months) comorbid DSM-5-TR mental disorders; (b) lifetime diagnosis of any substance use disorder (excluding TUD), bipolar disorder, or psychotic disorders; (c) current suicidal ideation; (d) ongoing pharmacological or psychotherapeutic treatment; (e) a history of brain injury; (f) pregnancy; and (g) contraindications for magnetic resonance imaging (MRI). Eligible participants received a total of €100 for completing pre- and post-intervention assessments.

Procedure and randomization

After initial screening via telephone, participants underwent three pre-intervention assessments: (1) completion of psychological questionnaires and a neuropsychological test battery, (2) a functional MRI (fMRI) scan, and (3) a comprehensive sports medical examination.

As part of the sports medical examination, all participants underwent a standardized fitness assessment at the Department of Sports Medicine of Charité–Universitätsmedizin Berlin to evaluate possible contraindications for the exercise intervention. The examination included a full clinical investigation and medical history, laboratory diagnostics, and a graded exercise test (GPX) on a bicycle ergometer (Ergoselect 100K, Ergoline GmbH, Bitz, Germany). The GPX protocol started individually (to avoid intensities that were initially too low or high) with 15–50 W increasing by 15–30 W every 3 min. During the last 30 s of each stage, 20 μL of blood from the earlobe was taken. Blood lactate (bLa) concentration was then analyzed automatically (Biosen S-line EKFDiagnostics, Barleben, Germany). The participants should have reached maximal volitional exhaustion at the end of the GPX. To establish individual workloads for the exercise intervention, the workload at the individual anaerobic threshold (IAT) were determined. The IAT was set at 1.5 mmol/L above the bLa concentration at the first rise of the bLa concentration over the baseline level as defined by[29–32]. The anaerobic threshold (AT) and the workload at IAT were calculated automatically with Ergonizer software (V5.0.1, Freiburg i. Brsg., Germany).

After completion of the three assessments, participants were allocated to one of the two treatment groups using a computer-generated randomization sequence implemented in MATLAB. The randomization procedure was stratified by age and pack-years to ensure balanced group allocation with respect to these key variables. Group assignment was performed only after completion of all baseline assessments, ensuring that allocation was not known in advance and thus was concealed from both the participants and the study personnel during the recruitment and assessment phase.

All baseline assessments were conducted within 2 weeks prior to the first CBT session. Post-intervention assessments were conducted 12 weeks later, and follow-up assessments were performed 12 weeks after the intervention (Fig. 1).

Because of the nature of the behavioral and exercise-based intervention, blinding of participants and intervention providers was not feasible. Outcome assessments were conducted by study personnel who were not involved in the CBT intervention whenever possible. In a small number of cases, practical constraints required the involvement of personnel from the exercise intervention in the outcome assessments, which may have introduced a potential source of bias.

Intervention

CBT

The CBT intervention was delivered as a structured group-based smoking cessation program in accordance with the German S3 guidelines for TUD[33] and based on the standardized manual by

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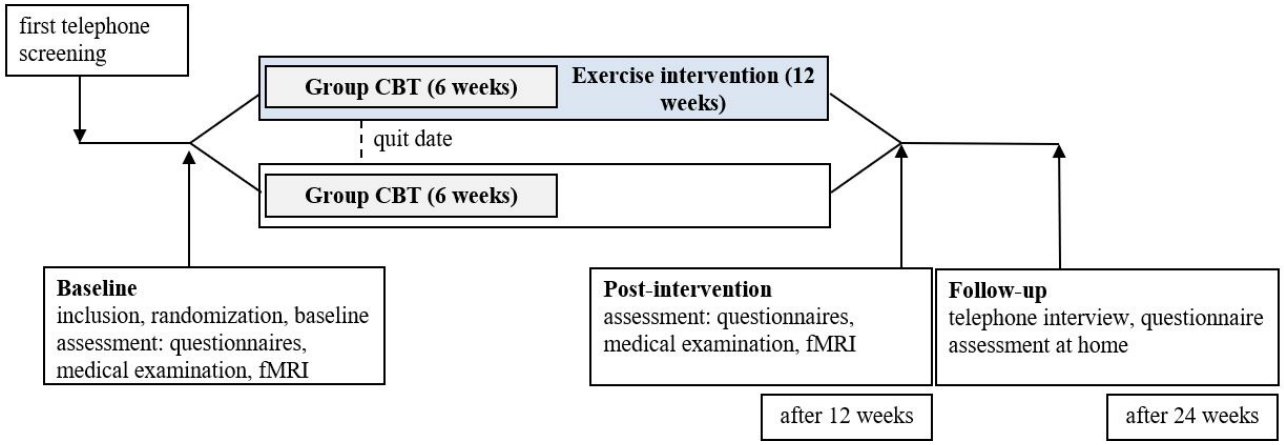

Fig. 1 Study protocol. All participants underwent group cognitive behavioral therapy (CBT) for smoking cessation. At the beginning of the intervention, the participants were still smokers; they set an individual quitting date between the second and the third CBT session. The exercise sessions started in the same week as the CBT, approximately 2–3 weeks prior to the quitting date of the participants.

