



## Efficacy and Feasibility of an Integrated Yoga Module as Add-On Therapy for Primary Headache: A Pilot Randomized Controlled Trial

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### Abstract

**Background.** Primary headache disorders, principally migraine and tension-type headache, are among the leading causes of disability worldwide, and a substantial proportion of patients remain dissatisfied with pharmacologic management alone. Integrated yoga has shown promise as an adjuvant therapy, but evidence from controlled trials remains limited. **Objective.** To evaluate the effect of a validated, 60-minute integrated yoga therapy module, delivered in a hybrid (online and offline) format as an add-on to conventional medical management, on pain, headache burden, psychological distress, sleep, quality of life, and analgesic use in adults with primary headache. **Methods.** In this single-centre, parallel-group randomized controlled trial, 40 adults (aged 20–70 years) with a clinical diagnosis of primary headache were randomly allocated 1:1 to Group 1 (integrated yoga module plus conventional medical management; n = 20) or Group 2 (conventional medical management alone; n = 20). Outcomes were assessed at baseline and at 3 months using the Visual Analogue Scale (VAS), monthly headache frequency, HIT-6, MIDAS, the Perceived Stress Scale (PSS), the Insomnia Severity Index (ISI), the WHOQOL-BREF, and a 30-day rescue-pill count. Within-group change was assessed by paired-samples t-tests and between-group difference by independent-samples t-tests. **Results.** The groups were demographically comparable at baseline (sex:  $\chi^2 = 1.026$ ,  $p = .311$ ; age group:  $\chi^2 = 3.796$ ,  $p = .434$ ). Group 1 improved significantly on all eight outcomes (all  $p < .001$ ); pain (VAS) fell from 8.40 to 2.65, and rescue-pill count from 60.0 to 30.5. Group 2 also improved on most outcomes, but the gains were generally smaller, and the change in HIT-6 was not significant ( $p = .267$ ). At 3 months, Group 1 was significantly superior to Group 2 for pain ( $p < .001$ ), HIT-6 ( $p = .003$ ), MIDAS ( $p < .001$ ), insomnia ( $p = .003$ ), and rescue-pill use ( $p < .001$ ); the groups did not differ significantly on headache frequency, perceived stress, or quality of life. **Conclusions.** Adding a validated 60-minute integrated yoga module to conventional care produced clinically meaningful improvements across pain, headache impact, disability, sleep, and analgesic use, and was superior to medical management alone on several key outcomes. A hybrid delivery model appears feasible and may broaden access to yoga-based adjuvant therapy for primary headache. Findings should be interpreted cautiously, given the small sample and single-centre design.

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## 1. Introduction

Primary headache disorders, mainly migraine and tension-type headache, are among the most prevalent neurological conditions and a leading global cause of years lived with disability.<sup>1,2</sup> Under the International Classification of Headache Disorders, third edition (ICHD-3), “primary” headaches are those that are not attributable to another underlying disorder, in contrast to secondary headaches caused by an identifiable structural, vascular, or systemic cause.<sup>3</sup> Migraine alone is the foremost cause of disability in people under the age of 50, with consequences that extend well beyond pain to lost productivity, impaired sleep, psychological distress, and reduced quality of life.<sup>4,5,6</sup>

Pharmacotherapy remains the first-line approach to primary headache, yet only about half of patients achieve clinically meaningful relief, a meaningful minority discontinue preventive drugs because of adverse effects, and many report dissatisfaction with available options.<sup>7,8</sup> These limitations have prompted interest in complementary, non-pharmacologic strategies that address the broader burden of headache.<sup>9</sup>

Yoga, a mind–body practice originating in India, integrates physical postures, regulated breathing, and meditative relaxation, and has documented effects on autonomic balance, stress physiology, and general well-being.<sup>10,26</sup> Controlled trials and systematic reviews suggest that yoga, when added to standard care, can reduce headache frequency, intensity, impact, and disability in patients with migraine and tension-type headache.<sup>11,12,13,24,25</sup> However, much of the existing evidence is limited by heterogeneous or unspecified yoga protocols, modest sample sizes, and a narrow focus on headache-specific endpoints, with limited attention to stress, sleep, quality of life, and analgesic consumption as parallel outcomes.

