Development, Validation, and feasibility of Integrated Yoga module on *Anidra* (Insomnia)

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Abstract

Background: Insomnia is described as "a complaint of trouble beginning or maintaining sleep associated with daily effects that are not attributed to environmental factors or insufficient chances to sleep." According to the study, Yoga was shown to be safe and effective in improving sleep for individuals experiencing insomnia *(Anidra)*. In this study, an Integrated Yoga Module (IYM) was specifically designed to manage *Anidra* (Insomnia). **Method:** The IYM was designed following a thorough review of classical yoga texts and prior research. Twenty-five yoga experts meeting the inclusion criteria were selected to validate the content of the IYM. The IYM comprised a total of 42 yoga practices, with each practice undergoing discussion and evaluation, categorized as (1) effective, (2) useful but less effective, or (3) not effective. The Content Validity Ratio (CVR) was calculated using Lawshe's formula. The feasibility of the IYM was assessed by experts using the Pittsburgh Sleep Quality Index (PSQI). To evaluate the feasibility of the intervention, we applied the developed program to 40 participants (20 in each group) in control and experimental groups for 45 days, with sessions conducted five days a week. **Result:** Data analysis revealed that, among the 22 IYM practices, 17 demonstrated significant content validity with a CVR exceeding the 0.44 cut-off, as determined by Lawshe's formula. Conversely, five yoga practices fell below the 0.44 CVR and were therefore rejected. Moreover, a significant improvement in sleep quality was observed in the experimental group. **Conclusion:** The yoga module designed and validated for the management of insomnia or *Anidra* is acknowledged as well accepted with good content validity and an efficacious program for insomnia management.

Keywords: Sleep Disorders, Insomnia, Development, Validation, Yoga

Introduction

Sleep is a necessary occurrence that renews our vitality. Insomnia is described as difficulty in initiating or maintaining sleep or both, or the experience of low-quality sleep[(1)]. Due to its major effects on health and well-being, insomnia[(2)], a common sleep condition marked by difficulties getting to sleep or staying asleep, is receiving increasing attention[(3)]. One of the most typical medical symptoms is sleeplessness. Lack of sleep is associated with significantly lower work performance, decreased daytime functioning, and increased healthcare costs[(4)]. Humans frequently endure periods of disturbed sleep as a result of acute stress or environmental change, but persistent idiopathic insomnia is an aberrant disease that has serious health consequences[(5)]. Over the course of a year, general sleep disturbance is thought to affect 85% of people, while identified chronic insomnia is thought to affect 10% of people[(6)]. Yoga and other complementary and alternative therapies have grown in popularity as viable treatments for insomnia[(7,8)].

Yoga reduces insomnia in a variety of ways, all of which involve different systems. Yoga practices frequently include breathing exercises, mindfulness meditation, and voluntarily controlled breathing *(pranayama)*[(9,10)]. These components work together to lower levels of tension, anxiety, and arousal[(11)], which are typically connected to insomnia. Yoga's effects on the Autonomic nervous system[(7)], particularly the stimulation of the parasympathetic branch, promote a state of relaxation favorable to sleep[(12)]. The mind-body connection greatly influences yoga's effect on insomnia[(13)]. Yoga improves bodily awareness and mindfulness when practiced regularly[(10)]. This increased awareness enables people to identify the physical symptoms of tension and stress, allowing them to control these symptoms and encourage the kind of relaxation that leads to sleep[(14)].

Numerous research studies have investigated how yoga can help people who suffer from sleeplessness. A simple integrated yoga protocol involving meditation practice for at least 25 minutes per day is a safe and applicable non-drug intervention for older people experiencing insomnia. It improves sleep quality, sleep latency, subjective sleep state, Slow Wave Sleep (SWS) phase duration, and psychological and emotional well-being[(15)]. The combination of Restorative and Gentle *Hatha yoga* employs a holistic sequence of meditation, breathing practices (*Pranayama*), and postures (*Asana*), requiring both the passive and active engagement of skeletal muscles, which may potentially offer an effective

approach for the improvement of sleep quality. Studies suggest yoga is beneficial in the treatment of anxiety, depression, fatigue, and other conditions associated with sleep disorders among healthy individuals and those with cancer[16]. The study aimed to develop an IYM for *Anidra* (Insomnia) and assess the feasibility of this module on insomnia.

Materials and Methods

In this study, a comprehensive review of ancient and classical texts[17] and recent research on Insomnia and sleep was conducted. The practices which showed distinct benefits were included and are shown in Table 1. The findings reveal that the yoga techniques delineated in these texts have demonstrated potential enhancements in memory, executive function, and health-related quality of life with relevance to insomnia. The observed positive effects of yoga asanas, whether manifested directly or indirectly, exhibit correlations with factors such as the vascular risk index and long-term psychological distress[8].

