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Yoga-based breathing and relaxation as adjunctive therapy for chronic migraine: A randomized controlled trial on clinical outcomes and autonomic regulation

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ABSTRACT

Background: Chronic migraine is a disabling neurological condition often associated with autonomic dysregulation. Yoga-based interventions, particularly pranayama and relaxation, may provide non-pharmacological benefits; however, few studies have systematically evaluated their physiological and clinical impact.
Objective: To assess the adjunctive effects of a structured pranayama and relaxation (P + R) program on clinical outcomes and autonomic function in patients with chronic migraine receiving standard medical treatment.
Methods: In this randomized controlled trial, 90 adults with chronic migraine were assigned to either a P + R intervention or a control group. The P + R group received daily guided sessions for 12 weeks alongside standard pharmacological care, while the control group continued standard care alone. The primary outcome was change in monthly headache frequency. Secondary outcomes included headache intensity (VAS), migraine-related disability (HIT-6), quality of life (SF-36), and autonomic function assessed through heart rate variability and standardized autonomic tests. Assessments were conducted at baseline and after 12 weeks.
Results: Both groups exhibited significant clinical improvement following the intervention period. However, the intervention group demonstrated a significantly greater reduction in headache frequency (mean reduction – 7.1 vs – 4.6 days/month, $p < 0.001$), pain intensity (ΔVAS – 6.8 vs – 3.2, $p < 0.001$), and disability scores (ΔHIT-6 – 33.0 vs –21.6, $p < 0.001$) compared to the control group. Quality of life improvements were more pronounced in the intervention arm, especially in physical and vitality domains. Objective autonomic assessment revealed increased HRV indices (higher RMSSD, HF_nu; lower LF/HF ratio) and significant reductions in resting heart rate and blood pressure only in the intervention group, indicating enhanced parasympathetic tone. No adverse events were reported, and adherence rates were high.

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Conclusion: A 12-week pranayama and relaxation program, when added to standard migraine therapy, resulted in significant clinical and autonomic improvements. These findings support the integration of mind-body techniques as effective adjuncts in the multidisciplinary management of chronic migraine.

1. Introduction

Migraine is a common chronic neurologic disorder characterized by recurrent moderate-to-severe headaches often accompanied by throbbing pain, nausea, vomiting, and sensory hypersensitivity (phonophobia and photophobia).[1] Migraines typically begin in adolescence or early adulthood and are most prevalent between the ages of 20 and 50.[2] Globally, migraine imposes a tremendous health burden, affecting over one billion people and about 15 % of the population each year. According to recent Global Burden of Disease (GBD) studies, migraine among the leading causes of disability worldwide, ranking as the second most common cause of years lived with disability (YLDs), particularly affecting women of reproductive age.[3]

The pathophysiology of migraine involves complex neurovascular processes and heightened cortical excitability.[4] Migraine attacks can be triggered by various factors, with stress (whether psychological or physical) being one of the most frequently reported triggers.[5,6] Stress can precipitate neuroendocrine changes (like cortisol release) and transient cerebral ischemia, which may lower the threshold for migraine headaches. These mechanisms reflect a breakdown in homeostatic regulation and often involve dysfunction of the autonomic nervous system.[7] In fact, a growing body of evidence indicates that individuals with migraine have an underlying autonomic imbalance. Studies show that, patients with chronic migraine exhibit reduced heart rate variability compared to healthy controls, signifying impaired parasympathetic (vagal) activity and/or excessive sympathetic drive.[8] Such autonomic dysfunction is thought to contribute to the increased frequency and severity of migraine attacks. This pathophysiological link between stress, autonomic dysregulation, and migraines provides a strong rationale for exploring interventions that target stress reduction and autonomic rebalancing as a means of migraine control.

Current standard treatments for migraine include acute medications (analgesics, triptans, etc.) and preventive pharmacotherapies (such as beta-blockers, anticonvulsants, tricyclic antidepressants).[9] While often effective, these drugs can have significant side effects and contraindications, and not all patients achieve satisfactory relief. Moreover, long-term use of certain medications can lead to medication-overuse headaches or other complications.[10,11] There is a clear need for complementary strategies that can help manage chronic migraines with fewer side effects and at lower cost. In this context, complementary and alternative medicine (CAM) approaches – particularly mind-body interventions – have gained attention in headache management.[12]

Yoga is one of the most popular mind-body therapies worldwide, encompassing physical postures (*asanas*), breathing techniques (*pranayama*), relaxation, and meditation. Yoga is inexpensive, relatively easy to implement, and confers diverse benefits for physical, mental, and emotional health.[13] Specifically, yoga practice has been shown to modulate the autonomic nervous system by increasing vagal tone and reducing sympathetic activity. Over the past decade, evidence has emerged that yoga-based interventions can be effective in stress-related medical conditions – including certain pain disorders and headaches.[14] In conditions such as tension-type headache and migraine, yoga is thought to help by promoting muscle relaxation, improving blood flow, and stabilizing autonomic function compared to other various exercise interventions.[14–16] A randomized trial by Kisan *et al.* (2014) found that adding yoga therapy to conventional care for migraine resulted in significantly greater reductions in headache frequency and intensity, along with enhanced parasympathetic tone, compared to medical care alone.[17] Similarly, John *et al.* (2007) reported that three months of yoga practice led to a significant decrease in migraine frequency and associated symptoms, as well as better quality of life, relative to standard care.[18] These studies, along with earlier systematic reviews, suggested that yoga is a promising adjunctive treatment for migraine, though research in this area was still limited in sample size and rigor. Pranayama, the yogic practice of controlled breathing, and guided relaxation techniques are particularly relevant to migraine management. Slow, diaphragmatic breathing exercises directly influence the autonomic nervous system by stimulating vagal afferents and activating the body's relaxation response. For instance, slow-paced breathing such as Bhramari pranayama has been shown to increase parasympathetic dominance (evidenced by increased HRV and gamma brain-wave activity) and to reduce heart rate and blood pressure.[19] Long exhalation breathing exercises improve baroreceptor sensitivity and can thereby induce bradycardia and peripheral vasodilation, counteracting the sympathetic overactivity associated with stress and pain.[20] These physiologic effects are highly relevant, as migraine patients often exhibit an adrenergic "hyper-reactivity" and reduced baroreflex function during attacks. Additionally, yogic relaxation techniques (such as progressive muscle relaxation, mindfulness, and meditation) can mitigate the psychological components of stress and pain. A six-week trial of progressive muscle relaxation for migraine demonstrated a substantial reduction in migraine days and attacks compared to no-treatment controls, highlighting that non-pharmacological relaxation can meaningfully improve clinical outcomes.[21] Yoga and relaxation may also exert central neurochemical effects. One study found that a single session of yoga increased brain GABA (an inhibitory neurotransmitter) levels by 27 %, correlating with reduced cortical excitability.[22] This is of interest given that migraine pathophysiology involves a state of cortical hyper-excitability and decreased GABAergic inhibition.

