

The Effects of Repeated Sessions of Neurofeedback Therapy in Patients with Chronic Tinnitus: A Randomized Controlled Study

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Highlights

- Neurofeedback therapy (NFT) is a promising approach to improve chronic tinnitus
- NFT could reduce tinnitus distress, loudness and intensity
- The impact of NFT on depression symptoms of tinnitus is not obvious

ABSTRACT

Background and Aim: Although neurofeedback therapy (NFT) has been proposed as a beneficial method for treating psychological and neurological disorders, no consensus exists regarding the feasibility of NFT in patients with chronic tinnitus. This study aimed to assess the effects of NFT on chronic tinnitus in adults with normal hearing levels. During this study, the effect of NFT on tinnitus severity, loudness and distress was explored.

Methods: In a randomized controlled trial, 96 adults with chronic tinnitus were equally assigned to either NFT or control group. The NFT protocol was based on the alpha/delta paradigm, and consisted of 20 therapy sessions over 4 consecutive weeks. The primary outcome of this study was the Tinnitus Handicap Inventory (THI) test, and the secondary outcome measures were Visual Analogue Scale (VAS), Beck Depression Inventory (BDI) and

Beck Anxiety Inventory (BAI) scales. Participants in the control group performed the pseudo-training and received no actual NFT.

Results: For the tinnitus distress (THI scale), loudness (VAS) and anxiety (BAI), the repeated-measures analysis of variance showed a significant main effect of Time, Group as well as a Group $\times$ Time interaction effect. Post-hoc pairwise comparisons indicated a significant reduction in THI, VAS, and BAI scores in the NFT group relative to the control group at each time points. However, we found no significant main effect of Time, Group or Time $\times$ Group interaction for the BDI test.

Conclusion: NFT is a promising approach to improve chronic tinnitus in adults; alleviating tinnitus distress, reducing tinnitus related-anxiety and loudness.

Keywords: Neurofeedback, tinnitus, anxiety, depression

Introduction

Tinnitus is the perception of sound in the absence of external acoustic stimulation, typically described as pulsatile, hissing, buzzing, tonal, or ringing [1]. Chronic tinnitus represents a highly prevalent condition, affecting approximately 10-15% of the general population worldwide, with around 6-25% of affected patients reporting severe symptoms that substantially impair daily functioning and quality of life (QoL) [1-3].

Tinnitus is a debilitating symptom since it is usually accompanied by several comorbidities including anxiety, depression, and sleep disturbances. Despite the availability of different therapeutic modalities, no definitive treatment for chronic tinnitus has been established to date, highlighting the persistent unmet need for effective, evidence-based interventions [4, 5]. Recent advances in elucidating the neurophysiological underpinnings of tinnitus-including aberrant cortical synchrony, maladaptive neuroplasticity, and thalamocortical dysrhythmia - have prompted the development of neuromodulatory approaches aimed at targeting these central mechanisms. Among these, several procedures have demonstrated promising efficacy in reducing tinnitus severity and improving QoL in affected individuals [6].

Neurofeedback therapy (NFT) is a non-invasive neuromodulation method that records a subject's neuronal activity, extracts relevant aspects of brain processes utilizing real-time electroencephalographic (EEG) signal processing, and returns feedback to the patient in auditory or visual form. NFT aims to normalize stable behaviours without continuous dependence on behavioural therapy or drugs [7,8]. NFT is generally conducted by means of teaching the patient to self-regulate his/her brain activity according to the reward or inhibition feedback of the individual's brain waves [9,10]. Through NFTneurofeedback training sessions, patients learn to volitionally modulate specific EEG frequency components - augmenting target frequencies while suppressing others - via a reinforcement-based paradigm [11,12]. It has been indicated that NFT can induce positive behavioural consequences such as relieving adverse cognitive symptoms (e.g., anxiety, depression, tinnitus, and hyperactivity), or improving particular cognitive performances (e.g., working memory, attention, and learning) [13-15].

