

Effect Of Deep Relaxation Technique On Sleep Quality In Primary Insomnia: A Study Protocol For A Randomized Controlled Trial

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Abstract:

Background: Primary insomnia is defined as sleep difficulties that affect day-time functioning. Its prevalence rates for the general adult population are approximately 1%-10% and elderly population is up to 25%. Deep Relaxation Technique (DRT) is guided relaxation technique in yogic practices. There are no scientific evidences available for DRT on primary insomnia. This is to find out the effect of Deep Relaxation Technique on Sleep Quality in Primary Insomnia.

Materials and Methods: This is a randomized controlled trial with sample size of 80. Subjects will be divided into two group namely, intervention group and control group with 40 subjects each. Participants fulfilling the diagnostic criteria of insomnia according to the Diagnostic and Statistical Manual of Mental Disorders between the age group of 18- 40 years will be included. In Intervention group, subjects will be practicing DRT for 20 min daily for 10 days. Whereas, there is no intervention in the control group. Sleep Quality will be assessing before and after intervention with Pittsburgh Sleep Quality Index and Athen's insomnia scale.

Results: Data will be analysed using statistical package for social sciences version 16. In this study, we will consider p value <0.05 is the statistically significant. Result will be represented in the bar diagram using mean value of the dependent variables.

Conclusion: This study may provide high quality clinical evidence on the safety and efficacy of DRT in the management of Primary Insomnia. If the observation ascertains the improvement of sleep quality, it could be recommended as adjuvant therapy for better care and management of the patients along with conventional care on primary Insomnia patients.

Keywords: Sleep, Insomnia, Relaxation technique, Yoga, Adjuvant therapy, Quality of life

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I. Introduction:

Primary insomnia (PI) is defined as sleep difficulties that affect day-time functioning. It does not occur in the presence of another sleep disorder, mental disorder. (1) PI prevalence rates for the general adult population is approximately 1%-10% and elderly population is up to 25%. PI typically begins in young adulthood or middle age and is very rare in children or adolescents. (2) PI develop often after a sudden onset of psychological, social, or medical stress, and typically persist long after the original causal factors resolve, due to the development of heightened arousal and negative conditioning. (3) PI can lead individuals to reduced productivity, work-related accidents, increased alcohol consumption, serious falls among the elderly, and a decreased sense of well-being. Insomnia treatment should be individualized based on the nature and severity of symptoms. (4) More than the pharmacological intervention, non-pharmacologic intervention like stimulus control therapy, paradoxical intention therapy, relaxation therapy, cognitive behavioural therapy, sleep restriction therapy, temporal control therapy, improving sleep hygiene, and moderate exercise found to be effective in the management of PI. (5)(6) Among non-pharmacological treatment, yoga therapy drawn key attention due to increased scientific evidence in past two decades. (7)

Yoga is one of the complementary and alternative medicine (CAM) have positive effect on physical and mental health. (8) Yoga helps to obtain a sense of relaxation and achieve tranquillity of the mind. In yoga, Deep Relaxation Technique (DRT), Yoga Nidra, Pranic Energization Technique (PET), Cyclic Meditation (CM), and Mind Sound Resonance Technique (MSRT) are available relaxation techniques to reduce the stress response in

individuals. (9) Deep Relaxation Technique (DRT) is one of the most useful relaxation techniques, that be used as intervention for various health issues especially psychological conditions. (10) DRT is a systemic guided relaxation method, which involves relaxation of all body parts by directing the attention of the mind on different parts of the body starting from toes to head in a sequential manner. (11) There were no scientific evidences available for DRT on primary insomnia. Hence, we have planned this randomized controlled trial to find the effect of DRT on Sleep Quality in Primary Insomnia.

II. Materials And Methods

Study Setting:

The present study is a randomized controlled trial. Subjects will be recruited from Out-patient department for International Institute of Yoga and Naturopathy Medical Sciences and Hospital, Chengalpattu, Tamilnadu. The study is planned to start from December 2023 and completed by September 2024. Institutional Ethical Committee (IEC) approval was obtained, vide letter number IEC-IYINMS/Approval/012/2023 and also registered this study protocol Clinical Trial registration vide No.CTRI/2023/11/0595557.

Study Design: Randomized controlled trial

Study Location: Subjects will be recruited from Out-patient department for International Institute of Yoga and Naturopathy Medical Sciences and Hospital, Chengalpattu, Tamilnadu.

Study Duration: The study is planned to start from August 2024 and completed by December 2024.

Sample size:

Sample size calculation will be based on a similar study that was conducted on 80 samples. With 80% power, two-tailed significance, an expected drop-out rate of 20%, and a 1:1 allocation, a total sample of 80 participants is estimated. (12)

Randomization and blinding:

All the subjects will be randomly allocated to either a subject or a control group (1:1 ratio) using computerized randomization. Random concealment will be done using SNOSE (Sequentially numbered, opaque, sealed envelope) technique. The participants will not be blinded to the study and control group.