Batra & Buchkremer[34]. Group-based CBT was chosen, as this format has been shown to be more effective than individual counseling in smoking cessation and allows for additional therapeutic mechanisms such as peer support, social learning, and group cohesion[35].

The intervention followed established cognitive behavioral principles and incorporated multiple evidence-based mechanisms, including classical conditioning, operant conditioning, reward-based learning, and cognitive control strategies. Sessions consisted of a structured combination of psychoeducation, guided group discussions, behavioral exercises, and individualized problem-solving. The intervention allowed for individualized tailoring within the group format, including individualized quitting plans, coping strategies, and planning for relapse prevention. Participants received written materials and worksheets derived from the treatment manual and were assigned to homework tasks between sessions to facilitate the acquisition of skills and their transfer into everyday life.

The CBT intervention was delivered in small groups consisting of approximately 4–8 participants. Group size was partially influenced by COVID-19-related restrictions, which limited the number of participants per session in order to comply with institutional hygiene and distancing regulations.

Sessions were conducted by trained psychologists with at least a Bachelor's degree in psychology. Therapists received regular supervision from a licensed psychological psychotherapist to ensure treatment fidelity and adherence to the treatment manual. Each session lasted approximately 90 min and took place in the facilities of Charité–Universitätsmedizin Berlin.

Attendance was taken for each session: Anyone who failed to attend a session without a reason was called by a member of the study team, encouraged to continue and scheduled for a make-up session via phone (maximum of two sessions).

Exercise

Participants in the CBT + exercise group additionally received a 12-week exercise intervention. The exercise protocol was specifically designed in collaboration with experienced colleagues from the Department of Sports Medicine to incorporate evidence-based parameters associated with improved smoking cessation outcomes, including vigorous-intensity exercise, frequent supervision, and initiation prior to the quitting date[25–27], while also aligning with WHO recommendations for physical activity[28].

(i) Frequency of the training: The participants were instructed to attend three exercise sessions per week for 12 weeks, which means 36 exercise sessions in total. Participants were allowed to miss 10% of the sessions to successfully complete the intervention protocol.

(ii) Intensity of the training: Each session consisted of 25 min of vigorous-intensity physical activity, divided into 5 × 5-min intervals and 2 min of light-intensity intervals between them. Additionally, 5 min of warm-up and cool-down were performed. The total exercise time was 43 min. The workload with vigorous intensity corresponded to the workload at the IAT. The average heart rate, as a percentage, related to maximum heart rate was 81.5%. This also is in line with the American College of Sports Medicine's recommendations for vigorous-intensity exercise[36].

(iii) Time point of the training: The exercise intervention started before the quitting date, simultaneously with the CBT program, and continued 6 weeks after the end of group CBT.

(iv) Supervision and load adjustments during intervention: Each session was supervised by trained staff. After each session, the participants were asked to report their rating of the session's perceived exertion (sRPE)[37]. Workload was increased by 10 W if the participants reported sRPE ≤ 13, or reduced by 10 W if the participants reported sRPE ≥ 16 in two consecutive sessions.

Exercise sessions were performed on electronically braked cycle ergometers at the facilities of the Department of Sports Medicine at Charité–Universitätsmedizin Berlin. Sessions were conducted individually or in small groups to allow close supervision and individualized workload adjustments. Group sizes were additionally influenced by COVID-19-related restrictions, which required small groups and adherence to institutional hygiene and distancing regulations. Study personnel were supervised by experienced sports medicine physicians to ensure adherence to the intervention's protocol and participants' safety. Heart rate and perceived exertion were continuously monitored to ensure adherence to the prescribed training intensity and to maintain the intervention's fidelity.

The description of the interventions follows the Template for Intervention Description and Replication (TIDieR) checklist[38]. The intervention schedule and assessment procedures were designed according to previous studies/manuals and feasibility considerations. No formal patient and public involvement was conducted during the study design.