Encouraged by these findings, we set out to investigate the benefits of a specific yoga-based breathing and relaxation regimen in migraine. The present study was designed as a randomized, controlled trial to evaluate the efficacy of *pranayama* and relaxation techniques as an adjunct to conventional medical treatment in patients with migraine. We hypothesized that adding this mind-body intervention would improve clinical outcomes (reducing headache frequency, severity, and disability) and enhance autonomic function (shifting the sympatho-vagal balance toward parasympathetic predominance) compared to conventional treatment alone. We also aimed to assess the impact on patients' quality of life and their self-perceived improvement. By following a rigorous study design and incorporating both subjective and objective measures (including HRV and standard autonomic tests), our goal was to generate high-quality evidence on the role of yoga-based therapy in migraine management, in line with international recommendations for non-pharmacologic treatments. Ultimately, this research seeks to support the integration of cost-effective, holistic therapies like pranayama and relaxation into mainstream migraine care, thereby improving outcomes and patient well-being.

2. Methods

2.1. Study design and participants

This study was a single-center, parallel-group randomized controlled trial examining the effect of pranayama and relaxation (yoga) therapy as an adjunct to conventional treatment in patients with migraine. The trial was conducted at a tertiary care neurology center and was approved by the Institutional Ethics Committee of the institute. All participants provided written informed consent before enrollment.

2.2. Selection criteria

Eligible participants were male or female patients aged between 18 and 60 years diagnosed with migraine (with or without aura) according to the International Headache Society criteria (International Classification of Headache Disorders, 2nd edition, ICHD-II). We included patients who had a history of migraines for at least 2 years and who were experiencing moderately frequent headaches (approximately 5–15 migraine days per month) but not daily chronic headaches. Patients were required to be otherwise medically stable and able to attend regular yoga therapy sessions. Key exclusion criteria were: significant comorbid neurological or psychiatric disorders (including uncontrolled epilepsy, major depression/anxiety requiring intensive treatment, psychosis), uncontrolled major medical illnesses (such as uncontrolled hypertension, diabetes or heart disease), history of basilar or hemiplegic migraine, medication-overuse headache, and women who were pregnant or lactating. Patients on any form of prophylactic migraine therapy were allowed to participate, as long as the medication regimen had been stable for at least one month prior to baseline. Those on sedatives or drugs that could significantly affect autonomic function were excluded.

2.3. Recruitment

Participants were recruited from the Neurology outpatient department of the tertiary care center. Following an initial screening, a neurologist performed a detailed physical and neurological examination to confirm the diagnosis of migraine and determine study eligibility. Baseline assessments included demographic characteristics, migraine history (such as duration of illness and migraine subtype), and headache-related disability, evaluated using the Migraine Disability Assessment (MIDAS) questionnaire. In addition, baseline autonomic function tests and heart rate variability (HRV) parameters were recorded.

2.4. Sample size estimation

The required sample size was estimated to detect a clinically meaningful between-group difference in the primary outcome—headache frequency. Based on prior studies[23,24] and an assumed effect size of Cohen's $d = 0.6$, with a two-sided α of 0.05 and 80 % power ($\beta = 0.20$), the minimum required sample size was estimated to be 45 participants per group (90 in total). To account for a potential 15 % attrition rate, the sample size was increased to 106 participants (53 per group). The calculation was performed using G*Power software (version 3.1), employing a two-sample *t*-test for independent means with equal group allocation.

2.5. Randomization

A total of 106 patients meeting inclusion criteria were enrolled and randomized in a 1:1 ratio to either the intervention group or the control group (53 patients in each). The randomization sequence was computer-generated by an independent biostatistician who had no role in participant recruitment, intervention delivery, or outcome assessment. Allocation concealment was ensured using sequentially numbered, sealed, opaque envelopes (SNOSE), which were opened only after completion of baseline assessments by a study coordinator independent of the investigators responsible for data collection and analysis.

Given the nature of the intervention, neither participants nor therapists could be blinded to group assignment. However, all outcome assessments, including HRV data analysis and questionnaire scoring, were performed by investigators blinded to group assignment to minimize assessment bias.

Randomization followed a simple random allocation procedure without predefined block sizes or stratification factors. Although no block or stratified randomization was applied, baseline characteristics were comparable between groups, confirming balanced allocation (Table 2).

After accounting for dropouts, 45 participants in each group ($n = 90$) completed the 12-week study protocol and were included in the final analysis (Fig. 1).

2.6. Participant flow and attrition

Of the 106 participants enrolled and randomized, 90 (45 in each group) completed the 12-week intervention and were included in the final analysis (Fig. 1). Sixteen participants did not complete follow-up assessments. The primary reasons for attrition included loss to follow-up due to travel or relocation ($n = 9$), work-related scheduling difficulties or irregular attendance ($n = 4$), and voluntary withdrawal citing personal reasons or time constraints ($n = 3$). No participant discontinued participation due to adverse events or symptom aggravation. The analysis followed a per-protocol approach, including participants who completed at least 80 % of the scheduled sessions and post-intervention assessments. Despite attrition, the final analyzed sample achieved the pre-specified target size, maintaining adequate statistical power. Baseline demographic and clinical characteristics of those who completed the trial did not differ significantly from those who dropped out.

2.7. Interventions

2.7.1. Conventional treatment (control group)

All participants, in both groups, continued to receive conventional migraine treatment as prescribed by their treating neurologist. This typically included acute headache medications (such as NSAIDs or triptans for attacks) and, where indicated, prophylactic medications such as beta-blockers (propranolol), calcium channel blockers (flunarizine), or other standard migraine preventives. Standard advice on lifestyle modifications and trigger avoidance was also given. Patients in the control group received no additional therapeutic intervention beyond their routine medical care and basic counseling. They were instructed to maintain their usual treatment regimen and lifestyle during the 12-week study period and were not taught any specific new exercise or relaxation technique.

2.8. Pranayama and relaxation therapy (intervention group)

Patients allocated to the Pranayama and Relaxation (P + R) group received a structured 12-week yoga-based breathing and relaxation program in addition to the same conventional medical care as the control group. The intervention was administered by a single certified yoga therapist as an adjuvant therapy for migraine to ensure procedural uniformity and minimize therapist-related variability. The therapist followed a standardized, manualized yoga therapy protocol developed under the supervision of senior yoga faculty and neurologists to maintain fidelity across sessions. Each supervised session lasted approximately 35 min and comprised three sequential components (Table 1). Sessions were conducted five days per week for four weeks in a dedicated hospital yoga therapy room.

