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Effectiveness of a combined paced-breathing and mobile app–based mindfulness intervention for chronic migraine: A randomized controlled trial

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Abstract

Background: Mindfulness has been proposed as a non-pharmacological strategy for chronic migraine management.

Objective: This study evaluated the effectiveness of a combined paced-breathing and mobile app–based mindfulness intervention in adults with chronic migraine.

Methods: A randomized controlled trial was conducted in adults with chronic migraine. Forty participants were randomized, and 38 were included in the final analyses. The intervention group was assigned to a 12-week combined intervention consisting of paced breathing followed by a mobile app–based mindfulness intervention delivered through the Petit BamBou® app; the control group remained on a waitlist and continued usual care. The primary outcome was migraine days per month. Secondary outcomes included migraine episode pain intensity and duration, headache-related quality of life (Headache Impact Test-6), anxiety sensitivity (Anxiety Sensitivity Index-3), kinesiophobia (Tampa Scale for Kinesiophobia-11), and sleep quality (Athens Insomnia Scale). Between-group differences at post-intervention were evaluated using analysis of covariance, adjusting each outcome for its corresponding baseline value.

Results: No statistically significant baseline-adjusted between-group differences were observed for migraine frequency or for any secondary outcome. For the primary outcome, the adjusted mean difference between the control and intervention groups was −3.07 migraine days per month (95% CI, −8.00 to 1.86; $F(1, 35) = 1.599$; $p = 0.214$; $\eta p^2 = 0.044$). Effect sizes were small for all outcomes.

Conclusion: A 12-week combined paced-breathing and mobile app–based mindfulness intervention was not superior to waitlist usual care for reducing migraine frequency or improving the evaluated clinical and psychological outcomes. These findings should be interpreted cautiously because of the small sample size, the marked baseline imbalance in migraine frequency, the use of a waitlist control group, and the absence of objective adherence monitoring. Future trials should include larger samples, active control conditions, objective measures of engagement, and longer follow-up periods. (Australian New Zealand Clinical Trials Registry, ACTRN12624000611527 [prospectively registered on May 10, 2024]).

Keywords: Mindfulness; Telemedicine; Migraine; Quality of life; Public Health

1. Introduction

Migraine is a disabling neurological disorder that affects approximately 12% of the global population, with a higher prevalence in women than in men.[1] According to the International Classification of Headache Disorders, 3rd edition (ICHD-3), migraine is categorized into two main types: episodic migraine and chronic migraine. Chronic migraine is defined as the presence of headache on 15 or more days per month for more than three months, with at least eight of those days featuring migraine-like characteristics.[2]

The incidence of chronic migraine ranges from 2% to 5% in the general population, and its frequency and intensity have a significant impact on patients' quality of life. Moreover, chronic migraine is associated with an increased risk of developing anxiety, depression, and other mental health disorders.[1]

Therapeutic management of chronic migraine is essential. A recent publication on updated pharmacological treatments for migraine describes the use of triptans and nonsteroidal anti-inflammatory drugs for acute attacks, while preventive treatment primarily includes antidepressants, botulinum toxin, and calcitonin gene-related peptide antagonists.[3] While these medications can be effective in reducing the frequency and severity of migraine attacks, their adverse effects may limit long-term treatment adherence. Common adverse effects include drowsiness, fatigue, dizziness, weight gain, and gastrointestinal disturbances. Furthermore, the excessive use of acute migraine medications may contribute to the development of medication-overuse headache.[4]

Excessive use of migraine medications may lead to the development of medication overuse headache, a condition in which headaches become more frequent and severe due to the repeated use of analgesics. This phenomenon may perpetuate a cycle of frequent medication use and worsening headache symptoms, highlighting the need for non-pharmacological therapeutic alternatives.[5]

In recent years, due to these adverse effects, two main strategies have emerged: individualized medication management[6] and the use of non-pharmacological therapeutic alternatives. These include both invasive and non-invasive neuromodulation techniques, such as transcranial magnetic stimulation, as well as dietary interventions and physiotherapy.[7]

Furthermore, since patients with chronic migraine often experience comorbid conditions—primarily psychological—it is estimated that 27% of migraine sufferers in Spain also suffer from depression.[8] This has led to growing interest in therapies aimed at reducing the impact of these comorbidities.[9] Among these interventions, mindfulness has proven to be an effective approach for reducing pain and improving psychological well-being in migraine patients. A recent study found that regular mindfulness practice reduced the frequency and severity of migraine attacks, as well as levels of perceived stress.[10] In addition, mindfulness and meditation have shown benefits in improving quality of life, reducing pain catastrophizing, and decreasing the frequency of attacks.[11]

A meta-analysis on mindfulness meditation for chronic pain, including chronic migraine, concluded that this intervention may reduce depressive symptoms in affected patients. However, it also emphasized the need for further research to better understand the underlying mechanisms and to establish long-term efficacy through well-designed controlled trials.[12]