A further practical question is one of delivery. Supervised, in-person yoga is resource-intensive and difficult to scale, whereas fully unsupervised home practice may compromise technique and adherence. A hybrid model combining supervised, in-person sessions with remotely delivered (online) sessions may preserve fidelity while improving access, but it has been little studied for headache.

Against this background, we conducted a randomized controlled trial at the Department of Neurology, Institute of Medical Sciences, Banaras Hindu University (IMS BHU), to evaluate a single, standardized 60-minute integrated yoga therapy module that had been designed and validated by subject-matter experts, and delivered in a hybrid (online and offline) format. We hypothesized that adding this module to conventional medical management would produce greater improvement than conventional management alone across a broad set of patient-centred outcomes: pain intensity, headache frequency, headache impact, disability, perceived stress, insomnia severity, quality of life, and rescue-medication use.

## 2. Methods

This trial was designed, conducted, and reported in accordance with the CONSORT 2010 statement and the CONSORT extension for trials of non-pharmacologic treatments.<sup>22,23</sup>

### 2.1 Trial design and setting

We conducted a single-centre, parallel-group, two-arm randomized controlled trial with a 1:1 allocation ratio at the Department of Neurology, IMS BHU, Varanasi, India. Patients were assessed at baseline (pre-intervention) and after 3 months (post-intervention). The allocation ratio and outcome schedule were fixed before recruitment; there were no changes to the methods after trial commencement.

### 2.2 Participants

**Inclusion criteria.** Adults aged 20–70 years, of either sex and any marital status, with a clinical diagnosis of a primary headache disorder established by a neurologist using ICHD-3 criteria, who were able to participate in a yoga programme and provided written informed consent.

**Exclusion criteria.** Any secondary headache (for example, headache attributed to trauma, vascular or non-vascular intracranial disorder, infection, substance use or withdrawal, or disorders of the cranial structures) was excluded, as were patients with significant medical, psychiatric, or musculoskeletal conditions precluding safe yoga practice, pregnancy, or concurrent enrolment in another trial. All secondary headache types were excluded by design so that the study population comprised primary headache only.

### 2.3 Interventions

**Group 1 (integrated yoga module + conventional medical management).** Participants received a standardized 60-minute integrated yoga therapy module, designed and content-validated by qualified yoga and medical subject-matter experts, in addition to their usual prescribed medical management. The module integrated a starting invocation, loosening and breathing practices, sun salutation, selected asanas (postures), guided deep relaxation, and pranayama (regulated breathing), structured to total approximately 60 minutes per session, consistent with previously validated integrated yoga modules for headache.<sup>11</sup> Sessions were delivered in a hybrid format combining supervised in-person (offline) sessions at the department with remotely supervised online sessions, allowing participants who could not attend in person to maintain guided practice. Conventional medical management was not altered for the study.

**Module development and validation.** The module was developed from a structured review of classical yoga texts (including the Patanjali Yoga Sutras, Hatha Yoga Pradipika, Gheranda Samhita, and Hatharatnavali), contemporary therapeutic yoga texts, and peer-reviewed literature, following established methodological guidelines for developing yoga interventions for randomized trials.<sup>10,11,24</sup> Each candidate's practice was rated by subject-matter experts on a structured scale, and the content validity ratio (CVR) was computed for every item using Lawshe's method, with the critical value determined from the Ayre–Scally table for the number of panellists. Practices meeting the predefined CVR threshold were retained; items below the threshold (for example, certain sectional-breathing and standing-balance practices) were removed. The mean CVR across retained items (content validity index) supported the overall content validity of the module, and inter-rater agreement was high. Experts judged a 60-minute session, inclusive of relaxation, to be appropriate. The finalized, validated module is shown in Table 2.

**Table 2.** The validated 60-minute integrated yoga module (retained practices with content validity ratios). Durations are approximate and sum to about 60 minutes.