After the supervised phase, participants continued the same sequence of practices at home for the remaining eight weeks using a video CD demonstration and printed instruction sheets prepared by the study team. The video CD contained a complete guided session led by the same yoga therapist, demonstrating each practice with verbal cues for breathing, relaxation, and transitions. Participants were advised to practice at least five days per week for about 30 min per session in a quiet, comfortable setting. Compliance during the home phase was tracked using self-maintained practice diaries and verified through weekly telephonic follow-ups by the therapist. Attendance logs and diary entries were cross-checked to calculate overall adherence, and $\geq$ 80 % cumulative participation (supervised + home practice) was

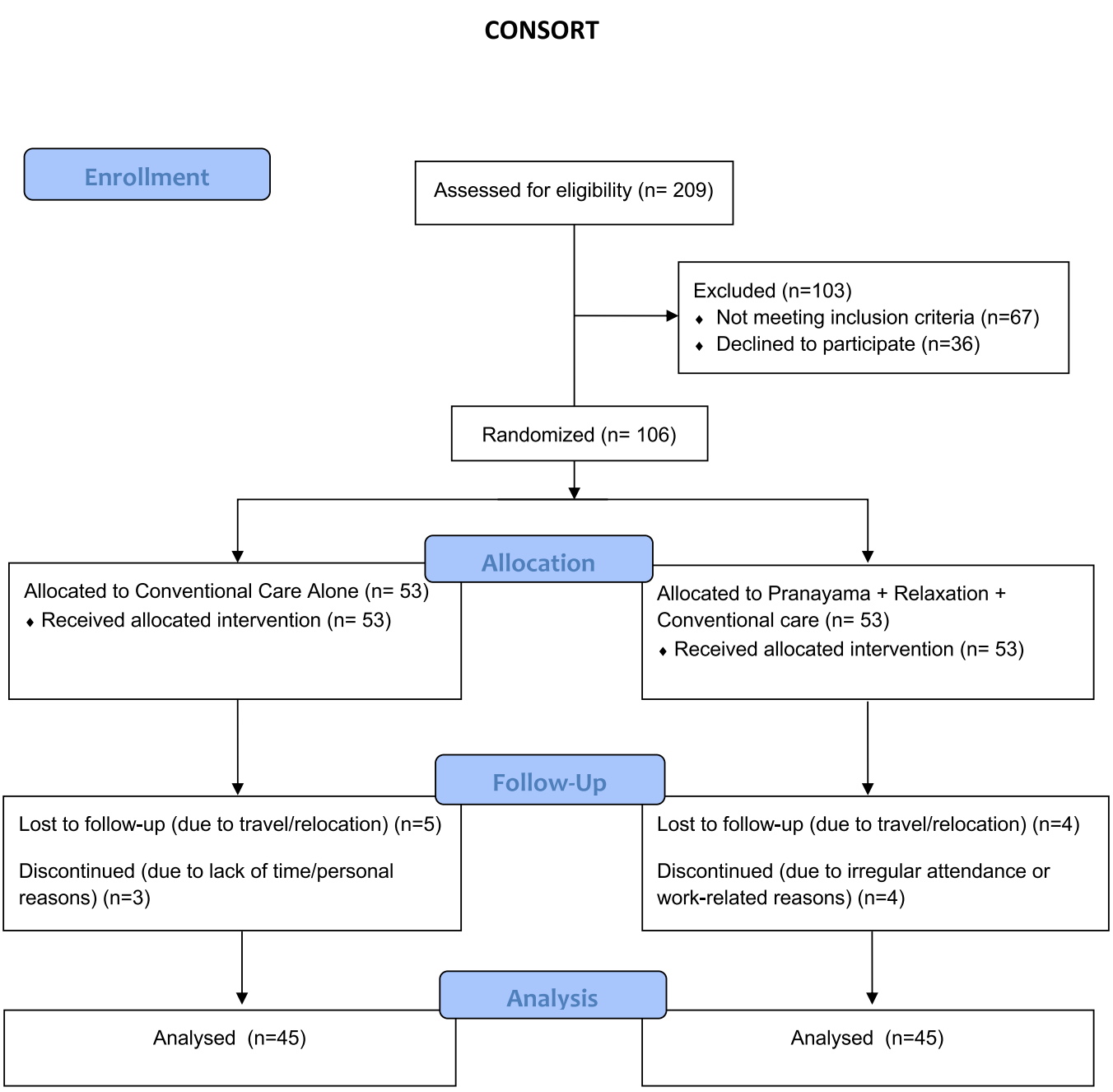

Fig. 1. CONSORT flow diagram.

considered satisfactory. In addition, a quantitative Practice Adherence Index was computed for each participant as the percentage of completed home-practice sessions relative to the prescribed frequency (five sessions per week × eight weeks). Mean adherence across the intervention group was 91.6 ± 6.8 %, confirming high compliance during the home phase. This quantitative assessment enabled verification of total exposure to the yoga regimen and supported exploratory evaluation of the relationship between practice intensity and clinical outcomes.

The first component included Sookshma Vyayama (loosening exercises; ~ 5 min), consisting of gentle movements of the fingers, wrists, elbows, shoulders, neck, knees and ankles (about 5 repetitions each) – to relieve muscle tension and prepare for breathing exercises. The second component (~ 20 min) was pranayama practice, which included a series of breathing techniques: deep diaphragmatic breathing with arm movements (hand stretch breathing and hand-in-and-out breathing, ~ 9 rounds each), full yogic breathing (combining abdominal, thoracic, and clavicular breathing), nadishuddhi (alternate nostril breathing), sheetali (cooling breath), and bhramari (buzzing bee breath) pranayama. All techniques were performed slowly and rhythmically, with brief pauses between rounds, under therapist supervision to ensure proper technique and comfort. The third component involved a guided relaxation (~ 10 min) using the Quick Relaxation Technique in Shavasana (corpse pose). Participants were guided to progressively relax different body regions while maintaining breath awareness and gentle abdominal focus, concluding with brief mental chanting of “Om” to promote calmness and mental clarity.

Sessions were held in the mornings in a quiet, well-ventilated yoga therapy room. All practices were mild to moderate in intensity, tailored to individual comfort levels, and participants were advised to omit any technique that exacerbated symptoms. Safety monitoring was conducted

Table 1
Structured yoga-based pranayama and guided relaxation module.

