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Effects of Alpha-Band Binaural Beat Entrainment on Anxiety and Aggression in Men With Opioid Use Disorder: A Randomized Sham-Controlled Trial Running Title: Binaural Beat Entrainment in Opioid Use Disorder

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Abstract

Background:

Opioid use disorder (OUD) is frequently accompanied by anxiety and aggression, both of which adversely affect treatment adherence, relapse risk, and long-term rehabilitation outcomes. Non-pharmacological neuromodulation approaches, including binaural beat stimulation, have attracted increasing attention as potential adjunctive interventions for improving emotional regulation. However, evidence regarding the efficacy of alpha-band binaural beat entrainment in individuals with OUD remains limited.

Objective:

To evaluate the efficacy of alpha-band binaural beat entrainment, compared with sham auditory stimulation, in reducing anxiety and aggression among men undergoing residential treatment for opioid use disorder.

Methods:

A two-arm randomized, sham-controlled, pretest–posttest clinical trial was conducted among 30 men with opioid use disorder recruited from a residential addiction treatment center. Participants were randomly allocated (1:1) to either an alpha-band binaural beat intervention group (n = 15) or a sham stimulation group (n = 15). The intervention consisted of ten 30-minute sessions of alpha-band binaural beat stimulation administered over three weeks, while the control group received an acoustically comparable sham intervention without binaural beat frequencies. Anxiety and aggression were assessed before and after the intervention using the Beck Anxiety Inventory (BAI) and the Buss–Perry Aggression Questionnaire (BPAQ), respectively. Between-group differences in post-intervention outcomes were analyzed using analysis of covariance (ANCOVA), adjusting for baseline scores. Statistical significance was established at $P < 0.05$.

Results:

After adjustment for baseline scores, the intervention group showed significantly lower post-intervention anxiety than the sham group ($P < 0.001$; partial $\eta^2 = 0.748$). Significant reductions were also observed in total aggression ($P < 0.001$; partial $\eta^2 = 0.814$), as well as in physical aggression (partial $\eta^2 = 0.692$), verbal aggression (0.588), anger (0.442), and hostility (0.521). No intervention-related adverse events were reported.

Conclusions:

Alpha-band binaural beat entrainment was associated with significant improvements in anxiety and aggression among men undergoing treatment for opioid use disorder compared with sham auditory stimulation. These findings suggest that alpha-band binaural beat stimulation may represent a promising, non-invasive adjunctive intervention that warrants further clinical evaluation for enhancing emotional regulation during addiction rehabilitation. Larger multicenter randomized trials with longer follow-up periods and neurophysiological outcome measures are warranted to confirm these preliminary findings

Trial registration

Iranian Registry of Clinical Trials (IRCT), IRCT20251206068230N1, retrospectively registered on 31 January 2026.

Introduction

Opioid use disorder (OUD) has become one of the most challenging public health problems worldwide, imposing substantial clinical, social, and economic burdens on healthcare systems. Although opioids remain indispensable for the management of acute and chronic pain, their non-medical use has escalated dramatically over the past two decades, contributing to unprecedented increases in dependence, overdose, disability, and premature mortality [1–2]. According to recent epidemiological estimates, approximately 296 million people used illicit drugs globally in 2021, including nearly 60 million opioid users, while almost 40 million individuals met diagnostic criteria for substance use disorders [1]. In the United States alone, more than 105,000 drug overdose deaths were recorded in 2023, of which approximately 80,000 were attributable to opioids, highlighting the continuing magnitude of the opioid epidemic despite recent improvements in mortality trends [3]. Beyond mortality, opioid misuse is associated with substantial psychiatric morbidity, impaired occupational functioning, family disruption, increased healthcare utilization, and heightened vulnerability to infectious diseases, emphasizing the urgent need for innovative and sustainable therapeutic strategies [4].

Current evidence indicates that opioid addiction is not merely a disorder of substance dependence but a chronic neurobehavioral condition characterized by persistent alterations in reward processing, emotional regulation, executive functioning, and stress responsiveness. Consequently, effective management requires an integrated approach that combines pharmacological treatment, psychological interventions, behavioral rehabilitation, and long-term psychosocial support [5]. Nevertheless, treatment outcomes remain suboptimal, largely because many patients continue to experience psychological symptoms that are insufficiently addressed by conventional therapeutic approaches. Among these, anxiety and aggression are particularly important because they interfere with treatment engagement, reduce adherence, impair psychosocial functioning, and substantially increase the likelihood of relapse [2].

Anxiety disorders are among the most prevalent psychiatric comorbidities in individuals with substance use disorders and exhibit a complex bidirectional relationship with substance misuse. Anxiety may precede substance use through self-medication behaviors or emerge as a consequence of neurobiological changes associated with chronic opioid exposure and withdrawal [2]. Clinically, persistent anxiety manifests as excessive worry, autonomic hyperarousal, irritability, sleep disturbances, and impaired emotional regulation, all of which adversely affect treatment outcomes [6–7]. Recent systematic evidence indicates that nearly one-half of individuals with substance use disorders meet diagnostic criteria for at least one anxiety disorder, with generalized anxiety disorder representing the most common condition [8–9]. Given the central role of anxiety in craving, stress reactivity, and relapse vulnerability, reducing anxiety has become an important therapeutic target during addiction rehabilitation.

Aggression represents another clinically significant yet frequently overlooked psychological manifestation of opioid addiction. Aggressive behaviors—including physical aggression, verbal aggression, anger, and hostility—not only compromise interpersonal relationships and social functioning but are also associated with poorer treatment adherence, increased impulsivity, and elevated relapse risk [10–11]. Neurobehavioral evidence suggests that chronic substance use disrupts cortical inhibitory control and emotional regulation, thereby increasing susceptibility to impulsive and aggressive behaviors [2]. Furthermore, anxiety and aggression appear to reinforce one another through shared neurobiological pathways involving stress regulation and executive dysfunction, creating a maladaptive cycle that complicates recovery [12–13]. Therefore, interventions capable of simultaneously targeting both anxiety and aggression may provide meaningful clinical benefits for individuals with OUD.

Despite advances in pharmacotherapy and psychotherapy, important therapeutic gaps remain. Medication-assisted treatment effectively reduces opioid use and overdose risk but often has limited impact on emotional dysregulation, while psychological interventions require sustained engagement and may not adequately address underlying neurophysiological dysfunctions [14–15]. Consequently, increasing attention has been directed toward adjunctive, non-invasive neuromodulation approaches capable of modulating neural circuits involved in emotional regulation.