In recent years, NFT has received increasing attention regarding its potential in the treatment of patients with tinnitus. The neurophysiological rationale for applying NFT in tinnitus is supported by EEG studies

demonstrating characteristic spectral abnormalities in tinnitus patients relative to healthy controls, including increased delta-band power and reduced alpha-band activity over temporal cortical regions - patterns consistent with thalamocortical dysrhythmia models of the condition. Therefore, targeting these aberrant oscillatory signatures through alpha/delta NFT protocols constitute a mechanistically grounded therapeutic strategy.

Crocetti et al. [16] studied the impact of NFT on 15 normal-hearing adults with subjective tinnitus in a 12-session alpha/delta protocol (3 sessions per week over a 4-week period). Tinnitus loudness and distress were evaluated at baseline and 6-month follow-up. Their findings indicated a significant and sustained improvement in both measures, accompanied by a stable increase in the tau/delta power ratio across the training period. Güntensperger et al. [5] also examined an individually calibrated alpha/delta NFT protocol in patients with chronic tinnitus, demonstrating significant reductions in tinnitus-related loudness and psychological distress, as well as a progressive improvement in the trained alpha/delta ratio throughout the intervention. In another study, Khoramzadeh et al. [17] explored the impact of NFT on the severity of tinnitus symptoms (as measured by Tinnitus Severity Index), and QoL in individuals with chronic tinnitus. The participants were received 15 sessions of alpha/delta NFT for 5 consecutive weeks. Their findings indicated that NFT training could significantly reduce the severity of tinnitus symptoms and improve the QoL of participants.

To our best knowledge, there are few studies evaluating the long-term influence of NFT on tinnitus patients with normal hearing levels. The present study aimed to evaluate the effects of multi-session NFT on chronic tinnitus in adults with normal audiometric thresholds. Furthermore, the effect of NFT on tinnitus severity, loudness, and distress was also assessed.

Methods

Participants

Ninety-six adults with chronic tinnitus (lasting more than six months) were recruited through our otology clinic. All patients who met the following criteria were included in this study: 1) subjective tinnitus of at least 6 months' duration; 2) age between 18 and 50 years; 3) hearing thresholds ≤ 20 dB HL bilaterally across the 250 to 8,000 Hz frequency range; and 4) right-handed as confirmed by the Edinburgh Handedness Inventory. Exclusion criteria were 1) history of acute or episodic tinnitus; 2) history of epileptic seizures, severe headaches, loss of consciousness; and 3) presence of an implanted intracranial device or cardiac pacemaker.

Experimental procedure

During a randomized controlled trial, participants were randomly assigned to the NFT (n=48) or control (n=48) groups (figure 1). All participants underwent a standardized baseline assessment conducted by an experienced audiologist who was not involved in the delivery of the therapeutic intervention. This assessment included detailed medical history, clinical examination, pure-tone audiometry (PTA), and tinnitus-specific outcome ratings.

Neurofeedback protocol

NFT was conducted using an 8-channel ProComp Infiniti System (Thought Technology Ltd., Montreal, QC, Canada). The NFT protocol was based on the alpha/delta paradigm proposed by Dohrmann et al. [18], which was developed specifically for the treatment of tinnitus. According to this protocol, alpha-band activity (8-12 Hz) was reinforced while delta-band activity (1-4 Hz) was concurrently suppressed, targeting the characteristic spectral imbalance associated with tinnitus pathophysiology. Four active electrodes were positioned at Fc1, Fc2, C3, and C4 according to the international 10-20 EEG system. This fronto-central electrode configuration was selected to optimally capture electrical activity generated by the tangentially oriented auditory cortex. Ground and reference electrodes were positioned on the right and left earlobes, respectively. During the NFT session, participants were seated in front of a laptop screen and received feedback and received visual feedback, which began once they achieved adequate focus for 20 seconds. Each NFT training session included three 10-minute animations - a moving ball, a roller coaster ride, and a flying duck - shown sequentially to the participant.