The COVID-19 pandemic led to an exponential increase in the use of telemedicine. A simple PubMed search using the keyword "Telemedicine" yields over 34,000 publications. Driven by this surge, recent studies have explored remotely delivered behavioral and relaxation-based interventions, showing promising results in reducing anxiety and depression associated with chronic pain.[13]

Mobile app–based mindfulness interventions have also been shown to be an effective intervention for treating depression related to pain conditions such as neuropathic pain.[14] Specifically, a recent study demonstrated that a mobile app–based mindfulness intervention may help reduce migraine-associated depression and related disability, although these findings should be interpreted with caution due to the absence of a control group (CG).[15] Therefore, evidence from randomized controlled trials evaluating mobile app–based mindfulness interventions for chronic migraine remains limited.

Given this evidence gap, and considering the growing role of psychological interventions delivered through digital health technologies, this randomized controlled trial was designed to evaluate the effectiveness of a combined paced-breathing and mobile app–based mindfulness intervention in patients with chronic migraine. Beyond its potential to reduce migraine burden, this study may contribute to the field of health psychology by improving

understanding of accessible psychological interventions targeting pain-related symptoms and psychological well-being in individuals with chronic migraine.

2. Methods

2.1. Study design

This study was a randomized, parallel-group, statistician-blinded controlled trial with a waitlist CG conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The study was carried out at the Hospital Universitario Infanta Sofía and Hospital Universitario de Getafe in Madrid over a period of 12 weeks. Participants were randomly allocated (1:1) to either the intervention group (IG), which was assigned to the combined paced-breathing and mobile app–based mindfulness intervention, or the waitlist CG using a computer-generated randomization sequence. Due to the nature of the intervention, participants could not be blinded to group allocation. However, the statistician responsible for data analysis remained blinded to treatment allocation throughout the analysis by using anonymized group codes until all analyses were completed. This study design was based on previous randomized controlled trials evaluating mindfulness interventions for chronic migraine.

This study was reviewed and approved by the Ethics Committee for Research at Rey Juan Carlos University (Comité de Ética de la Investigación de la Universidad Rey Juan Carlos), Spain (Approval No. 2209202333823; approved on December 15, 2023). The study was conducted in accordance with the Declaration of Helsinki, and written informed consent was obtained from all participants prior to enrollment. The trial was registered in the Australian New Zealand Clinical Trials Registry under the registration number ACTRN12624000611527.

2.2. Participants

The sample size was estimated *a priori* using G*Power software (version 3.1; Heinrich Heine University, Germany) before participant recruitment, as specified in the prespecified study protocol. The calculation was based on a repeated-measures analysis of variance (ANOVA; within–between interaction), which was the planned primary analytical approach at the time of study design. A large effect size (Cohen's $f = 0.40$) was assumed based on the magnitude of the intervention effects reported in previous randomized studies evaluating mindfulness-based interventions in patients with migraine.[16,17] Assuming a two-sided significance level of 0.05, a statistical power of 80%, two study groups, and two assessment time points, the estimated minimum sample size was 32 participants in total (16 per group). To account for an anticipated dropout rate of approximately 20%, the recruitment target was increased to 40 participants (20 per group).

Participants were eligible if they were between 18 and 65 years of age, had a neurologist-confirmed diagnosis of chronic migraine established before enrollment according to the complete criteria of ICHD-3, and had access to a smartphone to use the Petit BamBou® application. The diagnosis of chronic migraine was based on the participants' documented clinical diagnosis according to the ICHD-3 criteria and was not determined from the baseline headache diary. The study investigators did not independently reassess the diagnostic criteria, as eligibility was based on the pre-existing neurologist-confirmed diagnosis documented in the medical record.

The migraine frequency reported in this study corresponds to the number of migraine days recorded in the baseline headache diary as an outcome measure. A migraine day was defined as any calendar day on which the participant recorded at least one migraine episode. This measure should not be interpreted as the diagnostic criterion used to establish chronic migraine.

Participants were excluded if they had auditory impairments that prevented them from following the guided meditation sessions delivered through the application or if they were concurrently participating in another clinical trial during the study period, as this could have interfered with the intervention and outcome assessment.

A total of 68 patients were assessed for eligibility; 6 did not meet the inclusion criteria, and 22 declined to participate. Recruitment was completed within the predefined study period, and the 40 enrolled participants were randomly assigned to the IG ($n = 20$) or the waitlist CG ($n = 20$).

2.3. Randomization

Participants were randomly allocated (1:1) to either the intervention or waitlist CG using a computer-generated simple randomization sequence generated with Randomizer.org before participant recruitment. The sequence was generated by an independent researcher who was not involved in participant enrollment. A second independent researcher screened potential participants, verified eligibility, obtained informed consent, and enrolled participants without access to the allocation sequence. After enrollment and confirmation of eligibility and written informed consent, a third independent researcher assigned participants according to the pre-generated randomization sequence.

