

RAGA-BASED MUSIC THERAPY AND CBT FOR ANXIETY-INDUCED INSOMNIA: A RANDOMIZED TRIAL PROTOCOL ON SLEEP, ANXIETY, AND QUALITY OF LIFE

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Abstract

Anxiety insomnia is a common and debilitating comorbidity of anxiety disorders that affects the sleep patterns, emotional status, and general well-being of individuals. Purely pharmacological interventions might be inadequate, posing risks of dependency and adverse effects, whereas CBT, which is considered a primary form of treatment, might also be inadequate due to the severity of anxiety and insomnia together. The current research protocol is aimed at conducting a randomized control trial on the use of flute music therapy based on ragas and CBT for individuals with moderate to severe anxiety insomnia. A total of 72 participants will be randomly assigned 1:1 to either the experimental group, which will get CBT in addition to raga-based music therapy, or the control group, which will receive CBT alone in addition to standard medicine. Outcomes : sleep quality (PSQI), anxiety severity (GAD-7), and quality of life (WHOQOL-BREF) will be assessed at baseline and post-intervention using a quantitative methodology, with mixed-effects models applied for confirmatory analysis. It offers a structured, culturally relevant framework for evaluating adjunctive music-based therapy in psychiatric care.

Keywords: Raga-flute music therapy, Cognitive behavioral therapy, Anxiety, Insomnia, Sleep quality, Quality of life, Well Being.

INTRODUCTION

Insomnia often occurs together with anxiety disorders due to the two-way relationship between them: on one hand, high levels of mental and bodily arousal make it hard for the person to fall asleep and stay asleep; whereas on the other hand, poor sleep contributes to the increase of anxiety and to the person's hyperactivity during the day. Patients suffering from insomnia caused by anxiety usually show poor concentration, tiredness, lethargy, and low living standards and remain dependent on medications even when these medications are not always effective for long time.

Cognitive-behavioral therapy is considered the most preferred method in treatment of insomnia and anxiety as this method deals with the irrational thoughts, sleeping regulations, and false beliefs concerning sleep. However, there may be some questions about the efficiency of such an approach when it comes to treating insomnia in the conditions of severe anxiety.

It is evident that music therapy can be useful in the cases of anxiety and insomnia. It is believed that it affects the brain activity by stimulating alpha and theta waves, which are connected to being in a relaxed state to falling asleep, while also helping to reduce hyperarousal by responding to physiological relaxation processes, increasing β -endorphin levels, improving serotonin level regulation, and lowering sympathetic nervous system activity. A meta-analytic evaluation of randomized clinical trials shows evidence that music-related intervention has notably impacted the sleep quality of individuals suffering both acute and chronic sleep disorders (Wang, Sun, & Zang, 2014), while patients with general anxiety disorder have been reported to experience reduction of anxiety symptoms subsequent to receiving music therapy (Gutierrez & Camarena, 2015). The combination of music therapy and cognitive behavioral

therapy has shown equal efficacy: music therapy combined with techniques of cognitive behavioral therapy reduces anxiety of students during examination more than CBT alone (Ugwuanyi et al., 2020).

Indian classical ragas are a form of culturally relevant music therapy. The combination of musical modes and rhythm has a beneficial effect on one's mood and physiological arousal. According to Yang (2022), classical music is seen as a useful method to relieve psychological anxiety. Ragas like Neelambari, Bhagyashree, Bhairavi, and Bilahari have been traditionally associated with anxiety reduction and sleep induction (Varughese Abey et al., 2021; Krishna Ramachandran et al., 2022) and thought to influence neurotransmitter levels and sympathetic nervous system performance (Sunitha et al., 2018; Ugwuanyi et al., 2019). Ragas Sahana, Kanada, and Ritigowlai reduce anxiety levels and induce relaxation (Deekshitulu Balaji, 2014). In spite of these findings, little strong evidence is present regarding the effect of combining raga music therapy with CBT for treatment of anxiety related insomnia. The present protocol outlines a randomized controlled trial that will help determine if using raga music therapy in combination with CBT improves sleep, anxiety severity, and quality of life levels of the participants of the study by developing a comprehensive intervention plan.

OBJECTIVES

The study's main goals are to investigate how raga-based music therapy and cognitive-behavioral therapy interventions affect patients with moderate to severe anxiety-induced insomnia in terms of their quality of life, anxiety levels, and sleep quality. A secondary objective is to compare the combined intervention against CBT alone in improving sleep quality, anxiety severity, and quality of life, and to examine differences in the magnitude of improvement across these outcome measures.

METHODOLOGY

Purposive sampling is used to recruit participants for this study, which uses a randomized, controlled, parallel-group clinical trial design with a pre-test/post-test structure. Participants will be recruited from the Out-patient, Department of Psychiatry, Sri Ramachandra Hospital (Chennai). A total of 72 individuals aged 18-40 years of both male and female will be recruited for the participation. Inclusion criteria includes individuals experiencing insomnia due to anxiety disorder and who are on Psychotropics, and diagnosed with moderate to severe symptoms of Anxiety and Insomnia. Exclusions includes individuals with psychosis, substance abuse and other major psychiatric, medical or neurological co-existing conditions, and individuals with hearing deficit and who are not interested in listening to raga-based instrument music are excluded from the study. Hamilton Anxiety, Insomnia severity index are used

for pre screening for selection of participants. The procedure will be clearly explained and written consent will be obtained for all subjects.

