

Original Article

A study protocol for a randomized controlled trial on effect of yoga nidra on the levels of stress, anxiety and depression in patient released from Hansen's disease Treatment

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ABSTRACT

Background: Hansen's disease is a chronic illness that dates back thousands of years and is now regarded as a neglected tropical disease. In ancient medicinal texts, the term "Kushtha" has been mentioned. Hansen's disease and mental health issues have a close relationship that might result in chronic comorbidity. Hansen's disease affects 0.4 people out of every 10,000 in the nation. Along with multidrug therapy, they also require mind-body interventions. Yoga Nidra is a guided relaxation technique in yogic practices. No scientific evidence is available for yoga nidra in Hansen's disease (RFT). This study aims to find the effect of yoga nidra on stress, depression, and anxiety levels in Hansen's disease (RFT). **Objective:** The objective of the study is to assess the levels of stress, depression and anxiety using DASS21 scale and PHQ9 scales. In addition, the quality of life will be assessed using the WHOQOL-BREF questionnaire and the sleep quality using PSQI scale. **Materials and Methods:** This is a randomized controlled trial with sample size of 80. The subjects will be divided into two groups, namely, the intervention group and the control group with 40 subjects each. Participants will be classified as PAL (People affected by Leprosy) or RFT (released from treatment) between the age group 35 to 60 years of both genders will be included. In the intervention group, subjects will be practicing Yoga nidra for 30 minutes, 5 days a week for 12 weeks. Whereas, conventional treatment will be followed in the control group. The levels of stress, anxiety, depression and sleep quality will be assessing before and after the intervention with the DASS 21, PHQ-9, WHOQOL and PSQI scale. **Results:** Data will be analysed using statistical package for social sciences version 16. In this study, a p-value of <0.05 is considered statistically significant. The results could be significant in each outcome variable. **Conclusion:** The present study findings may provide high-quality clinical evidence on the safety and efficacy of yoga nidra in treating Hansen's disease (RFT) patients. If the study's observations show an improvement in stress, anxiety, depression and sleep quality in Hansen's disease (RFT) patients, it could be recommended as an adjuvant therapy for better care and management for the patients along with conventional care.

Key words: Mental health, Hansen's disease, Relaxation technique, Yoga nidra, Sleep

Hansen's disease is a chronic illness that dates back thousands of years and is now considered a neglected tropical disease (1). Hansen's disease and mental health issues are closely related, which may result in might result in chronic comorbidity. Hansen's disease has several effects, including stigma, social marginalisation, limited access to healthcare, a lack of educational and career opportunities, rights restrictions, an increase in disability, and early mortality. Each of these effects has the potential to worsen mental health by escalating emotions and actions like melancholy, despair, and social disengagement.

Anxiety and depression are two mental health issues that can develop as a result of poor mental health and other Hansen's disease -related effects (2). Hansen's disease is endemic in India, where 4.56 cases per 10,000 people are reported annually (3). Hansen's disease patients typically have a 50% prevalence of depression. Anxiety was reported by approximately 20% of patients with Hansen's disease. Higher levels of anxiety in patients have been linked to negative effects of conventional multi-drug therapy (4). Patients undergoing multidrug therapy experiences various adverse effects, including exfoliative dermatitis, jaundice and hemolytic anemia (5). As a post-RFT (Released from treatment)

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effect they may experience persistence of skin lesions, loss of sensation and deformity (6). To achieve mental well-being, certain complementary and non-pharmacological interventions must be included (7).

According to the WHO, if depression is not addressed immediately, it will become the most prevalent disease worldwide by 2030. Some interventions might help leprosy patients with their mental health. There is a considerable psychological benefit to relaxation (8). Yoga incorporates various practices, including physical postures, regulated breathing, profound relaxation (yoga nidra), and meditation, all of which appear to have an impact on one's mental state. Yoga demonstrated benefits in emotional self-regulation, resulting in lower levels of stress, anxiety, and sadness (9). One of yoga's most potent methods for relaxing is called Yoga Nidra.