Among these emerging interventions, binaural beat stimulation has attracted considerable scientific interest. Binaural beats are generated when two pure tones of slightly different frequencies are presented separately to each ear, resulting in the perception of a third auditory beat corresponding to the frequency difference [16]. According to the neural entrainment hypothesis, this auditory illusion may synchronize endogenous brain oscillations with externally presented frequencies, thereby influencing cognitive processing, autonomic regulation, and emotional functioning [17]. In particular, alpha-band (8–13 Hz) oscillations have consistently been linked to relaxation, attentional regulation, and emotional stability. Experimental evidence suggests that alpha-frequency entrainment may enhance parasympathetic activity, improve heart rate variability, attenuate physiological stress responses, and facilitate adaptive emotional regulation [16]. These neurophysiological mechanisms provide a

biologically plausible rationale for investigating alpha-band binaural beat stimulation as an adjunctive intervention for individuals with opioid use disorder.

Among the commonly investigated binaural beat frequencies, alpha-band stimulation appears to be particularly relevant for emotional regulation. Theta-frequency stimulation has primarily been associated with meditation, memory consolidation, and sleep-related processes, whereas beta-frequency stimulation may increase cortical arousal, and gamma-band stimulation has predominantly been investigated in relation to higher-order cognitive processing. In contrast, alpha oscillations have consistently been associated with relaxation, inhibitory control, autonomic balance, and anxiety reduction, making alpha-band entrainment a biologically plausible candidate for addressing emotional dysregulation in individuals with opioid use disorder.

Nevertheless, the current evidence remains inconclusive. Although several studies have demonstrated beneficial effects of binaural beat stimulation on anxiety reduction and psychological well-being [15], other investigations have reported limited or non-significant effects, particularly when different stimulation frequencies or heterogeneous populations were examined [18–19]. Moreover, previous studies have predominantly focused on healthy participants or individuals with generalized anxiety, whereas controlled investigations among patients with opioid use disorder remain scarce. Importantly, few studies have simultaneously evaluated both anxiety and aggression, despite their close neurobehavioral interrelationship and their established influence on treatment outcomes. Furthermore, the efficacy of frequency-specific alpha-band entrainment protocols has not been adequately investigated in individuals undergoing addiction rehabilitation [17–20]. Despite the growing literature on binaural beat stimulation, three important knowledge gaps remain. First, most randomized trials have been conducted in healthy volunteers or non-clinical populations rather than individuals with opioid use disorder. Second, previous studies have primarily evaluated anxiety, stress, or cognitive performance, whereas aggression—an important determinant of treatment adherence and relapse—has rarely been examined. Third, no randomized sham-controlled trial has comprehensively investigated whether frequency-specific alpha-band binaural beat stimulation simultaneously improves anxiety and multidimensional aggression in patients receiving residential treatment for opioid use disorder. Addressing these gaps may provide clinically relevant evidence for integrating auditory neuromodulation into addiction rehabilitation.

Addressing these gaps, the present randomized sham-controlled trial evaluated the effects of alpha-band binaural beat entrainment on anxiety and aggression among men undergoing residential treatment for opioid use disorder. Unlike previous studies, this investigation examined a frequency-specific neuromodulation protocol targeting two clinically important psychological outcomes within a controlled experimental framework. The study was intentionally restricted to men because the participating residential rehabilitation center exclusively admitted male patients, thereby ensuring a clinically homogeneous study population while limiting potential confounding related to sex-specific psychological and neurobiological differences.

We hypothesized

Materials and Methods

Study Design

This study was designed and conducted as a two-arm, parallel-group, randomized, sham-controlled clinical trial with a pretest–posttest design to evaluate the efficacy of alpha-band binaural beat entrainment on anxiety and aggression among individuals with opioid use disorder (OUD). The study compared an active binaural beat intervention with a sham auditory control condition to determine whether frequency-specific auditory entrainment produced greater improvements in psychological outcomes beyond those attributable to passive music listening or nonspecific therapeutic effects.

The trial followed a superiority framework with an allocation ratio of 1:1. Participants completed baseline assessments before randomization and underwent identical post-intervention evaluations immediately after completion of the intervention period using the same validated outcome measures.

The primary outcome of the study was the change in anxiety severity measured by the Beck Anxiety Inventory (BAI)(21). Secondary outcomes included changes in total aggression and the four dimensions of aggression (physical aggression, verbal aggression, anger, and hostility) assessed using the Buss–Perry Aggression Questionnaire (BPAQ)(22).

The intervention protocol, outcome assessment procedures, and statistical analyses were predefined before participant enrollment. The study was conducted in accordance with the principles of the Declaration of Helsinki and complied with the CONSORT 2010 Statement and the CONSORT Extension for Randomized Trials of Non-pharmacologic Treatments wherever applicable.

Study Setting and Participants

This randomized sham-controlled clinical trial was conducted at a residential addiction rehabilitation center in Tabriz, Iran. Participant recruitment and data collection were carried out over the study period under the supervision of the research team in collaboration with the clinical staff of the treatment center.

Potential participants were identified through consecutive screening of patients admitted to the rehabilitation center. The rehabilitation center provides inpatient treatment exclusively for male patients. Consequently, only men were eligible for recruitment. This restriction reflected the characteristics of the study setting rather than a biological rationale.

Individuals who met the eligibility criteria were invited to participate in the study and received a detailed explanation regarding the study objectives, intervention procedures, potential benefits, possible risks, and their rights as research participants. Written informed consent was obtained from all participants before enrollment.

A total of 30 adult men diagnosed with opioid use disorder were enrolled in the study. Following baseline assessment, participants were randomly assigned in a 1:1 ratio to either the alpha-band binaural beat intervention group (n = 15) or the sham auditory stimulation group (n = 15).

Eligibility Criteria

Eligibility criteria were established before participant recruitment to ensure clinical homogeneity and minimize potential confounding.

Inclusion Criteria

Participants were eligible for inclusion if they met all of the following criteria:

- Male sex, because recruitment was conducted in a male-only residential addiction treatment center
- Age within the predefined study eligibility range.
- Clinical diagnosis of opioid use disorder according to the admission criteria of the rehabilitation center.
- Residence in the treatment center throughout the intervention period.
- Ability to understand the study procedures and complete the study questionnaires.
- Normal hearing ability sufficient to perceive auditory stimulation through stereo headphones.
- Provision of written informed consent.

Exclusion Criteria

Participants were excluded if they met any of the following criteria:

- Withdrawal from the study at any stage.
- Failure to attend the scheduled intervention sessions.
- Development of acute medical or psychiatric conditions requiring immediate treatment during the intervention period.
- Inability to complete post-intervention assessments.
- Any condition judged by the investigators to interfere with safe participation or adherence to the study protocol.

Participant Flow

All eligible participants completed baseline assessments before randomization. Participants allocated to the intervention group received the complete alpha-band binaural beat protocol, whereas participants assigned to the control group received sham auditory stimulation with an identical intervention schedule.

Outcome assessments were conducted using the same standardized instruments before the first intervention session and immediately after completion of the intervention protocol.

Participant recruitment, allocation, follow-up, and analysis are summarized in the CONSORT participant flow diagram.

Randomization, Allocation Concealment, and Blinding

Following confirmation of eligibility and completion of baseline assessments, participants were randomly assigned in a 1:1 ratio to either the alpha-band binaural beat intervention group or the sham auditory stimulation group.