Component (Daily)	Practices (Description)	Duration
Loosening Exercises (Sookshma Vyayama) – gentle joint movements for warm-up.	Fingers, wrist and elbow flexion/extension; shoulder rotations; neck flexion/extension and rotation; knee flexion/extension; ankle rotations – about 5 repetitions each.	5 min
Breathing Techniques (Pranayama) – slow, deep breathing exercises.	a) Hand Stretch Breathing – 9 rounds. b) Hand In–Out Breathing – 9 rounds. c) Full Yogic Breathing (abdomen+chest+clavicle expansion). d) Nadi Shuddhi (alternate nostril breathing). e) Sheetali (cooling breath through tongue roll). f) Bhramari ("bee" humming breath). *(All performed in a relaxed seated posture, with slow inhalation and prolonged exhalation, and brief pauses between techniques.)*	20 min
Guided Relaxation – mindful relaxation in supine posture.	*Quick Relaxation Technique:* Lying in Shavasana (corpse pose) with eyes closed. Progressive muscle relaxation and body scan from feet to head, synchronized with the breath. Concludes with a short mental chanting of "Om" to further quiet the mind.	10 min
Total Session Duration	(Performed five days per week under supervision; patients were encouraged to also practice on their own on other days.)	35 min

throughout the intervention. Any new or worsening symptom temporally associated with the practice (e.g., headache exacerbation, dizziness, or fatigue) was defined as an adverse event. The therapist documented participant-reported issues in a safety log, which was reviewed weekly by the supervising neurologist. No adverse events were reported during the supervised or home-practice phases.

2.9. Outcome measures

All outcomes were assessed at two time points: baseline (pre-intervention) and after the 12-week intervention period. Evaluations for both groups were conducted under similar conditions, and the assessors were blinded to group assignment.

2.10. Primary outcome

The primary outcome was the change in monthly headache frequency, defined as the number of migraine days per 30-day period. Participants maintained daily headache diaries throughout the study period, and the monthly headache frequency was calculated from these logs at baseline and post-intervention.

2.11. Secondary outcomes

2.11.1. Headache intensity

Average pain severity of migraine attacks was assessed using a 10-cm Visual Analogue Scale (VAS), ranging from 0 = "no pain" to 10 = "worst imaginable pain." The VAS score for typical migraine episodes was recorded at baseline and 12 weeks.

2.12. Headache impact and disability

The Headache Impact Test-6 (HIT-6) was used to assess headache-related disability and functional impairment across domains of pain, social and cognitive functioning, and emotional well-being. The total score ranges from 36 to 78, with higher scores indicating greater disability. Participants completed the HIT-6 at both assessment points. The Migraine Disability Assessment (MIDAS) questionnaire was additionally administered at baseline to characterize the clinical severity of the study cohort for baseline comparability.

2.13. Quality of life (QOL)

Health-related quality of life was assessed using the Short Form-36 (SF-36) Health Survey (version 2) at baseline and after 12 weeks. The SF-36, comprises 36 items across eight domains: Physical Functioning (PF), Role Limitations due to Physical Health (RP), Role Limitations due to Emotional Problems (RE), Vitality (VT), Emotional Well-being (MH), Social Functioning (SF), Bodily Pain (BP), and General Health perceptions (GH).

2.14. Patient global assessment

At the 12-week final visit, participants completed a global assessment of their therapy. This included: 1) Perceived Helpfulness, where participants rated the net benefit of treatment as "more harmful than helpful," "neither helpful nor harmful," or "more helpful than harmful." 2) Improvement Rating, a 5-point Likert scale (0 = greatly worsened to 4 = greatly improved) assessing changes in migraine condition from baseline. These self-assessments allowed for comparison of overall satisfaction and perceived efficacy between groups.

2.15. Autonomic function outcomes

Objective autonomic function tests were conducted at baseline (1–3 days pre-intervention) and at the 12-week endpoint, scheduled when patients were headache-free for ≥ 3 days and had not taken rescue medication in the prior 48 h to minimize confounding factors. Heart Rate Variability (HRV) was assessed via short-term resting ECG recordings (5 min, 1024 Hz sampling), with analysis yielding time-domain (NN interval, SDNN, RMSSD) and frequency-domain (LF power, HF power, LF/HF ratio, LF_nu, HF_nu) parameters, all analyzed by a blinded investigator. Additionally, a battery of standard cardiovascular reflex tests, as described by Ewing, was performed to evaluate both parasympathetic and sympathetic components. These included the a.) Deep Breathing Test (DBT), assessing cardiac parasympathetic function via expiration-inspiration heart rate difference and E:I ratio; b.) the Valsalva Maneuver, indexing cardiovagal function and baroreflex integrity through the Valsalva ratio; c.) the Isometric Handgrip Test (IHGT), measuring sympathetic efferent function by the rise in diastolic blood pressure (ΔDBP); and d.) the Orthostatic Standing Test, evaluating transient vagal response (30:15 ratio) and postural systolic BP fall (ΔSBP).

All autonomic function tests were performed by an experienced neurophysiology technician trained in autonomic testing, under the supervision of a neurologist specializing in autonomic function. The assessor conducting the tests and analyzing the data was blinded to group allocation to minimize observer bias. To ensure methodological consistency, all tests were conducted in a temperature-controlled, quiet laboratory (maintained at 24–26 °C) between 9:00 and 11:00 a.m. to reduce diurnal variability. Participants were instructed to abstain from caffeine, nicotine, alcohol, heavy meals, and strenuous exercise for at least 12 h before each session. All procedures adhered to the standardized protocols proposed by Ewing and Clarke for cardiovascular autonomic function testing,[25,26] ensuring strict reproducibility and methodological consistency across pre- and post-intervention assessments.

2.16. Statistical analysis

Analyses were conducted in IBM SPSS (version 30). Distributional assumptions were examined using the Shapiro–Wilk tests and Q–Q plot inspection for each endpoint at baseline and for pre–post change scores;

homogeneity of variances was assessed with Levene's test. Several autonomic and clinical variables exhibited substantial skewness and heteroscedasticity, consistent with the bounded or ratio-scale nature of physiological data. Accordingly, rank rank-based non-parametric tests were employed—Wilcoxon signed-rank for within-group comparisons and Mann–Whitney U for between-group differences—to ensure distribution-robust inference under violated assumptions of normality and variance homogeneity. This conservative analytical approach aligns with established practices in autonomic research, where HRV parameters frequently demonstrate non-Gaussian distributions.[27,28] Statistical significance was set at $p < 0.05$ (two-sided).

