ISSN No: 0976-5921
Published online at https://ijam.co.in

International Journal of Ayurvedic Medicine, Supplement of International Conference on Ayurveda-Yoga-Nathpanth - 2025

A comparative study to assess the impact of an Integrated yoga module on different types of Headache: A study Protocol

Research Article

Viturv Tripathi[1], Vijaya Nath Mishra[2*]

1. PhD. Scholar, 2. Professor, Department of Neurology, Institute of Medical Sciences, Banaras Hindu University, Varanasi-221005, UP. India.

Abstract

Aim: The study is focusing on investigating the effect of yoga as a complementary therapy in reducing headache frequency, intensity, and duration, and its impact on quality of life in affected individuals. Background: Neurological disorders like headaches can significantly impact quality of life and daily routines. To manage these issues, patients can reduce stress, sleep, dietary changes, and physical activity. This study aims to evaluate the effectiveness of yoga as a physical movement in managing neurological issues like headaches. The intervention includes behavioral lifestyle modifications, asanas pranayama, and meditation sessions. The results will enhance yoga's effectiveness in controlling neurological disorders and their associated headaches. Future research will explore the potential mechanisms of yoga and its impact on chronic conditions. Methods: A comparative study trial has been designed for a study to be conducted in Sir Sundar Lal Hospital of Varanasi, Banaras Hindu University. A total of 100 patients will be recruited and will be offered to take medication and yoga or only take medications and will be evaluated from base line to follow-up through different parameters of headache frequency, headache intensity and quality of life. The yoga group will receive yoga session through online mode, weekly 2 sessions for aprox. 60-min and the control group will receive Medication of Standard therapy. Conclusion: The effect of a pre-designed yoga module in managing headaches, focusing on outcomes like intensity, frequency, and quality of life. The findings could lead to new healthcare opportunities and enhance neuro management research, practice, and policy.

Keywords: Yoga, Headache, Migraine, Tension-type headache, Mind-body therapy, Stress management, Complementary medicine.

Introduction

The nervous system has two primary types: the Central Nervous System (CNS) and the Peripheral Nervous System (PNS). Conditions that impact the Nervous System are referred to as neurological diseases. It is a disorder characterized by detrimental effects on the brain, spinal cord, peripheral nerves, or neuromuscular function. The primary symptoms associated with the aforementioned illnesses include pain, nausea, muscular weakness, loss of consciousness, tremors, seizures, imbalance, disorientation, and constipation. Numerous neurological illnesses are recognized, with some being somewhat prevalent while others being seldom. The 2006 World Health Organization estimate indicates that around one billion persons globally are impacted by neurological disorders and their direct consequences (1).

*** Corresponding Author:**

Vijaya Nath Mishra
Head of the Department,
Department of Neurology,
Institute of Medical Sciences,
Banaras Hindu University,
Varanasi- 221005, Uttar Pradesh, India.
Email Id: vnmishra_2000@yahoo.com

A headache is characterized by pain in the head, neck, or face. It can present in three primary forms: cluster headache, migraine, and tension-type headache (TTH) (2),(3),(4). Fatigue, stress, sleep deprivation, and dehydration are the aetiologies of headache. Headaches are among the most prevalent physical ailments, with migraine and tension-type headaches being the most common forms associated with neurological problems (5), (6), affecting over 848 million individuals globally. Prevalence of headache throughout various age groups; active headache diseases manifest in adulthood, 47% of headaches are general, 10% are migraines, 38% are tension-type headaches (TTH) (7), and around 3% are chronic headaches lasting more than 15 days (8). In youth, the primary site of headaches is the occipital region, with secondary headaches occurring sometimes. Headache is the primary cause of disease in children; to prevent the oversight of secondary headaches, a systematic strategy is essential (9). In the elderly population, headache is a prevalent neurological complaint; a secondary headache disease should be considered in older individuals presenting with new-onset headache (10). Two extensive epidemiological investigations conducted in Iran and Japan have shown a preference for female patients, comorbidity with migraine, and a prevalent bilateral characteristic of headache (11). The lifelong prevalence of headaches is