The random allocation sequence was generated before participant assignment using a web-based random number generator, ensuring an unpredictable allocation sequence throughout the enrollment process. Randomization was implemented only after all baseline demographic and outcome assessments had been completed to prevent selection bias and to ensure that pre-intervention measurements were not influenced by treatment allocation.

Allocation concealment was maintained throughout the enrollment process. The investigator responsible for participant recruitment enrolled eligible participants without prior knowledge of the upcoming treatment assignment. Group allocation was disclosed only after completion of enrollment and baseline assessment, thereby minimizing the risk of selection bias.

Because the intervention consisted of auditory stimulation delivered through stereo headphones, both groups underwent identical experimental procedures with respect to treatment environment, session duration, intervention schedule, equipment, and researcher–participant interaction. Participants in the intervention group received alpha-band binaural beat stimulation, whereas participants in the control group received an acoustically comparable sham auditory stimulus without embedded binaural beat frequencies. Consequently, participants were unable to distinguish whether they had received the active or sham intervention.

Outcome assessment was performed using standardized self-administered questionnaires at baseline and immediately after completion of the intervention protocol. The investigator responsible for collecting, checking, and entering questionnaire data remained blinded to group allocation throughout the assessment process. Blinding of the outcome assessor was maintained until completion of data collection, thereby reducing the potential for detection bias.

Due to the nature of the intervention, blinding of the investigator responsible for delivering the auditory stimulation was not feasible. Nevertheless, all participants received identical numbers of sessions, equivalent researcher contact time, standardized intervention procedures, and identical assessment schedules in order to minimize performance bias.

The procedures for sequence generation, participant enrollment, random allocation, follow-up, and statistical analysis are summarized in the CONSORT participant flow diagram.

Intervention

Participants allocated to the intervention group received alpha-band binaural beat stimulation as an adjunctive non-pharmacological intervention during their residential addiction treatment program. The intervention was designed to induce neural entrainment within the alpha frequency range, which has been associated with relaxation, emotional regulation, and modulation of autonomic nervous system activity.

The intervention consisted of ten supervised stimulation sessions delivered over approximately three to four weeks, with three sessions scheduled per week. Each session lasted 30 minutes and was administered individually in a quiet room within the rehabilitation center to minimize environmental distractions and external auditory interference.

During each session, participants listened to the binaural beat stimulus through stereo headphones while remaining comfortably seated. They were instructed to remain awake, minimize body movement, avoid conversation, and listen passively to the auditory stimulus throughout the session. No additional psychological intervention, relaxation training, meditation instruction, or behavioral coaching was provided during the auditory stimulation sessions in order to isolate the specific effect of binaural beat entrainment.

The auditory stimulus contained embedded alpha-band binaural beats generated by presenting two slightly different pure-tone frequencies separately to each ear, thereby producing the perception of an alpha-frequency beat within the central auditory pathways. The stimulation protocol remained identical across all intervention sessions with respect to auditory content, session duration, listening conditions, and treatment environment.

Participants allocated to the control group received sham auditory stimulation using an acoustically comparable audio program delivered through the same stereo headphones, under identical environmental conditions, session duration, and intervention schedule. The sham stimulus did not contain embedded binaural beat frequencies but was otherwise comparable to the intervention stimulus in order to minimize expectancy effects and maintain participant blinding.

To ensure intervention fidelity, all stimulation sessions were administered according to a standardized protocol under the supervision of the research team. The intervention setting, equipment, treatment schedule, session duration, and participant instructions were kept identical for both study groups throughout the study period. Attendance at each intervention session was monitored and recorded, and participants who were unable to complete the intervention protocol were managed according to the predefined study eligibility criteria.

No adverse events or participant-reported discomfort associated with auditory stimulation were observed during the intervention period.

Outcome Measures

The primary outcome of the study was the change in anxiety severity following completion of the intervention. Secondary outcomes included changes in total aggression and its four dimensions: physical aggression, verbal aggression, anger, and hostility. All outcome measures were assessed at baseline (pre-intervention) and immediately after completion of the intervention (post-intervention) using standardized self-report questionnaires administered under identical conditions for both study groups.

Beck Anxiety Inventory (BAI)

Anxiety was assessed using the Beck Anxiety Inventory (BAI), one of the most widely validated self-report instruments for measuring the severity of anxiety symptoms in both clinical and research settings. The BAI consists of 21 items assessing common cognitive, emotional, and physiological symptoms experienced during the previous week. Each item is rated on a four-point Likert scale ranging from 0 ("Not at all") to 3 ("Severely"), yielding a total score ranging from 0 to 63, with higher scores indicating greater anxiety severity.The BAI has demonstrated excellent psychometric properties across different clinical populations, including individuals with substance use disorders, with high internal consistency and satisfactory construct validity. The Persian version of the instrument has also demonstrated acceptable reliability and validity and has been widely used in Iranian clinical research.The total BAI score was considered the primary outcome variable for all statistical analyses[21].

Buss–Perry Aggression Questionnaire (BPAQ)

Aggression was assessed using the Buss–Perry Aggression Questionnaire (BPAQ), a widely used and validated multidimensional instrument developed by Buss and Perry.[23] The BPAQ consists of 29 items organized into four subscales: Physical Aggression, Verbal Aggression, Anger, and Hostility. Each item is rated on a five-point Likert scale, with higher scores indicating greater levels of aggression. Subscale scores are calculated separately, and an overall aggression score is obtained by summing the relevant item scores. The BPAQ has demonstrated good internal consistency and construct validity across different populations [22]. The Persian version of the BPAQ has also demonstrated satisfactory psychometric properties. Samani reported Cronbach's alpha coefficients of 0.79 for Physical Aggression, 0.79 for Verbal Aggression, 0.71 for Anger, and 0.82 for Hostility.[24] The total BPAQ score and the four subscale scores were considered secondary outcome variables in the present study [23].

Gnaural Software and Auditory Stimulation

The binaural beat stimuli were generated using Gnaural, a software specifically designed for creating and configuring binaural beats and auditory brainwave entrainment protocols. In this software, binaural beats are produced for each ear by simultaneously presenting two pure tones with slightly different frequencies, based on the selected frequency band and carrier frequency. The brain perceives the

difference between these two frequencies as a beat, known as the binaural beat [24]. In the present study, a carrier tone of 440 Hz was presented to the left ear and a 450 Hz tone to the right ear, resulting in a perceived binaural beat of 10 Hz within the alpha band. Both tones were delivered via KOTION EACH G9000 stereo headphones to ensure high audio quality and consistency of stimulation.

Outcome Assessment Procedures

Outcome assessments were conducted at two predefined time points: immediately before randomization (baseline) and immediately following completion of the ten-session intervention protocol. All questionnaires were completed in a quiet environment under standardized administration procedures. Participants received identical instructions regarding questionnaire completion, and sufficient time was provided to ensure accurate self-reporting.

