



The effectiveness of mindfulness as a complementary therapy in headache patients: a preliminary interventional study

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ABSTRACT

Background: Recent studies have highlighted that mindfulness-based therapies, particularly the Mindfulness-Based Stress Reduction (MBSR) program, can help foster greater awareness and improve the management of stress and chronic pain. Mindfulness is defined as a form of awareness that is intentionally cultivated in the present moment, characterized by an attitude of openness and non-judgment. Numerous studies have shown that the MBSR program can have positive effects on psychophysical adaptation in individuals suffering from various clinical conditions, including cardiovascular diseases, chronic pain, sleep disorders, migraine, anxiety, and depression.

Methods: The study included 14 participants suffering from chronic migraine with medication overuse headache (MOH) and tension-type headache associated with analgesic abuse. Each participant completed the MBSR protocol, consisting of eight weekly sessions. The intervention was accompanied by pre- and post-treatment assessments using the Hospital Anxiety and Depression Scale (HADS), the Mindful Attention Awareness Scale (MAAS), and the Short Form Health Survey (SF-36) questionnaires. Data collected at the two observation points, before (T0) and after (T1) the intervention, were subsequently analyzed to identify any statistically significant differences in scores.

Results: The application of the MBSR protocol resulted in a significant reduction in anxiety and depression levels, a notable increase in mindfulness propensity, and a significant improvement in perceived quality of life.

Conclusions: The study results confirm the effectiveness of the MBSR protocol in reducing anxiety and depression, enhancing mindfulness awareness, and improving the quality of life in patients with chronic headache-related pain. The intervention proved useful not only in managing physical pain but also in providing psychological support, thereby helping to alleviate emotional and psychosocial distress. The data suggest that MBSR can be effectively integrated into a multidisciplinary approach to chronic pain treatment, promoting overall well-being.

Key words: chronic migraine; mindfulness; mindfulness-based stress reduction; medication overuse headache; chronic pain.

Introduction

Headaches are among the most widespread neurological conditions globally and are a major contributor to disability, according to the World Health Organization. (1) The most common types – migraine and tension-type headaches – can severely impact daily life, work performance, and emotional health. (2) Yet, despite their prevalence and burden, many headache sufferers remain undiagnosed or inadequately treated.

While standard treatment often relies on medication, there is a growing interest in non-pharmacological strategies, especially due to the chronic nature of these conditions, potential side effects of medications, and patient preferences for more holistic care options. (3)

Recent research emphasizes the value of a biopsychosocial approach to understanding and managing migraines. This model acknowledges the complex interactions among biological, psychological, and social factors and enables more tailored, comprehensive care. (4)

Among the various non-pharmacological interventions, Mindfulness-Based Stress Reduction (MBSR) stands out as a promising option. Developed by Jon Kabat-Zinn in 1990, (5) MBSR is an eight-week group program that includes mindfulness meditation, body scans, and gentle yoga. Its goal is to cultivate awareness and reduce stress. Several studies have shown that MBSR can help decrease headache frequency, lessen pain intensity, and improve related symptoms such as anxiety and depression. (6-8)

More recent clinical findings further support the benefits of mindfulness for migraine sufferers. For instance, Wells *et al.* (2020) found that mindfulness training led to fewer migraine episodes and better emotional regulation. Similarly, Grazzi *et al.* (2023) reported notable improvements in headache-related disability and quality of life following MBSR, reinforcing its therapeutic value. (9,10)

Still, some aspects remain unclear. It is not fully understood how mindfulness influences pain perception in chronic headache patients, and long-term effectiveness in real-world clinical settings is still being studied. Also, not every patient responds equally – those with severe psychiatric conditions or poor adherence to home practice may see limited benefits. (11)

This underscores the need to better identify which patients benefit most from MBSR and how to incorporate it effectively into individualized treatment plans. Integrating it within a biopsychosocial model may help address the full spectrum of physical, emotional, and environmental factors affecting headache sufferers.