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Baseline variables

Sociodemographic variables included age, gender, years of education, and migration background and were collected with the baseline variables during the initial pre-intervention assessment. Migration background was assessed by asking whether participants, their parents, or grandparents had grown up outside Germany. Years of education referred to the number of years spent in secondary education, with 8 years corresponding to the German qualification for university entrance (Abitur). All baseline variables used were well established and validated instruments. A multiple-choice vocabulary test (MWT)[39] was applied to measure the global level of intelligence. Tobacco use was assessed using the Fagerstroem test for cigarette dependence[40]. Alcohol consumption was assessed using the Alcohol Use Disorder Identification Test (AUDIT)[41], anxiety as a personality trait was measured with the Spielberger Trait Anxiety Inventory[42]. The Anxiety Sensitivity Index 3 (ASI-3)[43] was used to assess the construct of anxiety sensitivity. We assessed impulsivity with Barratt's Impulsiveness Scale (BIS-15)[44], and applied the Perceived Stress Scale (PSS)[45] as well as the Positive and Negative Affect Schedule (PANAS)[46]. The behavioral inhibition system and behavioral approach system (BIS/BAS) were measured using the BIS/BAS questionnaire[47]. Furthermore, we used a questionnaire concerning the social support of our participants (Fragebogen zur Sozialen Unterstützung, F-SozU)[48]. To quantify the motivation for abstinence and therapy expectancies, TUD subjects were evaluated via goal attainment scaling (GAS)[49] and answered five questions concerning their motivation and therapy expectancies (ranging from 0 to 10, with 10 describing the highest therapy motivation and the greatest expectations). The Simple Physical Activity Questionnaire (SIMPAQ)[50] was applied to measure the daily activity of our participants.

Outcomes

Primary outcome

The primary outcome was defined as the change in abstinence days from before the intervention to after the intervention and at follow-up, measured by self-report using the Form90 interview. At the first assessment (pre-intervention), the participants were interviewed about how many days they had abstained from smoking within the last 90 days; at post-intervention and follow-up, the participants were interviewed how many days they had abstained between the actual time point and the last assessment. Therefore, the interview included different numbers of days between pre- and post-intervention and between post-intervention and follow-up individually for each participant (the mean length between pre- and post-intervention for the whole group was 105 days, with no significant difference between the two groups [$t(89) = 0.047$; $p = 0.963$] and the mean length between post-intervention and follow-up was 85 days, with no significant difference between the two groups [$t(78) = 0.132$; $p = 0.895$].

Secondary outcomes

As secondary outcomes, we evaluated changes in self-rating questionnaires concerning (i) smoking characteristics, (ii) clinical characteristics, and (iii) physical activity levels across time. The validated German version of the Questionnaire on Smoking Urges- (QSU-G)[51,52] was used to assess the level of current cigarette craving, and the validated Wisconsin Smoking Withdrawal Scale (WSWS)[53,54] was used to measure nicotine withdrawal symptoms. The validated German version of the Center for Epidemiological Studies Depression Scale (ADS-K)[55] measured depressive symptoms within the last week. The validated International Physical Activity Questionnaire-Short Form (IPAQ-SF)[56] was applied to assess the types of intensity of physical activity that people do as part of their daily lives and was considered to estimate the total physical activity in metabolic equivalent of task (MET)-min/week. One MET represents the energy expended while sitting quietly at rest and is equivalent to 3.5 mL/kg/min of maximal oxygen consumption (VO_2 max)[57]. All self-report questionnaires were assessed at all three time points.

Sample size

A priori sample size estimation was conducted assuming a Type I error rate of 5% and a statistical power of 80%. At the time of planning the study, evidence on the long-term effects of exercise interventions on smoking cessation outcomes was limited, particularly from randomized controlled trials combining multiple evidence-based parameters. Therefore, the estimation was informed by previous findings on the acute effects of exercise on tobacco craving[12]. As these effects may not directly translate to long-term smoking cessation outcomes, a conservative mild to moderate effect size ($f = 0.195$) was assumed. Based on this assumption, the required total sample size was estimated at $N = 68$ using G*Power. To account for an anticipated dropout rate of 20%, the target sample size was increased to $N = 82$.

Statistical analyses

We report the data using descriptive statistics, including the mean, standard deviation (SD), and frequencies, and used *t*-tests and χ^2-tests to examine possible group differences at baseline for the demographic data. We conducted our primary outcome analyses using the intention to treat (ITT) method, with participants remaining in their originally assigned groups after random allocation regardless of adherence or protocol deviation. In this analysis, all subjects who dropped out during the intervention were classified as having zero abstinence days at post-intervention and follow-up, as we can strongly assume that people who dropped out lost motivation to quit smoking. We also performed the same analyses using complete cases (CCs). For our confirmatory hypothesis, a linear mixed model was applied, with abstinence days as the dependent variable; treatment group, time points, and their interaction as fixed effects; and participant IDs as a random effect. Additionally, we investigated changes in our secondary outcomes across the time points and between the two groups. For these analyses, we report the mean values and SDs of our secondary outcomes separated for the two groups and time points, and applied linear mixed models using the secondary outcomes as dependent variables. We used the CC sample for our secondary outcome analyses, as we did not impute missing values. Furthermore, as the amount of exercise sessions could play an important role through its effects on smoking abstinence and secondary outcomes, we exploratively calculated Pearson correlations between the number of completed exercise sessions within the CBT + exercise group and our primary and secondary outcome variables. To account for baseline differences, partial correlations were calculated controlling for the respective baseline values of each outcome measure. In addition, exploratory post hoc analyses were conducted to examine differences in abstinence days between participants in the CBT + exercise group who met the predefined adherence threshold and participants in the CBT-only group who completed the intervention (CC sample), using Mann–Whitney U-tests. All analyses were performed in JASP Version 0.17.2 (JASP Team (2023) using the Frequentist framework, considering *p*-values lower than 5% as significant.