To minimize measurement bias, questionnaire administration, completeness checking, and data verification were performed by an outcome assessor who remained blinded to treatment allocation throughout the study. Data were reviewed for completeness immediately after collection, and any missing responses were clarified directly with the participant before leaving the assessment session whenever possible.

Statistical Analysis

All statistical analyses were performed using IBM SPSS Statistics software (Version 27). Statistical significance was defined as a two-sided P value < 0.05 for all analyses.

Continuous variables were summarized as mean ± standard deviation (SD), whereas categorical variables were presented as frequencies and percentages. Baseline demographic and clinical characteristics were compared between the intervention and control groups to evaluate the success of randomization. Continuous variables were compared using the independent-samples t test, whereas categorical variables were analyzed using the chi-square test or Fisher's exact test when expected cell frequencies were less than five.

Prior to inferential analyses, the assumptions underlying parametric statistical methods were evaluated. Normality of continuous outcome variables was assessed using the Shapiro–Wilk test together with visual inspection of histograms and Q–Q plots. Homogeneity of variances between study groups was evaluated using Levene's test. For analyses of covariance (ANCOVA), the assumptions of linearity between covariates and outcomes, homogeneity of regression slopes, independence of observations, and homoscedasticity of residuals were examined before model estimation.

The primary efficacy analysis evaluated post-intervention anxiety scores using analysis of covariance (ANCOVA), with treatment group entered as the fixed factor and baseline anxiety score included as a covariate. This approach was selected to improve statistical precision and to account for any baseline differences between groups.

Secondary analyses were performed using separate ANCOVA models to compare post-intervention total aggression scores and each aggression subscale (physical aggression, verbal aggression, anger, and hostility) between the intervention and sham-control groups while adjusting for their corresponding baseline values.

Adjusted mean differences between groups, together with their corresponding 95% confidence intervals, were estimated for all primary and secondary outcomes. In addition to statistical significance, effect sizes were calculated and reported to facilitate interpretation of the clinical relevance of the intervention effects.

All analyses were conducted according to the randomized group allocation. Participants with complete pre- and post-intervention assessments were included in the final efficacy analyses. Missing data were examined prior to analysis, and the completeness of the dataset was verified before statistical modeling.

The statistical analysis plan was finalized before analysis of the outcome data and was applied consistently across all predefined study outcomes.

Results

Participant Characteristics

Thirty men with opioid use disorder completed the study, with 15 participants allocated to the alpha-band binaural beat group and 15 to the sham-control group. No participants withdrew during the intervention period; therefore, all randomized participants were included in the final analyses.

The mean age of participants was 24.13 ± 2.19 years in the intervention group and 23.60 ± 1.40 years in the control group. Baseline age did not differ significantly between groups ($t = 0.79$, $P = 0.205$). All participants met the clinical diagnostic criteria for opioid use disorder and had a previous history of admission to a rehabilitation program. Consequently, sex, diagnosis, and treatment history were comparable across the study groups.

Assumption Testing

Prior to the primary analyses, the assumptions required for analysis of covariance were evaluated.

Levene's test demonstrated no significant differences in variance between the intervention and control groups for either anxiety ($F = 0.663$, $P = 0.422$) or aggression ($F = 0.921$, $P = 0.345$), indicating that the assumption of homogeneity of variances was satisfied (Table 1).

Similarly, no significant interactions were observed between treatment group and baseline scores for anxiety or any aggression outcome (all $P > 0.05$), confirming the assumption of homogeneity of regression slopes and supporting the application of ANCOVA and MANCOVA (Table 2).

Primary Outcome: Anxiety

At baseline, anxiety scores did not differ significantly between the intervention and control groups (Table 3). Following completion of the intervention, participants receiving alpha-band binaural beat stimulation demonstrated a marked reduction in anxiety scores, whereas anxiety levels remained largely unchanged in the sham-control group.

After adjustment for baseline anxiety scores, ANCOVA demonstrated a statistically significant effect of treatment allocation on post-intervention anxiety ($F = 80.09$, $P < 0.001$, partial $\eta^2 = 0.748$), indicating a large treatment effect (Table 4). Baseline anxiety scores were also significant predictors of post-intervention anxiety ($F = 95.79$, $P < 0.001$, partial $\eta^2 = 0.780$).

Secondary Outcome: Overall Aggression

No statistically significant between-group differences in overall aggression were observed at baseline (Table 3). After the intervention, participants allocated to the binaural beat group exhibited substantially lower aggression scores than those receiving sham stimulation.

ANCOVA revealed a significant treatment effect for overall aggression after adjustment for baseline values ($F = 118.05$, $P < 0.001$, partial $\eta^2 = 0.814$), representing a very large effect size (Table 4). Baseline aggression scores remained a significant covariate ($F = 144.43$, $P < 0.001$, partial $\eta^2 = 0.843$).

The temporal changes in anxiety and aggression scores across both study groups are illustrated in Fig. 1.

Secondary Outcome: Aggression Subscales

Descriptive analyses demonstrated consistent reductions across all aggression domains among participants receiving alpha-band binaural beat stimulation, whereas scores remained relatively unchanged in the sham-control group (Table 5).

After adjustment for baseline values, MANCOVA demonstrated statistically significant intervention effects across all aggression subscales (Table 6). Specifically, significant between-group differences were observed for physical aggression ($F = 53.94$, $P < 0.001$, partial $\eta^2 = 0.692$), verbal aggression ($F = 34.21$, $P < 0.001$, partial $\eta^2 = 0.588$), anger ($F = 18.99$, $P < 0.001$, partial $\eta^2 = 0.442$), and hostility ($F = 26.08$, $P < 0.001$, partial $\eta^2 = 0.521$).

Among the four dimensions, the largest intervention effect was observed for physical aggression, followed by verbal aggression, hostility, and anger. Baseline values remained significant predictors for all subscales (all $P < 0.001$).

Changes in aggression subscale scores before and after the intervention are presented graphically in Fig. 2.