Participants in the intervention group completed 20 NFT sessions over four consecutive weeks (5 sessions per week). Each session lasted approximately 45 minutes and followed a standardized structure: an initial 5-minute eyes-open relaxation period, followed by two 20-minute training blocks. Throughout each session, participants were instructed to remain in a relaxed but alert state with eyes open, minimize motor artifacts, and avoid sleep onset.

For the control group, the electrodes were located in the same locations as the active NFT group and performed the pseudo-training (received no actual NFT).

Clinical evaluation

Primary outcome measure: Tinnitus Handicap Inventory (THI) is a 25-item self-report questionnaire that measure the disabling effects of tinnitus across “emotional” (9 items), “functional” (11 items), and “catastrophic” (5 items) subscales. Each item is scored on a three-point Likert scale: “no” (0 points), “sometimes” (2 points), and “yes” (4 points), yielding a total score ranging from 0 to 100 [19].

Secondary outcomes: The tinnitus-related loudness was determined using a numerical Visual Analogue Scale (VAS) ranging from 0 to 10. The Beck Anxiety Index (BAI) scale was utilized to measure the severity of anxiety symptoms on a 4-point Likert scale ranging from 0=not at all to 3=severely. The BAI scores are classified into minimal (0-7 points), mild (8-15 points), moderate (16-25 points), and severe (26-63 points) degree of anxiety [20]. The Beck Depression Inventory (BDI) was also used to assess the presence and severity of affective, cognitive, behavioural, and somatic symptoms of depression in tinnitus patients. The BDI items (n=21) are rated on a four-point Likert scale (0-3), yielding a total score between 0 and 63 points. The BDI scores are categorized as none or minimal (0-13 points), mild (14-19 points), moderate (20-28 points), and severe (29-63 points) degree of depression [21]. In all three secondary outcome measures, higher scores reflecting greater severity.

All primary and secondary outcomes for both groups were measured at baseline (before the first NFT session) and at one week, two weeks, and four weeks after treatment initiation.

Data analysis

The primary outcome (THI) and secondary outcomes (BDI, BAI, and VAS) were analysed using mixed-factor repeated measures analysis of variance (RM-ANOVA). This analysis included “group” (NFT versus control) as the between-subjects factor and “time of assessment” as the within-subjects factor. In the presence of significant interactions or main effects, post-hoc Tuckey’ test was conducted. All statistical analyses were performed using IBM SPSS Statistics for Macintosh, Version 17.0 (IBM Corp., Chicago, IL, USA), and statistical significance was defined as a p -value <0.05 .

Results

Study population

We found no significant differences between both NFT and control groups with respect to sex, age, tinnitus duration, and tinnitus laterality (Table 1). The mean hearing thresholds did not differ significantly between groups or between ears ($p>0.05$), confirming the audiometric homogeneity of the sample. We also found no significant between-group differences in THI, BDI, and BAI scores at enrolment (Table 2), indicating comparable baseline levels of tinnitus-related handicap, depressive symptoms, and anxiety across both study groups.

Self-reported tinnitus outcomes

For the primary outcome parameter, THI, the RM-ANOVA demonstrated a significant main effect for both Time ($F(3,282)=106.88$; $p<0.001$) and Group ($F(1,282)=48.71$; $p<0.001$) factors, as well as a significant Time $\times$ Group interaction ($F(3,282)=147.23$; $p<0.001$). Post-hoc pairwise comparisons exhibited a significant reduction in THI scores in the NFT group relative to the control group at each time point: from baseline to week 1 (mean change: 4.79 ± 9.84 , $p=0.001$), baseline to week 2 (mean change: 16.12 ± 12.53 , $p<0.001$) and baseline to week 4 (mean change: 18.06 ± 10.46 , $p<0.001$), as outlined in Table 3. By the end of the intervention, 23 individuals (48%) in the NFT group had achieved a clinically meaningful improvement, defined as a drop of over 20 points on the THI.