## Integrated Yoga Module for Headache

### 1. Opening Prayer

Practice	Instructions	Breath	Time
Opening Prayer	Sit in a cross-legged position. Keep spine straight. Hands on knees in Gyana Mudra. Chant Om / Ameen / Amen 3 times.	3 rounds chanting Om	1 min

### 2. Warm-Up

Practice	Instructions	Breath	Time
Finger Movements	Open fingers wide and close into a fist (thumb inside).	Normal breathing	—
Elbow Bending	Bend elbows to touch shoulders and straighten. Repeat 10 times.	Inhale, bend. Exhale straighten	—
Elbow Rotation	Rotate elbows 360° clockwise & anticlockwise.	Slow breathing	—
Knee Movement	Place one leg over the other, gently lift and press the knee up/down.	Coordinate with breath	—
Complete Warmup	Perform each movement 10 times with breath awareness.	10 breaths	5–10 min

### 3. Vibhagya Pranayama (Sectional Breathing)

Practice	Instructions	Breath	Time
Sectional Breathing	Interlock fingers. Stretch arms upward, keeping spine straight. Repeat.	10 breaths	20 sec

### 4. Parivritta Sukhasana (Dynamic Cross-Leg Twist)

Practice	Instructions	Breath	Time
Cross Leg Twist	Sit cross-legged. Left hand on right knee, right hand behind. Twist back and look over shoulder. Repeat the other side.	20 breaths (both sides)	1 min

### 5. Mild Bhastrika (Relaxation)

Practice	Instructions	Breath	Time
Mild Bhastrika	Raise arms while inhaling. Bend elbows and lower arms while exhaling. 2–3 rounds.	10–20 breaths	1 min

### 6. Surya Namaskar

Practice	Instructions	Breath	Time
Surya Namaskar	Perform 12 steps of Surya Namaskar as taught. Synchronize breath with movement. 3–5 rounds.	As per the sequence	10 min
Standing Relaxation	Stand in a relaxed position, body loose.	Normal breathing	20–30 sec

### 7. Asana Practice

Practice	Instructions	Breath	Time
Urdhva Hastasana	Stand straight. Raise arms upward. Observe navel movement.	10 breaths	15 sec
Shashankasana	Sit in Vajrasana. Bend forward, stretch arms, forehead on the floor.	10 breaths	15 sec
Vakrasana	Sit with legs straight. Bend one knee. Twist the spine and look back.	10 breaths	30 sec
Bhujangasana	Lie prone. Palms beside the chest. Lift head & chest while inhaling. Hold.	10 breaths × 3	1 min
Makarasana	Lie prone. Head on palms. Relax body fully.	Normal breathing	20 sec
Jathara Parivarthana	Lie supine. Bend knees to chest. Twist knees one side, head opposite.	Hold 10 sec each side	1 min
Pawanmuktasana	Lie supine. Hug knees to chest. Try touching forehead to knees. Exhale fully.	Hold 10 sec	1 min
Shavasana	Lie supine. Relax whole body. Observe breathing.	Natural breathing	5 min

### 8. Pranayama

Practice	Instructions	Breath	Time
Nadi Shodhana	Close the right nostril, exhale left. Inhale left. Hold breath. Repeat the other side.	5 rounds	2 min
Mild Bhastrika	Inhale & exhale through both nostrils slowly (not forceful). Avoid if BP/heart issues.	10 breaths	3 min
Kapalbhati	Forceful exhalation, like blowing out a candle. Avoid in BP/heart issues.	15 strokes × 3 rounds	3 min
Anulom Vilom	Alternate nostril breathing. Inhale 3 sec, exhale 6 sec.	5 rounds (20–30 breaths)	2 min
Bhramari	Close ears with thumbs, produce a humming sound while exhaling.	3–5 rounds	1 min
Sheetali	Roll tongue, inhale through mouth, exhale through nose.	3–5 rounds	1 min
Sheetkari	Inhale through the teeth, exhale through the nose.	3–5 rounds	1 min

### 9. Yoga Nidra

Practice	Instructions	Breath	Time
Deep Relaxation	Lie on back. Keep legs slightly apart, arms away from the body. Relax completely.	Natural breathing	10 min

### 10. Meditation (Dhyan)

Practice	Instructions	Breath	Time
Meditation	Sit cross-legged. Spine straight. Eyes closed. Observe breath.	Normal breathing	2 min

### 11. Closing Prayer

Practice	Instructions	Breath	Time
Om Shanti	Chant Om Shanti Shanti Shanti with three Oms.	3 Oms	1–2 min

**Group 2 (conventional medical management alone).** Participants received standard acute and preventive pharmacologic management as prescribed by the treating neurologist, together with routine lifestyle counselling, but were not given the yoga module during the study period.