Some standardized neuropsychological tests suggest that migraine attacks may be linked to temporary declines in cognitive performance. (12) However, these difficulties typically do not persist between attacks, and there is insufficient evidence to claim that headache sufferers are more prone to long-term cognitive decline. The relationship between headaches and psychiatric conditions is also complex; it remains unclear whether one triggers the other or if they co-develop. (13) In many cases, the

two are intertwined, potentially leading to reduced well-being and increased medication use.

Several evidence-based behavioral therapies have demonstrated efficacy in the treatment of headaches, (3,14) particularly for patients who prefer to avoid pharmacological interventions or face psychological challenges contributing to their condition. Techniques like relaxation training and biofeedback help individuals lower physiological arousal and have been shown to reduce both the frequency and severity of headaches. (15,16)

Cognitive-behavioral therapy (CBT) also plays a key role in headache management by helping patients identify and change negative thought patterns and behaviors. It improves stress-coping skills and can be paired with lifestyle strategies such as trigger avoidance and mindfulness practices. (7,17) CBT is beneficial in addressing coexisting conditions like anxiety, depression, and sleep disturbances. (18)

The MBSR program was originally introduced by Jon Kabat-Zinn in 1979 at the University of Massachusetts Medical Center. It was developed to aid patients with chronic illnesses unresponsive to conventional treatments by teaching them mindfulness meditation techniques for symptom management. (19) Kabat-Zinn's goal was to adapt traditional Buddhist practices into a secular, evidence-based framework, offering patients a way to reconnect body and mind – an element often neglected in Western medicine.

Due to its success, MBSR has since spread to medical centers worldwide and inspired numerous mindfulness-based programs. The course spans eight weekly sessions, each lasting about 2.5 hours, *plus* an all-day retreat. Participants learn a variety of mindfulness techniques, including sensory awareness, breathing exercises, body scan, gentle yoga, and how to integrate mindfulness into everyday life. Sessions combine practical exercises with group dialogue and psychoeducation on stress and communication. Daily home practice is a key component, supported by guided recordings and worksheets. Participants are encouraged to take an active role in their own healing process. (19)

Research has shown that MBSR can help people cope with a wide range of physical and psychological issues, including chronic pain, cardiovascular conditions, sleep disorders, migraines, anxiety, and depression. (20) Importantly, the program is not limited to those with health problems; it is open to anyone seeking to improve their relationship with themselves and their daily life. (21)

The primary aim of this study is to investigate the role of the MBSR program as a complementary therapy to medication in patients with chronic headaches. Specifically, the objectives are: i) to reduce levels of anxiety and depression in individuals living with chronic headache-related pain; ii) to enhance mindfulness awareness, understood as the ability to remain present and attentive in a non-judgmental way; and iii) to improve overall quality of life.

Results

The study included a total of 14 participants. The mean age of the participants was 51.64 years, with a minimum of 22 years, a maximum of 76 years, and a standard deviation (SD) of 13.5. The sample composition showed a predominance of females, and most participants held a secondary education diploma.

Statistical analyses were performed using Jamovi software, version 2.4.14. To verify the normality of data distribution, the Shapiro-Wilk test was applied. As reported in **Table 1**, most variables did not show a Gaussian distribution. Consequently, non-parametric tests were chosen for data analysis, as they are more appropriate for non-normally distributed data. First, descriptive analyses were conducted to examine differences in the means of the variables. Subsequently, a nonparametric paired-samples t-test (Wilcoxon signed-rank test) was performed to assess whether there was a significant difference between T0 and T1.

Descriptive statistics for each variable at both time points, T0 and T1, are reported in **Table 2**. For each variable, the mean, SD, and median values are provided.