Yoga Nidra means sleep with a trace of awareness. It is a state of mind in between wakefulness and dream. Yoga Nidra opens up the deeper phase of the mind (10). Researches also shows that Yoga Nidra can be used as a therapeutic technique to cure psychological disorders like anxiety, depression, insomnia as well as psychosomatic diseases such as asthma,

hypertension, coronary heart disease etc. Yoga Nidra is an effective therapy for both recent and longstanding psychological disturbances, especially high anxiety levels and neurotic behaviour patterns (11). It is also considered as a best technique that provides a relaxation in the physical, mental and emotional aspects of life. It promotes relaxation by altering the level of brain waves. It also have been mentioned that being aware of the problem is an effective way to manage stress and related disorder. It is a practice in which one will be aware of all planes of existence (12). So, the purpose of my research is to assess how well yoga nidra cope up with stress, anxiety and depression in Hansen's disease.

MATERIALS & METHODS

The present study will be a randomised controlled trial, involving patients from the Government rehabilitation home. The study is planned to start in June 2024 and completed by September 2024. Institutional Ethical Committee (IEC) approval from the institution has been obtained, as shown in letter number IEC-IIYNMS/Approval/015/2023. The Clinical Trial registration: CTRI/2024/05/067980 registered on 28/05/2024. Outcome variables will be performed at baseline and after six months as depicted in [Table/Fig-1].

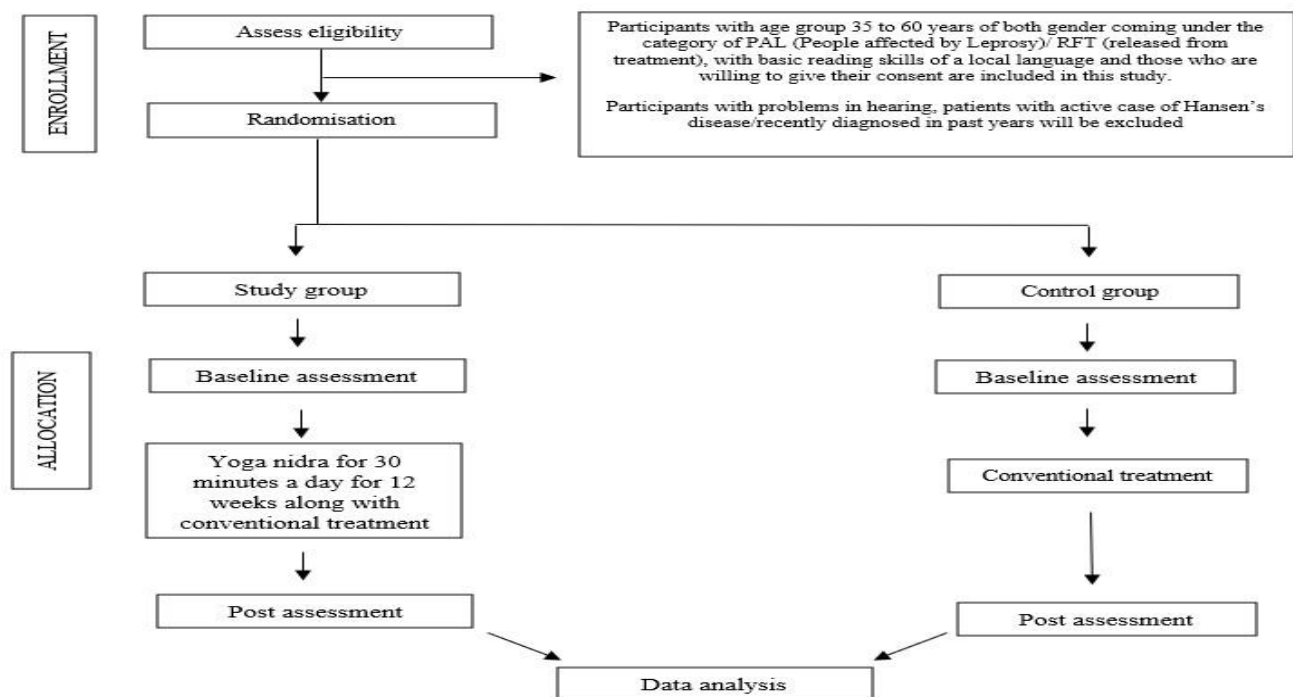


Figure 1: Trial profile

Sample size

The sample size calculation will be done on the feasibility and availability of the patients.

Randomization and blinding

A confidential list of randomizations will be prepared using computer-generated. The categorisation of allocation will be done using SNOSE (Sequentially Numbered Opaque Sealed envelope) technique. Subjects and investigators will not be blinded.

Selection of participants

Inclusion criteria

Participants with age group 35 to 60 years of both gender coming under the category of PAL (People affected by Leprosy)/ RFT (released from treatment) with basic reading skills of a local language and those who are willing to give their consent are included in this study.