#### 2.4 Outcomes

Outcomes were assessed at baseline and at 3 months using validated instruments: pain intensity on the 0–10 Visual Analogue Scale (VAS),<sup>16</sup> mean monthly headache frequency (headache days per month); headache impact on the HIT-

6;<sup>17</sup> headache-related disability on the MIDAS;<sup>18</sup> perceived stress on the Perceived Stress Scale (PSS);<sup>19</sup> insomnia severity on the Insomnia Severity Index (ISI);<sup>20</sup> health-related quality of life on the WHOQOL-BREF;<sup>21</sup> and analgesic use as a 30-day rescue-pill count. For VAS, frequency, HIT-6, MIDAS, PSS, ISI, and pill count, lower scores indicate improvement; for WHOQOL, higher scores indicate improvement.

## 2.5 Sample size

Forty participants (20 per arm) were enrolled. Given the exploratory nature of the trial and the single-centre setting, the sample was a convenience sample rather than formally powered to a pre-specified effect size.

## 2.6 Randomization and blinding

Eligible participants were randomly allocated 1:1 to the two groups. Because the intervention is a behavioural, participatory therapy, neither participants nor those delivering the yoga could be blinded to allocation; this is an inherent feature of trials of non-pharmacologic treatments.<sup>23</sup> Outcome data were recorded using standardized self-report instruments. Baseline comparability of the groups with respect to sex and age distributions was verified statistically (Section 3.1).

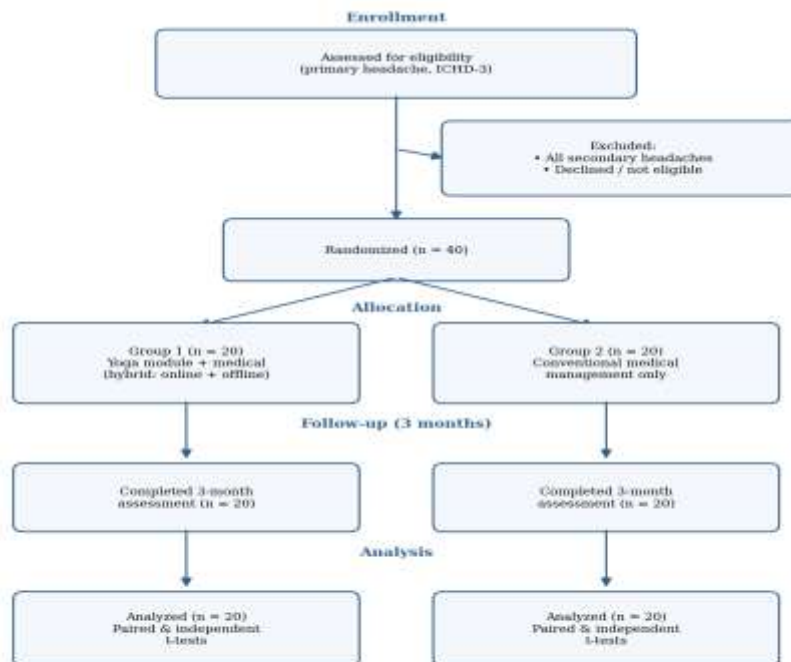
## 2.7 Statistical methods

Continuous outcomes are summarized as mean  $\pm$  standard deviation. Baseline categorical comparability (sex and age group) was tested with the chi-square ( $\chi^2$ ) test. Within-group change from baseline to 3 months was assessed for each arm using paired-samples t-tests, and between-group differences at 3 months were assessed using independent-samples t-tests. A two-sided  $p < .05$  was considered statistically significant. Analyses were performed on participants with complete pre- and post-intervention data.

## 3. Results

### 3.1 Participant flow and baseline comparability

Forty participants were randomized, 20 to each group, and all contributed baseline and 3-month data; participant flow is summarized in Figure 1. The two groups were comparable at baseline: there was no significant difference in sex distribution ( $\chi^2 = 1.026$ ,  $p = .311$ ) or age-group distribution ( $\chi^2 = 3.796$ ,  $p = .434$ ), indicating that post-intervention differences are unlikely to be explained by pre-existing demographic imbalance (Table 1).