around 96%, with tension-type headaches accounting for around 40% and migraines for 10%. Migraine predominantly manifests between the ages of 25 and 55, occurring three times more frequently. In pregnant women, migraine is the predominant cause of headache (12). Currently, standard medical care is the chosen initial treatment approach. Yoga therapy, physiotherapy, music therapy, and other alternative therapies are favored for certain musculoskeletal neurodegenerative disorders. Various organizations also conduct neuro-rehabilitation programs to improve neurological conditions. Additionally, some pain management programs and medications are preferred to alleviate symptoms of neurological deformities. These therapies effectively reduce both motor and non-motor symptoms associated with neurological disorders. These alternative therapies also mitigate the adverse effects of medications utilized in modern medical treatment. This research primarily examines Yoga Therapy, a technique that has been prevalent in India for hundreds of years. Currently, Yoga is increasingly adopted in the Western world as a supplemental therapy and is gaining global recognition. It is a conventional, secular mind-body activity that promotes health, prevents sickness, and benefits the nervous system. Yoga, deep breathing techniques, and meditation are frequently employed to enhance brain neuroplasticity (13),(14). The practice of yoga is categorized into eight components, known in yogic terminology as the eight limbs of Yoga: Yama, Niyama, Asana, Pranayama, Pratyahara, Dharana, Dhyana, and Samadhi. However, three of them are particularly prominent in contemporary society: Asanas (postures), Pranayama (breathing methods), and Dhyana (meditation). The biological mechanisms associated with the aerobic aspects of yoga include asana (the dynamic sequence of physical practice), pranayama (breath control), and meditation (a technique for alleviating mental stress). Yoga is instructed to mitigate the symptoms of neurological disorders and reduce the side effects of contemporary medicine. This study aims to assess the efficacy of Yoga Practice as an adjuvant treatment for individuals with neurological problems, specifically focusing on three neural issues: headache, Parkinson's disease, and stroke (5).

Aim & Objective

To assess the effect of yoga as an add on treatment for patients suffering from neurological disorders; Headache, Parkinson's Diseases and Stroke.

The aims and objectives of the study are listed below.

Table 1: Objective of the research

	Disorder	Primary	Secondary Objective
1	***Headache***	Change in Headache intensity,	Change in HIT Score, MIDAS score, HADS.

Methodology

Design

The study will employ comparative study design and will be randomized into experimental and control groups in a 1:1 ratio, with the control group receiving standard modern medical treatment, while the experimental group will receive training in a specific yoga module in addition to modern medical treatment. Sessions will be conducted both online and offline, with online sessions delivered via audio-visual platforms such as Zoom. Each session will last 60 minutes and occur twice weekly for a duration of six months.

Study Population

Recruitment strategies

This study will recruit patients of Headache, Parkinson's Disease and Stroke through physical examination of patients from Neurology Outpatient Department (OPD), Sir Sunder Lal Hospital, Institute of Medical Sciences (IMS), Banaras Hindu University (BHU), Varanasi, Utter Pradesh (UP) India.

Sample Size Calculation

Headache

The standards approach has been employed for the collecting of samples and the analysis of data pertaining to the patients. The sample size for this study has been determined based on the mean change in MIDAS scores following intervention in both the control group and the trial group (Yoga), referencing previously published studies on headaches. The formula for sample size concerning two sample means has been utilized, employing a 5% significance threshold and 90% power. Based on

$$n = 2(Z_{1-\alpha/2} + Z_{1-\beta})^2 S^2/d^2$$

Where, $Z_{1-\alpha} = 1.96$ at 5 percent level of significance.

$Z_{1-\beta} = 1.28$ at 90 % power

d= difference of mean of MIDAS score after treatment in control and trial groups

S= pooled standard deviation.

Thus, the sample size calculated n=80 for stress score and n=107 for MIDAS score.

Therefore; the maximum of second score

So; n=80 will be sample size.

Further, assuming 25% loss to follow up the required sample size for the present study will be

n = 100 in each group.

Inclusion Criteria

Headache

- Migraine with or without aura, Tension type headache & Trigeminal Autonomic Cephalalgias (TAC)
- Age above 18 years old and below 65 years

Exclusion Criteria

- Headache patients with Cough,
- Any Headache due to ear, Nose, Throat infection
- Chronic Head issues like injured head etc.

Drop-out criteria

1. Patients who refused to cooperate with the test and diagnostic errors after enrolment were considered as excluded cases;
2. During the study period, patients dropped out, did not complete the whole course of treatment, and poor compliance were considered as abscission cases.

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Published online at https://ijam.co.in
International Journal of Ayurvedic Medicine, Supplement of International Conference on Ayurveda-Yoga-Nathpanth - 2025

3. Patients who could not tolerate in Practicing Yoga Practice regularly, had serious adverse events during treatment, or had serious complications caused by other diseases would terminate the trial.

Intervention

Initial therapy

All patients will be allowed to routinely take their Standard medication.

The Treatment Group

Both groups will be informed what they will receive either yoga or Medication. The experimental group will ask to practice yoga through on line and offline methods, in online form we will use ZOOM/ Google meet platform. Also, Patients will be provided with an offline guide book where they will be asked to perform Physical/Breathing/Meditation Practice.

