

Effectiveness of Neurofeedback Therapy on Emotional Processing, Irrational Beliefs, and Aggression in Female Patients with Generalized Anxiety Disorder

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ABSTRACT

Objective: The present research aimed to examine the effectiveness of neurofeedback therapy on emotional processing, irrational beliefs, and aggression in patients with generalized anxiety disorder.

Method: This study was a quasi-experimental pre-test, post-test, and follow-up design with a control group. The research population comprised all women with generalized anxiety disorder visiting psychiatric treatment centers in Golpayegan in the first half of 2019, from which 30 female patients were purposefully selected based on inclusion criteria and randomly assigned to either the experimental or control groups. The experimental group received eight 30-minute sessions of neurofeedback therapy. Meanwhile, the control group did not receive this intervention during the research process. The questionnaires used in this research included the Spitzer Generalized Anxiety Scale (2006), the Baker Emotional Processing Scale (2007), the Jones Irrational Beliefs Questionnaire (1968), and the Buss and Perry Aggression Questionnaire (1992). Data were analyzed using repeated measures analysis of variance with SPSS-24 software.

Findings: The results of the data analysis indicated that neurofeedback therapy significantly affected emotional processing ($F=10.89$, $P<0.001$), irrational beliefs ($F=10.83$, $P<0.001$), and aggression ($F=8.16$, $P<0.008$).

Conclusion: Given the confirmed effectiveness of neurofeedback therapy on emotional processing, irrational beliefs, and aggression in patients with generalized anxiety disorder, it is recommended that workshops be organized to familiarize counselors and therapists more thoroughly with the principles and techniques of this treatment in the field of this disorder.

Keywords: Emotional processing, neurofeedback therapy, irrational beliefs, aggression.

1. Introduction

Generalized anxiety disorder (GAD), particularly prevalent in the United States, is among the most common mental health issues, associated with significant functional impairments and substantial healthcare costs. GAD is a chronic, pervasive condition that is often disabling, misunderstood, misdiagnosed, and unsuccessfully treated (American Psychiatric Association, 2022). Its main characteristic is excessive, chronic, and uncontrollable worry. In Iran, the one-year prevalence rate among the population aged 18-65 is reported to be 2.5% (Khodayarifard et al., 2017). The one-year prevalence in other countries ranges from 0.4% to 3.6%, with a lifetime risk of 9%. GAD occurs twice as often in women as in men, peaks in mid-life, and decreases in later years (American Psychiatric Association, 2022).

Multiple biological, cognitive, behavioral, emotional, interpersonal, and neurobiological factors contribute to the development of GAD. Research literature indicates that factors such as temperament, behavioral inhibition, negative affect, harm avoidance, negative life events, parental psychiatric problems, maltreatment, and biases in emotional information processing are significant risk factors (MacNamara et al., 2019). Emotional processing is considered a fundamental element in the clinical literature on anxiety disorders (MacNamara et al., 2016). Emotional processing is a process by which emotional disturbances are absorbed and reduced to a level that allows other experiences and behaviors to occur without disturbance (Mehrinejad et al., 2016). Vulnerable individuals tend to select, store, and recall disorder-specific information more frequently, leading to a cognitive bias that enhances negative mood states and further biases toward emotional information, such as remembering more threat-related incidents, perpetuating and intensifying anxiety (Panasiti et al., 2020; Pascual-Leone & Greenberg, 2007). Emotional processing is categorized into three levels: recognition and experience, control and expression, and inadequate processing, each of which can be impaired (Rude et al., 2002; Steward et al., 2016; Zakeri et al., 2017). In this context, Mehrinejad et al. (2016) demonstrated that individuals with GAD are more likely to use dysfunctional emotional processing styles such as rumination, suppression, lack of control, and splitting compared to non-affected individuals (Mehrinejad et al., 2016).

Irrational beliefs, viewed as rigid, extreme, and unreasonable, play a significant role in the onset and

persistence of anxiety disorders due to negative cognitive assessments (Vassou et al., 2021). These beliefs are complex schemas and structures that reflect an individual's structured concepts based on reality and behavioral responses to that reality. According to Albert Ellis, human behavior and emotions stem from an individual's beliefs, convictions, and mindset. Anxiety, depression, sadness, anger, and fear all originate from an individual's mindset and beliefs about the world and others, termed irrational beliefs by Ellis. These beliefs represent desires and goals that become mandatory preferences such that if unmet, they lead to anxiety and disturbance. Irrational beliefs, based on suspicion and assumption, often conflict with reality and hinder successful interaction with life's demands and events (Ellis et al., 2009). Studies have shown that irrational beliefs play a significant role in anxiety manifestation, reduced social performance, depression, anger, guilt, emotional instability, social and emotional adjustment, and mental health (Vassou et al., 2021).

