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Study Protocol

# A protocol of the study "Effectiveness of psychobehavioural interventions for sleep disturbances in undergraduate medical students"

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**Abstract**

***Background:*** Medical students carry a huge academic load which can be a contributing factor in sleep disturbances. Studies have shown that the prevalence of sleep disturbance is comparatively higher in medical students than in non-medical students or the general population. Despite various psychological and behavioral interventions for sleep improvement, not much is known about their effectiveness in real-world scenarios. Our study aims to compare the effectiveness of psychobehavioural interventions on sleep disturbances compared to sleep hygiene for undergraduate medical students.

***Methods:*** A randomized trial will be used to assess the effectiveness of psychobehavioural interventions in improving sleep quality using the following tools: Semi-structured sociodemographic proforma, Pittsburgh Sleep Quality Index (PSQI), Insomnia Severity Index (ISI), Glasgow Sleep Effort (GSE) scale, Pre-sleep Arousal Scale (PAAS), and Kentucky Inventory of Mindfulness Skills (KIMS). Inclusion criteria: participants scoring 5 or higher on the PSQI will be recruited for psychobehavioural interventions after obtaining informed consent. The participants will be randomly assigned to intervention and control groups.

***Discussion:*** SPSS will be used to analyse the data. Descriptive statistics will be used to describe the sample. An intention-to-treat analysis will be performed to assess the effectiveness of the interventions. This study will provide valuable insights into the feasibility and effectiveness of non-pharmacological sleep interventions to address sleep difficulties among undergraduate medical students.

## Introduction

Sleep disturbance, a widespread public health concern, has significant adverse effects on quality of life.[1] The prevalence of insomnia has been found to be 32.6% in a survey conducted among people attending primary care settings in ten countries.[2] A study conducted in India showed the prevalence of insomnia among adults to be 33.0%.[3] Various other studies have shown prevalence of poor sleep quality in medical students to be 19.0%, 38.9%, and 59.4%, respectively.[4-6] A study conducted in India among 150 medical students found that the sleep duration of 16% of undergraduates was less than 6 hours.[7] Thus, a significant proportion of medical students have sleep difficulties. Sleep difficulties result in short-term consequences such as increased stress responsivity, somatic problems such as headache and abdominal pain (which alters cognition and domains that include attention, emotional reactivity, executive function, memory formation, decision making and judgment), is a causative factor for depression, and reduces health-related quality of life in people suffering from medical conditions.[8,9] Long-term consequences can include hypertension, metabolic syndrome, dyslipidemia, weight-related issues, coronary vascular disease, and diabetes mellitus in otherwise healthy people.[8]

Sleep disturbances may lead to a significant burden in students by impacting their learning, memory, grades, automobile driving performance, perception of effort, and mood.[10] In medical students, several factors, such as knowledge about sleep and academic demands, have been identified as principal causative factors in sleep disturbances.[11] In addition, long periods of study contribute to stress in medical students, which in turn also causes sleep deprivation.[12] Other environmental, social, stress, and general health factors play a role in sleep quality.[12] Because of the relationship between sleep and mental health, research on sleep disturbances in undergraduate medical students is of particular interest.[11,13]

Pharmacotherapy is the most common treatment modality for insomnia.[14] Psychotherapy may be considered as an option, since pharmacological agents

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used to treat sleep disturbances (such as hypnotics) can lead to tolerance and dependence.[15] Non-pharmacological management is safer and better in terms of providing long-lasting effects.[15] Psychotherapies recommended for insomnia include sleep hygiene education, stimulus control therapy, relaxation training, cognitive behavioral therapy, sleep restriction, paradoxical intention, and bio-feedback.[15]A systematic review off fifteen studies found that sleep hygiene interventions were effective in improving sleep.[16] Mindfulness-based interventions were found to have beneficial effects on stress, insomnia, pain, and weight reduction based on an overall review.[17]A systematic review on the effects of mindfulness-based stress reduction (MBSR) on sleep disturbances found that sleep quality and duration were significantly improved with MBSR.[18] MBSR, when combined with brief sleep hygiene, achieved improvement in sleep quality in comparison with a sedative-hypnotic.[19] Cognitive behavioral therapy for insomnia has been shown to produce better results in improving sleep in postmenopausal women.[20] Combining mindfulness meditation with cognitive behavior therapy for insomnia has been shown to improve sleep and reduce sleep-related arousal.[21] There have been few studies conducted among different populations around psychological and behavioral therapies for insomnia, but there are even fewer among medical students. This study aims to address sleep difficulties in undergraduate medical students and provide them with psychotherapeutic interventions to improve sleep and explore their effectiveness. A novel aspect of this study is the use of tele-based intervention for feasibility during COVID-19 lockdown restrictions, with minimal stigma, absence of infection risk, and lower costs.