**Figure 1.** CONSORT participant flow diagram. All secondary headache types were excluded at screening.

**Table 1.** Baseline demographic comparability between groups (chi-square test).

Characteristic	Group 1 (Yoga + medical, n=20)	Group 2 (Medical only, n=20)	$\chi^2 / t$	p
Age (years), mean $\pm$ SD	—	—	3.796	.434

Characteristic	Group 1 (Yoga + medical, n=20)	Group 2 (Medical only, n=20)	$\chi^2 / t$	p
Sex (M / F)	—	—	1.026	.311
Age-group distribution	comparable	comparable	3.796	.434

Both groups were demographically comparable at baseline. SD = standard deviation; NS = not significant.

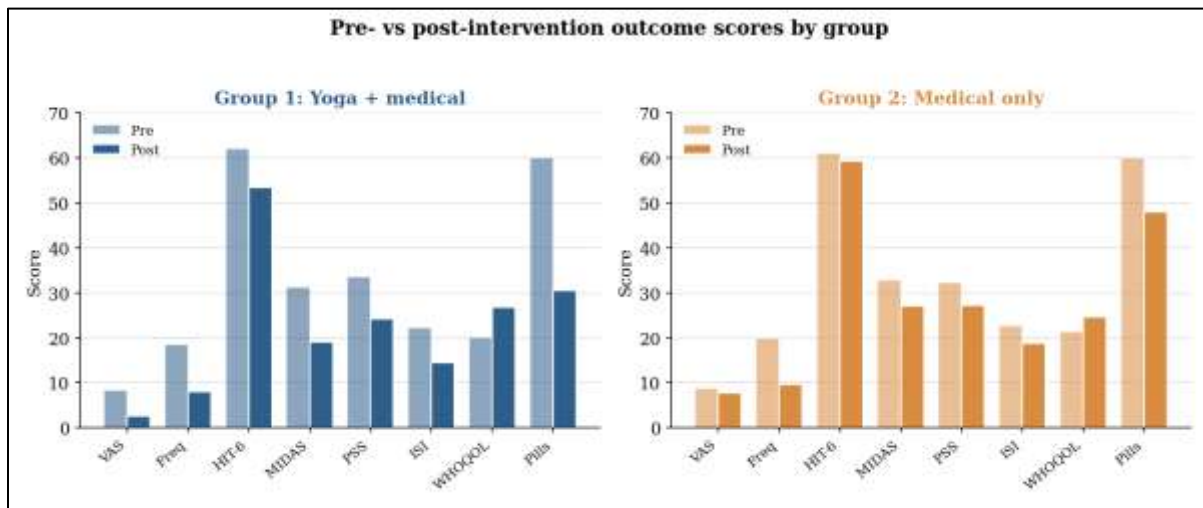
### 3.2 Within-group effects: Group 1 (yoga + medical)

Group 1 showed statistically significant improvement on all eight outcomes after the intervention (all  $p < .001$ ). Pain (VAS) fell from 8.40 to 2.65, headache frequency from 18.50 to 8.05 days per month, HIT-6 from 61.95 to 53.40, MIDAS from 31.25 to 19.15, perceived stress (PSS) from 33.60 to 24.30, and insomnia severity (ISI) from 22.25 to 14.50. Quality of life (WHOQOL) increased from 20.15 to 26.75, and rescue-pill count was approximately halved, from 60.0 to 30.5 over 30 days (Table 3, Figure 2).

**Table 3.** Within-group pre–post comparison for Group 1 (paired-samples t-test).

Variable	Pre, mean $\pm$ SD	Post, mean $\pm$ SD	Mean diff	t	p
VAS (pain)	8.40 $\pm$ 0.99	2.65 $\pm$ 0.49	5.75	26.605	< .001
Headache frequency (days/mo)	18.50 $\pm$ 4.49	8.05 $\pm$ 4.74	10.45	12.808	< .001
HIT-6	61.95 $\pm$ 7.59	53.40 $\pm$ 7.47	8.55	4.838	< .001
MIDAS	31.25 $\pm$ 5.60	19.15 $\pm$ 6.56	12.10	9.663	< .001
PSS (stress)	33.60 $\pm$ 4.27	24.30 $\pm$ 4.85	9.30	10.463	< .001
ISI (insomnia)	22.25 $\pm$ 2.83	14.50 $\pm$ 3.66	7.75	10.238	< .001
WHOQOL (QoL)	20.15 $\pm$ 2.62	26.75 $\pm$ 4.56	-6.60	-8.396	< .001
Rescue pill count	60.00 $\pm$ 0.00	30.50 $\pm$ 1.28	29.50	103.284	< .001

A negative mean difference for WHOQOL reflects an increase (improvement) in quality of life. All comparisons  $p < .001$ .