For tinnitus loudness, RM-ANOVA showed a significant main effect of Time ($F(3,282)=16.63$; $p<0.001$), and Group ($F(1,282)=14.57$; $p<0.001$) factors and a significant Time $\times$ Group interaction ($F(3,282)=9.49$; $p<0.001$), indicating that the pattern of change in loudness over time varied significantly between groups. Pairwise comparisons demonstrated a gradual decline in perceived tinnitus loudness within the NFT group. Compared to baseline, significant improvements emerged by week 2 (mean change: 0.65 ± 1.17 , $p=0.001$) and were further pronounced at week 4 (mean change: 1.56 ± 1.71 , $p<0.001$), as detailed in Table 3.

For the BAI, we observed a significant main effect of Time ($F(2.66,250.59)=30.86$; $p<0.001$), Group ($F(2.66,250.59)=37.89$; $p<0.001$) and Time $\times$ Group interaction ($F(2.66,250.59)=10.56$; $p<0.001$). Post-hoc comparisons revealed a progressive and significant reduction in BAI scores in the NFT group relative to the control group, with the magnitude of improvement increasing across successive assessment points: week 1 (mean

change: 2.08 ± 0.77 , $p=0.008$), week 2 (mean change: 3.52 ± 0.89 , $p=0.001$) and week 4 (mean change: 5.81 ± 0.88 , $p<0.001$), as detailed in Table 3.

In the case of BDI, the results of RM-ANOVA indicated no significant main effect of Time ($F(1.89,178.56)=3.82$; $p=0.054$), Group ($F(1,178)=0.44$; $p=0.51$) or Time $\times$ Group interaction ($F(1.89,178.56)=1.39$; $p=0.24$) was observed, indicating that depressive symptoms did not differ significantly between the NFT and control groups across any assessment time point.

Discussion

The current study investigated the effects of a structured alpha/delta neurofeedback protocol on chronic tinnitus in adults with normal hearing thresholds. The principal finding was that NFT delivered over one month produced obvious improvements in tinnitus-related handicap, loudness, and anxiety, as measured by the THI, VAS, and BAI scales, respectively. However, depression as indexed by the BDI did not differ significantly between the two groups, suggesting that the therapeutic benefits of NFT may be more closely linked to tinnitus-specific distress and anxiety modulation than to generalised mood regulation.

Recent neuroscientific models conceptualise tinnitus not as a peripheral auditory phenomenon but as a disorder of central neural networks [22]. According to the thalamocortical dysrhythmia (TCD) model, deafferentation of peripheral auditory input disrupts the normal inhibitory gating function of the thalamus, leading to a pathological shift in thalamocortical oscillatory dynamics. Specifically, this deafferentation leads to a reduction in thalamocortical alpha-band (8-12 Hz) drive, which in turn disinhibits slow delta-band (1-4 Hz) oscillations in auditory cortical areas, generating a self-sustaining phantom percept [23,24].

Converging evidence from quantitative EEG studies consistently indicates that tinnitus patients typically show decreased alpha-band power and enhanced delta-band power over temporal and temporoparietal cortical regions compared to healthy controls [25-27]. Importantly, the degree of alpha suppression has been shown to correlate with tinnitus distress and handicap scores, suggesting that alpha-band deficits are not merely epiphenomenal but may actively contribute to the subjective severity of the condition [28]. Beyond the auditory cortex, source-localisation analyses have also indicated a broader tinnitus network encompassing the anterior cingulate cortex, prefrontal cortex, and parahippocampal regions, reflecting the involvement of attentional, memory, and emotional processing networks in the maintenance and amplification of the tinnitus percept [29]. This distributed network perspective underscores the rationale for targeting fronto-central, rather than exclusively temporal, scalp regions in NFT protocols, as utilised in the present study [30-32].