## Objectives

1) To explore the effectiveness of psychobehavioural interventions in improving the quality of sleep.

## Materials and Methods

### *Setting*

This study will be conducted at the Sri Ramachandra Medical College and Research Institute (SRMC & RI) in Chennai. Participants will be undergraduate medical students of SRMC & RI. Participants will use Zoom meeting software to receive the intervention.

### *Design*

An open-label, randomized trial will be performed to assess the effectiveness of two psychobehavioural interventions (mindfulness and sleep hygiene) in improving sleep quality.

### *Participants: Inclusion and exclusion criteria*

In this study, undergraduate medical students over 18 years off age with poor sleep quality and willing to provide informed consent will be included. Participants with medical conditions known to impact sleep, major psychiatric disorders, or unwillingness to participate will be excluded.

Estimated period: We estimate that the study will be conducted from January to September of 2021.

### *Sample size calculation and sampling*

The calculated sample size was 25 in each group with an alpha error of 5% and an effect size of 1.8 based on a study involving similar interventions.[22] Convenience sampling will be used to recruit participants; participants will then be randomly assigned to either the mindfulness group or the sleep hygiene group.

### *Recruitment procedure*

Undergraduate medical students will be informed about the study, and students with sleep disturbances will take the Pittsburgh Sleep Quality Index (PSQI) to assess sleep quality. Students with poor sleep quality scores (5 or higher) will be recruited for psychobehavioural interventions after obtaining informed consent. Participants will be assigned through computerized random number generation. The participants in one group will receive mindfulness-based therapy for insomnia, and the other group will receive sleep hygiene education. Since participants are assigned through computerized random number generation, allocation concealment is accomplished and selection bias is addressed. Observer and evaluation bias are addressed since standardized scales are used for the assessment, and all scales are self-rated. As this study involves behavioral interventions, participants will not be blinded; the staff assessing the data will be blinded.

### *Outcome measures*

PSQI, Insomnia Severity Index (ISI), Glasgow Sleep Effort (GSE) scale, Pre-sleep Arousal Scale (PSAS), and Kentucky Inventory of Mindfulness Skills (KIMS)will be used to measure outcomes.

Sleep quality and quantity during the last month before and after the intervention will be measured using PSQI. The severity of insomnia symptoms before and after the intervention will be assessed using ISI. Sleep effort before and after the intervention is measured using the GSE scale (GSE). Cognitive and somatic components of arousal before and after the intervention will be assessed using the PSAS.

Mindfulness skills such as observing, describing, acting with awareness, and accepting without judgment before and after the intervention will be assessed using the KIMS.

### *Interventions*

Interventions will include mindfulness-based therapy for one group and sleep hygiene education for the other group. Each session will be an 1 hour, and a total of 6 sessions will be given over 3 weeks.

For mindfulness, the first session will focus on

psychoeducation of the participants about the concept of mindfulness and explaining about doing versus being mode. The second session will be targeted on mindfulness of the body and breathing. The third session will be a body scan meditation. The fourth session will be on mindful movement meditation. The fifth session will focus on sounds and thoughts meditation. The sixth session will focus on three-minute breathing space meditation.

The participants in the other group will receive awareness on sleep hygiene on the same schedule (6 hourly sessions over 3 weeks). After 3 weeks of intervention, participants in both groups will be followed up at the end of 4 weeks and 12 weeks, when they will be assessed for quality of sleep and compared with their baseline scores. Methodology flow chart is given in Figures 1 and 2.

### *Assessment of sleep disturbances and mindfulness skills*

For social science research, a Cronbach's alpha score of 0.7 or higher is considered acceptable.