Session Plan and Duration

Eligible participants will be randomized in a 1:1 ratio to an experimental group (raga-based music therapy plus CBT plus routine medication) or a control group (CBT plus routine medication alone), using stratified randomization for moderate and severe subgroups. Socio-demographic data and baseline scores on the Pittsburgh Sleep Quality Index, Generalized Anxiety Disorder-7, and WHOQOL-BREF will be recorded prior to intervention. Post-test assessment using the same three measures will be repeated at the end of treatment (week 10) for both groups. Participants will receive a combined raga-based flute music listening and CBT intervention for 60 minutes per session at the Psychiatry OPD, weekly once for eight weeks.

Each session begins with breathing exercises and brief relaxation techniques, followed by 20 minutes of recorded raga-based flute music delivered via laptop and headphones at a controlled volume of 70% and concludes with a CBT component addressing cognitive restructuring, sleep hygiene education, anxiety management techniques, and relapse prevention. In addition to the in-clinic sessions, participants will be instructed to listen to the raga-based flute playlist at home for 45 minutes daily at 70% volume, in a relaxed lying or sitting posture, in a quiet environment free of other noise, for eight weeks, ideally one hour before bedtime. Participants will maintain a sleep log and a practice log, which will be reviewed by the Principal Investigator at each follow-up, and brief feedback forms will be collected after completion of the music-listening component. Participants in the control group will receive the identical CBT protocol delivered to the experimental group combined with routine medication, without the raga-based music therapy component.

Development of the Music Therapy Component

The raga-based music therapy component uses standardized instrumental (flute) recordings of classical Indian ragas selected on the basis of their documented calming and anxiolytic properties in the literature: Neelambari, Bhairavi, and Bhagyashree, traditionally associated with reducing anxiety and promoting restful sleep (Varughese Abey et al., 2021); Sama and Bhairavi, described as effective for anxiety reduction (Krishna Ramachandran et al., 2022); Kalyani, supported by experimental evidence of anxiolytic effect (Rathod et al., 2024); and Sahana, Kanada, and Ritigowlai, described as easing tension (Deekshitulu Balaji, 2014). Standardized instrumental (flute) versions of all these ragas will be prepared under the guidance of a qualified music therapist for use in both the clinic-based and home-based components of the intervention.

STATISTICS

Mixed-effects models will be used to examine within and between-group changes in sleep quality, anxiety level, and quality of life over time, accommodating the repeated-measures structure of the data. Mediation analyses will additionally be conducted to explore potential mechanisms underlying the combined effect of raga-based music therapy and CBT on the targeted outcomes.

DISCUSSIONS

This protocol outlines a clinical methodology in studying the interaction of the two treatments, namely, music therapy using ragas and CBT in treating anxiety-induced insomnia among those with moderate and severe cases. The implementation of a randomized, controlled methodology will permit a comparison of the efficacy of the treatments through variables such as sleep quality, anxiety level, and quality of life. It is especially significant considering the heterogeneity of symptom presentation and inconsistent efficacy of CBT among patients with anxiety-induced insomnia.

The structured nature of the intervention protocol, which includes standardized clinic-based interventions along with supervised home-based listening, allows for consistency in different clinical settings and strengthens the applicability of the intervention model in practice. The intervention protocol will also have an applicability towards translation to future research involving more general psychiatric populations in which both anxiety and sleep problems interactively determine clinical outcome.

The difference in the responses of patients to music-based treatment might be a factor in their effectiveness. The objective of the current study is to increase the feasibility of such treatment by standardizing raga selection, structuring sessions, and using stratified randomization according to the severity. This protocol can have implications not only for research but also for practice regarding treatment of insomnia associated with anxiety.

Outcome Measures

The first main outcome from this experiment is going to be the degree of changes in sleep quality, anxiety severity, and quality of life due to the implementation of both ragas and CBT. The Pittsburgh Sleep Quality Index (PSQI), which measures subjective sleep quality, latency, duration, efficiency, disruptions, medication use, and daytime functioning, will be used to assess sleep quality.

Anxiety severity will be measured using GAD-7 (Generalized Anxiety Disorder-7) and will reflect changes in symptoms of anxiety throughout the course of the intervention. Quality of life will be measured using WHOQOL-BREF and will be evaluated using changes in physical, psychological, social and environmental domains of well-being. Instruments for screening used at the time of enrolment (the HAM-A - Hamilton Anxiety Rating Scale, ISI – Insomnia Severity Index) will be used to stratify the participants by their baseline severity of anxiety and insomnia respectively in order to compare the results for participants with moderate and severe levels of insomnia separately.

Expected Outcomes

The following protocol has been designed to prove the three hypotheses that (1) the combined intervention will show significantly more improvement in sleep quality than the control condition; (2) it will show significantly more reduction in anxiety levels than the control condition; and (3) it will show significantly more enhancement in quality of life than the control condition. The trial is further expected to reveal whether the magnitude of improvement differs between moderate and severe insomnia subgroups, informing whether the combined intervention should be tailored by baseline severity in future clinical application.

Data availability

Data generated in this study will be available upon reasonable request, subject to

institutional ethical guidelines.

Ethical considerations:

The Institutional Ethics Board of Sri Ramachandra Institute of Higher Education and Research approved the study, which included human participants and was carried out in compliance with the Declaration of Helsinki, with approval number : IEC-NI/24/DEC/99/177. The study was also registered in Clinical Trial Registry of India CTRI:CTRI/2025/03/083274. The study was conducted according to the institutional requirements and following local legislation. All the participants were given the consent signed before participating in the research and informed of the rights to withdraw. The data will be solely used only for the research purposes.

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Conflict of interest

The authors affirm that none of the work described in this publication was influenced by any known financial or personal relationships.

Generative AI

There is no use of AI in the manuscript writing or preparation.

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