The researcher responsible for participant enrollment

did not have access to the allocation sequence until participant eligibility had been confirmed and written informed consent had been obtained, thereby reducing the possibility of foreknowledge of treatment allocation. No formal allocation-concealment mechanism was implemented. Due to the nature of the intervention, participants could not be blinded to group allocation. However, the statistician responsible for the data analysis remained blinded to treatment allocation by using anonymized group codes throughout all analyses. During follow-up, one participant from each group withdrew without providing a reason. Consequently, the final analyses were conducted on 38 participants (19 per group). **Figure 1** presents the CONSORT flow diagram of participant recruitment, allocation, follow-up, and analysis.

2.4. Intervention description

2.4.1. Intervention group

Participants assigned to the IG were contacted by email or telephone and received instructions on how to download the Spanish version of the Petit BamBou® mobile application (www.petitbambou.com) onto their electronic devices. Once the application had been installed, participants were provided with a free access code valid for three months.

Participants were instructed to complete the intervention twice weekly on non-consecutive days for 12 weeks. Participants were also instructed to maintain their usual preventive migraine treatment throughout the study period and not to modify it during the intervention. Each session consisted of two consecutive components. First, participants performed 5 minutes of paced breathing using a 6:6 breathing pattern (6-second inhalation followed by a 6-second exhalation). To standardize this component, all participants received the same prerecorded audio instructions, prepared by the research team and distributed individually via WhatsApp or email, with instructions to complete the breathing exercise immediately before each mindfulness session.

Participants were instructed to complete the application's "Meditation of the Day," a guided mindfulness session lasting approximately 10–15 minutes, immediately after each paced-breathing exercise. Although the specific meditation varied from day to day, all sessions were designed to cultivate the same core mindfulness skills, including present-moment awareness, attention regulation, breathing awareness, and non-judgmental observation of thoughts, emotions, and bodily sensations. Participants were instructed to complete the sessions in a quiet environment where they could remain undisturbed. No live guidance or supervision was provided by the research team. This procedure followed validated mindfulness approaches reported in previous studies.[18]

Weekly reminder emails were sent throughout the intervention period to encourage regular practice. However, objective application usage data (e.g., completed sessions, practice duration, or login frequency) and self-reported adherence data were not available. Therefore, actual exposure to the intervention could not be verified, and participants should be considered as having been assigned to the combined paced-breathing and mobile app–based mindfulness intervention, with instructions to engage in regular practice, rather than as having completed a predefined intervention dose.

2.4.2. Control group (waitlist)

Participants allocated to the CG remained on a waitlist and continued receiving their usual medical care throughout the study period. Usual care included both acute pharmacological treatment (e.g., nonsteroidal anti-inflammatory drugs and/or triptans) and preventive migraine medication when prescribed by their treating neurologist, with no modifications requested as part of the study protocol. Participants in this group did not receive the combined paced-breathing and mobile app–based mindfulness intervention during the study period. After completion of the post-intervention assessment, they were offered free access to the Petit BamBou® application for three months. Baseline and post-intervention assessments obtained during the waiting period were used for comparative analyses.

2.5. Outcome measures

The study variables were assessed at two time points: immediately before the start of the study (baseline) and at the end of the 12-week intervention. Participants completed self-administered questionnaires using Microsoft Forms, distributed via email, and recorded migraine-related outcomes in an Excel-based headache diary.

The primary outcome was the monthly number of migraine days recorded in the headache diary. Secondary outcomes included migraine episode pain intensity and duration, headache-related quality of life (Headache Impact Test-6 [HIT-6]), anxiety sensitivity (Anxiety Sensitivity Index-3 [ASI-3]), kinesiophobia (Tampa Scale for Kinesiophobia-11 [TSK-11]), and sleep quality (Athens Insomnia Scale [AIS]).

Physical activity (International Physical Activity Questionnaire [IPAQ]) and daily screen time were collected at baseline only to characterize the study sample and were not prespecified as study outcomes or covariates.

No modifications to the study protocol or outcome

measures were made during the trial. Although no formal structured adverse event questionnaire was administered, participants were routinely asked during study contacts whether they had experienced any adverse effects or unintended events related to the intervention. No adverse events were reported.