3. Results

3.1. Participant characteristics

A total of 90 patients, evenly randomized into the Control (n = 45) and Pranayama and Relaxation (P + R; n = 45) groups, completed the 12-week trial. Baseline demographic and clinical characteristics were comparable, confirming successful randomization. The mean age was 33.4 ± 7.9 years in the Control group and 31.7 ± 8.9 years in the P + R group ($p = 0.437$). Both groups had higher female representation (Control, 4 males:26 females; P + R, 10 males:20 females; $p = 0.690$). Migraine subtypes (with or without aura) were evenly distributed ($p = 0.451$). Mean illness duration (~ 6 years), monthly headache frequency (~ 8 days/month), pain intensity (VAS ~ 9), and headache disability (HIT-6 ~ 75) were similar between groups at baseline (all $p > 0.05$) (Table 2).

3.2. Headache frequency, intensity, and disability

At 12 weeks, both groups demonstrated significant reductions in migraine frequency, intensity, and disability scores compared to baseline ($p < 0.001$ for all comparisons). However, improvements were markedly greater in the P + R group. Migraine frequency decreased significantly from 7.9 ± 1.8 to 3.2 ± 1.3 days/month in Controls, and from 8.3 ± 1.8 to 1.2 ± 1.0 days/month in the P + R group. The between-group difference in frequency reduction (7.1 vs. 4.6 days/month, $p < 0.001$) favored the P + R group, with 60 % of patients reporting 0–1 headache days compared to none in the Control group.

Headache intensity also improved significantly in both groups (Control: 8.9 ± 0.5–5.7 ± 1.4; P + R: 9.0 ± 0.4–2.7 ± 1.5), with a greater reduction in the P + R group (mean reduction ~ 6.8 vs. ~ 3.2, $p < 0.001$). HIT-6 scores, indicating headache-related disability, decreased substantially from 76.6 ± 2.8 to 55.0 ± 9.0 in Controls, and 74.6 ± 5.8 to 41.6 ± 5.7 in P + R. The mean decrease was significantly greater in the yoga group (33.0 ± 7.6 vs. 21.6 ± 9.8, $p < 0.001$), suggesting a clinically meaningful improvement in migraine-related functional impairment (Table 3).

Table 2
Baseline characteristics of participants in the control and P + R (Yoga) groups.

Variable	Control (n = 45)	P + R (Yoga) (n = 45)	*p*-value
Age (years)	33.4 ± 7.9	31.7 ± 8.9	0.437
Gender (M: F)	4: 26	10: 20	0.690
Migraine type (MA: MO)	10: 35	12: 33	0.451
Duration of illness (years)	6.3 ± 2.1	6.2 ± 1.1	0.401
Monthly headache frequency	7.9 ± 1.8	8.3 ± 1.8	0.480
VAS pain score (0–10)	8.9 ± 0.5	9.0 ± 0.4	0.550
HIT-6 score (36–78)	76.6 ± 2.8	74.6 ± 5.8	0.110
MIDAS score (0–270)	25.6 ± 3.9	26.9 ± 4.7	0.342

*M = male; F = female; MA = migraine with aura; MO = migraine without aura. Values are mean ± SD or counts. *$p < 0.001$.

3.3. Quality of life and patient-perceived improvement

Significant improvements in multiple SF-36 quality-of-life domains occurred in both groups post-intervention, with notably larger improvements in the P + R group in specific domains. Physical functioning improved similarly in both groups ($p < 0.001$), but Role limitations due to physical health showed significant improvement only in the P + R group ($p < 0.001$ between groups). The Bodily Pain domain improved modestly in Controls ($p = 0.036$) but markedly in P + R ($p < 0.001$), with significant between-group differences. General health perception showed a significantly greater improvement in the yoga group ($p < 0.001$ between groups). Vitality increased significantly in both groups, again with greater gains in P + R ($p = 0.003$ between groups). Emotional role limitations improved significantly only in P + R ($p < 0.001$). Social functioning and emotional well-being changes were minimal and non-significant (Table 4).

Subjectively, 93.3 % of P + R participants rated their migraine condition as "greatly improved," compared to none in Controls ($p < 0.001$). Additionally, 95.5 % of yoga participants found therapy "more helpful than harmful," versus 33 % in Controls ($p < 0.001$) (Table 5).

3.4. Adverse events

All participants were monitored for adverse events throughout both the supervised and home-based phases of the study. Any new or worsening symptoms temporally related to the intervention, such as headache aggravation, dizziness, or fatigue, were predefined as potential adverse events. The yoga therapist documented participant-reported issues in a safety log, which was reviewed weekly by the supervising neurologist. No adverse events, injuries, or treatment-related complications were reported in either group during the 12-week intervention period. The pranayama and relaxation program was well tolerated, and no participant discontinued due to adverse effects.

3.5. Autonomic function outcomes

Resting heart rate (HR) and blood pressure (BP) improved significantly only in the P + R group. HR reduced from 75.6 ± 6.1 to 71.4 ± 5.9 bpm ($p < 0.001$), while diastolic BP dropped from 77.2 ± 6.8 to 72.8 ± 6.3 mmHg ($p < 0.001$). Systolic BP decreased modestly but significantly in the P + R group ($p = 0.023$ between groups), reflecting increased parasympathetic tone.

Heart Rate Variability (HRV) analysis showed significant autonomic modulation in the yoga group. Time-domain parameters (RMSSD) significantly increased only in the P + R group (31.8 ± 18–40.8 ± 21.6 ms; $p < 0.001$, between-group $p = 0.018$). Frequency-domain HRV showed significant increases in normalized high-frequency (HF_nu) power ($p < 0.001$) and decreases in the LF/HF ratio ($p < 0.001$), confirming a shift toward enhanced parasympathetic and reduced sympathetic dominance exclusively in the yoga group (Table 6).

Standard Autonomic Function Tests (AFT) further validated these findings. Deep breathing heart rate difference improved significantly in both groups, with greater enhancement in P + R ($p < 0.001$). Diastolic BP response during the isometric handgrip test significantly improved only in P + R ($p < 0.001$), suggesting improved sympathetic cardiovascular reactivity. The Valsalva ratio improved modestly in both groups without significant between-group differences. The orthostatic 30:15 HR ratio improved significantly in Controls but minimally in P + R, likely due to ceiling effects in P + R at baseline. Orthostatic systolic BP changes remained stable without significant between-group differences (Table 7). Overall, these autonomic improvements occurred alongside the clinical reductions in headache frequency and severity observed in the P + R group, suggesting potential mechanistic insights linking autonomic modulation to migraine relief.

Table 3
Effect of treatment on headache frequency, intensity, and HIT-6 scores (within- and between-group comparisons).