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow Diagram of the study

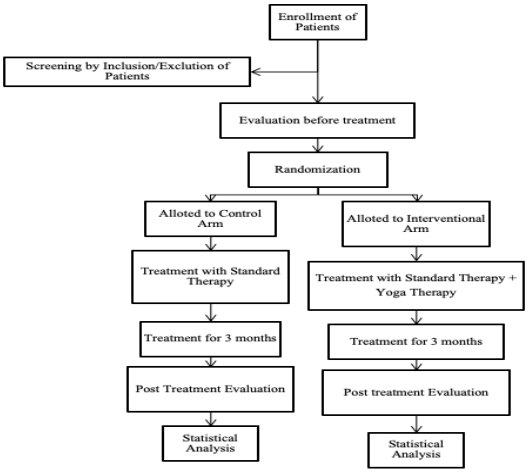

Table 2: Yoga Module for Headache

S.No.	Module	Procedure	Rounds	Time(min)
1	Opening Ritual	3 deep Breath 3 Times OM	2 min	2
2	Warm Up	Cross legged mov movements Relax with mild E	10-10 Breaths	5
		Surya Namaskar	3 to 5	10
3	Asana Practice	Urdwa Hastasana Shashankasana Bhujangasana Makarasana Setubandhasana Pawan Muktasana Shavasana (QRT) Technique	10 breaths 10 breaths 10 breaths 10 breaths 10 breaths 10 breaths 10 breaths	15
4	Pranayama	Naadishodhana Mild Kapalabhati Anulom Vilom Bhramari	15 to 20 bre 1:1 and 5 to 3 to 5 Breat	10
5	Yoga	Deep relaxation	10 mins	10
6	Dhyana	Meditation	2 to 5	3
7	Closing	Om Shanti	2 min	5
	TOTAL TIME			60 minutes

Content Validity

To ensure the validity of the novel mindfulness yoga intervention regarding its appropriateness, safety, and applicability, the yoga protocol was evaluated by a representative panel of 64 experts with clinical expertise. The content was validated by three neurologists, one physical education researcher specializing in balance and falls, one physiotherapist, and 64 yoga instructors, all of whom possess experience in teaching individuals with chronic illnesses. Many of the experts hold certifications in “Mindfulness-based Cognitive Therapy” (MBCT) and “Mindfulness-based Stress Reduction” instruction. All specialists were selected from various institutions, including Patanjali Yogpeeth, Haridwar; Dev-Sanskriti Vishwa Vidyalaya, Haridwar; Morarji Desai, New Delhi; Kaivalya Dham, Pune; S-VYASA, Bengaluru; AIIMS, New Delhi; and AIIMS, Rishikesh. The yoga regimen has been substantiated.

The content validity of each intervention item was assessed using the Item-Content Validity Index (I-CVI), which informed the judgments about item retention or rejection. An I-CVI of 0.78 or above was deemed to indicate strong content validity. Simultaneously, professional feedback informed the creation of new goods and the modification of existing ones.

Outcomes Measures

i) Headache intensity
ii) Headache Frequency
iii) Headache Impact Test (HIT)–6 score
iv) MIDAS score
v) HADS (Hamilton Anxiety and Depression Scale) test
vi) QoL score

Data collection

The principal investigator will verify the eligibility of potential participants. Eligible people will receive an Information Sheet on the study, and signed informed consent will be obtained. Subsequently, demographic and health background data will be collected. All primary and secondary outcomes will be evaluated at baseline (T0), one months (T1; post-intervention), and third months (T2) following the end of the intervention. Participants will be directed to adhere to their regular medication regimen and physical activity, refraining from initiating any new, instructor-led exercise programs throughout the research time.

Risk and Safety

Yoga is generally perceived as safe, with adverse consequences being few. Muscle injuries or strains are the most significant risks in yoga. This program emphasizes the need of adequate warm-up and cool-down activities. The use of props, including a towel, chair, and wall, will assist participants in attaining some of the more challenging postures. Additionally, each pose in this yoga program has been meticulously designed and evaluated by an expert panel to guarantee its gradual and safe implementation for those with mild-to-moderate Parkinson's disease or stroke. The

interveners will possess a minimum of two years of teaching experience with clients suffering from chronic diseases. Participants will be directed to report any unforeseen or atypical symptoms to the primary investigator regarding any adverse occurrences.