Aggression is another variable closely related to anxiety disorders and is defined as any form of behavior that can harm others; aggression can be physical, verbal, and indirect (Buss & Perry, 1992). Individuals with GAD often fail to satisfy their needs and desires due to dependency and fearfulness, and when they face obstacles in achieving their goals, they exhibit aggressive behavior (Alijani et al., 2015; Elsaesser et al., 2017; Faani et al., 2021; Jahangasht Aghkand et al., 2021). When individuals with GAD feel negatively evaluated by others, they shift their attention to self-review and observation, increasing access to negative feelings and thoughts, which, in turn, increases aggression (Deschênes et al., 2012; Kosson, 2018; Meeus et al., 2016).

Another significant therapeutic approach for improving anxiety disorders is neurofeedback (Aghaziarati et al., 2023; Dinarvand et al., 2020). Neurophysiological research examining the relationship between electroencephalography, underlying thalamocortical brain mechanisms, and psychological states has shown that creating optimal oscillations and changes in brain wave rhythm and frequency through neurotherapeutic methods can induce optimal changes in psychological states, particularly in patients with anxiety disorders (Abdian et al., 2021; Banerjee & Argáez, 2017; Dinarvand et al., 2020; Ghayour-Kazemi et al., 2015; Gholizadeh & Abdollahi, 2017; Hosseini et al., 2022; Naeinian et al., 2009). Neurofeedback training is a non-invasive and pain-free method that involves attaching sensors to the patient's head. Neurofeedback essentially involves conditioning the brain's

electrical activity, where desirable brain activity is rewarded, and undesirable activity is inhibited. This feedback provides individuals with clear and direct feedback from their physiological systems, aiding in the control of these systems' functions (Hosseini et al., 2022; Naeinian et al., 2009). Targeting frontal lobe waves and enhancing hemispheric symmetry, considering the relationship between alpha and beta waves in the right and left frontal lobes, neurofeedback is effective in reducing anxiety (Dinarvand et al., 2020). Banerjee & Argis (2018) demonstrated the effectiveness of neurofeedback training in reducing symptoms of mood and anxiety disorders (Banerjee & Argáez, 2017). Similarly, Hosseini et al. (2015) showed significant effectiveness of neurofeedback training in reducing symptoms and signs in military personnel with GAD (Hosseini et al., 2022).

Generalized anxiety disorder is one of the most common anxiety disorders. If not correctly diagnosed and treated, it can have severe negative consequences, increasing individual problems and healthcare and treatment costs. Given the importance of intervening and treating GAD, the high effectiveness of modern treatments in managing mental disorders, and the noted research gap, this study aims to examine the effectiveness of neurofeedback therapy on emotional processing, irrational beliefs, and aggression in female patients with GAD. This research seeks to answer the following questions:

Is neurofeedback therapy effective on emotional processing, irrational beliefs, and aggression in female patients with GAD in the post-test phase?

Is the effect of neurofeedback therapy on emotional processing, irrational beliefs, and aggression in female patients with GAD sustained in the follow-up phase?

2. Methods

2.1. Study design and Participant

The research method used was a quasi-experimental design with pre-test, post-test, and follow-up with a control group. The research population consisted of all women with generalized anxiety disorder who visited daily psychiatric treatment centers in Golpayegan during the first half of 2019. For the selection of the sample size, a purposive non-random sampling method was employed. For this purpose, after visiting the daily psychiatric treatment centers in Golpayegan and reviewing the files of patients with generalized anxiety disorder based on inclusion and exclusion criteria, 30 individuals were selected and randomly assigned to experimental (15 participants) and

control (15 participants) groups. The inclusion criteria were being over the age of 18, having at least a high school diploma, a confirmed diagnosis of generalized anxiety disorder by a psychiatric specialist, awareness of the research objectives, and consent to participate in the study. The exclusion criteria included relapse of the disorder, hospitalization during the intervention, any physical illness that prevented participation in therapy sessions, absence in more than three therapy sessions, failure to perform designated tasks during the training course, and the occurrence of unforeseen events.