Since the Shapiro-Wilk test indicated that the data did not follow a normal distribution, the Wilcoxon signed-rank test, a non-parametric alternative to the paired-samples t-test, was chosen. To examine differences in scores between the pre-intervention (T0) and post-intervention (T1) periods, the paired-samples t-test was applied to all variables. The results (**Table 3**) showed statistically significant differences across all measurements, suggesting improvement after the intervention. Specifically, participants showed a significant reduction in anxiety, with Hospital Anxiety and Depression Scale (HADS)-Anxiety scores decreasing from M=11.79 (SD=5.39) to M=8.07 (SD=5.44), W=81.00, p=0.014. Similarly, HADS-Depression scores significantly decreased from M=6.79 (SD=4.34) to M=3.71 (SD=3.22), W=76.00, p=0.004. In contrast, mindfulness awareness, as measured by the Mindful Attention Awareness Scale (MAAS), significantly increased from M=58.93 (SD=14.14) to M=68.36 (SD=13.70), W=14.00, p=0.030, indicating enhanced mindfulness following the intervention. Regarding the Short Form Health Survey (SF-36), all subscales showed significant improvement between T0 and T1. Notably, physical functioning increased from M=67.14 (SD=29.07) to M=80.00 (SD=18.71), W=0.00, p=0.006; role limitations due to physical health improved from M=28.57 (SD=35.16) to M=54.64 (SD=34.44), W=2.50, p=0.011; role limitations due to emotional problems increased from M=45.00 (SD=40.43) to M=76.00 (SD=27.68), W=0.00, p=0.008; energy/fatigue scores rose from M=46.57 (SD=16.34) to M=56.43 (SD=19.65), W=4.00, p=0.006; emotional well-being improved from M=50.00 (SD=21.33) to

Table 1. Shapiro-Wilk test for normality (T0 vs. T1).

	W	p
HADS-Anxiety	0.979	0.967
HADS-Depression	0.943	0.459
MAAS	0.923	0.246
Physical functioning	0.685	<.001
Role limitations due to physical health	0.935	0.358
Role limitations due to emotional problems	0.847	0.020
Energy/fatigue	0.917	0.197
Social functioning	0.833	0.013
Pain	0.980	0.978
General health	0.733	<.001

HADS, Hospital Anxiety and Depression Scale; MAAS, Mindful Attention Awareness Scale.

M=66.21 (SD=20.41), W=0.00, p=0.002; social functioning increased from M=47.50 (SD=17.86) to M=65.14 (SD=25.60), W=0.00, p=0.009; pain scores improved from M=31.57

(SD=19.88) to M=50.43 (SD=23.85), W=3.50, p=0.010; and general health scores rose from M=42.86 (SD=21.64) to M=55.00 (SD=20.57), W=1.50, p=0.015.

Table 2. Descriptive analysis of the variables under examination (n=14).

	Mean	Median	SD	Min	Max
HADS-Anxiety T0	11.79	13.00	5.39	1.00	21.00
HADS-Anxiety T1	8.07	8.50	5.44	0.00	17.00
HADS-Depression T0	6.79	5.00	4.34	1.00	16.00
HADS-Depression T1	3.71	3.00	3.22	0.00	9.00
MAAS T0	58.93	63.50	14.14	35.00	78.00
MAAS T1	68.36	69.00	13.70	38.00	102.00
Physical functioning T0	67.14	80.00	29.07	0.00	100.00
Physical functioning T1	80.00	85.00	18.61	30.00	100.00
Role limitations due to physical health T0	28.57	12.50	35.16	0.00	100.00
Role limitations due to physical health T1	54.64	50.00	34.44	0.00	100.00
Role limitations due to emotional problems T0	45.00	49.50	40.43	0.00	100.00
Role limitations due to emotional problems T1	76.00	83.50	27.68	33.00	100.00
Energy/fatigue T0	46.57	48.50	16.64	15.00	75.00
Energy/fatigue T1	56.43	55.00	19.65	20.00	90.00
Emotional well-being T0	50.00	48.00	21.33	16.00	76.00
Emotional well-being T1	66.21	62.00	20.41	30.00	96.00
Social functioning T0	47.50	44.00	17.86	25.00	88.00
Social functioning T1	65.14	50.00	25.60	25.00	100.00
Pain T0	31.57	35.00	19.88	0.00	68.00
Pain T1	50.43	45.00	23.85	22.00	100.00
General health T0	42.86	42.50	21.64	0.00	90.00
General health T1	55.00	52.50	20.57	25.00	95.00

SD, standard deviation; HADS, Hospital Anxiety and Depression Scale; MAAS, Mindful Attention Awareness Scale.