Discussion

The outcomes of this study will augment current knowledge from previous research demonstrating the benefits of yoga for improving physical health, including the relief of headaches. Mitigation of pain in headache disorders, motor symptoms of Parkinson's disease, postural instability, functional mobility, spasticity post-stroke, and other associated illnesses. This project will enhance research on the use of yoga to mitigate psychological distress in patients experiencing headaches and those with mild to moderate Parkinson's disease or stroke. This discourse will highlight proactive self-care strategies within a cohesive, multidisciplinary framework, empowering patients to acknowledge their condition and supporting their path to self-transcendence in pursuit of well-being while traversing the challenging trajectory of illness. Headaches are among the most prevalent neurological illnesses, affecting millions of people worldwide. Primary headaches, including migraines, tension-type headaches (TTH), and cluster headaches, may lead to considerable disability and diminished quality of life (4),(5). Despite the accessibility of pharmaceutical interventions, several individuals encounter insufficient alleviation or adverse consequences, resulting in a growing interest in non-pharmacological therapy, such as yoga. This study protocol delineates a comparative evaluation of the effects of an Integrated Yoga Module (IYM) on various headache kinds, specifically targeting migraines and tension-type headaches (8).

The therapeutic function of yoga in the management of neurological illnesses has gained recognition, especially for its capacity to treat both physical and psychological aspects of health. Yoga, via its integration of physical postures (asanas), regulated breathing (pranayama), and meditation, seeks to facilitate relaxation, equilibrate the autonomic nervous system, and alleviate stress—elements that are pivotal in the pathophysiology of headaches (12). Studies have shown that yoga can beneficially affect the neuroendocrine system, therefore decreasing the frequency and severity of headaches, especially in those with migraines and tension-type headaches (TTH).

A principal feature of the current study protocol is its integrative strategy, which amalgamates various parts of yoga to build a comprehensive therapy module (14). The Integrated Yoga Module (IYM) utilized in this study incorporates particular pranayama techniques recognized for improving respiratory efficiency and alleviating stress-induced hyperventilation, frequently linked to headache causes. The integration of meditation and mindfulness activities in the IYM may further alleviate emotional and psychological stresses, which are recognized factors to headache episodes.

Numerous researches have corroborated the efficacy of yoga in alleviating headache-related symptoms. A randomized controlled experiment showed substantial decrease in both the frequency and intensity of headaches among migraine patient who engaged in yoga for 12 weeks (15). A study discovered that a yoga intervention decreased the severity of tension-type headaches and enhanced general well-being (16). These data indicate that yoga may serve as a valuable complement to traditional therapies, decreasing dependence on medicine and alleviating adverse effects linked to prolonged pharmacotherapy.

Although the data supporting yoga's effectiveness in headache therapy is encouraging, further rigorous and comparative research are necessary, particularly across various headache kinds. A significant drawback in the current data is the variability in study designs, treatments, and outcome measurements, which complicates the standardization of yoga programs for certain headache kinds. This study aims to fill this gap by adopting a well-defined and standardized Integrated Yoga Module and evaluating its effects on migraines and tension-type headaches.

Another crucial factor to contemplate is the enduring durability of yoga's benefits. Numerous researches indicate enhancements during the intervention period but neglect to assess the sustainability of these effects once the intervention concludes. This study will incorporate follow-up examinations to examine the enduring effects of the IYM, therefore providing significant evidence on the durability of yoga's therapeutic benefits.

Possible obstacles for this study are participant compliance with the yoga routine and diversity in individual reactions to the intervention. To alleviate these problems, the research will incorporate supervised sessions and regular follow-ups to assure adherence and address any concerns participants may possess. Furthermore, endeavours will be undertaken to categorize the outcomes according to participant characteristics, including age, headache history, and baseline psychological stress levels, to investigate if specific subgroups may get greater benefit from the intervention compared to others.

This study protocol delineates a methodical strategy to evaluating the effectiveness of an Integrated Yoga Module in the management of various headache types. This study seeks to further understanding of yoga's role as an adjunct therapy for headache problems by addressing existing gaps in the literature. The results are anticipated to enhance the existing evidence for integrative methods in headache therapy and may significantly impact clinical practice and patient care.

Acknowledgement

The authors wish to acknowledge the effort and support provided by the expert panel. Thanks to all the researchers who participated in this test for their help and efforts.

Funding

The funding will be done by Indian Council of Social Sciences Research(ICSSR), New Delhi.

Ethics approval and consent to participate

Ethics approval was obtained from IMS, BHU, Research Ethics Committee. Got CTRI approval for the work (CTRI no.: CTRI/2023/05/053346), written informed consent will be obtained from eligible participants before any assessment or intervention.

Consent for publication: Not applicable

Conflict of interest:

The authors declare that the research was conducted without any conflict of interest.

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