Following the acquisition of necessary permissions from the Islamic Azad University, Zarrin-dasht Branch, and coordination with daily psychiatric centers in Golpayegan city, essential information regarding the execution and significance of this research was provided to the clinic officials. Subsequently, after identifying individuals meeting the criteria for participation (age over 18, minimum diploma education, definitive diagnosis of the disorder by a psychiatric specialist, awareness of the research objectives, and consent to participate), they were invited to cooperate, and they received detailed explanations regarding the sessions and other relevant matters. Then, 30 individuals were randomly selected and assigned to two groups: experimental and control. Both groups underwent pre-tests. Neurofeedback therapy was administered over eight sessions for the experimental group, while the control group received no intervention. The control group was closely monitored parallel to the experimental group; the selection and assessment of participants, questionnaire administration, were conducted similarly to the experimental group, except for the therapeutic intervention, which was only provided to the experimental group. Post-tests were conducted for both groups upon completion of the sessions.

To adhere to ethical considerations, all participants received information about the research and could withdraw from the study at any time. Assurance was given that all data would remain confidential and be used solely for research purposes. To maintain privacy, participants' identities were not recorded.

2.2. Measures

2.2.1. Generalized Anxiety

This scale was developed by Spitzer in 2006 to assess the symptoms of generalized anxiety disorder over the past two weeks. It contains 7 items and is scored on a four-point Likert scale (not at all=0, several days=1, more than half the

days=2, nearly every day=3). The total anxiety score is derived from the sum of the seven main questions, ranging from 0 to 21. The Cronbach's alpha coefficient of the scale was reported as 0.92, indicating excellent internal consistency in an external sample, and a test-retest reliability coefficient of 0.83 was obtained after two weeks, indicating good reliability of the scale. The convergent validity was established by correlating it with Beck's Anxiety Inventory and the anxiety subscale of the Clinical Symptom Checklist, reported as 0.72 and 0.74, respectively. Research by Naeinian and colleagues showed that the scale has an appropriate Cronbach's alpha and the reliability coefficient of the scale was also evaluated based on two test runs (Naeinian et al., 2009).

2.2.2. Emotional Processing

This scale was created by Baker et al. in 2007 and consists of 25 questions. It is rated on a five-point Likert scale (1 = not at all to 5 = extremely), with a score range from 25 to 125. The scale has five components: suppression, lack of emotion regulation, lack of emotional experience, signs of unprocessed emotion, and avoidance. Construct and content validity were confirmed by the creators, and the reliability using Cronbach's alpha method for suppression was 0.81, lack of emotion regulation 0.87, lack of emotional experience 0.84, signs of unprocessed emotion 0.80, avoidance 0.78, and the overall scale 0.89 (Baker, Thomas, 2007). In Bakhtiyarpour's research, construct and content validity were confirmed, and the reliability using Cronbach's alpha for suppression was 0.80, lack of emotion regulation 0.81, lack of emotional experience 0.78, signs of unprocessed emotion 0.75, avoidance 0.74, and the overall scale 0.83 (Mehrinejad et al., 2016; Pascual-Leone & Greenberg, 2007).

2.2.3. Irrational Beliefs

This questionnaire was developed by Jones in 1968 to measure irrational beliefs. It includes 100 statements and is constructed from 10 subscales that are rated on a five-point scale. A lower score indicates more rational thinking. Scores range from 1 to 5. At the end, the individual's scores in each subscale are summed to obtain the total score. Jones reported a reliability of 0.92 for this questionnaire, and the reliability of each of the ten scales ranged from 0.66 to 0.88 (Jones, 1968). In the research by Barghi Irani and Dehghan Saber (2021), concurrent validity of the questionnaire with overt anxiety ($r=0.64$) and covert anxiety ($r=0.61$) was obtained,

indicating the concurrent validity of this questionnaire. Additionally, the reliability of the questionnaire using Cronbach's alpha for the need for approval was 0.72, high expectations of oneself 0.76, tendency to blame 0.70, reaction to failure 0.68, emotional irresponsibility 0.74, excessive worry accompanied by anxiety 0.78, avoidance of problems 0.68, dependency 0.74, helplessness regarding change 0.74, perfectionism 0.76, and for the entire scale 0.74 (Asmand et al., 2014).