The following measurement instruments were used:

(i) Headache diary: Participants completed a daily headache diary in Excel format throughout the 12-week intervention. All participants had a neurologist-confirmed diagnosis of chronic migraine established before enrollment according to the ICHD-3 criteria. Before starting the study, participants received written instructions explaining the clinical characteristics of a migraine episode (including unilateral location, pulsating quality, moderate-to-severe pain intensity, aggravation by routine physical activity, and associated symptoms such as nausea, photophobia, or phonophobia). Participants were instructed to record only episodes that they identified as migraine according to these characteristics, rather than all headache episodes. For each recorded migraine episode, participants documented its occurrence, pain intensity on a 0–10 numerical rating scale, and duration in hours. The monthly number of recorded migraine days was used as the primary outcome measure. Because migraine identification relied on participant self-report based on these standardized instructions, the diary did not include a structured checklist of migraine-associated symptoms or migraine-specific acute medication use.[19]

(ii) HIT-6 Scale: The HIT-6 Scale measured the impact of headache episodes on the patient's daily life. It was a globally recognized instrument used to assess how migraine affected quality of life, particularly in work, social relationships, and overall well-being. The HIT-6 comprises six items assessing the impact of headaches on daily activities, emotional well-being, and work performance. Each item has five response categories, scored as 6, 8, 10, 11, or 13 points, resulting in a total score ranging from 36 to 78. Higher scores indicate greater impact on daily life.[20]

(iii) ASI-3: ASI-3 was used to assess participants' sensitivity to anxiety symptoms. This scale was useful for identifying how participants perceived the physical and psychological symptoms associated with anxiety, which is a common comorbidity in chronic migraine patients. The ASI-3 consisted of 18 items that assessed three main dimensions: physical concerns (fear of physical anxiety symptoms), cognitive concerns (fear of mental effects of anxiety), and social concerns (fear of social evaluation of anxiety symptoms). Each item was rated on a scale from 0 to 4, where 0 meant "not at all" and 4 meant "very much." The validated Spanish version of ASI-3 has demonstrated good psychometric properties in Spanish-speaking populations.[21]

(iv) TSK-11: TSK-11 measured fear of movement or re-injury due to the fear of experiencing pain or injury. This instrument was relevant in chronic migraine patients, as kinesiophobia (fear of movement) could exacerbate pain and disability. The TSK-11 consisted of 11 items that assessed how the patient perceived the risk of injury or worsening pain with movement. Each item was rated on a scale from 1 to 4, where 1 meant "strongly disagree" and 4 meant "strongly agree." The maximum score was 44, indicating a high level of kinesiophobia. The validated Spanish version of the TSK-11 has demonstrated good reliability and validity for assessing pain-related fear in Spanish-speaking patients.[22]

(v) AIS: The AIS was used to evaluate the quality of sleep in patients, which was a key factor in chronic migraine, as sleep disorders could exacerbate pain and disability. The AIS consisted of 8 items that assessed various aspects of sleep, including difficulty falling asleep, frequency of waking during the night, perceived sleep quality, and the impact of sleep quality on daily activities. Each AIS item is scored from 0 to 3, with higher scores indicating greater sleep-related difficulties. A total score above 6 indicated insomnia. The validated Spanish version has demonstrated good reliability and validity in Spanish-speaking populations.[23]

(vi) IPAQ: The IPAQ measured the level of physical activity of participants. Physical activity was an important factor in managing migraine, as regular exercise could help reduce the frequency and intensity of headache episodes. The International Physical Activity Questionnaire–Short Form (IPAQ-SF) included questions about the time spent on physical activities of varying intensities (low, moderate, and vigorous) over the past seven days. The questionnaire also asked about physical activity during work, commuting, and leisure time. The score was calculated in terms of metabolic equivalent of task-minutes/week. The validated Spanish version of the IPAQ has demonstrated acceptable reliability and validity for assessing physical activity in the Spanish adult population.[24]

Physical activity, assessed using IPAQ-SF, and daily screen time were collected as baseline descriptive variables to characterize the study population and assess baseline

comparability between groups. These variables were not prespecified as study outcomes or covariates, as they were not targets of the mindfulness intervention.

All assessment instruments were used in accordance with their respective terms of use and the original validation publications. No copyrighted questionnaire items are reproduced in this manuscript.

2.6. Statistical analysis

The data collected were analyzed using SPSS v29 software (IBM, USA). To assess the distribution of data, the Shapiro–Wilk test was used. Descriptive statistics were used to summarize the baseline characteristics of the study participants. Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables were presented as frequencies and percentages. Baseline between-group comparisons were conducted using the independent *t*-test for normally distributed variables or the Mann–Whitney *U* test for non-normally distributed variables. Categorical variables were compared using Fisher's exact test.

The original statistical analysis plan specified repeated-measures ANOVA. Following completion of the study, an additional baseline-adjusted analysis using analysis of covariance (ANCOVA) was performed to address the marked baseline imbalance in migraine frequency. The ANCOVA results are presented as a post hoc analysis.

For each outcome, ANCOVA was performed using the post-intervention value as the dependent variable, treatment group as the fixed factor, and the corresponding baseline value as the covariate. The assumptions of ANCOVA, including homogeneity of error variances and homogeneity of regression slopes, were evaluated prior to model interpretation.