Table 3. Paired-samples Wilcoxon signed-rank test results (T0 vs. T1).

	Test	Statistics	df	p
HADS-Anxiety	Student's t	3.16	13.0	0.007
	Wilcoxon	81.00		0.014
HADS-Depression	Student's t	4.30	13.0	<.001
	Wilcoxon	76.00		0.004
MAAS	Student's t	-2.69	13.0	0.019
	Wilcoxon	14.00		0.030
Physical functioning	Student's t	-2.52	13.0	0.026
	Wilcoxon	0.00		0.006
Role limitations due to physical health	Student's t	-3.48	13.0	0.004
	Wilcoxon	2.50		0.011
Role limitations due to emotional problems	Student's t	-3.81	13.0	0.002
	Wilcoxon	0.00		0.008
Energy/fatigue	Student's t	-3.35	13.0	0.005
	Wilcoxon	4.00		0.006
Emotional well-being	Student's t	-6.74	13.0	<.001
	Wilcoxon	0.00		0.002
Social functioning	Student's t	-3.53	13.0	0.004
	Wilcoxon	0.00		0.009
Pain	Student's t	-3.45	13.0	0.004
	Wilcoxon	3.50		0.010
General health	Student's t	-2.38	13.0	0.033
	Wilcoxon	1.50		0.015

HADS, Hospital Anxiety and Depression Scale; MAAS, Mindful Attention Awareness Scale.

Discussion

This study aimed to explore and demonstrate the effectiveness of the MBSR protocol as a complementary therapeutic tool for managing chronic headache pain. This condition often causes not only physical discomfort but also a significant impact on

patients' psychological and emotional quality of life. The main objective was to verify whether applying the MBSR protocol could lead to significant reductions in anxiety and depression levels (Figures 1 and 2), increased mindfulness awareness (Figure 3), and improved overall quality of life (Figure 4). The results suggest an overall improvement in the patients' condition after the inter-

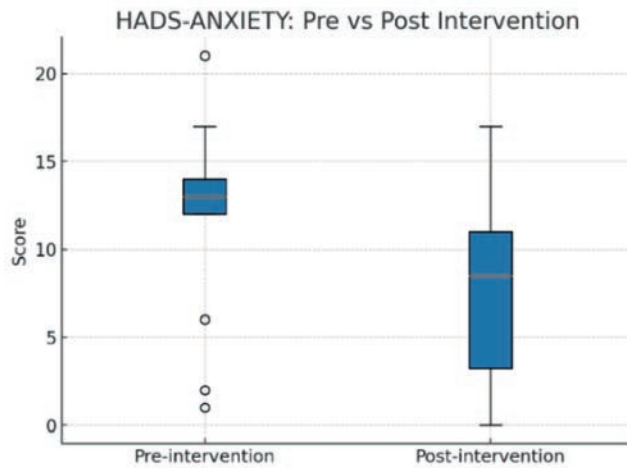


Figure 1. Boxplot showing the distribution of HADS-Anxiety scores before and after the intervention. Pre-intervention: scores are generally higher and more clustered around the upper range, with a median close to 13. Some outliers show lower values, but most participants had elevated anxiety levels. Post-intervention: scores show a wider spread and are overall lower, with a median around 8-9. The distribution extends toward very low values, indicating that several participants experienced a marked reduction in anxiety. The graph suggests that the intervention was associated with a reduction in anxiety symptoms, as reflected by the lower median and broader spread in the post-intervention scores.