Table 1
Results of Homogeneity of Variances (Levene's Test)

Variables	F statistics	P
Anxiety	0.663	0.422
Aggression	0.921	0.345

Table 2
Results of Homogeneity of Regression Slopes

Source	Dependent Variable	F	P
Group*Pretest of variable	Anxiety	2.690	0.106
	Aggression	0.103	0.751
	Physical	0.201	0.658
	Verbal	1.353	0.255
	Anger	1.923	0.203
	Hostility	1.335	0.258

Table 3
Results of Descriptive Statistics for main variables

Variable		Groups		Independent t-test
		Experiment	Control	
Mean ± Std.Dev	Mean ± Std.Dev			
Anxiety	Pre test	29.06 ± 11.78	23.66 ± 10.98	1.298(0.205)
	Post test	12.00 ± 6.15	22.93 ± 11.46	-3.254(0.004)
Paired t-test		8.87(0.001)	1.62(0.127)	
Aggression	Pre test	107.06 ± 17.01	100.33 ± 19.96	0.994(0.329)
	Post test	79.53 ± 13.79	98.60 ± 15.52	-3.555(0.001)
Paired t-test		12.51(0.001)	0.982(0.343)	

Table 4
Results of ANCOVA for Anxiety and Aggression

Variable	Source	F	Sig	η^2	Power
Anxiety	Group	80.09	0.001	0.748	1
	Pre	95.79	0.001	0.780	1
Aggression	Group	118.05	0.001	0.814	1
	Pre	144.43	0.001	0.843	1

Table 5
Results of Descriptive Statistics for subscales of Aggression

Variable	Groups			
	Experiment		Control	
	Pre test	Post test	Pre test	Post test
Physical	31.93 ± 6.88	23.86 ± 5.26	30.73 ± 7.42	31.53 ± 5.47
Verbal	18.06 ± 3.30	14.86 ± 3.96	17.33 ± 3.57	17.53 ± 3.44
Anger	27.93 ± 3.78	18.93 ± 3.21	25.40 ± 6.09	22.46 ± 5.57
Hostility	29.13 ± 6.67	21.86 ± 6.71	26.86 ± 7.31	27.06 ± 5.45
Mean ± Std.Dev				

Table 6
Results of MANCOVA for subscales of Aggression

Subscales of Aggression	Source	F	Sig	η^2	Power
Physical	Group	53.94	0.001	0.692	1
	Pre	50.05	0.001	0.676	1
Verbal	Group	34.21	0.001	0.588	1
	Pre	51.63	0.001	0.683	1
Anger	Group	18.99	0.001	0.442	0.987
	Pre	20.172	0.001	0.457	0.990
Hostility	Group	26.08	0.001	0.521	0.998
	Pre	16.92	0.001	0.414	0.976

Discussion

Principal Findings

This randomized sham-controlled trial evaluated the effects of alpha-band binaural beat entrainment on anxiety and aggression among men undergoing residential treatment for opioid use disorder. After controlling for baseline scores, participants receiving alpha-band binaural beat stimulation demonstrated significantly greater reductions in anxiety and overall aggression than those receiving sham auditory stimulation. Significant improvements were also observed across all four dimensions of aggression, including physical aggression, verbal aggression, anger, and hostility. The magnitude of these effects was consistently large, suggesting that frequency-specific auditory entrainment may provide clinically meaningful improvements in emotional regulation during addiction rehabilitation.

Comparison with Previous Studies

The findings of the present study are broadly consistent with an expanding body of evidence suggesting that binaural beat stimulation can improve psychological functioning by modulating neural oscillatory activity and promoting adaptive emotional regulation [9, 17, 25, 26]. The significant reductions observed in anxiety following alpha-band binaural beat stimulation are in agreement with previous investigations reporting anxiolytic effects of frequency-specific auditory entrainment in both clinical and non-clinical populations [15, 18, 19, 25]. In particular, studies employing alpha- and theta-frequency stimulation have demonstrated improvements in perceived stress, autonomic regulation, and anxiety symptoms, supporting the hypothesis that auditory entrainment may facilitate a shift toward a more relaxed neurophysiological state [27, 28, 29, 16].

Our findings are also consistent with recent reports indicating that alpha-frequency stimulation may influence autonomic nervous system activity by enhancing parasympathetic predominance and reducing sympathetic arousal [16]. Because anxiety is characterized by heightened physiological activation and impaired emotional regulation, modulation of cortical alpha oscillations may contribute to restoring neural homeostasis, thereby reducing both subjective

anxiety and physiological stress responses [7, 8, 16, 30]. This mechanism provides a biologically plausible explanation for the substantial reduction in anxiety observed among participants receiving binaural beat stimulation [16].

With respect to aggression, the present study extends the existing literature by demonstrating significant improvements not only in overall aggression but also across all four aggression domains, including physical aggression, verbal aggression, anger, and hostility. Previous research examining binaural beat interventions has primarily focused on anxiety, stress reduction, cognitive performance, sleep quality, or pain perception, whereas aggression has received considerably less attention [9, 17, 4, 25, 31]. Consequently, the present findings contribute novel evidence suggesting that alpha-band auditory entrainment may influence broader aspects of emotional and behavioral regulation beyond anxiety alone [20, 32].

Nevertheless, the literature evaluating binaural beat interventions remains heterogeneous. While several studies have reported significant psychological benefits following alpha- or theta-frequency stimulation, others have found minimal or no therapeutic effects [18, 9, 25]. These inconsistencies are likely attributable to substantial methodological differences across studies rather than an absence of biological efficacy. Important sources of heterogeneity include variation in stimulation frequency, carrier frequencies, session duration, intervention intensity, total treatment exposure, participant characteristics, outcome measures, and study design [9, 25]. Furthermore, many previous investigations have been conducted in healthy volunteers or university students, whereas relatively few studies have evaluated individuals with clinically diagnosed substance use disorders [16, 15, 33]. Therefore, direct comparisons between studies should be interpreted with caution.

The present study addresses several of these methodological limitations by employing a randomized sham-controlled design, standardized intervention procedures, blinded outcome assessment, and validated psychometric instruments. The inclusion of individuals with opioid use disorder undergoing residential rehabilitation also increases the clinical relevance of the findings, as psychological symptoms such as anxiety, irritability, and aggression are highly prevalent during addiction treatment and are closely associated with treatment adherence, relapse risk, and psychosocial functioning [8, 13, 20, 34].

An additional contribution of the present study is its comprehensive evaluation of aggression. Rather than examining aggression as a single construct, individual dimensions of aggressive behavior were analyzed separately. The observation that significant improvements occurred across

physical aggression, verbal aggression, anger, and hostility suggests that alpha-band binaural beat stimulation may exert broad regulatory effects on multiple components of emotional dysregulation. This multidimensional pattern of improvement strengthens the overall consistency of the findings and supports the hypothesis that auditory neuromodulation may influence common

neuropsychological processes underlying both anxiety and aggressive behavior

[10, 11, 12, 20].

Taken together, the present findings strengthen the growing evidence supporting frequency-specific auditory neuromodulation as a promising complementary intervention for individuals with opioid use disorder. Although larger multicenter randomized trials are still required, the consistency of the observed improvements across multiple psychological outcomes suggests that

alpha-band binaural beat stimulation may represent a valuable adjunct to conventional addiction treatment rather than a replacement for established pharmacological and psychosocial therapies [5, 14].

Possible Neurobiological Mechanisms

Although the present study was not designed to investigate the neurophysiological mechanisms underlying the observed behavioral improvements directly, several biologically plausible pathways may

explain the beneficial effects of alpha-band binaural beat stimulation on anxiety and aggression in individuals with opioid use disorder.