**Figure 2.** Pre- versus post-intervention scores in each group across all eight outcomes.

### 3.3 Within-group effects: Group 2 (medical only)

Group 2 also improved significantly on most outcomes, including headache frequency, MIDAS, PSS, ISI, WHOQOL, and rescue-pill count (all  $p < .001$ ), with a smaller but significant reduction in pain (VAS,  $p = .013$ ). The change in HIT-6 headache impact was not statistically significant ( $t = 1.143$ ,  $p = .267$ ). In general, the magnitude of improvement in Group 2 was smaller than that observed in Group 1 (Table 4, Figure 4).

**Table 4.** Within-group pre–post comparison for Group 2 (paired-samples t-test).

Variable	Pre, mean $\pm$ SD	Post, mean $\pm$ SD	Mean diff	t	p
VAS (pain)	8.75 $\pm$ 1.02	7.75 $\pm$ 1.55	1.00	2.757	.013

Variable	Pre, mean $\pm$ SD	Post, mean $\pm$ SD	Mean diff	t	p
Headache frequency (days/mo)	19.90 $\pm$ 4.73	9.70 $\pm$ 4.93	10.20	8.305	< .001
HIT-6	61.05 $\pm$ 6.77	59.35 $\pm$ 3.73	1.70	1.143	.267 (NS)
MIDAS	32.80 $\pm$ 5.15	27.15 $\pm$ 5.78	5.65	6.903	< .001
PSS (stress)	32.25 $\pm$ 5.25	27.20 $\pm$ 5.64	5.05	7.574	< .001
ISI (insomnia)	22.60 $\pm$ 3.83	18.80 $\pm$ 4.68	3.80	8.431	< .001
WHOQOL (QoL)	21.30 $\pm$ 2.70	24.65 $\pm$ 2.72	-3.35	-6.646	< .001
Rescue pill count	60.00 $\pm$ 0.00	48.05 $\pm$ 1.05	11.95	50.894	< .001

NS = not significant. A negative mean difference for WHOQOL reflects improvement in quality of life.

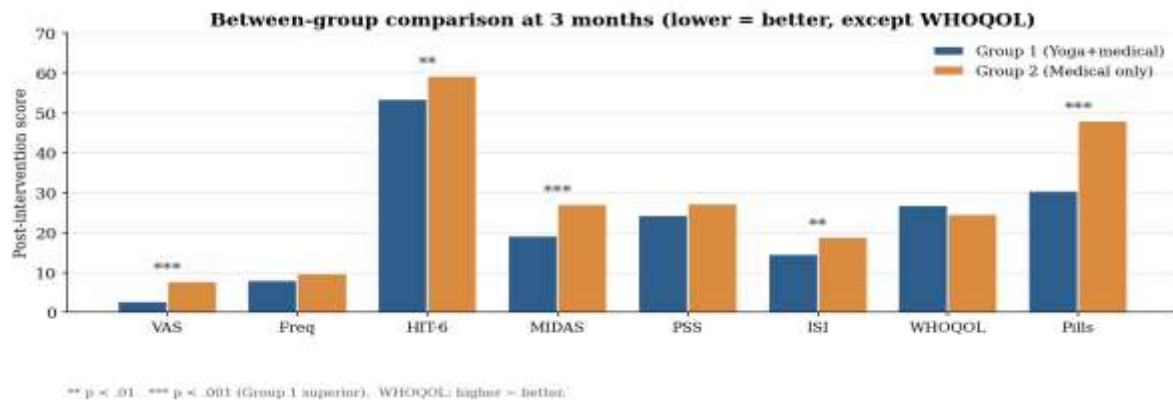
### 3.4 Between-group comparison at 3 months