Results

Participants

In total, 132 participants were randomized into the two treatment arms, with 65 assigned to the CBT + exercise group and 67 to the CBT-only group. Figure 2 shows the flow of participants through the study. Retention rates were comparable between groups, with 67.7% of the CBT + exercise group and 70.1% of the CBT-only group completing the post-intervention assessment. At the 12-week follow-up, 56.9% of participants in the CBT + exercise group remained in the study compared with 65.7% in the CBT-only group. A χ^2-test revealed no significant difference in dropout rates between the groups ($p = 0.302$).

Baseline characteristics were well balanced across the two groups (Table 1). Participants did not differ significantly in terms of age, gender, education, migration background, smoking history, or psychological traits. The only exception was vocabulary-based intelligence (Wortschatztest, WST), which was slightly higher in the CBT-only group ($p = 0.033$), although the difference was modest and unlikely to be clinically meaningful.

Adherence to the intervention

Adherence to the exercise intervention varied (see Fig. 3). Within the ITT sample, participants in the CBT + exercise group attended 52% of the scheduled exercise sessions on average, completing approximately 35 min of vigorous-intensity activity and 60 min of total exercise time per week. In the CC sample, adherence was higher, with participants attending roughly 78% of sessions and performing just over 51 min of vigorous-intensity exercise and 90 min of total exercise weekly. The variability in attendance likely reflects the constraints imposed by the COVID-19 pandemic, which affected access and motivation for in-person sessions.

Adherence to the CBT intervention was comparable between the two groups. In the ITT sample, participants in the CBT-only group attended 5.10 sessions on average (SD = 1.48), compared with 4.88 sessions (SD = 1.62) in the CBT + exercise group, with no significant difference [$t(130) = 0.822$, $p = 0.421$].

A similar pattern was observed in the CC sample, with a mean attendance of 5.36 sessions (SD = 1.00) in the CBT-only group and 5.24 sessions (SD = 1.04) in the CBT + exercise group, again without significant differences [$t(79) = 0.530$, $p = 0.595$].

Primary outcome

With regard to the primary outcome, i.e., the number of self-reported abstinent days, no significant differences emerged between groups at either post-intervention or follow-up. In the ITT sample, the CBT-only group reported slightly higher abstinence rates both after treatment and at follow-up (47% and 45%, respectively) compared with the CBT + exercise group (37% and 34%, respectively). The CC analysis yielded similar patterns, with higher average abstinence in the CBT-only group across both intervals. Linear mixed model analyses of the ITT sample confirmed a significant main effect of time [$\chi^2(2) = 134.315$; $p < 0.001$] but not for treatment group [$\chi^2(1) = 2.061$; $p = 0.151$], nor the interaction of group × time [$\chi^2(1) = 4.066$; $p = 0.131$], indicating increased abstinence over time regardless of the condition (see also Fig. 4). The same pattern could be observed in the CC sample, namely no significant effect of treatment group [$\chi^2(1) = 1.064$; $p = 0.302$], a significant effect of time [$\chi^2(2) = 170.924$; $p < 0.001$], and no significant group by time point interaction [$\chi^2(2) = 3.665$; $p = 0.160$].