One of the most widely accepted explanations is the brainwave entrainment hypothesis, which proposes that exposure to binaural beats promotes synchronization of endogenous cortical oscillations with externally presented auditory frequencies [35, 16]. In the present study, alpha-frequency stimulation was selected because alpha oscillations are closely associated with wakeful relaxation, attentional regulation, emotional stability, and inhibitory cortical processing [36, 37, 38]. Enhancement of alpha activity may therefore facilitate a transition from a hyperaroused neurophysiological state toward a more regulated pattern of cortical activity, thereby reducing anxiety-related symptoms [36, 32, 30].

Another potential mechanism involves modulation of the autonomic nervous system. Individuals with opioid use disorder frequently exhibit chronic sympathetic hyperactivity, impaired parasympathetic regulation, and heightened physiological responses to stress. Previous investigations have suggested that alpha-band auditory stimulation may increase parasympathetic activity while simultaneously reducing sympathetic activation, resulting in improved autonomic

balance [16, 27]. Restoration of autonomic homeostasis may attenuate physiological manifestations of anxiety, decrease emotional reactivity, and improve resilience to stress-related triggers that commonly occur during addiction recovery.

The observed reductions in aggression may also reflect improvements in emotion regulation and executive control. Aggressive behavior in individuals with substance use disorders is often associated with impaired inhibitory control, increased impulsivity, and dysfunction within prefrontal–limbic neural circuits [10, 20, 39, 40]. Enhanced alpha synchronization has been proposed to improve communication between cortical regions involved in cognitive control[35, 37] while reducing excessive activation of limbic structures responsible for threat perception and emotional reactivity[16, 40]. Consequently, participants may have become more capable of regulating impulsive emotional responses and responding to stressful situationswith greater behavioral control.

An additional explanation relates to the close interaction between anxiety and aggression. These psychological constructs share several overlapping neurobiological substrates, including dysregulation of stress-responsive neural networks, altered autonomic function, and impaired executive functioning [8, 20]. Anxiety frequently amplifies irritability, emotional instability, and aggressive reactions, particularly among individuals experiencing opioid withdrawal or early recovery. Therefore, the substantial reduction in anxiety observed in the intervention group may have contributed indirectly to the parallel reductions observed across all dimensions of aggression. Rather than representing two independent treatment effects, the improvements in anxiety and aggression may reflect coordinated modulation of shared neurobehavioral

pathways [20, 41].

It is also conceivable that repeated exposure to alpha-band binaural beat stimulation induced cumulative neuroplastic adaptations over the intervention period. Repeated neural entrainment has been hypothesized to strengthen functional connectivity within large-scale brain networks involved in attentional control, emotional regulation, and self-monitoring [16]. Although the present study did not include neurophysiological measurements such as electroencephalography or functional neuroimaging, the consistency and magnitude of the observed behavioral improvements are compatible with this hypothesis and warrant further investigation.

Taken together, these mechanisms suggest that alpha-band binaural beat stimulation may influence multiple interconnected neurobiological systems rather than acting through a single pathway. Future randomized trials incorporating objective neurophysiological biomarkers—including electroencephalography, heart rate variability, functional magnetic resonance imaging, and autonomic indices—will be essential for clarifying the neural mechanisms underlying the psychological benefits observed in individuals with opioid use disorder.

Clinical Implications

The present findings have several important clinical implications for the management of individuals with opioid use disorder. Although pharmacological treatments such as methadone and buprenorphine remain the cornerstone of opioid dependence management, psychological symptoms including anxiety, irritability, emotional dysregulation, and aggressive behavior frequently persist despite successful detoxification and maintenance therapy[8. 20, 5, 34]. These unresolved symptoms are recognized contributors to poor treatment adherence, interpersonal conflict, premature treatment discontinuation, and increased risk of relapse [20, 34].

The substantial reductions observed in anxiety and aggression following alpha-band binaural beat stimulation suggest that this intervention may represent a valuable adjunct to existing rehabilitation programs. Because binaural beat stimulation is non-invasive, inexpensive, easy to administer, and

generally well tolerated, it could be incorporated into routine psychosocial treatment without imposing substantial additional demands on clinical resources [9, 25, 42]. Importantly, the intervention requires minimal specialized equipment, can be delivered within outpatient or residential treatment settings, and does not interfere with standard pharmacological therapies[43].

The multidimensional improvements observed across all domains of aggression are of particular clinical relevance. Aggressive behavior among individuals with opioid use disorder not only compromises therapeutic engagement but also increases the likelihood of conflict with healthcare providers, family members, and other patients within rehabilitation facilities [12, 13, 44]. Interventions capable of reducing hostility, anger, and impulsive aggressive behavior may therefore contribute to a safer therapeutic environment while simultaneously improving treatment participation and retention[44, 34].

The marked reduction in anxiety also has important implications for relapse prevention. Anxiety is one of the strongest psychological triggers for craving and substance reuse during early recovery[45, 46].

Consequently, interventions that improve emotional regulation may indirectly strengthen recovery processes by reducing vulnerability to stress-related relapse [47]. Although relapse outcomes were not evaluated in the present study, the observed psychological improvements provide a strong rationale for investigating whether alpha-band binaural beat stimulation can enhance long-term recovery when integrated with comprehensive addiction treatment programs.

From a broader public health perspective, binaural beat stimulation may represent a scalable supportive intervention for addiction services, particularly in resource-limited settings where access to specialized psychological therapies is constrained. Because the intervention is relatively

simple to implement and requires limited clinical supervision, it has the potential to complement multidisciplinary rehabilitation programs while reducing the burden placed on mental health professionals [33, 42].

Nevertheless, binaural beat stimulation should not be regarded as a replacement for evidence-based pharmacological or psychosocial interventions. Instead, the present findings support its role as a complementary therapeutic strategy within integrated addiction care [5, 14]. Future implementation studies evaluating feasibility, cost-effectiveness, patient acceptability, and long-term clinical outcomes will be essential before widespread adoption in routine clinical practice can be recommended.

Strengths and Limitations

The present study has several notable strengths that enhance the credibility and clinical relevance of its findings. First, to our knowledge, this is among the few randomized sham-controlled studies investigating the effects of alpha-band binaural beat stimulation specifically in individuals with opioid use disorder. By focusing on a clinically diagnosed population undergoing residential rehabilitation, the study extends the existing evidence beyond healthy volunteers and non-clinical samples, thereby improving the applicability of the findings to addiction treatment settings.

Second, the study employed a randomized controlled design with a sham auditory control condition, blinded outcome assessment, standardized intervention procedures, and validated psychometric instruments. These methodological features reduced the potential for selection, performance, and detection bias and strengthened the internal validity of the study. Furthermore, adjustment for baseline values using analysis of covariance increased the precision of treatment effect estimates while accounting for pre-intervention variability.

Another important strength is the comprehensive assessment of aggression. Rather than evaluating aggression as a single construct, the study examined four distinct dimensions—physical aggression, verbal aggression, anger, and hostility—thereby providing a more detailed understanding of the psychological effects of alpha-band binaural beat stimulation. The consistent improvement observed across all aggression domains supports the robustness of the intervention effect.