Analyses of the secondary outcomes were considered exploratory; therefore, *p*-values are reported without adjustment for multiple comparisons and should be interpreted accordingly. Effect size was quantified using partial eta squared (ηp^2), with values < 0.06 considered small, 0.06–0.14 medium, and >0.14 large, according to Cohen's guidelines.[25] Adjusted between-group estimates, 95% confidence intervals, test statistics, and effect sizes are reported for all outcomes.

Complete-case analyses were conducted separately for each outcome, including only participants with the required baseline and post-intervention data. Participants were analyzed according to their original randomized allocation, and no imputation of missing data was performed. Statistical significance was set at $p < 0.05$ for all analyses.

3. Results

Identification and preliminary screening of potentially eligible patients began in February 2024. The trial was registered in the Australian New Zealand Clinical Trials Registry on May 10, 2024. No participant provided informed consent, was formally enrolled, or was randomized before trial registration. Formal enrollment and randomization began after registration and continued until June 2024. A total of 68 patients were assessed for eligibility. Of these, 6 did not meet the inclusion criteria, and 22 declined to participate. Forty participants were randomized (20 per group). During follow-up, one participant from each group was lost to follow-up without providing a reason. Consequently, the final analysis included 38 participants (19 per group). Figure 1 presents the CONSORT flow diagram of participant recruitment, allocation, follow-up, and analysis.

Although enrollment and randomization were completed in June 2024, participants began the intervention at different times, with some starting in June and others at later dates. Consequently, the 12-week intervention and follow-up period ended at different times for individual participants, with the final data collection completed in November 2024. The 38 participants included in the final analysis had a mean age of 41.87 ± 12.29 years, and 84.21% were female. The analyzed sample comprised 19 participants in the CG and 19 in the IG. Consequently, the final statistical analyses were conducted on 38 participants (19 per group). Table 1 summarizes the demographic and anthropometric characteristics of the analyzed sample. There were no significant between-group differences in baseline characteristics, except for migraine frequency, which was significantly lower in the CG than in the IG (CG: 9.11 ± 6.69 vs. IG: 20.42 ± 8.48 days/month; $p < 0.001$). These values correspond to the baseline headache diary recordings and do not represent the diagnostic criteria used to establish chronic migraine.

Baseline and unadjusted post-intervention values, together with baseline-adjusted post-intervention estimates, are presented in Table 2.

After adjustment for the corresponding baseline value, no statistically significant between-group differences were observed for migraine days per month, migraine episode duration or severity, HIT-6, any ASI-3 subscale, TSK-11, or Athens Insomnia Scale scores (all $p > 0.05$). For the primary outcome, the adjusted post-intervention means were 12.38 days/month in the CG and 15.46 days/month in the IG, yielding an adjusted mean difference of −3.07 days/month (95% confidence interval [CI], −8.00 to 1.86; $F(1, 35) = 1.599$; $p = 0.214$; $\eta p^2 = 0.044$). Effect sizes for all adjusted between-group comparisons were small (ηp^2

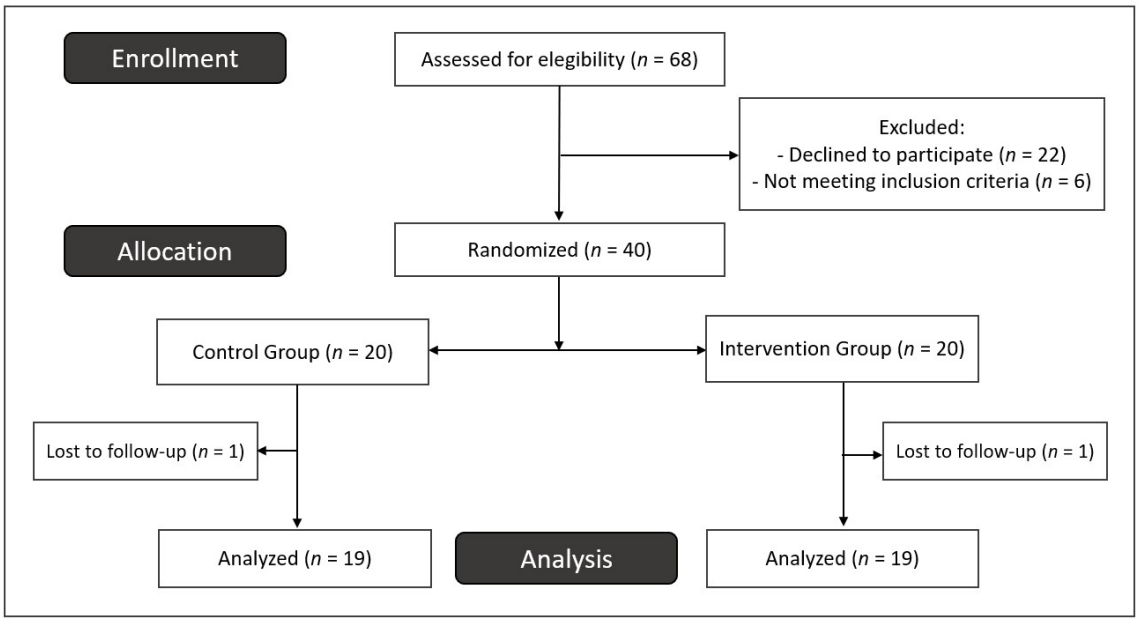


Figure 1. CONSORT flow diagram of participant enrollment, allocation, follow-up, and analysis

