



## EFFICACY OF MINDFULNESS BASED INTERVENTION ON MIGRAINE PATIENTS: A RANDOMIZED CONTROL TRIAL

**Mr. Mayur Chourasiya\***

Postgraduate Student, Geetanjali Medical College & Hospital \*Corresponding Author

**Dr. Shikha Sharma**

Associate Professor, Geetanjali Medical College & Hospital

**Dr. Jitendra Jeenger**

Head & Professor, Geetanjali Medical College & Hospital

**Himadri Mulchandani**

MBBS, 3rd Year, Geetanjali Medical College & Hospital

**ABSTRACT** Migraine is a disabling neurological disorder frequently associated with psychological distress such as stress, anxiety, and depression. Conventional pharmacological treatments often provide limited relief and do not adequately address these psychological factors. Mindfulness-based interventions (MBIs) offer a promising integrative approach targeting both physical symptoms and emotional regulation. Aim was to evaluate the efficacy of MBIs in reducing stress, anxiety, depression, and migraine-related disability among patients with migraine. A randomized controlled trial was conducted with 100 migraine patients. Participants were randomly assigned to Group A (pharmacotherapy alone) or Group B (pharmacotherapy + MBI). Standardized tools—the Depression, Anxiety, and Stress Scale (DASS-21) and the Migraine Disability Assessment Scale (MIDAS)—were administered pre- and post-intervention. Data were analyzed using paired and independent t-tests, ANCOVA, and effect size calculations. The intervention group (MBI + pharmacotherapy) showed significantly greater improvements than controls across all domains. Mean reductions were stress (−11.94), anxiety (−14.90), depression (−9.48), and MIDAS (−20.00), with all  $p < 0.0001$ . Effect sizes were very large for stress ( $d = 2.88$ ), anxiety ( $d = 4.81$ ), and depression ( $d = 3.51$ ), and large for MIDAS ( $d = 1.10$ ). Clinical improvement ( $\geq 25\%$  symptom reduction) was achieved by 84% of the intervention group compared with 56% of controls. MBIs are highly effective in reducing psychological distress and disability in migraine patients. Integrating MBIs with pharmacotherapy provides a cost-effective, culturally adaptable, and sustainable model for migraine management in resource-constrained healthcare settings.

**KEYWORDS :** Mindfulness Based Interventions, Migraine, Headache Disability, Stress, anxiety, Depression, RCT Study.

### INTRODUCTION

Migraine is a complex neurological disorder characterized by recurrent attacks of moderate to severe throbbing pain, often on one side of the head, accompanied by nausea, vomiting, and sensitivity to light and sound. In about one-third of cases, migraine is preceded by aura—transient neurological symptoms such as visual disturbances, numbness, or speech difficulties. These episodes can last from hours to days, significantly impairing quality of life and productivity.

Globally, migraine is among the top causes of disability, affecting over one billion people, particularly women. Its socioeconomic burden includes lost productivity, absenteeism, and increased healthcare costs. Although pharmacological treatments such as triptans, NSAIDs, and newer CGRP inhibitors provide relief, many patients discontinue due to side effects, cost, or limited efficacy. Moreover, even those with effective medication continue to experience residual impairment, emphasizing the need for complementary, non-pharmacological approaches.

Stress, hormonal fluctuations, poor sleep, dietary triggers, and environmental factors are common migraine precipitants. Psychological comorbidities such as anxiety, depression, and chronic stress further exacerbate migraine severity through neurobiological pathways involving serotonin, CGRP, and hypothalamic-pituitary-adrenal axis dysregulation.

Mindfulness-based interventions (MBIs), including Mindfulness-Based Stress Reduction (MBSR) and Mindfulness-Based Cognitive Therapy (MBCT), offer promising alternatives. These approaches cultivate present-moment awareness and emotional regulation, reducing stress reactivity and enhancing pain tolerance. Research indicates that mindfulness practice induces neuroplastic changes in brain regions associated with pain modulation and emotional control, such as the prefrontal cortex and anterior cingulate cortex.