Despite these strengths, several limitations should be considered when interpreting the findings. First, the study included a relatively small sample recruited from a single rehabilitation center. Although statistically significant and large treatment effects were observed, the limited sample size may reduce the precision of effect estimates and restrict the generalizability of the findings to broader populations of individuals with opioid use disorder.

Second, all participants were male. Consequently, the present findings cannot be assumed to apply to women with opioid use disorder, who may differ in neurobiological responses, psychological characteristics, treatment experiences, and patterns of emotional regulation. Future studies should include more diverse populations to evaluate potential sex-related differences in treatment response.

Third, the intervention effects were evaluated only immediately after completion of the treatment protocol. The durability of the observed improvements remains unknown because no medium- or long-term follow-up assessments were performed. Future longitudinal studies are needed to determine whether the reductions in anxiety and aggression are maintained over time and whether they translate into improved treatment retention, reduced relapse, and better psychosocial functioning.

Fourth, psychological outcomes were assessed using validated self-report questionnaires. Although these instruments have demonstrated satisfactory reliability and validity, self-reported measures are inherently susceptible to recall bias, social desirability bias, and response-related measurement error. Future investigations should complement subjective assessments with clinician-rated instruments and objective neurophysiological or behavioral outcome measures.

Finally, the present study did not incorporate biological or neurophysiological biomarkers such as electroencephalography, heart rate variability, salivary cortisol, or functional neuroimaging. Consequently, although several plausible mechanisms have been proposed, the underlying neural pathways responsible for the observed clinical improvements cannot be confirmed directly. Integrating multimodal neurophysiological assessments into future randomized trials would substantially strengthen mechanistic understanding of binaural beat stimulation in opioid use disorder.

Future Research

The present findings provide a foundation for several important ditions for future investigation. First, adequately powered multicenter randomized controlled trials involving larger and more diverse populations are required to confirm the reproducibility and external validity of the observed effects. Inclusion of participants from different treatment settings, socioeconomic backgrounds, and cultural contexts would substantially enhance the generalizability of future findings.

Second, future studies should evaluate the long-term sustainability of binaural beat-induced psychological improvements. Extended follow-up assessments at 3, 6, and 12 months would help determine whether reductions in anxiety and aggression persist beyond the immediate post-intervention period and whether these improvements translate into clinically meaningful outcomes such as enhanced

treatment retention, reduced opioid craving, lower relapse rates, improved quality of life, and sustained recovery.

Third, optimization of stimulation parameters represents an important research priority. Comparative studies evaluating different stimulation frequencies (e.g., alpha, theta, beta, and gamma), carrier frequencies, session durations, treatment intensity, and cumulative exposure are needed to identify the most effective neuromodulation protocols for individuals with opioid use disorder. Dose–response investigations may further clarify the minimum effective intervention and the optimal treatment schedule.

Future research should also incorporate objective neurophysiological and biological outcome measures to elucidate the mechanisms underlying binaural beat stimulation. Simultaneous assessment of electroencephalographic activity, heart rate variability, functional magnetic resonance imaging, salivary cortisol, inflammatory biomarkers, and autonomic nervous system function would provide valuable insight into the neural and physiological processes associated with improvements in anxiety and aggression.

Another important area for investigation is the identification of treatment-response modifiers. Future randomized trials should examine whether intervention effectiveness differs according to age, sex, duration of opioid use, severity of dependence, psychiatric comorbidities, medication-assisted treatment, or baseline psychological status. Such subgroup analyses could facilitate the development of more personalized and precision-based neuromodulation strategies.

In addition, future studies should compare alpha-band binaural beat stimulation with other non-invasive interventions commonly used in addiction rehabilitation, including mindfulness-based interventions, music therapy, cognitive behavioral therapy, biofeedback, neurofeedback, transcranial direct current stimulation, and transcranial magnetic stimulation. Comparative effectiveness studies would clarify the relative clinical value of auditory neuromodulation within comprehensive addiction treatment programs.

Finally, the rapid expansion of digital health technologies provides new opportunities for translating binaural beat interventions into routine clinical practice. Future implementation studies should evaluate the feasibility, patient acceptability, adherence, cost-effectiveness, and clinical effectiveness of smartphone-based, wearable, and telehealth-delivered binaural beat platforms. Such investigations may facilitate broader dissemination of personalized digital neuromodulation as a scalable supportive intervention for individuals with opioid use disorder.

These findings support the hypothesis that alpha-band binaural beat stimulation can serve as an effective adjunctive intervention for improving psychological outcomes among individuals with opioid use disorder. Although medication-assisted treatment remains the cornerstone of opioid dependence management, persistent anxiety, irritability, emotional dysregulation, and aggressive behaviors frequently continue despite successful detoxification and maintenance therapy. The present findings suggest that targeting neural oscillatory activity through non-invasive auditory neuromodulation may complement

conventional addiction treatment by addressing psychological symptoms that are often insufficiently controlled by pharmacological approaches alone.

Importantly, the beneficial effects observed in the present study extended beyond reductions in anxiety and included consistent improvements across multiple behavioral dimensions of aggression. Because anxiety and aggression share overlapping neurobiological pathways involving stress processing, executive control, and emotional regulation, simultaneous improvements in these domains may represent an integrated therapeutic response rather than independent treatment effects. This observation highlights the potential value of frequency-specific neuromodulation as part of multidisciplinary rehabilitation programs for opioid use disorder.

Conclusion

This randomized sham-controlled trial demonstrated that alpha-band binaural beat stimulation was associated with significant reductions in anxiety and aggression among men undergoing residential treatment for opioid use disorder. After adjustment for baseline values, participants receiving alpha-band binaural beat stimulation exhibited substantially greater improvements than those receiving sham auditory stimulation, with beneficial effects consistently observed across all dimensions of aggression, including physical aggression, verbal aggression, anger, and hostility.

These findings suggest that frequency-specific auditory neuromodulation may represent a potentially useful complementary intervention for addressing psychological symptoms that commonly interfere with recovery from opioid use disorder. Given its non-invasive nature, ease of administration, low implementation cost, and compatibility with standard pharmacological and psychosocial treatments, alpha-band binaural beat stimulation has the potential to be incorporated into comprehensive addiction rehabilitation programs as an adjunctive therapeutic strategy.

Nevertheless, the findings should be interpreted in light of the study's limitations, including the relatively small sample size, inclusion of only male participants, absence of long-term follow-up, and lack of objective neurophysiological outcome measures. Accordingly, the present results should be considered preliminary until confirmed by larger multicenter randomized controlled trials with extended follow-up and mechanistic assessments.