The exclusion criteria encompassed activities characterized by vague descriptions, complex, advanced, or balancing postures, as well as those typically contraindicated in cardiovascular, cerebrovascular, and uncontrolled hypertension conditions[18]. The yoga-based intervention was suitable for each age group by modifying selected yoga poses and incorporating suitable props and supports when necessary. A comprehensive module was developed to address all dimensions of yoga, comprising *sukshmavyayam* (warm-up practices), yoga *asanas* (body postures), *kriyas* (purification techniques), *pranayama* (breathing practices), and meditation, specifically nadanusadhana and Mind Sound Resonance Technique (MSRT).

Table 1: Basis for development of module

Type of the practice	Name of the practice	Round each (Duration in Minutes)	Expected benefit
Prayer	Beginning with *OM* Chanting (3 times)	3 (2)	*OM* chanting enhances parasympathetic nervous system activity, improves sleep quality, fosters relaxation, reduces insomnia symptoms, and enhances calmness.
Chandra Namaskar	*Chandra Namaskar* 3 rounds	3 (3)	*Chandra Namaskar* has a cooling effect on the body, reduces stress, rejuvenates the senses, relaxes muscles, refreshes the mind, balances fiery energies, and induces calmness.
Standing postures	*Pad-Hastasana* 1 minute	2 (1)	Reduces localized adiposity, particularly in the abdomen, hips, and arms, while enhancing emotional stability during stress.
Sitting posture	*Badhdhkonasana*, *Shanshankasana*, *Parvatasana* 3 min	2 (3)	
Prone postures	*Makarasana*, *Bhujangasana* 2 minutes	2 (2)	
Supine postures	*Viparitkarani Mudra*, *Matsyasana*, *Savasanan* 3 minutes	2 (3)	
Breathing practices	*Nadi Shodhan*, *Bhastrika*, *Ujjai*, *Bhramari* 12 minutes	12 minutes	Practice of pranayama decreased daytime sleepiness, snoring and, improves sleep quality.
Deep relaxation	MSRT 30 min	30 minutes	MSRT reduces the levels of stress, fatigue, anxiety, and psychological distress and increases vagal dominance, which may enhance sleep quality.
Meditative practice	*Nadanusandhana*	5 minutes	The practice of *nadanusandhana* may improve sleep quality.

Abbreviations: MSRT: Mind Sound Resonance Technique

Validation of Yoga Module

The Yoga Module was distributed to 60 yoga experts, of whom 42 responded with their scores and notes. Subsequently, 25 experts were shortlisted. The expert panel responsible for validating the Yoga Module consisted of individuals with a minimum of five years of clinical experience and a Master's degree in Yoga (M. Sc. Yoga), as well as those from Ayurveda, Yoga and Naturopathy, Unani, Siddha, Homeopathy (AYUSH) streams of medicine holding post-graduate degrees in Yoga. Additionally, researchers with doctoral degrees in Yoga and practitioners of Yoga and Naturopathy with over five years of clinical experience were included in the panel. (Figure 1)

The response of each expert was categorized as

1. Effective: very important for improving sleep quality
2. Useful but less Effective: useful in improving general health but not much effective for insomnia
3. Not Effective: has no role in insomnia

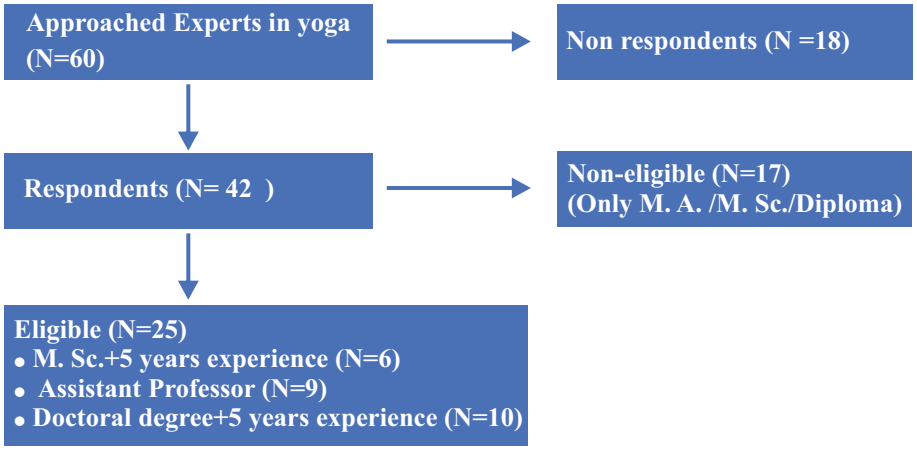

Figure 1: Steps for Recruitment of Experts

Feasibility test for validity

The feasibility of the developed Yoga module of *Anidra* (Insomnia) was tested. The cut-off value of 0.44 was calculated by applying Lawshe's formula for the Content Validity Ratio (CVR)[19]. The formula is

$$\text{Lawshe's formula : } CVR = \frac{(Ne - N/2)}{N/2}$$

Where:

Ne = total number of experts indicating "essential" for each practice

N = Total number of experts

CVR = Content validity ratio

The mean CVR across the items was used as an indicator of the overall test content validity.

Study participants

Forty participants were taken from Sir Sundra Lal Hospital, OPD No. 15. We selected adaptive participants in two groups, 20 participants each. We also excluded patients with critical diseases. No participants had a mental or psychiatric history. Participants were aged between 18 and 50 years. They had less than three months of yoga experience in the past year and were not currently engaged in any structured yoga practice. Participants were recruited from university campuses, local community centers, and online advertisements. The study aimed to assess the effects of the intervention on a relatively yoga-naive population, ensuring that the observed outcomes were not influenced by prior yoga practice.

Intervention

The 20 participants of the experimental group practiced the earlier-mentioned validated yoga module for five days each week, with each session lasting one hour and five minutes; for 45 days. The sessions were held on a specialized platform using a hybrid mode. A certified yoga instructor led the session. As each session progressed, the Principal Investigator kept close tabs on everything. Furthermore, there was no drop out in follow-up data after the conclusion of the research. Consistent phone calls or text messages served as reminders to the participants. Major adverse effects were not recorded. No intervention was given to the 20 participants in the control group.

Outcome

Anidra (Insomnia) was measured using Pittsburg Sleep Quality Index (PSQI) where a lower score indicates better sleep quality and a higher score indicates poor sleep quality. Participants scored 10 or more on the PSQI.

Statistical analysis

A paired sample t-test was used to compare PSQI scores at baseline and after intervention.

Result

Among the 22 selected yoga practices subjected to validation, 17 received a CVR score of ≥ 0.44, signifying robust content validity. These specific practices are detailed in (Table 2).

Table 2: Practices with a Content Validity Ratio score of ≥ 0.44

Yoga Practice items	Ne	N	N/2	Ne-N/2	CVR	Remarks
Beginning with *OM* Chanting	25	25	12.5	12.5	1	Retain
Chandra Namaskar (Moon Salutation)	25	25	12.5	12.5	1	Retain
Pad-Hastasana (hand to foot pose) -with Props	19	25	12.5	6.5	0.52	Retain
Parvatasana (Mountain pose)	20	25	12.5	7.5	0.6	Retain
Shanshankasana (pose of the moon)	25	25	12.5	12.5	1	Retain
Badhdhkonasana (cobbler's pose)	18	25	12.5	5.5	0.44	Retain
Viparitkarani Mudra (inverted psychic attitude)	24	25	12.5	11.5	0.92	Retain
Matsyasana (Fish pose)	22	25	12.5	9.5	0.76	Retain
Bhujangasana (Cobra pose)	19	25	12.5	6.5	0.52	Retain
Makarasana (Crocodile pose)	21	25	12.5	8.5	0.68	Retain
Savasanan (Corpse pose)	24	25	12.5	11.5	0.92	Retain
Nadi Sodhan (Psychic network purification)	25	25	12.5	12.5	1	Retain
Bhastrika (bellows breath)	20	25	12.5	7.5	0.6	Retain
Ujjai (the psychic breath)	22	25	12.5	9.5	0.76	Retain
Bhramari (Humming bee breath)	25	25	12.5	12.5	1	Retain
Nada-Anusandhana (Meditation Technique)	23	25	12.5	10.5	0.84	Retain
Mind Sound Resonance Technique (MSRT)	25	25	12.5	12.5	1	Retain

Conversely, five practices (Table 3) scored < 0.44 in CVR, indicating low content validity.

Table 3: Practices with a Content Validity Ratio score of < 0.44

Yoga Practice items	Ne	N	N/2	Ne-N/2	CVR	Remarks
Warm-up Practice*Chakki Chalan Asana*	11	25	13	-2	-0.15	Reject
Warm-up Practice*Parivrrta Upavistha Konasana* (Revolved Seated Straddle Pose)	14	25	13	1	0.07	Reject
Vajrasana (Thunderbolt pose)	16	25	13	3	0.23	Reject
Janu-sirasana (head to knee pose)-Both side	15	25	13	2	0.15	Reject
Surya-bhedi Pranayama (vitality stimulating breath)	11	25	13	-2	-0.15	Reject

Table 4 provides efficacy of the yoga module.