#### *Pittsburgh Sleep Quality Index*

The PSQI is an effective instrument used to measure the quality and pattern of sleep. It differentiates "poor" from "good" sleep by measuring seven areas: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction over the past month. The client self-rates each of these seven areas of sleep. Scoring is based on a 0 to 3 Likert scale, where 0 is the most positive and 3 reflects the negative extreme. A global sum of "5" or greater indicates a "poor" sleeper. The PSQI has internal consistency and a reliability coefficient (Cronbach's alpha) of 0.83 for its seven components.[23]

#### *Insomnia Severity Index*

The ISI is a 7-item self-report questionnaire assessing the

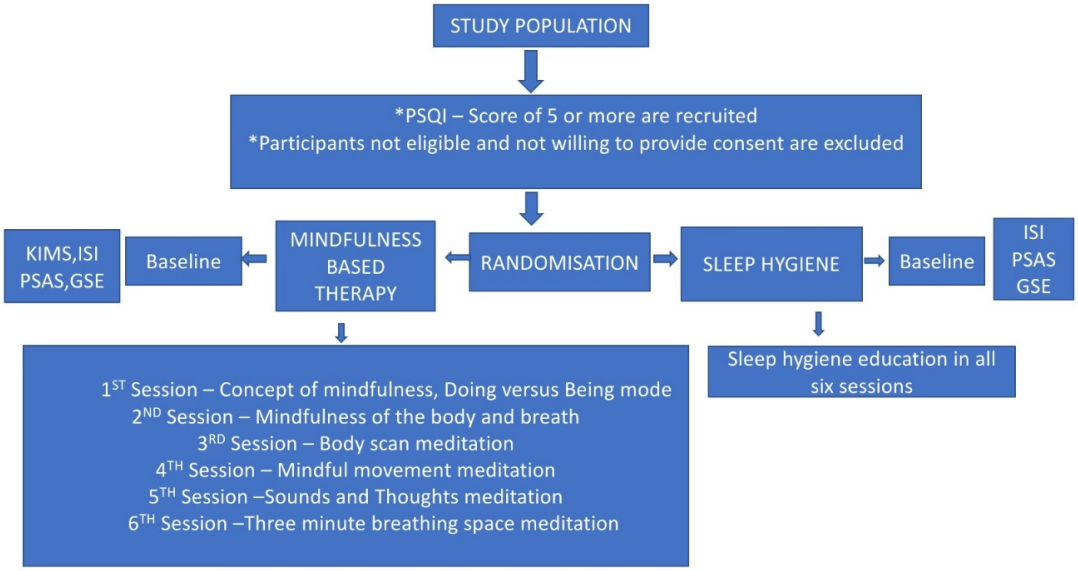


**Figure 1.** Flowchart of the methodology

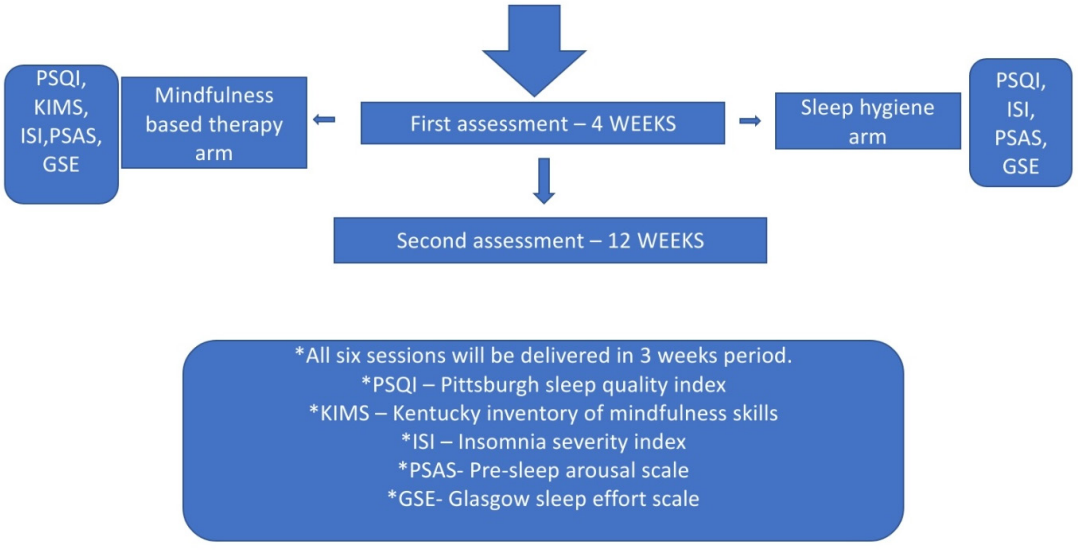


**Figure 2.** Assessments for Mindfulness based therapy armed participants

nature, severity, and impact of insomnia. The usual recall period is the "last month," and the components evaluated are severity of sleep onset, sleep maintenance, and early morning awakening problems, sleep dissatisfaction, interference of sleep difficulties with daytime functioning, noticeability of sleep problems by others, and distress caused by the sleep difficulties. A 5-point Likert scale is used to rate each item (e.g., 0 = no problem; 4 = very severe problem), yielding a total score ranging from 0 to 28. The total score is interpreted as follows: absence of insomnia (0–7); sub-threshold insomnia (8–14); moderate insomnia (15–21); and severe insomnia (22–28). The reliability of the ISI was 0.74. Three versions are available—patient, clinician, and significant others.[24]