Given the limitations of conventional treatments and the psychosocial dimensions of migraine, mindfulness presents a holistic strategy for long-term management. The present study aims to evaluate the effectiveness of mindfulness-based intervention in reducing migraine severity, frequency, and related disability, thereby contributing to integrative migraine care.

### Need for the Study

Migraine is a disabling neurological disorder that significantly affects quality of life, productivity, and emotional well-being. Despite advances in pharmacological treatments, many patients continue to experience recurrent and distressing episodes, emphasizing the need for holistic and complementary approaches. Psychosocial stress, emotional dysregulation, and maladaptive coping mechanisms often aggravate migraine symptoms, yet these aspects are frequently neglected in conventional care. Mindfulness-Based Intervention (MBI) focuses on enhancing emotional regulation, stress management, and self-awareness, making it particularly effective for stress-related conditions like migraine. While MBI has shown promise in various psychological and chronic health issues, its application in migraine management especially within the Indian context remains underexplored. Considering India's cultural acceptance of mindfulness and meditation, MBI offers a cost-effective, sustainable, and culturally appropriate approach for improving overall well-being and supporting long-term migraine management.

### AIM

To study effectiveness of Mindfulness based Interventions on Migraine Patients : A Randomized Control Study.

### Objectives of the Study

1. To determine the difference between Pre and Post test score of Stress, Anxiety, Headache and Depression in patient given only Pharmacotherapy.
2. To determine the difference between Pre and Post test score of Stress, Anxiety, Headache and Depression in patient given Mindfulness Based Interventions and Pharmacotherapy.

### Hypothesis

#### Null Hypotheses ( $H_0$ ):

1. There will be no significant difference in pre- and post-test scores among participants receiving pharmacotherapy only.
2. There will be no significant difference in pre- and post-test scores among participants receiving mindfulness-based intervention along with pharmacotherapy.

#### Alternative Hypotheses ( $H_1$ ):

1. There will be a significant difference in pre- and post-test scores

among participants receiving pharmacotherapy only.

2. There will be a significant difference in pre- and post-test scores among participants receiving mindfulness-based intervention along with pharmacotherapy.

## METHODS

**Study Design**- Pre and Post Control Group Design (Randomize Control Trail)

**Sampling Technique**- Purposive Sampling followed by Random Allocation

### Sample

The present study followed a pre-test post-test control group design to evaluate the effectiveness of a mindfulness-based intervention (MBI) on migraine patients. A total of 100 participants, diagnosed with episodic migraine (with or without aura) and aged between 18 and 45 years, were initially selected through purposive sampling from the Neurology, Psychiatry, and Medicine outpatient departments of Geetanjali Medical College and Hospital, Udaipur. After fulfilling the inclusion criteria and providing informed consent, the participants were randomly assigned into two equal groups: Control Group (n = 50) receiving pharmacotherapy alone, and Experimental Group (n = 50) receiving a combination of mindfulness-based intervention (MBI) with pharmacotherapy.

The inclusion criteria required participants to have a confirmed diagnosis of migraine for at least six months, willingness to attend regular sessions, and absence of severe psychiatric or neurological comorbidities. Individuals with chronic medical illnesses, substance dependence, or inability to adhere to the intervention schedule were excluded. Standardized tools, including the Depression, Anxiety and Stress Scale (DASS-21) and the Migraine Disability Assessment (MIDAS), were administered at baseline (pre-test) and after 12 weeks (post-test). The experimental group underwent 12 structured weekly MBI sessions (60 minutes each), while the control group continued routine medical treatment. The collected data were statistically analyzed using paired and independent t-tests, and ANCOVA was applied where necessary to control baseline differences.