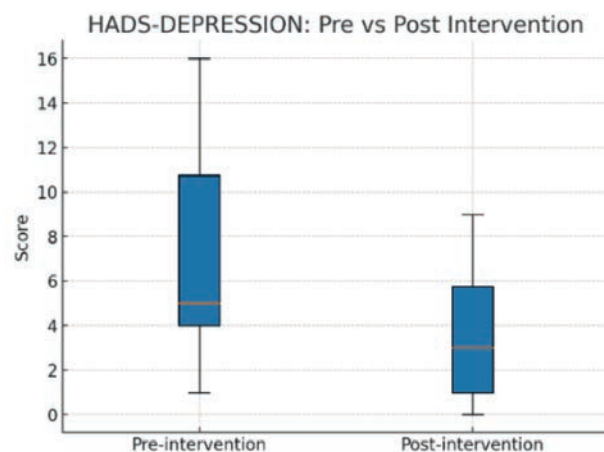


Figure 2. Boxplot showing the distribution of HADS-Depression scores before and after the intervention. Pre-intervention: scores are generally higher, with a wider range and several participants showing elevated depression levels. Post-intervention: scores are lower on average and more concentrated around the lower values, indicating a reduction in depressive symptoms. The median decreased noticeably, and the overall spread (interquartile range) is smaller after the intervention. Overall, the graph suggests that the intervention was associated with a reduction in depression levels.

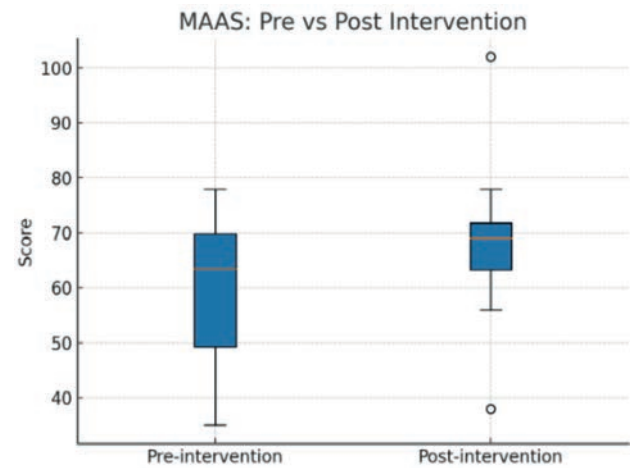


Figure 3. Boxplot showing the distribution of MAAS scores before and after the intervention. Pre-intervention: scores show greater variability, with the median around the low 60s. The range is wider, with several participants scoring at lower levels of mindfulness. Post-intervention: the distribution shifts upward, with a higher median close to 70. The scores are more concentrated, although one participant shows a very high outlier above 100. Overall, the graph suggests that mindfulness levels increased after the intervention, as indicated by the higher median and upward shift in the score distribution.

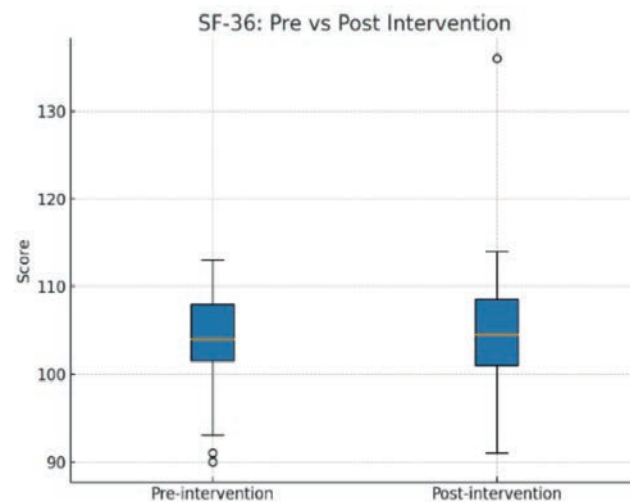


Figure 4. The boxplot illustrates the distribution of SF-36 scores before and after the intervention. The median scores are very similar between the two conditions, both around 104-105, indicating no substantial shift in the central tendency. The spread of the scores is comparable in both groups, but the post-intervention group shows slightly higher variability. There are a few outliers: on the lower side (around 90-91) in both conditions, and one high outlier (136) in the post-intervention group. Overall, the results suggest that the intervention did not lead to a significant change in the median SF-36 scores, although individual responses varied, with some participants showing higher improvement.

vention. Specifically, a significant reduction in anxiety and depression levels was observed. This finding is particularly relevant given that anxiety and depression are frequently associated with chronic pain and often contribute to a vicious cycle that worsens the patient's quality of life.