Clinical Outcome	Groups	Pre (Mean ± SD)	Post (Mean ± SD)	Pre-Post Change (Δ)	p Value (within group)	Between group p (Group C Vs Group P + R(Y))
Frequency of Headache – Migraine Log (Per month)	Group C (n = 45)	7.9 ± 1.8	3.2 ± 1.3	4.6 ± 1.2	0.000^{***}	0.000^{+++}
	Group P + R(Y) (n = 45)	8.3 ± 1.8	1.2 ± 1.0	7.1 ± 1.3	0.000^{***}	
Intensity of headache– (VAS 1–10)	Group C (n = 45)	8.9 ± 0.5	5.7 ± 1.4	3.17 ± 1.5	0.000^{***}	0.000^{+++}
	Group P + R(Y) (n = 45)	9.0 ± 0.4	2.7 ± 1.5	6.8 ± 1.6	0.000^{***}	
HIT Score (36–78)	Group C (n = 45)	76.6 ± 2.8	55.0 ± 9.0	21.6 ± 9.8	$< 0.000^{***}$	0.000^{+++}
	Group P + R(Y) (n = 45)	74.6 ± 5.8	41.60 ± 5.7	33.0 ± 7.6	$< 0.000^{***}$	

*Within-group p from Wilcoxon signed-rank tests; $^{+}$between-group p from Mann–Whitney U. Δ = Pre–Post change (baseline minus follow-up; a positive Δ indicates reduction in symptom severity). ***p < 0.001 within groups; $^{+++}$p < 0.001 between groups.

Table 4
Effect of treatment on SF36 questionnaire (Short form health survey 36 questions) in two groups of patients.

SF36	Groups	Pre (Mean± SD)	Post (Mean ± SD)	Pre-Post Change (Δ)	p Value (within group)	Between group p (Group C Vs Group P + R(Y))
Physical functioning	Group C	25.3 ± 3.7	29.3 ± 3.5	− 4.1 ± 3.8	0.000^{***}	0.349
	Group P + R (Y)	23.6 ± 2.7	26.8 ± 2.0	− 3.13 ± 3.7	0.000^{***}	
Role limitation due to physical health	Group C	4.9 ± 3.2	5.7 ± 2.3	− 0.8 ± 2.6	0.256	0.000^{+++}
	Group P + R (Y)	4.2 ± 0.7	7.9 ± 0.5	− 3.6 ± 1.0	0.000^{***}	
Role limitations due to emotional problems	Group C	3.6 ± 2.5	3.9 ± 1.3	− 0.23 ± 2.3	0.492	0.000^{+++}
	Group P + R (Y)	3.2 ± 0.7	5.9 ± 0.5	− 2.7 ± 0.9	0.000^{***}	
Vitality (energy/fatigue)	Group C	15.5 ± 1.9	17.0 ± 2.8	− 1.5 ± 2.7	0.011*	0.003^{++}
	Group P + R (Y)	14.7 ± 3.2	18.4 ± 1.9	− 3.7 ± 3.3	0.000^{***}	
Emotional Well being	Group C	19.5 ± 3.2	18.8 ± 2.4	0.7 ± 2.1	0.165	0.169
	Group P + R (Y)	21.4 ± 4.4	20.8 ± 1.9	0.17 ± 3.9	0.846	
Social functioning	Group C	6.5 ± 1.1	6.6 ± 1.1	− 10 ± 1.9	0.952	0.875
	Group P + R (Y)	6.2 ± 1.2	6.2 ± 0.6	0.00 ± 1.4	0.876	
Pain	Group C	7.5 ± 1.6	6.7 ± 2.0	0.7 ± 1.9	0.036*	0.000^{+++}
	Group P + R (Y)	6.6 ± 2.5	2.8 ± 0.8	3.8 ± 2.4	0.000^{***}	
General health	Group C	16.0 ± 1.7	15.4 ± 1.6	0.6 ± 0.8	0.001^{***}	0.000^{+++}
	Group P + R (Y)	17.2 ± 2.8	13.8 ± 1.2	3.4 ± 3.1	0.000^{***}	

Values expressed as Mean ± SD; *Within-group p from Wilcoxon signed-rank tests; $^{+}$between-group p from Mann–Whitney U. Δ = Pre–Post change (baseline minus follow-up; a positive Δ indicates reduction in symptom severity). [* = p < 0.05, ** = p < 0.01, *** = p < 0.001 within groups; + = p < 0.05, ++ = p < 0.01, +++ = p < 0.001 between groups].

Table 5
Comparison of self-perceived benefits of the intervention and assessment of therapy in two groups of migraine patients.

Comparison of the assessment of therapy by two groups						
	More harmful than helpful		Neither harmful nor helpful		More helpful than harmful	p value
Group C (n = 45)	0		30		15	0.000^{***}
Group P + R (Y)(n = 45)	0		1		43	0.000^{***}
	Greatly worsened my clinical condition (0)	(1)	(2)	(3)	Greatly improved my clinical condition (4)	p value
Group C	0	0	3	42	0	0.000^{***}
Group P + R (Y)	0	0	0	3	42	0.000^{***}

4. Discussion

This randomized controlled trial evaluated the adjunctive impact of a structured 12-week pranayama and relaxation (P + R) program on individuals with chronic migraine receiving standard pharmacological treatment. Our findings demonstrate that integrating yoga-based breathing and guided relaxation techniques significantly enhances migraine-related outcomes and autonomic regulation beyond what is achieved with conventional care alone. These improvements were observed in both subjective self-reports and objective physiological parameters, supporting a biobehavioral model of migraine regulation through mind-body practices.

Participants in the intervention group showed a substantial reduction in headache frequency, averaging an 85 % decrease from baseline, compared to a 60 % reduction with conventional therapy alone. This difference translated clinically into approximately two fewer headache days per month. Pain intensity and headache-related disability (HIT-6 scores) also improved more significantly in the yoga group, demonstrating clinical relevance beyond mere statistical significance. These changes are both statistically significant and clinically meaningful,

Table 6
Effect of treatment on time and frequency domain HRV parameters within two groups of patients with migraine.