At 3 months, Group 1 was significantly superior to Group 2 on five outcomes: pain (VAS;  $t = -14.018$ ,  $p < .001$ ), headache impact (HIT-6;  $t = -3.186$ ,  $p = .003$ ), disability (MIDAS;  $t = -4.094$ ,  $p < .001$ ), insomnia severity (ISI;  $t = -3.238$ ,  $p = .003$ ), and rescue-pill count ( $t = -47.465$ ,  $p < .001$ ). No statistically significant between-group differences were found for headache frequency ( $p = .288$ ), perceived stress ( $p = .089$ ), or quality of life ( $p = .085$ ), indicating that both arms achieved broadly comparable gains on these particular outcomes (Table 5, Figure 3).

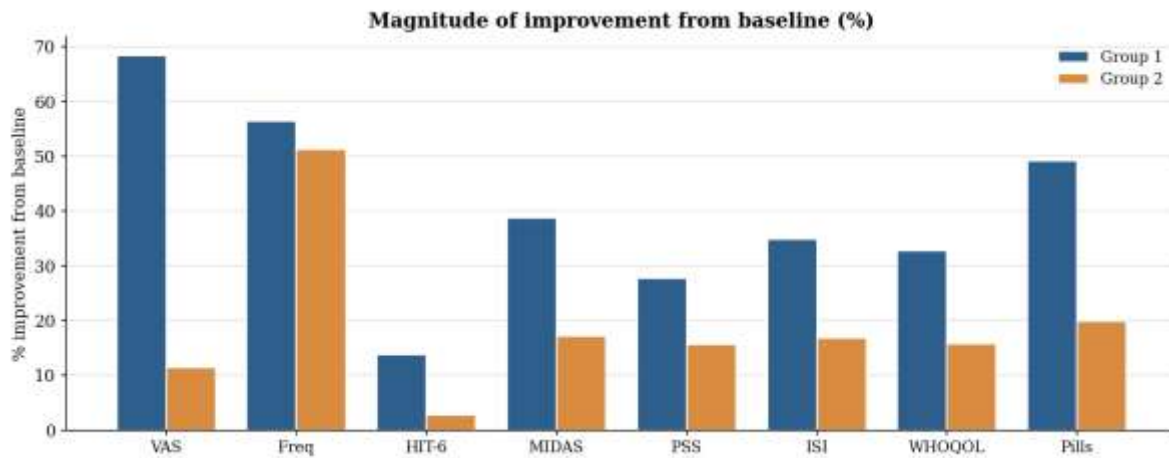
**Table 5.** Between-group comparison of post-intervention outcomes (independent-samples t-test).

Outcome (post)	Group 1, mean $\pm$ SD	Group 2, mean $\pm$ SD	t	p
VAS (pain)	2.65 $\pm$ 0.49	7.75 $\pm$ 1.55	-14.018	< .001
Headache frequency	8.05 $\pm$ 4.74	9.70 $\pm$ 4.93	-1.079	.288 (NS)
HIT-6	53.40 $\pm$ 7.47	59.35 $\pm$ 3.73	-3.186	.003
MIDAS	19.15 $\pm$ 6.56	27.15 $\pm$ 5.78	-4.094	< .001
PSS (stress)	24.30 $\pm$ 4.85	27.20 $\pm$ 5.64	-1.743	.089 (NS)
ISI (insomnia)	14.50 $\pm$ 3.66	18.80 $\pm$ 4.68	-3.238	.003
WHOQOL (QoL)	26.75 $\pm$ 4.56	24.65 $\pm$ 2.72	1.768	.085 (NS)
Rescue pill count	30.50 $\pm$ 1.28	48.05 $\pm$ 1.05	-47.465	< .001

Negative t values indicate that Group 1 had lower (better) post-intervention scores for pain, HIT-6, MIDAS, ISI, and pill count. NS = not significant.



**Figure 3.** Between-group comparison of post-intervention scores; asterisks mark outcomes on which Group 1 was significantly superior.