Table 1. Baseline characteristics

Characteristic	Control group (*n* = 19)	Intervention group (*n* = 19)	*p*-value
Demographics			
Age, years	38.47 ± 10.88	45.26 ± 13.14	0.100
Female, *n*	16 (84.21 %)	16 (84.21 %)	1.000
Anthropometrics			
Height (cm)	168.58 ± 7.85	166.53 ± 5.43	0.355
Weight (kg)	64.68 ± 9.40	68.32 ± 13.43	0.341
BMI (kg/m^2)	22.77 ± 3.03	24.52 ± 3.89	0.131
Screen time (hours/day)	7.47 ± 3.52	6.37 ± 3.66	0.349
High-intensity physical activity (minutes/week)	20.00 ± 35.12	22.63 ± 33.14	0.814
Moderate-intensity physical activity (minutes/week)	93.68 ± 115.67	82.11 ± 123.67	0.767
Migraine days/month	9.11 ± 6.69	20.42 ± 8.48	<0.001*
Duration of migraine episodes (hours)	12.37 ± 12.16	14.61 ± 12.12	0.578
Severity of migraine episodes (0–10)	7.35 ± 1.17	7.37 ± 1.46	1.000

Notes: Continuous variables are presented as mean ± standard deviation, whereas categorical variables are presented as frequencies and percentages (*n* [%]). *$p < 0.05$ indicates statistical significance.
Abbreviation: BMI: Body mass index.

= 0.002–0.048).

Levene's test indicated homogeneity of error variances for migraine frequency, duration, severity, HIT-6, ASI-3 physical concerns, TSK-11, and AIS (all $p > 0.05$). The test was significant for the ASI-3 social concerns ($p = 0.007$) and cognitive concerns ($p = 0.049$) subscales, indicating violations of the homogeneity-of-variances assumption. The corresponding ANCOVA findings should therefore be interpreted with additional caution.

No harms or unintended effects were reported by participants in either group during the study period.

4. Discussion

Mindfulness has been proposed as a potentially beneficial non-pharmacological approach for patients with central sensitization disorders, such as migraine, because of its potential to reduce stress and modify pain perception. However, the current body of scientific evidence remains limited, and although previous studies have suggested that mindfulness practice may reduce the frequency and intensity of migraine episodes, the available evidence remains inconsistent.[10,11]

The results of this randomized clinical trial indicate

Table 2. Baseline, post-intervention, and ANCOVA-adjusted between-group comparisons

Outcome	Baseline, CG / IG	Post-intervention, CG / IG	Adjusted post-intervention means, CG / IG	Adjusted difference (95% CI)	*F*(df)	*p*	ηp^2
Migraine days/month	9.11 ± 6.69 / 20.42 ± 8.48	8.79 ± 6.35 / 19.05 ± 8.71	12.38 / 15.46	−3.07 (−8.00 to 1.86)	1.599 (1, 35)	0.214	0.044
Duration (hours)	12.37 ± 12.16 / 14.61 ± 12.12	11.95 ± 11.83 / 17.78 ± 13.84	12.66 / 17.03	−4.37 (−11.25 to 2.52)	1.661 (1, 34)	0.206	0.047
Severity (0–10)	7.35 ± 1.17 / 7.37 ± 1.46	6.79 ± 1.48 / 7.05 ± 1.22	6.79 / 7.05	−0.26 (−1.00 to 0.48)	0.521 (1, 35)	0.475	0.015
HIT-6	63.16 ± 4.51 / 66.05 ± 6.82	59.79 ± 6.56 / 63.63 ± 5.58	60.49 / 62.93	−2.44 (−6.17 to 1.29)	1.763 (1, 35)	0.193	0.048
ASI-3 physical concerns	6.95 ± 6.58 / 5.95 ± 3.33	6.26 ± 6.33 / 4.32 ± 2.98	5.90 / 4.68	1.22 (−0.92 to 3.37)	1.337 (1, 35)	0.255	0.037
ASI-3 cognitive concerns	5.05 ± 5.36 / 7.11 ± 5.56	5.26 ± 4.79 / 5.21 ± 4.38	5.89 / 4.59	1.30 (−0.85 to 3.45)	1.500 (1, 35)	0.229	0.041
ASI-3 social concerns	8.63 ± 5.33 / 7.32 ± 5.31	8.00 ± 4.31 / 6.74 ± 4.58	7.58 / 7.16	0.42 (−1.51 to 2.35)	0.197 (1, 35)	0.660	0.006
TSK-11	21.32 ± 5.76 / 23.42 ± 6.69	20.53 ± 5.40 / 22.37 ± 6.01	21.27 / 21.62	−0.35 (−2.81 to 2.10)	0.085 (1, 35)	0.773	0.002
AIS score	7.89 ± 4.12 / 10.05 ± 3.46	7.05 ± 5.09 / 9.53 ± 3.50	8.03 / 8.55	−0.51 (−2.37 to 1.35)	0.312 (1, 35)	0.580	0.009