	HRV	Pre (n = 45) Mean ± SD	Post (n = 45) Mean ± SD	Pre-Post Change (Δ)	p Value (within group)	Between group p (Group C Vs Group P + R(Y))
SDNN (ms)	Group C	50.0 ± 34.2	47.3 ± 29.5	2.7 ± 15.9	0.910	0.167
	Group P + R(Y)	39.1 ± 15.9	42.9 ± 15.8	− 3.7 ± 10.25	0.053	
RMSSD (ms)	Group C	43.2 ± 38.0	43.9 ± 34.2	− 0.6 ± 22.2	0.405	0.018^{+}
	Group P + R(Y)	31.8 ± 18	40.8 ± 21.6	− 9.02 ± 11.83	0.000^{***}	
TP (ms^2)	Group C	3399 ± 5457	3002.9 ± 3988	396.3 ± 3647.1	0.688	0.442
	Group P + R(Y)	1803 ± 1373	2049.6 ± 1433	− 246.2 ± 1192	0.136	
LF (ms^2)	Group C	356.6 ± 539.6	455.3 ± 6	− 98.6 ± 660.6	0.125	0.81
	Group P + R(Y)	299.5 ± 461	265.9 ± 327.0	33.5 ± 345.3	0.665	
LF (nu)	Group C	44.1 ± 17.2	41.6 ± 17.2	2.5 ± 10.1	0.171	0.041^{+}
	Group P + R(Y)	194.2 ± 331.7	165 ± 238.5	28.4 ± 274.0	0.047*	
HF(ms^2)	Group C	1086.0 ± 2063	1223.2 ± 2179	− 137.1 ± 1567	0.082	0.104
	Group P + R(Y)	442.6 ± 527.2	743.3 ± 877.6	− 300.6 ± 484.4	0.000^{***}	
HF(nu)	Group C	60.9 ± 75.8	67.2 ± 82.9	− 6.2 ± 11.5	0.004^{**}	0.023^{+}
	Group P + R(Y)	39.4 ± 15.9	52.7 ± 16.3	− 13.3 ± 12.3	0.000^{***}	
LF/HF	Group C	1.4 ± 2.1	1.1 ± 1.5	0.24 ± 0.7	0.077	0.001^{+++}
	Group P + R(Y)	1.4 ± 0.8	0.7 ± 0.4	0.7 ± 0.7	0.000^{***}	

Values expressed as Mean ± SD; [* = p < 0.05, ** = p < 0.01, *** = p < 0.001; + = p < 0.05, ++ = p < 0.01, +++ = p < 0.001]. HRV – Heart rate variability; SDNN – Standard deviation of NN intervals (ms); RMSSD – square root of the mean of the sum of squares of differences between adjacent R-R intervals (ms); TP – Total power (ms2); LF – Low frequency power (ms2); HF– High frequency power (ms2); nu – normalized units; LF/HF – Low frequency/ High frequency (Sympathovagal Balance).

Table 7
Effect of treatment on conventional cardiac autonomic functions tests in two groups of patients with migraine.

Cardiac Autonomic functions	AFT	Pre (n = 45) Mean ± SD	Post (n = 45) Mean ± SD	Pre-Post Change (Δ)	p Value (within group)	Between group p (Group C Vs Group P + R(Y))
DBD (bpm)	Group C	17.0 ± 4.6	17.7 ± 4.05	− 0.76 ± 1.7	0.004^{**}	0.000^{+++}
	Group P + R(Y)	14.3 ± 4.9	17.0 ± 4.0	− 2.6 ± 1.8	0.000^{***}	
Valsalva ratio	Group C	1.3 ± 0.2	1.4 ± 0.2	− 0.05 ± 0.10	0.010*	0.562
	Group P + R(Y)	1.14 ± 0.08	1.17 ± 0.07	− 0.02 ± 0.04	0.011*	
M:m ratio	Group C	1.0 ± 0.063	1.1 ± 0.08	− 0.03 ± 0.04	0.000^{***}	0.013^{+}
	Group P + R(Y)	1.08 ± 0.07	1.09 ± 0.07	− 0.01 ± 0.02	0.022*	
Δ DBP IHG (mmHg)	Group C	12.1 ± 4.1	11.8 ± 4.2	0.27 ± 1.8	0.557	0.000^{+++}
	Group P + R(Y)	11.7 ± 4.0	14.1 ± 3.0	− 2.3 ± 1.8	0.000^{***}	
Δ SBP OST (mmHg)	Group C	− 7.17 ± 7.2	− 6.5 ± 5.7	− 0.60 ± 4.0	0.461	0.929
	Group P + R(Y)	− 5.50 ± 5.9	− 4.87 ± 4.2	− 0.63 ± 3.7	0.337	

Values expressed as Mean ± SD; [* = p < 0.05, ** = p < 0.01, *** = p < 0.001; + = p < 0.05, ++ = p < 0.01, +++ = p < 0.001]. DBD (bpm): deep breathing difference (beats per minute); M: m ratio: maximum: minimum ratio; Δ DBP IHG: diastolic pressure changes with isometric handgrip test; Δ SBP OST: systolic pressure changes with orthostatic test (2nd minute).

surpassing the minimal clinically important differences (MCIDs) established for migraine studies.

Our results are consistent with the CONTAIN trial by Kumar et al. (2020), which showed that a three-month yoga intervention led to significant reductions in migraine days, pain severity, and headache-related disability.[29] While their intervention incorporated asanas, pranayama, and relaxation, our study isolated pranayama and relaxation, suggesting these components alone are sufficient to produce clinically significant benefits. Furthermore, a recent open-label RCT by Kaushal et al.[30] evaluating pranayama over six weeks found intragroup improvements, though between-group significance was not achieved—possibly due to shorter duration or methodological limitations. Our rigorous design, daily frequency of practice, and high adherence may explain the stronger outcomes observed.

The improvements in headache impact and quality of life we observed are consistent with findings from recent reviews. A 2022 meta-analysis by Wu et al.[31] reported that yoga significantly reduced migraine frequency and headache-related disability (pooled SMD: –2.3), though effects on pain intensity were modest. In contrast, our trial showed substantial reductions in all three domains, including pain severity. Additionally, a randomized trial by Hisham et al.[32] that combined patient education with relaxation exercises observed significant improvements in migraine frequency, duration, and quality of life—findings that parallel the multidimensional benefits seen in our cohort.