Exclusion criteria

Participants with problems in hearing, patients with active case of Hansen's disease/recently diagnosed in past years will be excluded from this study.

Study group

The subjects will receive one day orientation program of Yoga nidra before the trial and will be evaluated according to consideration of the subjects. The Yoga nidra will be delivered via an audio with pre-recorded voice. This was done to maintain uniformity in terms of instruction and voice quality. Subjects will receive 30 minutes of Yoga nidra per day for a period of 12 weeks along with conventional treatment.

Intervention procedure

Yoga Nidra

Yoga Nidra involves a specific set of steps. The steps are as follows: preparation for the practice, taking a personal resolution, or Sankalpa, followed by a rotation of consciousness, breath awareness, mental visualization, a repetition of personal resolution, or Sankalpa, and an ending session (13).

Preparation

The practitioner adopts Shavasana, or "corpse pose," to enter a conscious sleep state of yoga nidra. As a preparatory phase for relaxing the body, this posture reduces the sensation of touch and induces suspension of the mind. This posture performed by lying on the back with arms and legs spread (45°), palms upwards, eyes closed, and taking deep breathes.

Sankalpa

In the following stage, the practitioner must mentally fix a personal resolution to themselves called SANKALPA, which should be short, clear and positive, for example, "I resolve to stop being lazy". This should be repeated mentally 3 times. The mind is in a passive state, so the self-suggested resolution is easily absorbed into the unconscious mind.

Rotation of consciousness

In this stage, the practitioner mentally visualise various body parts and it is shifted in an organized systemic manner. The sequence begins on the right side of the body, with the awareness over the right-hand thumb, and then ends with little

toe of the right foot, before shifting awareness to the left side of the body and sequence is repeated from fingers of the left hand to toes of the left foot, then to the back of the body, moving from the heels to the back of the head and finally to the front of the body, starting with the forehead and moving down to the legs. This practice is an actual means of learning motor skills.

Breath awareness

Several techniques are used at this stage to allow the practitioner to become aware of the natural breathing passively and without changing its flow. The practitioner is asked to visualize the breath moving in and out of the nostrils, chest and abdomen. The practitioner is asked to count the number of inhalation and exhalation mentally.

Visualization

The next practice stage is visualization, in which the practitioner is instructed to shift their awareness towards the dark space in front of the closed eyes and termed as Chidakasha.

Sankalpa

The practitioner repeats Stage 2 mentally three times with complete determination.

Ending of the session

Before concluding the yoga nidra session, the awareness shifts to the external environment, and he becomes aware of his body and surroundings as he moves and stretches the body parts before turning to the right side, slowly sitting up, and opening his eyes.

Control group

The control group will be continuing their usual conventional treatment.

Outcome variables

Primary outcome variables

A pair of primary outcome measures are evaluated: DASS 21 scale and PHQ-9 scale. The DASS 21 scale is employed because of its strong validity and reliability (14) and PHQ 9 has sound psychometric properties (15).

Depression Anxiety Stress Scale 21

The Depression Anxiety Stress Scale (DASS 21) questionnaire, which consists of 21 items, is a self-report screening tool that measures the frequency of behaviors or intensity of feelings based on three subscales of depression (DASS-D), anxiety (DASS-A), and stress (DASS-S). A DASS total score was computed from the three subscale scores of items rated on a four-point scale (i.e., from 0 = "Did not apply to me" to 3 = "Applied to me very much or most of the time"). The total equals 63 points (16).

Interpreting DASS 21 scores

Table 1: showing the interpreting DASS 21 scores

| | DEPRESSION | ANXIETY | STRESS |
|-------------------------|------------|---------|--------|
| NORMAL | 0-4 | 0-3 | 0-7 |
| MILD | 5-6 | 4-5 | 8-9 |
| MODERATE | 7-10 | 6-7 | 10-12 |
| SEVERE | 11-13 | 8-9 | 13-16 |
| EXTREMELY SEVERE | 14+ | 10+ | 17+ |

Patient Health Questionnaire

Patient Health Questionnaire (PHQ-9) questionnaire is a self-rated, standard, and validated depression screening tool. It consists of nine questions regarding the patient's feelings. Each response is assigned a score out of three. The maximum score is 27 for nine questions. A score is obtained for each of the nine questions, either with the clinician asking questions or filling in the form themselves (17).