2.2.4. Aggression

This questionnaire was developed by Buss and Perry (1992) and consists of 29 questions assessing four factors: verbal aggression, physical aggression, anger, and hostility. Scoring is based on a Likert scale from 1 (completely unlike me) to 5 (exactly like me). The total score is the sum of all questions, ranging from 29 to 145. Higher scores indicate greater aggression. In Mohammadi's research (2006), the validity of the aggression questionnaire was analyzed using three methods: Cronbach's alpha, test-retest, and split-half, which yielded coefficients of 0.89, 0.78, and 0.73, respectively. The validity of this questionnaire was also confirmed through concurrent convergent validity index and factor analysis (Alijani et al., 2015; Faani et al., 2021).

2.3. Intervention

2.3.1. Neurofeedback

In the present study, the ProComp 6 device was utilized. Sensors, referred to as electrodes, were attached to the subject's scalp. Brainwaves were amplified and then transmitted to the computer. Subsequently, the desired feedback was presented to the individual through the display screen (visual feedback) and speakers (auditory feedback). In this setup, participants, aided by an examiner and the presentation of audio-visual stimuli, could manipulate brainwaves. Prior to electrode placement, the scalp was thoroughly cleaned with alcohol and medical gel, and the electrodes were secured in the designated area with adhesive (10-20 paste).

2.4. Data Analysis

Data obtained from this study were analyzed using descriptive statistics (mean and standard deviation) and inferential statistics (repeated measures ANOVA). Before hypothesis testing, assumptions of normality, assessed through Kolmogorov-Smirnov and Shapiro-Wilk tests, and

homogeneity of variances, evaluated via Levene's test, were checked for all variables in both groups. All statistical analyses were performed using SPSS-24 software.

3. Findings and Results

The findings from the demographic data indicated that the research sample consisted of individuals aged 20 to 50, with the 20-30 year age group being the most frequent (66.7%). In terms of education level, the individuals ranged from high school diploma to Master's degree, with the majority having a Bachelor's degree (53.33%). Additionally, all participants were married. Before presenting the results of the covariance analysis, the assumptions of parametric tests were assessed. Accordingly, the results of the Kolmogorov-Smirnov test

confirmed the assumption of normal distribution for the sample data across the variables of emotional processing, irrational beliefs, and aggression in both the experimental and control groups in the pre-test and post-test stages ($p < .05$). The assumption of homogeneity of variance was also assessed using Levene's test, and the results for emotional processing ($F = 1.22$, $p = .30$), irrational beliefs ($F = 1.56$, $p = .22$), and aggression ($F = 2.4$, $p = .10$) were not significant, thus confirming the homogeneity of variances. Additionally, Box's test results indicated that the assumption of equality of covariance matrices was met ($p < .05$). Analysis of variance with repeated measures was used to investigate the impact of neurofeedback treatment on emotional processing, irrational beliefs, and aggression in patients with generalized anxiety disorder.

Table 1

Mean Results of Pre-test, Post-test, and Follow-up of Emotional Processing, Irrational Beliefs, and Aggression by Group

Variable	Stage	Experimental Group Mean	Experimental Group SD	Control Group Mean	Control Group SD
Emotional Processing	Pre-test	76.97	22.89	74.86	20.72
	Post-test	62.13	17.41	75.33	21.63
	Follow-up	60.12	16.40	75.14	21.51
Irrational Beliefs	Pre-test	216.6	75.50	223.63	77.16
	Post-test	189.66	63.24	218.25	76.14
	Follow-up	182.63	62.20	219.41	76.51
Aggression	Pre-test	86.87	21.88	87.93	23.33
	Post-test	67.85	17.85	86.66	22.28
	Follow-up	65.63	16.63	87.56	23.20

The results from Table 1 indicate a difference between the pre-test and post-test in the experimental group, but not much difference in the control group. A repeated measures

analysis of variance was used to examine the score differences between the two groups.