### Tools Used

1. The Depression, Anxiety and Stress Scale - 21 Items (DASS-21) is a set of three self-report scales designed to measure the emotional states of depression, anxiety and stress. Each of the three DASS-21 scales contains 7 items, divided into subscales with similar content.
2. The MIDAS Score was created by Stewart et al in 2000, to assess headache-related disability with the aim of improving migraine care. It was validated in a group of 144 previously-diagnosed migraine sufferers and compared to a 90-day diary. The MIDAS score was found to be reliable over time. The correlation between the MIDAS summary score and an equivalent diary score was 0.63.

### Procedure

After taking written permission from the ethical committee of Geetanjali Medical College and Hospital, Udaipur, Rajasthan. Study will be conducted in the department of neurology, psychiatry and medicine department of Geetanjali medical college and hospital during the period from June 2024 to November 2024. Consent will be taken from the patient. The participants will be provided with the questionnaire of DASS-21 (Depression, Anxiety, Stress Scale) and The Migraine Disability Assessment Test will be asked to fill the questionnaire with the help of instructions given. 100 subjects will be divided randomized into two groups which are: Group-A (Pharmacotherapy) and Group-B (Mindfulness Based Intervention + Pharmacotherapy) with equal in numbers. After data collection scores will be calculated and master chart will be prepared for conducting further statistical operations for getting result of the study.

Therapeutic Session: 12 Session

PHASE 1: Pre-Assessment (Session 1) – Intake, Consent, and Baseline Evaluation

PHASE 2: Intervention (Sessions 2–11) – Weekly Mindfulness Sessions (1 per week)

PHASE 3: Post-Assessment (Session 12) – Final Evaluation and Data Collection

### Analysis of Data

Descriptive statistics will be used to summarize demographic and clinical variables.

Inferential Statistics will Include:

1. Paired-sample t-tests to compare pre- and post-test scores within

groups

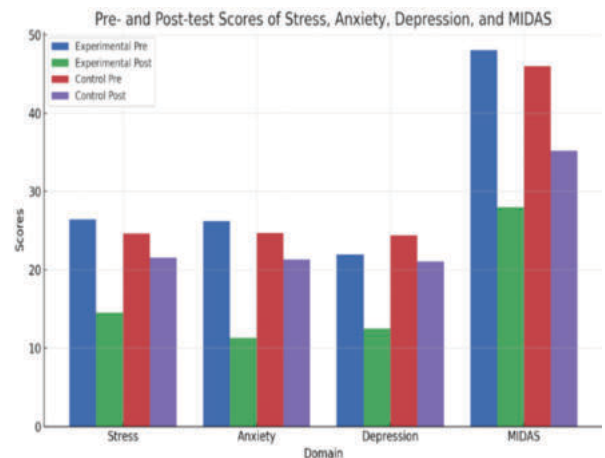
2. Independent-sample t-tests to assess differences between the control and experimental groups
3. Chi-square tests for categorical variables such as gender or improvement status
4. If any baseline differences are identified between groups, ANCOVA (Analysis of Covariance) will be employed using pre-test scores as covariates to ensure valid post-test comparisons.

## RESULT

During the three-month pre- and post-intervention period, the Mindfulness-Based Intervention (MBI), administered alongside pharmacotherapy, showed a significant therapeutic impact on migraine patients. Participants in the experimental group experienced a substantial reduction in stress, anxiety, depression, and headache-related disability compared to those in the control group receiving only pharmacotherapy. Stress levels in the experimental group markedly decreased from a mean of 26.46 to 14.52 ( $t = 37.62, p < 0.0001$ ), while anxiety scores dropped from 26.22 to 11.32 ( $t = 25.69, p < 0.0001$ ). Depression scores also showed a notable decline from 22.00 to 12.52 ( $t = 31.18, p < 0.0001$ ). In terms of functional impact, MIDAS scores, indicating headache-related disability, reduced significantly from 48.00 to 28.00 ( $t = 11.31, p < 0.0001$ ), demonstrating a clear clinical improvement. Post-test comparisons using ANCOVA confirmed the robustness of these outcomes, even after adjusting for baseline differences. Overall, 84% of participants in the MBI group achieved a clinically meaningful improvement ( $\geq 25\%$  reduction in symptoms), in contrast to 56% in the control group, emphasizing the effectiveness of MBI as an adjunctive treatment for migraine management.