In the present study, we found a significant reduction in THI scores in the NFT group relative to the non-NFT (control) group at all assessment time points. Our results also demonstrate that clinically meaningful improvement - defined as a reduction exceeding 20 THI points - is achievable in a substantial proportion of participants, with 48% of NFT-treated patients meeting this threshold by the end of treatment. The progressive increase in the magnitude of THI reduction from week 1 through week 4 further supports a dose-dependent therapeutic relationship, consistent with the cumulative neuroplastic effects of repeated NFT training.

According to our data, a significant reduction in tinnitus-perceived loudness was observed in the NFT group, with the magnitude of reduction increasing at later time points. Jensen et al. [30] investigated the effect of two different neurofeedback protocols on tinnitus intensity (as measured by the Tinnitus Magnitude Index). Individuals with chronic tinnitus were randomly assigned to alpha/delta ratio NFT, beta/theta ratio NFT, and non-NFT (control) groups. Tinnitus intensity was measured at pre-, mid- and post-interventions and at a 3-month follow-up. Their findings revealed that both the beta/theta ratio and alpha/delta NFT groups reported an obvious reduction in tinnitus intensity compared to the control group. EEG data analysis demonstrated a consistent pattern for the alpha/delta ratio protocol during the training course. In addition, alpha/delta NFT exhibited an elevated response compared to the beta/theta neurofeedback paradigm.

Anxiety is widely recognized as one of the most prevalent and debilitating comorbidities associated with chronic tinnitus, with a well-documented bidirectional relationship between tinnitus distress and anxiety levels [33,34]. In the current study, BAI scores exhibited a gradual and consistent reduction over time across different evaluation points. This improvement may be attributed to NFT training, which appears to alleviate anxiety levels through two interconnected pathways: first, by directly modulating cortical excitability through EEG-guided reinforcement; and second, by reducing tinnitus-related distress, thereby indirectly attenuating anxiety [8,21, 35]. The absence of significant change in BDI scores could stem from the relatively low initial levels of depression in our study population. Alternatively, it may suggest that depressive symptoms in patients with chronic tinnitus are less responsive to short-term interventions and might require extended treatment or additional therapeutic approaches to produce detectable improvements.

From a neurophysiological perspective, the therapeutic effects observed in this study are consistent with the thalamocortical dysrhythmia model of tinnitus. This model suggests that the tinnitus arises from aberrant low-frequency brain activity - particularly increased delta-band power and decreased alpha-band activity - in cortical areas associated with tinnitus [36]. The neurofeedback protocol used in this study aimed directly at these abnormal patterns by reinforcing alpha-band activity and concurrently suppressing delta-band oscillations over fronto-central regions of the scalp. The gradual improvement observed over the four-week training period suggests that the benefits likely result from genuine neuroplastic reorganizations, rather than placebo effects or non-specific factors. This interpretation is strengthened by the lack of similar alterations in the control group.

The fronto-central electrode configuration employed in this study - specifically C3, C4, FC1, and FC2 - deserves methodological consideration. While conventional tinnitus NFT protocols have predominantly targeted temporal electrodes on the basis of their proximity to the primary auditory cortex, the selection of fronto-central sites in the present study was motivated by evidence that these electrode sites optimally capture activity from the tangentially oriented auditory cortex and are less susceptible to myogenic artifacts [8].

Several limitations of this study should be considered. First, the absence of EEG recordings before and after treatment precludes direct verification of NFT-induced alterations in cortical oscillatory activity and their potential relationship to clinical outcomes. Incorporating EEG recordings in future research would help

support stronger causal inference. Second, the study did not include a follow-up assessment beyond one month, limiting conclusions regarding the durability of the observed.

Conclusion

These findings suggest that the application of an Alpha/Delta neurofeedback protocol could be a practical neuromodulation approach in the management of chronic tinnitus. Our findings indicated that neurofeedback resulted in improvements in tinnitus-related distress, anxiety, and intensity in individuals with chronic tinnitus.