Table 2

Repeated Measures Analysis of Variance for Comparing Pre-test, Post-test, and Follow-up of Emotional Processing, Irrational Beliefs, and Aggression in Experimental and Control Groups

Scale	Effect Source	Sum of Squares	Degrees of Freedom	Mean Square	F	Significance	Eta Squared
Emotional Processing	Time*Group	59.267	2	29.633	12.761	.001	.313
	Group	35.267	1	35.267	10.891	.003	.280
Irrational Beliefs	Time*Group	70.067	2	35.033	4.262	.001	.132
	Group	187.267	1	187.267	10.830	.001	.402
Aggression	Time*Group	156.800	2	78.400	15.116	.001	.351
	Group	56.067	1	56.067	8.162	.008	.226

The results from Table 2 demonstrate that the F-ratios for the group factor in emotional processing, irrational beliefs, and aggression were significant ($p < .01$). This finding indicates that neurofeedback treatment was effective on emotional processing, irrational beliefs, and aggression in

female patients with generalized anxiety disorder. A repeated measures analysis of variance was conducted for the experimental group across three stages of therapeutic intervention, showing significant improvements in

emotional processing, irrational beliefs, and aggression ($p < .01$).

Table 3

Within-Group Bonferroni Post-hoc Test Results of Neurofeedback Treatment on Emotional Processing, Irrational Beliefs, and Aggression in the Experimental Group

Variable	Time	Mean Difference	Standard Error	Sig
Emotional Processing	Pre to Post	14.39	2.50	.001
	Pre to Follow-up	16.54	2.51	.001
	Post to Follow-up	2.72	2.44	.063
Irrational Beliefs	Pre to Post	27.25	2.50	.001
	Pre to Follow-up	34.15	2.63	.001
	Post to Follow-up	6.33	2.58	.076
Aggression	Pre to Post	19.54	2.51	.001
	Pre to Follow-up	21.61	1.10	.001
	Post to Follow-up	2.86	1.23	.069

Changes in the experimental group over time shown in Table 3 indicated that the components of emotional processing, irrational beliefs, and aggression were significantly different in the post-test compared to the pre-test ($p < .001$). However, no significant differences were observed in the follow-up stage compared to the pre-test and post-test.

4. Discussion and Conclusion

The present study was conducted with the aim of treating neurofeedback on emotional processing, irrational beliefs, and aggression in patients with generalized anxiety disorder. The results of the present study showed that neurofeedback treatment led to an improvement in emotional processing in patients with generalized anxiety disorder. This finding is consistent with the prior findings (Abdian et al., 2021).

In explaining this finding, it can be said that neurofeedback is a method for learning active and conscious control of different brainwave states. The pioneers of this method claim that by presenting a specific sound or image in exchange for feedback from brain neural activities, brain waves can be directed toward the desired frequency and the pattern of brain activity can be changed (Hunkin et al., 2021). Neurofeedback training changes the frontal lobe, affecting three parts of the cortex: motor, sensorimotor, and cingulate. The function of the sensorimotor cortex is more than merely directing sensory-motor functions; this part assists in encoding cognitive and physical activities to the brain cortex. Therefore, individuals who have difficulty with cognitive and emotional tasks can benefit from the effects of neurofeedback on the left sensorimotor cortex (Abdian et al.,

2021). Neurofeedback also increases beta waves in the frontal and central lobes and reduces theta waves, thus reducing symptoms of generalized anxiety disorder and improving emotional processing. Additionally, the increase in beta waves with increased alertness, focus, and metabolism can improve emotional processing (Hosseini et al., 2022).

In neurofeedback, the individual becomes aware of their abnormal brain waves and tries to modify them to receive reinforcement. The individual consciously realizes the connection between external processes and their brain waves. On an unconscious level, the brain learns how to place its waves in a specific condition. Gradually, both conscious and unconscious skills are learned and transferred to real life, affecting the individual's performance. Neurofeedback can aid proper brain function through the changes it introduces in the brain wave profile. This compensation for abnormalities helps the individual become more aware and enhance their attention, better manage their emotions, and consequently have better emotional processing (Abdian et al., 2021).

The results of the present study showed that neurofeedback treatment led to a reduction in irrational beliefs in patients with generalized anxiety disorder. This finding aligns with the findings of prior studies (Banerjee & Argáez, 2017; Gholizadeh & Abdollahi, 2017; Naeinian et al., 2009).