Overall, this study contributes novel clinical evidence supporting the potential role of alpha-band binaural beat stimulation in improving anxiety- and aggression-related outcomes among individuals with opioid use disorder. By demonstrating concurrent reductions in anxiety and multiple dimensions of aggression within a randomized sham-controlled design, the study expands the emerging evidence base for non-invasive auditory neuromodulation and provides a foundation for future translational research aimed at integrating neuroscience-informed complementary interventions into addiction treatment.

Abbreviations

OUD
Opioid Use Disorder
BAI
Beck Anxiety Inventory
BPAQ
Buss–Perry Aggression Questionnaire.

Declarations

Ethics approval and consent to participate

The study protocol was reviewed and approved by the Research Ethics Committee of Islamic Azad University, Tabriz, Iran (Ethics Committee reference number: IR.IAU.TABRIZ.REC.1404.135). All study procedures were conducted in accordance with relevant ethical standards. Written informed consent was obtained from all participants before their participation in the study.

Consent for publication

All authors consent to the publication of this article in this journal.

Competing Interests

The authors declare no competing interests.

Use of AI-assisted technologies

During the preparation of this manuscript, the authors used ChatGPT (OpenAI) solely for language editing, including correction of grammar, spelling, and English-language phrasing. The authors reviewed and edited the content as necessary and take full responsibility for the content of the manuscript.

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Author Contribution

D.S. conceived and designed the study, collected and analyzed the data, performed the statistical analyses, and wrote the manuscript. N.M. supervised the study and contributed to the interpretation of the findings and critical revision of the manuscript. Both authors reviewed and approved the final manuscript.

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Data Availability

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Figures

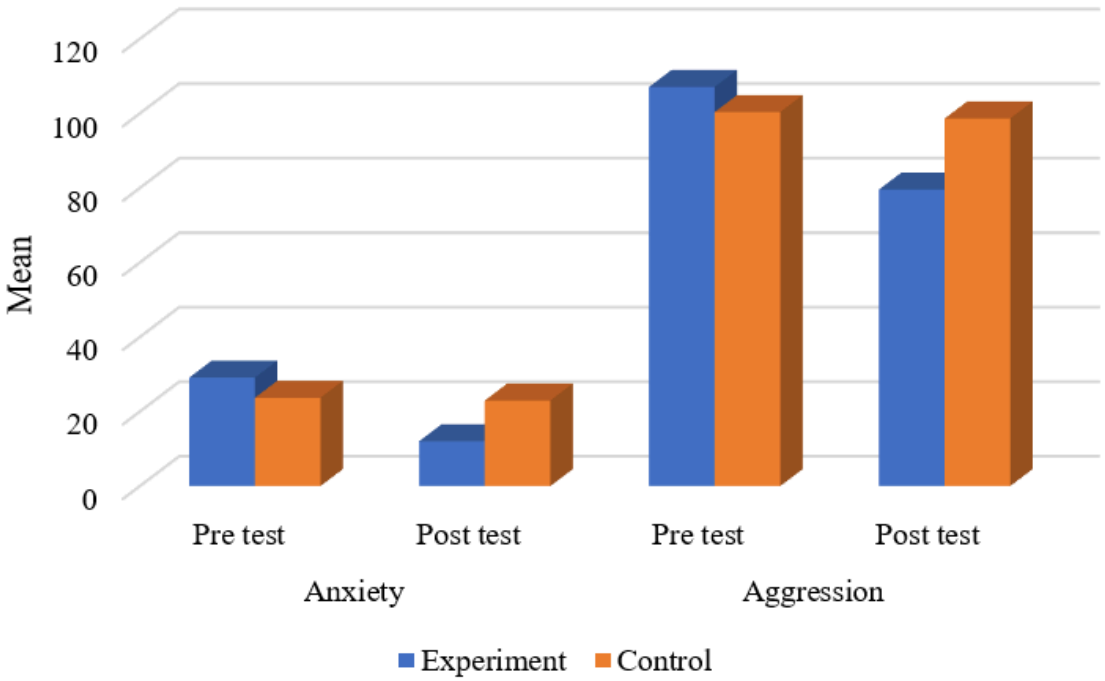


Figure 1

Comparison between Pre-test and Post-test for anxiety and aggression in experimental and control groups

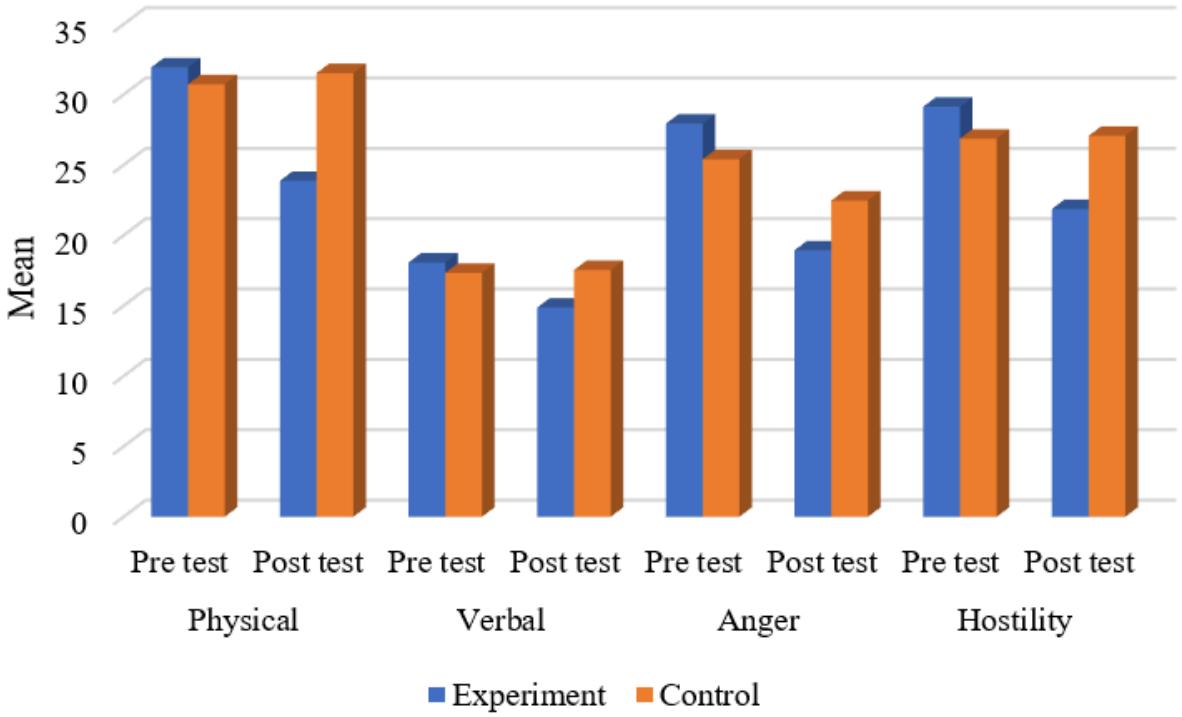


Figure 2

Comparison between Pre-test and Post-test for Subscales of aggression in experimental and control groups

Supplementary Files

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