Ethical Considerations

Compliance with ethical guidelines

The current study was approved by the institutional Ethics Committee (Ethics code: IR.AJUMS.REC.1405.081) and also registered in the Iranian Registry of Clinical Trials database (Registration number: IRCT20151026024710N1). Written informed consent was obtained from all participants prior to enrolment, following a comprehensive explanation of study procedures and potential risks.

Authors' contributions

AB: Study design, acquisition of data, interpretation of the results, statistical analysis, and drafting the manuscript; GM: Study design, Statistical analysis, and drafting the manuscript; NS: Study design, Interpretation of the results and drafting the manuscript.

Conflict of interest

The authors declare that they have no conflict of interest.

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Table 1. Demographic and clinical features of participants

Variable	Group		p-value
	NFT (n=48)	Control (n=48)	
Age (yrs); mean $\pm$ SD	40.69 $\pm$ 8.43	43.17 $\pm$ 9.95	t=1.253; p=0.21
Tinnitus duration (yrs); mean $\pm$ SD	7.93 $\pm$ 3.78	7.06 $\pm$ 2.75	t=1.546; p=0.125
Gender (n)	22 M; 26 F	30 M; 18 F	χ^2 =2.680; p=0.151
Tinnitus laterality	Left ear (n=13)	Left ear (n=10)	χ^2 =1.174; p=0.551
	Right ear (n=16)	Right ear (n=21)	
	Bilateral (n=19)	Bilateral (n=17)	

NFT: Neurofeedback Therapy

Table 2. Comparison of baseline primary and secondary outcome measures between the neurofeedback and control groups

Measure	Group		p-value
	NFT (n=48)	Control (n=48)	
THI	48.62 $\pm$ 8.12	49.33 $\pm$ 10.91	0.782
BDI	17.55 $\pm$ 3.37	18.35 $\pm$ 3.52	0.309
BAI	25.04 $\pm$ 53.03	24.89 $\pm$ 3.37	0.801
Tinnitus loudness	6.27 $\pm$ 1.58	6.45 $\pm$ 1.07	0.547

Values are presented in mean $\pm$ Standard Deviation (SD)

NFT: neurofeedback therapy; THI: tinnitus handicap inventory; BDI: Beck depression inventory; BAI: Beck anxiety inventory

Table 3. Summary of self-reported clinical measures across time and group

Measure	Group	Post- intervention phase			p-value
		1-week	2-week	4-week	
THI	NFT	43.83 $\pm$ 11.05	32.50 $\pm$ 9.68	30.58 $\pm$ 8.09	<0.001
	Control	51.33 $\pm$ 9.37	49.81 $\pm$ 9.56	51.92 $\pm$ 7.23	0.118
BAI	NFT	20.77 $\pm$ 4.01	18.69 $\pm$ 4.38	17.46 $\pm$ 4.72	<0.001
	Control	22.85 $\pm$ 3.51	22.21 $\pm$ 4.42	23.27 $\pm$ 4.01	0.055
BDI	NFT	18.31 $\pm$ 3.19	17.72 $\pm$ 4.01	17.65 $\pm$ 4.14	0.434
	Control	17.71 $\pm$ 3.40	17.38 $\pm$ 3.49	17.54 $\pm$ 4.50	0.226
Tinnitus loudness	NFT	6.12 $\pm$ 1.49	5.63 $\pm$ 1.21	4.71 $\pm$ 1.23	<0.001
	Control	6.37 $\pm$ 1.02	6.46 $\pm$ 0.87	6.12 $\pm$ 1.12	0.339

Values are in mean $\pm$ standard deviation.