Table 4: Pre & post-Pittsburgh Sleep Quality Index scores

Category	Group	pre-mean	post-mean	p-value
Control	20	12.75	12.2	0.308
Experimental	20	12.1	9.45	0.0001

The study involved participants aged 18-35, with a majority of females (55% female and 45% male). The PSQI Score in the yoga group showed a significant decrease, signifying an improvement in sleep quality. Conversely, there was an increase in the control group; however, it was not statistically significant. Remarkably, participants provided exceptional subjective feedback during the practice, expressing that the module was highly convenient, comfortable to use, and well-received.

Discussion

In this study, we created an effective yoga module for *Anidra* (Insomnia). From classical yoga literature and the results of earlier research, we choose several yoga practices, such as breathing practices, yoga postures, and relaxation and meditation methods based on yoga. This module was validated by 25 certified experts who fulfilled the research requirements. Seventeen of the practices that underwent validation and were incorporated into the final validated yoga module had a CVR score of more than 0.44. Designing the yoga module for *Anidra* (insomnia) and expert validation of the module for *Anidra* (Insomnia) were the two aspects of this project. The validation of a yoga module for *Anidra* (Insomnia) has not yet been the subject of any prior investigations.

This study is unique because there was no validation of Yoga module for insomnia before, and the feasibility of the study was determined with no side effects or any participant complaints. Finally, the sleep quality of the participants improved significantly.

The *OM* Chanting in this module cleanses your surroundings and generates uplifting energy that makes you feel happier and less stressed[20]. *Chandra Namaskara's* (Moon Salutations) fourteen positions correspond to the lunar phases, *Shukla paksha* (Fourteen days before the full moon) and *Krishna paksha* (Fourteen days after the full moon). The lunar energy flows within *ida nadi.* It has cool, relaxing and creative qualities[21]. *Ida* is the introverted, feminine, or mental force that is responsible for consciousness[22]. They aid in mental and physical relaxation[7,23]. Pad-hastasana aided in increasing metabolism[24] and sharpening focus. Other supine and prone positions improved with mobility by increasing flexibility[25] and strength. This pose also reduces stiffness in the muscles of the back, hips, and lower limbs[26].

Nadi-sodhan helps infuse the body with oxygen and clear and release toxins. Bhastrika Pranayama helps to calm the mind[27] and energizes the entire body and mind[28]. *Bhramari Pranayama* induces calm, quiets the mind, and releases cerebral tension[29].

Techniques for mindfulness-based meditation to support the harmony of the mind and Yoga have aided in stress reduction, health promotion[30], and the promotion of positive moods[31]. The feelings of anxiety and depression that cause sleep disturbances can be managed once there is a decrease in stress hormones[22,31].

All methods of relaxing improved physical and mental relaxation[33] by lowering tension and anxiety[34]. All these are the causes of insomnia and their reduction leads to improvement in insomnia.

Limitations

In this study, the sample size was small, which can be increased in future research. Also, its results should be seen by using it in different environments. Appropriate results can be obtained by increasing the numbers based on age and gender. By addressing these limitations and defining criteria, the reliability and validity of the yoga module can be enhanced, leading to more meaningful and applicable results.

Conclusion

This Integrated Yoga Module (IYM) was formulated through a synthesis of insights from traditional yoga literature and recent research, subsequently undergoing validation by experts. Feasibility tests yielded significant results. While future research is imperative to ascertain the practicality and efficacy of the IYM, the current findings suggest that this yoga module holds suitability in the interim.

Conflict of Interest: Nil

Sources of funding: Nil

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Ethical consideration

This study was approved by the Institutional Ethics Committee of the Institute of Medical Sciences, Banaras Hindu University, and registered in the Clinical Trial Registry of India (CTRI/2023/08/056821).

Authors' Contribution

VSY: Planning, Conceptualization, design, data collection, implementation, data analysis, Yoga Instructor, interpretation, and manuscript writing; MP: Conceptualization, design, implementation, data analysis, interpretation, and manuscript writing; BNM: Reviewing the manuscript Conceptualization, design, Senior Investigator,

data collection, implementation; VT: Design, data collection, data analysis, interpretation; MK: Design, data collection, data analysis, interpretation; AM: data collection, design, implementation, manuscript writing

Data availability statement

Data will be available with corresponding author on request

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