Selection of Participants:

Inclusion criteria:

Participants fulfilling the diagnostic criteria of insomnia according to the Diagnostic and Statistical Manual of Mental Disorders (Fourth Edition, DSM-IV) under the age group of 18- 40 years will be included. They should experience insomnia for less than 2 years. (13)

Exclusion criteria:

Participants with serious cardiovascular, liver, kidney, or hematopoietic system disease, and insomnia caused by nervous system disease and participants had a history of sleep apnea will be excluded. Participants who had taken anti-depressant drugs or anti-psychotic drugs two weeks before the trial and subjects who are under any other intervention for insomnia will be excluded. (13)

Intervention group:

Intervention group will undergo practice Deep Relaxation Technique for the duration of 20 minutes for 10 consecutive days. DRT will be performed with the closed eyes in 8 phases guided by pre-recorded audio. (14)

DRT procedure:

Subjects will be instructed in supine lying position (*Shavasana*) with closed eyes throughout the session. Subjects will be asked to do conscious relaxation of each of the part of the body from toes to hip region. Followed by that they will be asked to chant 'A' kara for 5 times by relaxing lower part of the body. Later, subjects will be asked to do conscious relaxation of the body parts from hip to neck including both hands. Followed by that they will be asked to chant 'U' kara for 5 times by relaxing middle part of the body. After completion of 'U' Kara, subjects will be instructed to do conscious relaxation of entire head region. Followed by that subjects will be asked to chant 'M' kara for 5 times. Finally, subjects will be asked to do entire body conscious relaxation followed by that chanting of 'AUM' altogether for 5 times. Subjects will be asked to feel the resonance of the sound produced by 'AUM'. Later subjects will be asked to imagine that they can visualize their own body from the height of the roof and to imagine that they can visualize the sky by flying, after imagine subjects can come to

present awareness. They will ask to move their body by doing mild movements and slowly come to sitting position and open the eyes gently. (14)

Control group:

Subjects in the control group will be receiving no intervention and they will be sitting quiet for 20 minutes a day for 10 days.

Outcome measures:

Sleep Quality will be assessing before and after intervention with Pittsburgh Sleep Quality Index and Athen's insomnia scale.

Pittsburgh Sleep Quality Index (PSQI):

The PSQI is a self-rated questionnaire that assesses sleep quality and sleep disturbances. It consists of 19 self-rated questions. The 19 self-rated questions assess a wide variety of factors relating to sleep quality, including estimates of sleep duration and latency and of the frequency and severity of specific sleep-related problems. These 19 items are grouped into seven component scores, each weighted equally on a 0-3 scale. The seven component scores are then summed to obtain a global PSQI score, which ranges from 0-21; higher scores indicate the worse quality of sleep. (16)

Athens Insomnia Scale (AIS):

The Athens Insomnia scale use to assesses the severity of insomnia using diagnostic criteria set by the International Classification of Diseases (ICD-10). The eight-item questionnaire evaluates sleep onset, night and early-morning waking, sleep time, sleep quality, frequency and duration of complaints, distress caused by the experience of insomnia, and interference with daily functioning. (17)

III. Result

Data will be analysed using statistical package for social sciences version 16. In this study, we will consider p value <0.05 is the statistically significant. Result will be represented in the bar diagram using mean value of the dependent variables.

IV. Discussion

The current study is the first of its kind to explore the Effect Deep Relaxation Technique (DRT) on quality of sleep-in primary insomnia patients. Previous literature suggests that yoga improves sleep quality by relieving stress, tension, fatigue. (18)

Previous studies concluded that integrated approach of yoga therapy including *yoga nidra* can reduced the insomnia severity and improve the quality of life. (19) Another study shows that DRT improves quality of sleep and reduced stress. (14) Recent study by Shathirapathi *et al*, found that 45 minutes of *Trataka* may improve sleep quality. (23)

Balance of sympathetic and para-sympathatic nervous system is essential for optimal health. Imbalance may cause misregulation in physiological function. (24) Several studies concluded that yogic practices like pranayama, meditation and relaxation techniques may help to regulate the autonomic functions. (25)

Insomnia is associated with increased psychological symptomatology, arousal, perceived stress, and poor quality of life. Insomnia is precipitated by many other factors. Relaxation techniques of yoga enhance the capacity of the mind to influence bodily functions and symptoms. It is hypothesized yogic relaxation technique act by restoring the balance between sympathetic parasympathetic balance and decreasing arousals. (26) Yogic mindfulness component regulates the hypothalamic-pituitary-adrenal (HPA) system decreases cortisol levels and also acts on a recalibration of the sympathetic nervous system via vagal stimulation. (27)) Hyperactivity of the HPA axis raises cortisol levels in the body, which can negatively affect sleep by causing fragmentation of sleep, a reduction in deep, slow-wave sleep, and a reduction in total amount of sleep duration. (28)

If the result of this current study shows positive impact on sleep for insomnia subject means, that may be due to reduction in the sympathetic arousal, balance in autonomic function, decrease in the cortisol secretion

V. Conclusion

The present study finding may provide high quality clinical evidence on the safety and efficacy of Deep Relaxation Technique (DRT) in the management of Primary Insomnia. If the observation ascertains the improvement of sleep quality, it could be recommended as adjuvant therapy for better care and management of the patients along with conventional care on primary Insomnia patients.

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