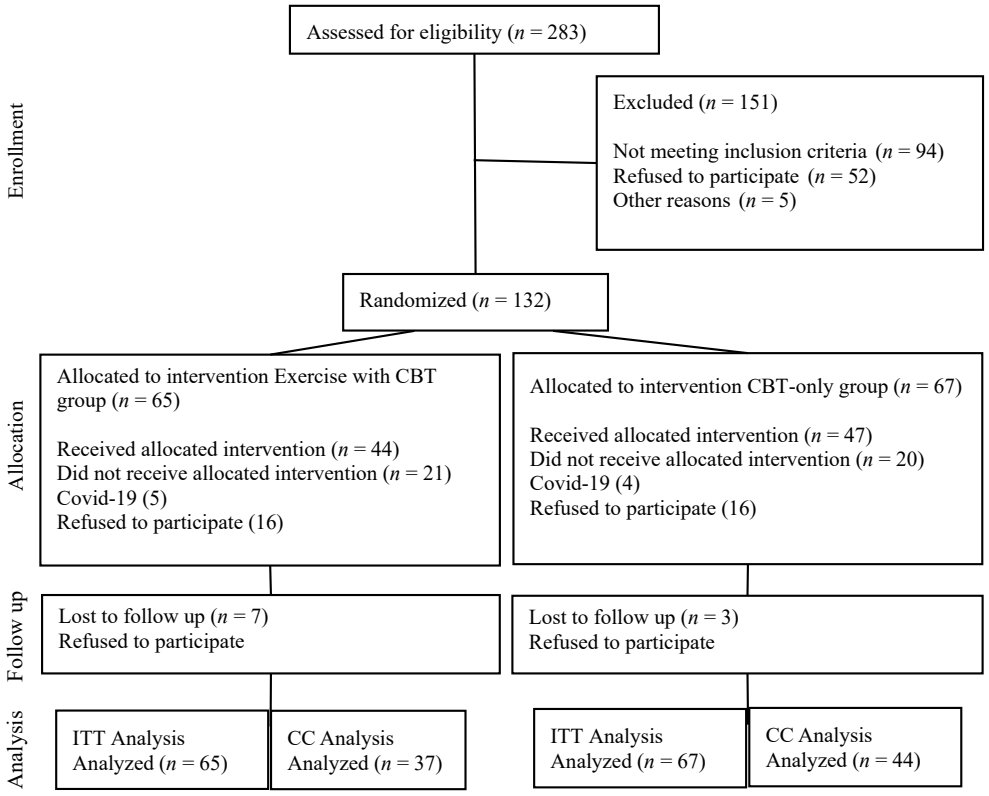

Fig. 2 Consolidated Standards of Reporting Trials (CONSORT) flowchart of study participants' inclusion, randomization, the intervention, and follow-up analyses. ITT, intention to treat; CC, complete cases.

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Table 1. Baseline demographic and clinical characteristics of the sample ($N = 132$).

Characteristics	Missing (N)	Exercise with CBT group ($N = 65$) Mean (SD)	Missing (N)	CBT-only group ($N = 67$) Mean (SD)	Statistic, p-value
Sociodemographics					
Age	0	38.28 (10.67)	0	39.28 (12.57)	$t = 0.503$, $p = 0.621$
Gender (female %)	0	56.25%	0	62.69%	$\chi^2 = 1.476$; $p = 0.487$
Years of education*	0	7.15 (1.25)	0	7.22 (1.24)	$t = 0.310$; $p = 0.753$
Migration background (%)	1	32.81%	0	23.88%	$\chi^2 = 1.291$; $p = 0.262$
Intelligence (WST)	0	28.36 (4.14)	0	29.81 (3.60)	$t = 2.149$; $p = 0.033$*
Nicotine information					
Cigarettes per day	0	14.15 (7.03)	0	14.57 (8.50)	$t = 0.301$; $p = 0.766$
Nicotine dependence (FTND)	0	3.86 (2.01)	0	3.93 (2.47)	$t = 0.177$; $p = 0.862$
Pack years	0	11.42 (10.62)	0	15.47 (15.98)	$t = 1.690$; $p = 0.095$
QSU	1	100.89 (30.28)	0	102.63 (32.17)	$t = 0.318$; $p = 0.751$
WSWS	1	35.18 (16.45)	0	36.075 (13.45)	$t = 0.339$; $p = 0.735$
Clinical characteristics					
AUDIT	0	7.06 (4.56)	0	5.49 (4.67)	$t = -1.947$; $p = 0.054$
ADS-K	0	8.77 (6.70)	0	7.612 (5.52)	$t = -1.078$; $p = 0.283$
STAI-T	10	39.86 (9.43)	5	38.86 (9.09)	$t = -0.584$; $p = 0.561$
ASI-3	10	20.67 (12.92)	6	16.56 (10.71)	$t = -1.865$; $p = 0.065$
Personality characteristics					
PSS	0	14.34 (6.27)	0	14.34 (5.83)	$t < 0.001$; $p = 1.0$
PANAS	0	30.28 (5.74) 16.64 (6.39)	0	31.76 (5.93) 15.40 (4.85)	$t = 1.450$; $p = 0.150$ $t = -1.253$; $p = 0.212$
Barratt impulsiveness scale	10	32.80 (5.70)	5	33.57 (6.61)	$t = 0.672$; $p = 0.503$
BIS	11	19.83 (3.84)	5	19.62 (3.73)	$t = -0.292$; $p = 0.771$
BAS	11	41.35 (4.77)	5	40.72 (5.32)	$t = -0.669$; $p = 0.505$
Other					
SIMPAQ (total activity)+	0	5.48 (3.25)	0	5.99 (3.07)	$t = 0.913$; $p = 0.363$
IPAQ MET total (min/week)	2	3,620.532 (2,254.722)	7	3,329.950 (2,662.031)	$t = 0.654$; $p = 0.514$
Therapy expectancy/motivation	0	40.73 (5.79)	0	40.43 (7.16)	$t = -0.264$; $p = 0.792$
F-SozU	11	91.87 (14.97)	7	95.233 (13.79)	$t = 1.244$; $p = 0.216$