Secondary outcome variables

There are two secondary outcome measures assessed using WHOQO-BREF as it assesses how a person feels about their quality of life, health and other areas of life (18), and PSQI is an effective tool for measuring the quality of sleep and it have higher validity and reliability (19).

WHO Quality of Life Scale

WHO Quality of Life Scale (WHOQOL)-BREF is a self-report questionnaire that contains 26 items and classifies 4 domains: physical domain (7 items), psychological domain (6 items), social relations domain (3 items), and environmental domain (8 items). It is a five-point Likert scale ranging from 1 to 5. The responses will be analyzed using a Likert scale, distributed an intensity scale, capacity, frequency and evaluation (20).

Pittsburgh Sleep Quality Index

The Pittsburgh Sleep Quality Index (PSQI) includes 19 self-rated questions and 5 questions rated by the partner or roommate. The last 5 questions are not included in the PSQI scoring but are used for clinical purpose. The 19 self-rated questions determine the factors related to quality of sleep and sleep duration. The 19 items are categorized into 7 component scores, each measured equally on a 0-3 scale and then the 7 component scores are added to produce global PSQI score, ranging from 0-21; high scores represent worse sleep quality (21).

Data analysis

The data will be analysed using statistical package for social sciences, version 16. In this study, we will consider *p* value <0.05 as statistically significant.

DISCUSSION

The current study is the first of its kind to investigate the effect of yoga nidra on the levels of stress, anxiety, depression and sleep quality in Hansen's disease (RFT) patients. Anxiety and depression are two mental health issues that can develop as a result of poor mental health and other Hansen's disease-related effects (2). Previous studies have shown positive impact on Hansen's disease (RFT) patients by reducing anxiety and depression by progressive muscle relaxation technique (8). Another study examined the effect of mental imagery on depression, anxiety and stress in leprosy patients concluded that yoga nidra can be used as an effective adjuvant with conventional aerobic exercises to reduce depression, anxiety and stress (22). One more study was conducted on leprosy patients by practicing Jala neti, for nasal comfort and hygiene (23).

Yoga Nidra has neurological, neurocognitive, psychological, and physical effects on the individual (13). It improves brain wave patterns and release of the neurotransmitters such as dopamine and thus has positive effect on stress, anxiety, depression and sleep quality (24). A previous study showed the effect of 30 minutes yoga nidra on stress, sleep and well-being. The results showed that yoga nidra regulates hyperarousal by reducing it. The study also mentioned yoga nidra as a specific form of mindfulness meditation and that it increases mindfulness (12).

The parameters are assessed using various scales, and a study was conducted to identify the levels of stress, anxiety, and depression in students. The results showed that that yoga had a positive impact on these parameters using the DASS 21 scale, with no impact on depression, a mild positive effect on anxiety, and a highly positive effect on stress levels(25). A study was conducted to find the effect of yoga classes on the mental health of female college students and to evaluate their mental health status. Three scales were used: Patient health questionnaire (PHQ-9), the Generalized Anxiety Disorder scale (GAD-7) and the Connor-Davidson resilience scale (CD-RISC), with the result indicating that yoga classes can increase the level of psychological resilience, improve depression and anxiety, promote mental health, improve subjective wellbeing and improve the quality of college life (26). A study aims to evaluate the quality of life in adult yoga practitioners who practice yoga for 2 hours per week for at least a year.

The WHOQOL-BREF questionnaire was used to assess quality of life, and the results confirmed that yoga practitioners have a high quality of life (27). Another scale Pittsburgh Sleep Quality Index (PSQI) is a powerful tool for measuring the sleep quality in an individual and a study was conducted to evaluate the impact of long-term yoga practice on sleep quality in elderly people, and results showing regularly practicing yoga gives better sleep quality and reduces the frequency of disturbed sleep, and reduces the

sleep delay and dependence of sleeping pills in elderly adults (28). The study may have some limitations such as measuring only subjective variables. In the future it may be expanded to include objective measures to evaluate the mental health parameters such as stress, depression, anxiety, quality of life and sleep.

CONCLUSION

The present study's findings may provide high quality clinical evidence on the safety and efficacy of yoga nidra in the treatment of Hansen's disease (RFT). If the observations of the study ascertain the improvement in stress, anxiety, depression and sleep quality in Hansen's disease (RFT) patients, it could be recommended as an adjuvant therapy for better care and management in conjunction with conventional care.

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