**Figure 4.** Percentage improvement from baseline in each group, illustrating the larger gains in the yoga arm.

## 4. Discussion

In this randomized controlled trial, adding a validated 60-minute integrated yoga module to conventional medical management produced significant improvement across all measured domains: pain, headache frequency, headache impact, disability, perceived stress, insomnia, quality of life, and analgesic use in adults with primary headache. Crucially, the yoga-plus-medical arm was significantly superior to medical management alone for pain intensity, headache impact, disability, insomnia severity, and rescue-medication use. These findings are consistent with previous controlled trials and meta-analyses reporting that yoga, as an adjuvant to standard care, improves headache frequency, intensity, impact, and disability.<sup>11,12,24,25</sup>

A distinctive feature of the present study is its breadth of patient-centred outcomes. Whereas much earlier work focused chiefly on headache frequency, intensity, and impact, our results show parallel benefit for stress, sleep, and quality of life, alongside a halving of rescue-pill consumption in the yoga arm. The reduction in analgesic use is clinically relevant given the risk of medication-overuse headache and the costs of long-term drug use, and echoes prior reports of reduced pill counts with adjuvant yoga.<sup>11</sup> Plausible mechanisms include enhanced parasympathetic (vagal) tone and reduced sympathetic drive, lowered muscle tension around cranial and cervical structures, and improved stress regulation of pathways that have been proposed to mediate the benefit of yoga in headache.<sup>13,15,26</sup>

A second contribution is the hybrid delivery model. By combining supervised in-person sessions with remotely supervised online sessions, the programme aimed to preserve technique and adherence while improving access for patients who could not attend in person. The favourable results in the yoga arm suggest that hybrid delivery is a feasible way to extend yoga-based adjuvant therapy beyond specialist centres, a consideration of particular importance in resource-limited settings.

The improvements observed in the medical-only arm warrant comment. Group 2 improved significantly on most outcomes, and the groups did not differ significantly on headache frequency, perceived stress, or quality of life at 3 months. Several factors may contribute to this pattern, including regression to the mean among patients enrolled at a symptomatic peak, the natural fluctuation of primary headache, the non-specific benefits of structured clinical attention and lifestyle counselling, and expectancy effects inherent to an unblinded behavioural trial. The relatively large within-group changes in the control arm should therefore be interpreted with caution, and the between-group comparisons, which control for these shared influences, provide a more conservative and informative estimate of the specific effect of the yoga module.

### 4.2 Limitations

This trial has several limitations. The sample was small ( $n = 40$ ) and drawn from a single centre, limiting precision and generalizability. The intervention is inherently unblinded, so participant expectancy and reporting bias cannot be excluded, and most outcomes were self-reported. The 3-month horizon does not establish whether benefits persist. Outcomes were analysed by pairwise t-tests without adjustment for multiple comparisons or baseline covariates, and the convenience sample was not formally powered. The marked improvement in the control arm raises the possibility of regression to the mean and non-specific effects. Finally, although patients were diagnosed with primary headache under ICHD-3 and all secondary headaches were excluded, the primary-headache population was analysed together rather than separately by subtype.

### 4.3 Implications and future directions

These findings support integrating a validated, time-efficient 60-minute yoga module into the multidisciplinary management of primary headache, and indicate that hybrid delivery is a practical route to wider access. Larger, multi-centre, adequately powered trials with longer follow-up, blinded outcome assessment, subtype-specific analysis (migraine versus tension-type headache), and, where feasible, an active or attention-matched comparator are needed to confirm and extend these results and to clarify the underlying mechanisms.

## 5. Conclusion

A validated 60-minute integrated yoga therapy module, delivered in a hybrid online–offline format as an add-on to conventional medical management, produced significant and broad-based improvement in pain, headache impact, disability, sleep, quality of life, and analgesic use in adults with primary headache, and was superior to medical management alone on several key outcomes. With appropriate caution regarding sample size and design, these results support yoga as a feasible, low-cost, and patient-centred adjuvant therapy for primary headache and justify larger confirmatory trials.

**Conflict of Interest:** The authors declare no conflicts of interest, financial or otherwise, related to this study.

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### Ethics Approval

The study was registered with the Clinical Trials Registry–India (CTRI) under registration number CTRI/2023/05/053346. Ethical approval was obtained from the Institutional Ethics Committee, Institute of Medical Sciences, Banaras Hindu University, Varanasi, India (Approval No. Dean/2022/EC/4072; IEC Registration No. ECR/526/Inst/UP/2014/RR-20), dated 15 April 2023.

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