Note: * Years of education refers to years spent in secondary education. Eight years correspond to the German university entrance qualification (Abitur). +Average activity per day in hours (without sleeping and sitting) WST, Wortschatztest, vocabulary-based intelligence; FTND, Fagerstroem Test for Cigarette Dependence; QSU, Questionnaire on Smoking Urges; WSWS, Wisconsin Withdrawal Scale; AUDID, Alcohol Use Disorder Identification Test; ADS-K, German version of the Center for Epidemiological Studies Depression Scale; STAI-T, Spielberger Trait Anxiety Inventory; ASI-3, Anxiety Sensitivity Index-3; PSS, Perceived Stress Scale; PANAS, Positive and Negative Affect Schedule; BIS/BAS, Behavioral Inhibition System and Behavioral Approach System; SIMPAQ, Simple Physical Activity Questionnaire; IPAQ, International Physical Activity Questionnaire, short form; F-SozU, Fragebogen zur Sozialen Unterstützung.

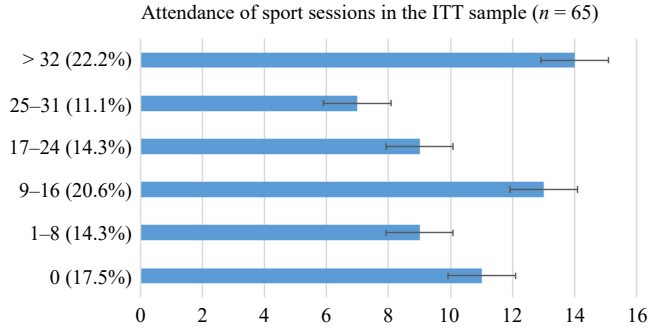

Fig. 3 Number of completed sport sessions and attendance rates (as a percentage) in the CBT + exercise group. Error bars indicate standard errors of the mean (SE). ITT, intention to treat.

Secondary outcomes

Secondary outcomes followed a similar pattern (see also Table 2). Across the entire sample, craving levels (QSU) declined significantly from baseline to post-intervention and follow-up, with no significant difference between groups. Withdrawal symptoms (WSWS) decreased during the intervention but rebounded slightly at follow-up. Depressive symptoms (ADS-K) increased over time in both groups, though the average scores remained below clinical cutoffs. Physical activity, as measured by the IPAQ-SF, increased from baseline to post-intervention and stabilized thereafter. In all cases, linear mixed models indicated significant time effects, but no main effects of group or time × group interactions.

Correlation analysis

Exploratory analyses were conducted within the CBT + exercise group to examine whether the number of completed exercise sessions was associated with outcomes. In participants who completed the intervention, a clear positive association emerged between exercise adherence and abstinence: Those who attended more exercise sessions reported more abstinent days at both post-intervention ($r = 0.620$, $p < 0.001$) and follow-up ($r = 0.528$, $p = 0.001$). Furthermore, higher session attendance was correlated with lower craving levels at post-intervention ($r = -0.400$, $p = 0.001$). However, no significant correlations were found between exercise adherence and depressive symptoms, withdrawal, or physical activity scores (see Table 3).

Exploratory *post hoc* analysis of adherence effects

An exploratory *post hoc* analysis was conducted among participants in the CBT + exercise group who met the predefined adherence threshold for the exercise intervention ($N = 14$). At post-intervention, these participants showed higher total numbers of

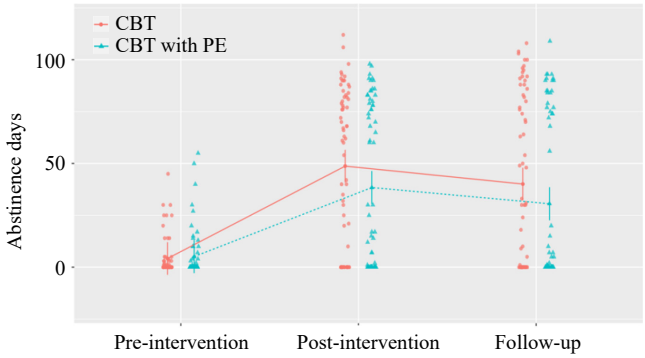

Fig. 4 Abstinence days for the three time points and the two groups in the ITT sample. Error bars represent 95% confidence intervals around the mean.

abstinence days (mean = 76.93, SD = 18.63) compared with participants in the CBT-only group who completed the intervention (N = 44; mean = 68.48, SD = 24.89). However, this difference was not statistically significant (U = 243.509, p = 0.245). A similar pattern was observed at follow-up, with descriptively higher numbers of abstinent days in the CBT + exercise group (mean = 70.07, SD = 30.28) compared with CBT-only completers (mean = 61.05, SD = 35.10), but without statistical significance (U = 239.501, p = 0.216).