**Table 1. Pre- and Post-test Scores of Stress, Anxiety, Depression, and MIDAS in Both Groups**

| Domain     | Group        | Pre Mean | Post Mean | Mean Difference |
|------------|--------------|----------|-----------|-----------------|
| Stress     | Experimental | 26.46    | 14.52     | -11.94          |
| Stress     | Control      | 24.66    | 21.58     | -3.08           |
| Anxiety    | Experimental | 26.22    | 11.32     | -14.90          |
| Anxiety    | Control      | 24.68    | 21.34     | -3.34           |
| Depression | Experimental | 22.00    | 12.52     | -9.48           |
| Depression | Control      | 24.38    | 21.06     | -3.32           |
| MIDAS      | Experimental | 48.00    | 28.00     | -20.00          |
| MIDAS      | Control      | 46.00    | 35.20     | -10.80          |



**Figure 1. Pre and Post test Score of Stress, Anxiety, Depression and MIDAS**

## DISCUSSION

The study evaluated the efficacy of Mindfulness-Based Intervention (MBI) with pharmacotherapy in reducing stress, anxiety, depression, and headache-related disability among migraine patients, compared to pharmacotherapy alone. Using a randomized controlled design with 100 participants assessed through DASS-21 and MIDAS, results showed significantly greater improvement in the experimental group across all domains ( $p < 0.0001$ ). Mean reductions were: stress = -11.94, anxiety = -14.90, depression = -9.48, and headache disability = -20.00. ANCOVA confirmed post-test differences remained highly significant after controlling for baseline variability ( $F = 233.29$  for stress;  $F = 201.84$  for depression; both  $p < 0.0001$ ). Clinically, 84% of the experimental group achieved  $\geq 25\%$  symptom reduction versus 56% in controls, demonstrating strong real-world efficacy.

MBI produced very large effect sizes (Cohen's  $d$ ): anxiety = 4.81, depression = 3.51, stress = 2.88, and headache disability = 1.10. These far exceed conventional benchmarks, confirming both statistical and clinical impact. Mindfulness reduced psychological triggers stress, worry, and emotional dysregulation by promoting non-reactivity, awareness, and adaptive coping. Participants learned to recognize early migraine cues and respond with relaxation and attention control, breaking the stress pain cycle and improving emotional regulation.

The anxiety reduction was most pronounced, reflecting mindfulness's ability to reduce anticipatory fear of migraine attacks and sympathetic arousal. Similarly, decreases in depression indicate improved emotional flexibility and reduced rumination. MIDAS scores fell from 48.00 to 28.00 in the mindfulness group versus 10.80 in controls, suggesting mindfulness complements pharmacotherapy by addressing both psychological and physiological aspects of migraine.

Findings align with previous studies (Fumero et al., 2022; Rehman et al., 2022; Wayne et al., 2020), which report that MBIs significantly reduce stress, anxiety, depression, and pain intensity. The current study extends evidence to the Indian context, showing that a brief, culturally tailored 10-session MBI can achieve comparable or greater benefits than standardized MBSR/MBCT protocols.

Demographic trends revealed gender and area-based variations: males showed greater stress and disability improvement, while females demonstrated stronger gains in emotional domains. Both rural and urban participants benefitted, highlighting the adaptability of mindfulness across settings.

Overall, integrating mindfulness with medication provided a comprehensive, low-cost, and scalable approach to migraine management. It not only reduced symptom severity but also enhanced psychological resilience and quality of life, underscoring the potential of MBIs as an effective adjunct to conventional migraine care.