In explaining this finding, it can be stated that neurofeedback is a complementary and alternative method to pharmacotherapy, in which the individual with generalized anxiety disorder learns how to control bodily functions such as heart rate with the help of the mind, and

the individual is connected to electrical sensors that help them receive and measure information about their body. Additionally, biofeedback sensors teach the individual how to gradually perform subtle and skilled changes in their body, such as calming certain muscles to achieve, for example, a reduction in stress (Nori et al., 2022).

Since neurofeedback, apart from its therapeutic effect, creates a suggestion and belief in improvement in the individual, the expectation of improvement created through this treatment makes these individuals face their anxiety situations with greater strength and ability, analyze their experiences better, change their irrational beliefs, and consequently have a greater reduction in avoidance and, consequently, a reduction in anxiety symptoms. Neurofeedback is a method for learning active and conscious control of different brainwave states. The pioneers of this method claim that by presenting a specific sound or image in exchange for feedback from brain neural activities, brain waves can be directed toward the desired frequency and the pattern of brain activity can be changed, encouraging the individual to change irrational beliefs and increase logical beliefs. Indeed, neurofeedback through operant conditioning causes a simultaneous increase in the sensory-motor rhythm or beta waves in specific brain areas that do not have a good frequency, therefore, regulating brain waves through neurofeedback reduces anxiety symptoms in patients (Gholizadeh & Abdollahi, 2017).

The results of the present study showed that neurofeedback treatment led to a reduction in aggression in patients with generalized anxiety disorder. This finding is consistent with the findings of prior studies (Ghayour-Kazemi et al., 2015).

In explaining this finding, it can be said that neurofeedback refers to a method in which neural information about brain function is fed back to the central nervous system of individuals, and an effort is made for them to learn how to correct their brain function. The logic of this therapeutic method is based on operant conditioning. Normally, we are unable to control and change our brain waves because we are not aware of these waves. In neurofeedback therapy, this awareness is created through very rapid feedback (milliseconds after occurrence) to the individual. As this training continues, the brain learns how to produce more of the waves that lead to better performance. Which waves increase and which decrease in the brain (Viviani & Vallesi, 2021).

In neurofeedback treatment, brainwave activities (including alpha, beta, theta, and delta), which are

unconscious and involuntary processes, become perceptible to the patient, and the patient is able to detect waves that are outside the normal form with higher and lower frequencies or greater or lesser intensity, and control them during sessions, normalizing them, thus enabling the reduction of slow wave activity and the increase of fast wave activity. Neurofeedback training, aimed at reducing theta and increasing beta sensory-motor rhythm (central brain area), is an effort to achieve an appropriate level of self-initiated arousal through self-regulation of brain waves. In fact, therapeutic protocols aimed at increasing sensory-motor sensitivity increase the likelihood of future activity of postsynaptic cells. With an increased excitation threshold, we can witness a reduction in cortical and thalamocortical hyperexcitability, and consequently a reduction in aggression in patients with generalized anxiety disorder (Viviani & Vallesi, 2021). In summary, it can be said that neurofeedback through continuous feedback for producing and regulating brain waves, increasing beta wave activity and its activity in the frontal lobe, and reducing slow wave activity like theta, reduces problematic symptoms such as aggression and anxiety (Viviani & Vallesi, 2021).

5. Suggestions and Limitations

Like other studies, the present research faced limitations. The sample was selected only from individuals with generalized anxiety disorder attending daily psychiatric treatment centers in the city of Golpayegan, and this poses a caution in generalizing the results. In line with the limitations of this research, it is suggested that follow-up studies be conducted to examine the long-term effects of neurofeedback treatment and that research be conducted in a larger sample of individuals with generalized anxiety disorder to ensure greater generalizability. Given the confirmed efficacy of neurofeedback treatment on emotional processing, irrational beliefs, and aggression in patients with generalized anxiety disorder, it is suggested that training workshops be held to further acquaint counselors and therapists working in this field with the principles and techniques of this training.

Authors' Contributions

All authors have contributed significantly to the research process and the development of the manuscript.

Declaration

In order to correct and improve the academic writing of our paper, we have used the language model ChatGPT.

Transparency Statement

Data are available for research purposes upon reasonable request to the corresponding author.

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Declaration of Interest

The authors report no conflict of interest.

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Ethical Considerations

The study protocol adhered to the principles outlined in the Helsinki Declaration, which provides guidelines for ethical research involving human participants.

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