Discussion

Main findings

The present randomized controlled trial investigated whether the addition of a supervised, vigorous-intensity exercise intervention to group-based CBT would enhance smoking cessation outcomes. In contrast to our initial hypothesis, the combined intervention did not lead to superior abstinence rates, nor did it produce greater improvements in craving, withdrawal symptoms, depressive mood, or physical activity levels compared with CBT alone. These findings are consistent with previous meta-analytic evidence[19] that have failed to demonstrate consistent additive effects of exercise when integrated into standard cessation programs.

Notably, exploratory analyses provided a more nuanced picture. Within the exercise group, a dose–response pattern became apparent: Participants who attended more training sessions reported more abstinent days and lower craving levels. This suggests that the absence of group-level effects may not reflect a lack of efficacy of the exercise intervention per se but insufficient adherence to the training protocol. This interpretation is consistent with prior studies emphasizing the critical role of exercise dose and engagement[23]. Participants in the CBT + exercise group who met the predefined adherence threshold (≥ 32 sessions) showed descriptively higher numbers of abstinent days compared with the CBT-only group; however, this difference was not statistically significant and should be interpreted with caution, given the small subgroup size and *post hoc* nature of the analysis.

The lack of between-group effects may also be partly attributable to contextual factors related to the COVID-19 pandemic. The study was conducted during periods of varying public health restrictions, including phases of strict lockdowns that led to temporary interruptions of the intervention. In addition, participants may have experienced quarantine or illness, which could have affected both adherence to the intervention and outcome measures. However, detailed data on the timing and extent of these restrictions, as well as individual quarantine periods, were not systematically recorded. Therefore, the specific impact of these factors cannot be quantified in the present study. These contextual influences should be considered when interpreting the findings.

Another consideration concerns the characteristics of the study sample. Participants were treatment-seeking individuals with moderate to high motivation to quit, as evidenced by their high quitting readiness and attendance at CBT sessions. Under these conditions, the potential added value of exercise may have been more difficult to detect, as CBT alone may have already yielded substantial effects in this sample. Future studies may consider targeting subgroups with a general lower intrinsic motivation,

Table 2. Secondary outcome variables across the three time points, separated for the two treatment groups.

	N	Baseline mean (SD)	*N*	12 weeks mean (SD)	*N*	24 weeks mean (SD)	Effect of time	Effect of group	Interaction of time × group
Smoking characteristics									
QSU- craving							$\chi^2(2) = 126.229$ $p < 0.001$	$\chi^2(1) = 0.072$ $p = 0.788$	$\chi^2(2) = 2.571$ $p = 0.276$
CBT only	67	102.627 (32.167)	47	54.702 (20.201)	26	69.615 (35.669)			
CBT + exercise	64	100.891 (30.282)	43	62.977 (24.996)	22	65.409 (30.767)			
WSWS (withdrawal)							$\chi^2(2) = 7.404$ $p = 0.025$	$\chi^2(1) = 0.209$ p =0.647	$\chi^2(2) = 1.364$ $p = 0.506$
CBT only	67	35.653 (13.449)	47	32.319 (15.743)	26	36.654 (8.588)			
CBT + exercise	64	35.100 (16.449)	43	33.558 (13.715)	22	38.273 (11.209)			
Clinical characteristics									
ADS-K–depressive symptoms							$\chi^2(2) = 17.198$ $p < 0.001$	$\chi^2(1) = 0.401$ $p = 0.526$	$\chi^2(2) = 0.736$ $p = 0.692$
CBT only	67	7.612 (5.516)	47	9.298 (7.018)	27	11.704 (9.380)			
CBT + exercise	64	8.766 (6.699)	43	9.977 (5.970)	23	10.826 (5.606)			
Physical activity									
IPAQ-SF MET total (min/week)							$\chi^2(2) = 7.711$ $p = 0.021$	$\chi^2(1) = 0.410$ $p = 0.522$	$\chi^2(2) = 0.217$ $p = 0.897$
CBT only	63	3,620.532 (2,254.722)	44	4,480.170 (2,731.361)	24	4,252.313 (2,652.092)			
CBT + exercise	60	3,329.950 (2,662.031)	43	4,451.279 (2,884.689)	19	3,833.763 (2,224.601)			

Note: Not all participants who completed the follow-up assessment interview finished the questionnaires at follow-up. QSU, Questionnaire on Smoking Urges; WSWS, Wisconsin Withdrawal Scale; ADS-K, German version of the Center for Epidemiological Studies Depression Scale; IPAQ, International Physical Activity Questionnaire, short form.