### *Glasgow Sleep Effort scale*

The GSE consists of seven items and was developed by Broomfield and Espie. This scale assesses a present state of sleep effort. Responses are recorded on a 3-point Likert scale: not at all (0), to some extent (1), and very much (2). Higher scores indicate more significant effort to sleep over the past week. Psychometric properties of this scale have been examined in insomniac patients and good sleepers. Results showed that the GSES had adequate internal consistency (Cronbach's alpha = 0.77) and can differentiate good sleepers from insomniac patients appropriately.[25]

### *Pre-sleep Arousal Scale*

It includes 16 items, and it was developed by Nicassio, Mendlowitz, Fussell, and Petras to assess both cognitive and somatic components of arousal.[26] Participants are asked to rate each item from 1 (not at all) to 5 (extremely). Test-retest reliability of the scale in a sample of college students (n = 30) has been reported as 0.72 and 0.76 for cognitive and somatic components, respectively. The Cronbach's alpha for the cognitive and somatic components were 0.67 and 0.84 for the normal sleepers, and 0.76 and 0.81 for the insomniacs, respectively.

### *Kentucky Inventory of Mindfulness Skills*

KIMS was developed by Ruth A. Bears. This 39-item instrument contains four subscales designed to measure four elements of mindfulness: observing, describing, acting with awareness, and accepting without judgment. Items are rated on a 5-point Likert-type scale (never or very rarely=1 to true to always or almost always true=5). Cronbach's alpha is between .76 to .91 for the four scales.[27]

### *Socio-semographic Proforma*

A semi-structured proforma with the following content is intended to collect information about participants:

a) Age and sex
b) Current place of residence
c) Living arrangement
d) Average screen time per day

### *Statistical analysis*

SPSS will be used to perform the statistical analysis. Descriptive statistics will be used to describe the sample. Paired *t* test will be used to assess the significance of the interventions.

## Discussion

Sleep disturbances not only affect academic performance but also potentially impact students' quality of life. Pharmacological treatments are in widespread use for sleep disturbances. Though also in use, psychotherapies are not widely implemented. Our study intends to address sleep disturbances through psychobehavioural interventions and to explore their effectiveness. This study will pave the way for administering and assessing similar psychotherapies in the future in a broader population. Based on the results of our study, in the future it can be translated into practical use by making these therapies easily accessible to students in medical colleges and can be made as a part of medical curriculum, thereby promoting students' mental and physical well-being. If proven effective, these therapies could be potentially used and generalized to other young adults, as most students share a similar academic load and constitute a significant proportion of the Indian population.

Our study is a comprehensive and holistic one and the first study of its kind in medical students. As a follow-up is conducted at the end of 3 months, the study assesses some medium-term effects of the therapies. However, the study is not devoid of limitations. The study population consists only of students who are willing to participate, and hence other students with significant burdens might be missed. The sample size is small and includes only medical students, hence cannot be extrapolated to the general population. Moreover, the assessments are subjective, and no objective measures such as actigraphy or polysomnography are used to assess sleep. Last, 3 months is an effective medium-term follow-up period, but future studies may consider longer-term follow-up periods of 6 or 9 months.

## Conclusion

This study will provide valuable insights regarding the feasibility and effectiveness of non-pharmacological sleep interventions among medical students. It will help to compare the effectiveness of mindfulness-based sleep strategies with sleep hygiene for sleep improvement.

### Authors' contribution

SJK planned the study, designed the framework, and wrote the methodology section of the manuscript.AN did the first draft of the article. SJK refined the manuscript and contributed to the subsequent drafts. Both authors agreed on the final version of the manuscript submitted for publication.

### Ethical approval

This study is approved by the Institutional Ethics Committee, Sri

Ramachandra Institute of Higher Education and Research. (Ref: CSP-MED/20/NOV/63/156).

**Competing interests**

The authors declare that they do not have any competing interests.

**Consent to participate**

Informed written consent will be obtained from the participants at the time of recruitment to the study. They will have the right to withdraw their consent at any phase of the study.

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