Notes: Values are mean ± standard deviation for observed baseline and post-intervention data and estimated marginal mean for adjusted post-intervention values. Adjusted mean differences are expressed as control group minus intervention group. Each ANCOVA used the post-intervention outcome as the dependent variable, treatment group as the fixed factor, and the corresponding baseline value as the covariate. The duration analysis included 37 participants because one baseline value was missing; all other models included 38 participants. Secondary outcomes were exploratory, and *p*-values were not adjusted for multiple comparisons. Significance was set at <0.05.

Abbreviations: AIS: Athens Insomnia Scale; ASI-3: Anxiety Sensitivity Index-3; CG: Control group; CI: Confidence interval; HIT-6: Headache Impact Test-6; IG: Intervention group; TSK-11: Tampa Scale for Kinesiophobia-11; ηp^2: Partial eta squared.

that a combined paced-breathing and mobile app–based mindfulness intervention (Petit BamBou®) delivered over a 12-week period did not produce significant between-group differences in any of the evaluated outcomes. In this regard, our findings are consistent with the review by Anheyer *et al*.,[26] which concluded that mindfulness does not lead to significant improvements in the characteristics or impact of headaches in patients with chronic migraine. After adjustment for baseline values, no significant between-group differences were observed for the primary outcome (migraine days per month) or for any of the secondary outcomes, and all effect sizes were small. Although descriptive improvements were observed from baseline to post-intervention in some variables, particularly migraine severity, headache-related quality of life (HIT-6), and the physical dimension of anxiety sensitivity (ASI-3), these changes should be interpreted cautiously because the present analysis was designed to estimate adjusted between-group treatment effects rather than within-group changes over time. Overall, these findings do not support the effectiveness of the combined paced-breathing and mobile app–based mindfulness intervention compared with a waitlist control under the conditions evaluated. Because paced breathing and app-based mindfulness were delivered consecutively as components of the same intervention, their independent contributions to the observed findings cannot be disentangled.

Preliminary studies have reported that an eight-week Mindfulness-Based Stress Reduction program in adults with migraine was associated with significant reductions in episode duration, improvements in migraine-related disability, and enhanced self-efficacy. However, evidence regarding the effectiveness of mindfulness interventions remains inconsistent across studies.[27] Other studies have reported no effect of mindfulness on migraine characteristics when compared to a CG.[28] The present findings are more consistent with the latter studies, as no significant adjusted between-group differences were observed for migraine frequency, duration, severity, or headache-related quality of life.

Regarding anxiety-related variables, no significant baseline-adjusted between-group differences were observed for any of the ASI-3 dimensions, whereas no significant between-group differences were observed in sleep quality (AIS), kinesiophobia (TSK-11), migraine frequency, or episode duration. Although the IG showed descriptively lower post-intervention values for the physical concerns subscale, the adjusted between-group comparison was not statistically significant, and the observed effect size was small. Although previous neuroimaging research has proposed potential mechanisms through which mindfulness could influence pain processing and migraine-related symptoms,[29] the present trial did not demonstrate superiority of the combined intervention over the waitlist control.

4.1. Generalizability

The generalizability of these findings should be interpreted with caution. Participants were recruited from two tertiary hospitals, and all had a neurologist-confirmed diagnosis of chronic migraine according to the ICHD-3 criteria, in addition to requiring access to a smartphone to participate in the intervention. Furthermore, the mindfulness component of the intervention was delivered using a single commercially available mobile application (Petit BamBou®). Therefore, the results may not be directly applicable to patients with other headache disorders, different healthcare settings, or alternative digital mindfulness interventions.

4.2. Limitations

This study has several limitations that should be considered when interpreting the findings. First, although the planned sample size was achieved with only two participants lost to follow-up, the study was powered to detect a large effect size. Consequently, it may have been underpowered to detect small or moderate between-group effects. Furthermore, the absence of long-term follow-up precluded assessment of the sustainability of the observed outcomes.