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Table 3. Pearson correlation analysis between number of completed sport sessions with abstinence days, depressive symptoms (ADS-K), craving (QSU), withdrawal (WSWS), and physical activity levels (IPAQ-SF) within the sports group using the CC sample only ($n = 37$).

	Post-intervention	Follow-up
Abstinence days	$r = 0.620$ ($p = < 0.001$)	$r = 0.528$ ($p = 0.001$)
ADS-K	$r = 0.024$ ($p = 0.882$)	$r = –0.056$ ($p = 0.808$)
QSU	$r = –0.400$ ($p = 0.001$)	$r = –0.079$ ($p = 0.739$)
WSWS	$r = –0.045$ ($p = 0.781$)	$r = 0.294$ ($p = 0.208$)
IPAQ	$r = 0.113$ ($p = 0.494$)	$r = –0.050$ ($p = 0.849$)

Note: The baseline values served as a covariate in the correlation analysis. QSU, Questionnaire on Smoking Urges; WSWS, Wisconsin Withdrawal Scale; ADS-K, German version of the Center for Epidemiological Studies Depression Scale; IPAQ, International Physical Activity Questionnaire, short form.

higher stress levels, or comorbid affective symptoms, where the mood-regulating and stress-buffering effects of exercise could be more impactful.

Strengths

Methodologically, the trial had several strengths. It had a robust randomized controlled design, clearly defined inclusion and exclusion criteria, and validated measures of smoking behavior, affect, and physical activity. The exercise protocol was based on individualized thresholds (IAT), supervised by trained staff, and aligned with current best-practice recommendations for vigorous physical activity. To our knowledge, this is one of the few studies to implement a high-frequency, high-intensity, supervised training model pre-quitting in the context of smoking cessation.

Limitations

Nonetheless, several limitations must be acknowledged. First, abstinence was assessed via self-reports and was not biochemically verified. Although timeline follow-back methods are widely accepted, they may be vulnerable to recall or social desirability biases, which could have influenced the accuracy of the reported abstinence rates. Second, the study was not powered to detect small effect sizes in subgroup or moderation analyses. Third, the reliance on in-person attendance for the exercise component may have reduced feasibility and generalizability, particularly in post-pandemic or resource-limited settings. Fourth, patient and public involvement was not formally incorporated into the study design. Fifth, the relatively intensive intervention schedule, including frequent exercise sessions and repeated assessments, may have increased the burden on the participants. This should be considered when interpreting adherence and dropout rates and may limit generalizability to real-world settings. Sixth, ethnicity and social deprivation were not assessed in this study. Although migration background was recorded, this variable does not fully capture ethnic or socioeconomic diversity, which may limit generalizability. Seventh, outcome assessors were not fully independent from the intervention's delivery, particularly for the exercise component, which may have introduced assessment bias.

Clinical implications

Overall, the findings indicate that a structured, vigorous-intensity exercise program, even when implemented under optimal conditions and in conjunction with CBT, may not uniformly improve smoking cessation outcomes at the group level. However, the dose-dependent effects observed within the CBT + exercise group underscore the potential value of physical activity—provided that adherence is achieved. Future research should prioritize interventions that optimize engagement, perhaps through flexible formats (e.g., home-based or digital training), motivational enhancement strategies, or adaptive exercise prescriptions tailored to individual preferences and readiness.

Conclusions

In conclusion, although exercise did not yield superior outcomes when added to CBT in this trial, it remains a promising adjunctive strategy for smoking cessation, particularly for individuals who engage with it consistently. Maximizing adherence appears to be the key factor in unlocking its potential therapeutic value.

Ethical statements

The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of Charité–Universitätsmedizin Berlin (EA4/189/18) on 9 January 2019.

Informed consent for participation was obtained from all subjects involved in the study.

The study's clinical trial registration number (ClinicalTrials.gov identifier) is NCT04251936. Participant registration took place between December 2019 and April 2022. Recruitment was interrupted for a total of four months during the COVID-19 lockdowns.

Author contributions

The authors confirm their contributions to this study as follows: study conception and design: Kunas S, Stuke H, Grummt M, Drumev V, Ströhle A, Bermpohl F, Wolfarth B; data collection: Kunas S, Stuke H, Grummt M, Drumev V, Kanse S; analysis and interpretation of the results: Kunas S, Stuke H, Grummt M, Plank I, Bermpohl F; draft manuscript preparation: Kunas S. All authors reviewed the results and approved the final version of the manuscript.

Data availability

The datasets generated and analyzed during the current study are not publicly available for ethical reasons and the privacy of the participants but are available from the corresponding author on reasonable request.

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Conflict of interest

The authors declare that they have no conflict of interest.

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