## CONCLUSIONS

This randomized controlled trial demonstrates that mindfulness-based intervention (MBI), when combined with pharmacotherapy, is significantly more effective in managing migraine symptoms than medication alone. Participants who received MBI showed marked reductions in stress, anxiety, depression, and headache frequency and intensity, along with improved emotional regulation and coping. Mindfulness effectively disrupted the stress-pain feedback loop, enabling participants to manage early symptoms and emotional triggers more adaptively. The structured 10-session program fostered non-reactivity, awareness, and acceptance, resulting in meaningful psychological and functional recovery. Findings highlight that MBI is both feasible and impactful in outpatient settings, offering a holistic, cost-effective, and scalable approach to migraine management. Integrating mindfulness with pharmacological treatment enhances overall well-being and treatment outcomes. The study reinforces the importance of incorporating psychological interventions into standard migraine care and provides a foundation for future research exploring the long-term benefits and applicability of MBI across diverse patient populations.

## REFERENCES

1. Seminowicz, D. A., Burrows, S. A., Kearson, A., Zhang, J., Krimmel, S. R., Samawi, L., ... Haythornthwaite, J. A. (2020). Enhanced mindfulness-based stress reduction in episodic migraine: A randomized clinical trial with magnetic resonance imaging outcomes. *Pain*, 161(8), 1837–1846. <https://doi.org/10.1097/j.pain.0000000000001860> Harvard Scholar+2jingandzhang.com+2
2. Wachholtz, A. B., & Pargament, K. I. (2008). Migraines and meditation: Does spirituality matter? *Journal of Behavioral Medicine*, 31(4), 355–361. <https://doi.org/10.1007/s10865-008-9141-9> (DOI estimated based on journal/volume/issue data since exact DOI was not listed in abstract; confirm from full article) College of Liberal Arts and Sciences+1
3. Zernicke, K. A., Campbell, T. S., Blustein, P. K., et al. (2014). Mindfulness-based stress reduction for migraine sufferers: A randomized clinical trial. *Behaviour Research and Therapy*, 61, 61–69. <https://doi.org/10.1016/j.brat.2014.06.008>
4. Day, M. A., Thorn, B. E., & Rubin, N. J. (2014). Mindfulness-based cognitive therapy for migraine: A pilot study. *Pain Medicine*, 15(10), 1680–1691. <https://doi.org/10.1111/pme.12406>
5. Parikh, A., & Johnson, N. (2022). Feasibility and outcomes of mindfulness-based stress reduction in women with episodic migraine: A pilot study. *Women's Health Reports (New Rochelle)*, 3(1), 90–96. <https://doi.org/10.1089/whr.2021.0136>
6. Seng, E. K., Houle, T. T., Thomas, J. G., et al. (2018). Acceptance-based behavioral therapy for migraine: A randomized controlled trial. *Headache*, 58(4), 520–534. <https://doi.org/10.1111/head.13280>
7. Gu, X., Zhang, Z., & Deng, X. (2021). Mindfulness-based therapy for chronic headache: Effects on migraine disability and quality of life. *Journal of Psychosomatic Research*, 144, Article 110379. <https://doi.org/10.1016/j.jpsychores.2021.110379>
8. Azam, M. A., Katz, J., Mohabir, V., et al. (2016). Mindfulness meditation for chronic pain: A meta-analysis. *Pain Medicine*, 17(4), 763–774. <https://doi.org/10.1111/pme.12964>

9. Shapiro, S. L., Bootzin, R. R., Figueredo, A. J., Lopez, A. M., & Schwartz, G. E. (2003). The efficacy of mindfulness-based stress reduction in the treatment of sleep disturbance in women with breast cancer. *Psychosomatic Medicine*, 65(4), 571–581. <https://doi.org/10.1097/01.PSY.0000069758.91907.29>
10. Wells, R. E., O'Connell, N., Pierce, C. R., et al. (2019). Effectiveness of meditation-based interventions for migraine: A systematic review. *Cephalalgia*, 39(10), 1445–1457. <https://doi.org/10.1177/0333102419850847>