The broad improvements observed in quality-of-life domains—particularly physical health, bodily pain, and vitality, are also consistent with recent evidence indicating yoga's beneficial impact on patient-reported outcomes in chronic headache populations.[31,32] Such broad improvements suggest the intervention's holistic nature, likely reflecting simultaneous physiological and psychological benefits. Patients practicing pranayama and relaxation may experience reduced anxiety, improved sleep quality, and enhanced coping abilities, all critical components in managing chronic migraine.[13,33]

A unique contribution of our study lies in its detailed assessment of autonomic function through HRV and standardized autonomic reflex tests. Migraine patients often exhibit impaired vagal tone and heightened sympathetic drive, associated with reduced resilience to stressors and increased headache susceptibility.[8,34] Our intervention significantly increased time-domain HRV indices (RMSSD) and frequency-domain indices (HF power), alongside reductions in the LF/HF ratio, clearly indicating enhanced parasympathetic modulation. These results validate pranayama's physiological impact on autonomic balance, supporting previous research on slow-breathing practices promoting vagal tone and reducing sympathetic arousal.[19,20] Furthermore, the observed reductions in resting heart rate and diastolic blood pressure underscore the cardiovascular stabilization induced by yoga, analogous to effects reported with biofeedback and mindfulness-based stress reduction interventions.[35,36]

Mechanistically, pranayama likely exerts its beneficial effects through multiple interacting pathways. Slow diaphragmatic breathing enhances baroreceptor sensitivity and respiratory sinus arrhythmia, directly increasing vagal afferent stimulation and central autonomic

integration.[20] This autonomic recalibration may enhance cerebrovascular reactivity, potentially mitigating cortical spreading depression—a key event in migraine pathogenesis.[4] Additionally, yoga-induced increases in inhibitory neurotransmitters such as GABA could reduce cortical hyperexcitability, another fundamental migraine mechanism.[22] Furthermore, enhanced parasympathetic activity could attenuate neuroinflammation through vagal-mediated cholinergic anti-inflammatory pathways, potentially influencing migraine pathophysiology at a systemic level.[36] Beyond autonomic effects, yoga's psychological benefits cannot be understated. Mindfulness, increased body awareness, and active self-regulation through pranayama and relaxation practices likely reduce psychological stress, anxiety, and perceived pain intensity. Participants often reported feeling empowered by the self-management skills learned through yoga, breaking the stress-headache cycle commonly seen in migraine sufferers.[33]

Despite the substantial improvements observed in the intervention group, our control group also demonstrated meaningful clinical improvements, likely due to optimized standard care, regular follow-ups, and diary monitoring effects. However, the consistently larger benefits observed with pranayama and relaxation strongly suggest that the intervention's benefits surpass nonspecific factors alone.

4.1. Strength and limitations

This study has several notable strengths, including a rigorous randomized controlled design, comprehensive clinical and physiological assessments, and high participant adherence, enhancing both internal and external validity. The integration of standardized autonomic function testing with clinical outcomes provides a multidimensional understanding of the mind–body interactions underlying migraine pathophysiology and its modulation through pranayama and relaxation practices.

However, several limitations should be acknowledged. Although this was a single-center study conducted at a tertiary neurology hospital, the institution serves as a national referral center with patients from diverse regions and socioeconomic backgrounds, including both urban and rural populations. Thus, the sample represents a broad clinical population. Nonetheless, future multicenter trials across varied settings would strengthen external validity and confirm generalizability. The modest sample size and short follow-up period limit the assessment of long-term effects. Although attrition was modest (15 %), the per-protocol analysis may introduce potential attrition bias, and future studies employing intention-to-treat analyses could further strengthen robustness of inference. Moreover, no stratification or block randomization was applied; while baseline comparability was achieved, future studies could employ stratified block designs to enhance covariate balance. While adherence was quantitatively assessed through attendance logs and a calculated Practice Adherence Index, the absence of objective device-based tracking (such as wearable sensors) limits precise dose–response evaluation. Future studies may benefit from incorporating digital adherence monitoring to more accurately correlate practice intensity with therapeutic outcomes.

The absence of an active or attention-matched control group may also have introduced expectancy or therapist contact bias, particularly affecting subjective outcomes. Although the use of objective autonomic measures mitigates this risk, future studies incorporating active comparators interventions—such as relaxation training, biofeedback, or mindfulness-based programs—are warranted to better delineate the specific effects of pranayama and relaxation.

Although the overall sample size was adequate for parametric inference, several HRV and clinical measures exhibited non-normal distributions, justifying the use of rank-based non-parametric tests. This approach ensured robust inference under violated assumptions, while future multicenter studies could employ model-based approaches such as ANCOVA or mixed-effects models when distributional assumptions are met. The lack of an active control group may introduce expectancy bias, although objective autonomic measures partly mitigate this concern.

Future research should involve larger multicentric trials with longer follow-up periods. Additionally, exploring neuroimaging and biochemical mediators may further elucidate underlying mechanisms and support the integration of yoga-based therapies in migraine care.

5. Conclusion

This randomized controlled study demonstrated that a 12-week pranayama and relaxation program, delivered as an adjunct to conventional therapy, produced significant improvements in headache frequency, headache-related disability, quality of life, and autonomic function among patients with migraine. These findings suggest that yoga-based breathing and relaxation practices may serve as a feasible and beneficial adjunct in migraine management.

However, given the modest sample size, single-center design, and absence of an active control group, the results should be interpreted with caution. While improvements in autonomic parameters indicate a potential physiological mechanism linking mind–body regulation and migraine modulation, these mechanistic inferences remain preliminary. Future large-scale, multi-center randomized trials employing active comparator groups and mechanistic biomarkers—such as neuroimaging and biochemical correlates—are warranted to confirm and extend these findings.

CRediT authorship contribution statement

Madhu Jahnavi V: Resources, Methodology, Data curation. **H S Vadiraja:** Writing – review & editing, Resources, Conceptualization. **Mohan Raghavendra Rao:** Writing – review & editing, Supervision, Software, Methodology, Formal analysis, Conceptualization. **Ganagarajan Inbaraj:** Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Meghana Adoor:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Conceptualization. **Ravikiran Kisan:** Supervision, Methodology, Conceptualization. **Shilpa Mulakur:** Supervision, Methodology. **Talakad N Sathyaprabha:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Conceptualization. **MU Sujan:** Writing – review & editing, Writing – original draft, Resources, Project administration, Methodology, Investigation, Data curation, Conceptualization. **Atchayaram Nalini:** Supervision, Project administration, Methodology, Conceptualization. **Babina Nandakumar:** Project administration, Conceptualization. **M S Raghuram:** Investigation, Data curation.

Ethical Approval and Consent to Participate

The study received approval from the Institutional Ethics Committee, and written informed consent was obtained from all participants prior to enrollment, in accordance with the Declaration of Helsinki. This study was conducted as part of an MD dissertation project initiated before registration with the Clinical Trials Registry–India (CTRI) became mandatory for postgraduate thesis protocols under institutional regulations. Nevertheless, full ethical clearance was obtained before commencement, and the research was conducted in compliance with national and international ethical standards governing human participant research.

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Competing Interests

The authors declare that they have no competing interests related to this work.

Conflict of Interest Statement

The authors declare no conflicts of interest.

Declaration of Competing Interest

The authors declare that they have no conflicts of interest, financial or otherwise, that could have influenced the conduct, outcomes, or interpretation of this study. No financial support or personal relationships exist that could have appeared to influence the work reported in this manuscript.

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Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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