THI: Tinnitus Handicap Inventory, NFT; Neurofeedback Therapy, BAI: Beck Anxiety Inventory, BDI: Beck Depression Inventory

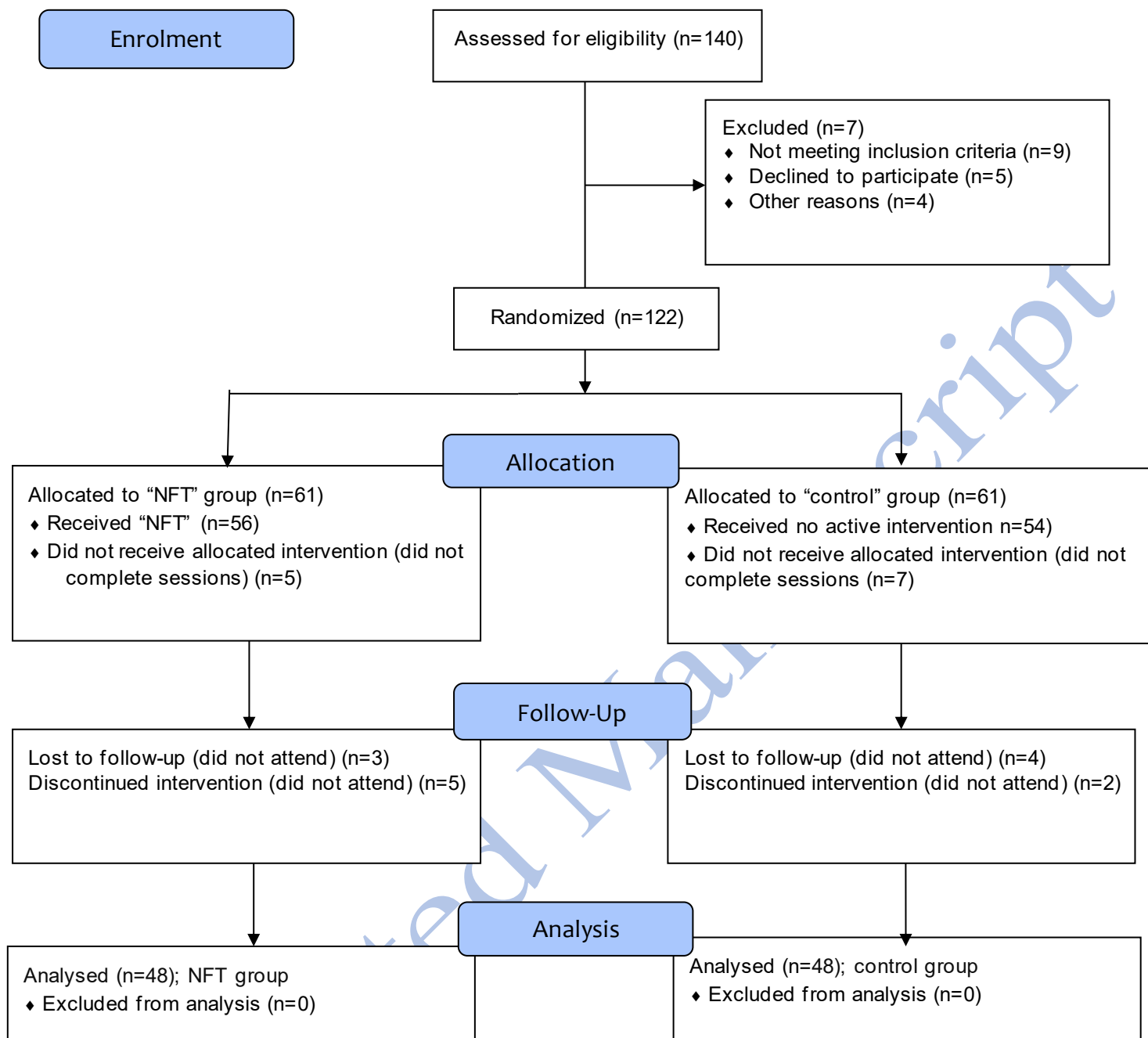


Figure 1. Consort diagram of the study. NFT; neurofeedback therapy