Second, despite randomization, the IG presented a significantly higher baseline migraine frequency than the CG. Although all between-group comparisons were adjusted for baseline values using ANCOVA, the marked baseline imbalance in the primary outcome may have reduced the precision of the estimated treatment effects despite statistical adjustment and should therefore be considered when interpreting the findings. In addition, the analyses were conducted as complete-case analyses because two participants were lost to follow-up and no imputation of missing data was performed. Although attrition was low (5%), this approach may have introduced a risk of attrition bias. Furthermore, although the researcher responsible for participant enrollment did not have access to the randomization sequence, a formal allocation concealment mechanism (e.g., centralized randomization or sequentially numbered, opaque, sealed envelopes) was not implemented, which may have introduced a potential risk of selection bias.

Third, descriptive changes observed between baseline and post-intervention may have been influenced by non-specific effects associated with participation in a clinical trial, including regular monitoring, participant expectancy,

regression to the mean, natural symptom fluctuation, or unmeasured lifestyle and treatment changes. However, because the revised analysis focused on baseline-adjusted post-intervention between-group differences, no formal conclusions regarding within-group improvement or overall time effects should be drawn. In addition, the use of a waitlist CG did not control non-specific effects such as therapist attention or engagement with the digital intervention.

Although participants were instructed not to modify their preventive migraine treatment during the study period, adherence to this instruction was not formally monitored, and detailed information on preventive medication, acute medication use, medication-overuse headache, treatment modifications, or other concomitant interventions was not collected. Consequently, residual confounding due to unmeasured changes in concomitant treatments cannot be excluded and should be considered when interpreting the findings.

Fourth, the lack of participant blinding and the reliance on self-reported outcome measures may have increased the risk of performance and detection bias. Although participants were routinely asked about adverse effects throughout the intervention period, no formal structured safety assessment instrument was used. No adverse events or unintended effects were reported.

Finally, objective app usage data (e.g., completed sessions, frequency of access, or time spent using the application) were not available. Consequently, individual adherence to the intervention could not be quantified, limiting the ability to examine the relationship between engagement with the mindfulness program and clinical outcomes. This limitation is particularly relevant given that previous systematic reviews of smartphone-based mental health interventions have reported substantial dropout rates and declining engagement over time.[30] Similarly, digital interventions in other health conditions have shown higher dropout rates than traditional approaches,[31] suggesting that reduced adherence may have limited the effective dose of the intervention and, consequently, the ability to detect potential treatment effects. In addition, the findings for the secondary outcomes should be interpreted as exploratory because no adjustment for multiple comparisons was applied.

Future randomized controlled trials should incorporate active CGs, objective adherence monitoring, structured safety assessments, and longer follow-up periods to strengthen the internal validity and generalizability of the findings. These methodological improvements would help determine whether adherence to the combined intervention influences clinical outcomes and clarify the effectiveness of this intervention for chronic migraine.

5. Conclusion

In conclusion, this small randomized controlled trial found no evidence that a 12-week combined paced-breathing and mobile app–based mindfulness intervention was superior to waitlist usual care for reducing migraine frequency or improving migraine-related, psychological, or sleep outcomes after adjustment for baseline values. These findings should be interpreted cautiously because of the limited sample size, baseline imbalance in migraine frequency, lack of objective adherence monitoring, and use of a waitlist CG. Larger randomized trials incorporating active comparators, stratified randomization, objective engagement measures, and longer follow-up are needed to clarify the effectiveness of combined paced-breathing and mobile app–based mindfulness interventions for chronic migraine.

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Conflict of interest

The authors declare no conflicts of interest.

Author contributions

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Ethics approval and consent to participate

The study was conducted according to the guidelines of the Declaration of Helsinki and was approved by the Ethics Committee for Research at Rey Juan Carlos University (Comité de Ética de la Investigación de la Universidad Rey Juan Carlos) (Approval No. 2209202333823; approved on December 15, 2023), in Spain. Informed consent was obtained from all subjects involved in the study.

Consent for publication

All participants provided informed consent for the publication of anonymized data derived from this study.

Availability of data

Most of the results and data supporting the findings of this study are included in the article. The supplementary dataset has been de-identified, and demographic variables that could potentially increase the risk of participant re-identification, including age, sex, height, and weight, have been removed from the publicly available dataset. Additional individual-level data may be made available upon a justified request to the corresponding author, subject to applicable ethical and privacy requirements. For any additional information or clarification, please contact the corresponding author by email.

AI tools statement

ChatGPT (OpenAI, GPT-5.5) was used exclusively as a language assistance tool to support the translation of the manuscript into English and to improve grammar, wording, and readability. AI-generated suggestions were limited to language editing and phrasing improvements. The AI tool was not used for study design, data collection, statistical analysis, data interpretation, or the development of the study conclusions. All AI-assisted text was carefully reviewed, verified, and edited by the authors, who take full responsibility for the accuracy, originality, and integrity of the final manuscript.

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