The significant improvements observed in anxiety and depression levels following the MBSR intervention have important clinical implications. Anxiety and depression are common comorbidities in chronic headache patients that often exacerbate pain perception and contribute to increased disability. (18) By reducing these psychological burdens, MBSR may help break the vicious cycle where emotional distress amplifies headache severity and frequency. Additionally, patients demonstrated a greater ability to focus on the present moment without judging their thoughts and feelings, a skill crucial for managing stress and pain, as reflected in increased mindfulness awareness. This shift in perspective can reduce catastrophizing and emotional reactivity, which are known to worsen pain experiences and diminish quality of life. (22) Improvements were also observed in various quality-of-life domains, including physical functioning, role limitations due to physical and emotional problems, emotional well-being, energy/fatigue levels, and general health. These improvements suggest that the MBSR approach not only helps reduce pain but also enhances patients' overall ability to manage the emotional, psychological, and social aspects related to chronic pain.

Clinically, enhancements in physical functioning and role limitations reflect patients' improved capacity to engage in daily activities and social roles, which are often compromised by chronic headaches. Increased energy and better emotional well-being also suggest that patients may have developed more effective coping mechanisms and resilience, contributing to a more adaptive management of their condition. The significant reduction in anxiety and depression levels observed in this study aligns well with previous research demonstrating the effectiveness of MBSR in alleviating psychological distress among patients with chronic pain conditions, including chronic headache. For example, Garland *et al.* (2015) reported that MBSR significantly decreased symptoms of anxiety and depression in individuals suffering from chronic pain, supporting the role of mindfulness in emotional regulation. (23)

Similarly, the notable increase in mindfulness propensity, as measured by the MAAS, is consistent with Grossman *et al.* (2004), who found that participation in MBSR programs enhances individuals' mindfulness skills, fostering greater present-moment awareness and non-judgmental acceptance. (20) Improvements in perceived quality of life also correspond to prior studies. A meta-analysis by Hilton *et al.* (2017) found that MBSR interventions lead to significant improvements in quality-of-life indicators for patients with various chronic conditions, including migraine and tension-type headaches. (24) Furthermore, studies specifically focusing on headache populations, such as Wells *et al.* (2014), have highlighted MBSR's ability to reduce headache frequency and improve coping strategies, which likely contribute to better quality of life and reduced psychological comorbidities. (25) Taken together, these literature findings reinforce the clinical relevance of MBSR as an effective adjunctive therapy for chronic headache sufferers, confirming the results obtained in this study.

One major limitation of this study is the small sample size, which may affect the robustness and generalizability of the results. A limited number of participants reduces statistical power and the ability to explore differences across headache subtypes or psychological profiles. Future studies should include larger, more diverse samples to validate these findings and better understand the factors that influence MBSR's effectiveness. Based on the encouraging outcomes observed, future research will continue to focus on MBSR to further evaluate its effectiveness in treating chronic headache pain.

Conclusions

In conclusion, the study results fully confirmed the initial hypotheses, demonstrating that the MBSR protocol is effective in reducing anxiety and depression levels, promoting greater mindfulness awareness, and improving quality of life in patients suffering from chronic headache-related pain. This intervention proved to be not only useful for managing physical pain but also a valuable tool for psychological and emotional support, helping to alleviate the psychosocial distress associated with the chronic condition. The data reinforce the idea that the MBSR approach can be integrated into a multidisciplinary treatment for chronic pain, with positive effects across multiple dimensions of patient health, thereby contributing to overall well-being.

Materials and Methods

Specific inclusion criteria were used to select participants. Eligible participants were adults aged 18 to 80 years diagnosed with chronic migraine with medication overuse headache (MOH) or tension-type headache associated with analgesic overuse. Diagnoses were established based on the International Classification of Headache Disorders (ICHD-3) criteria (2018). After meeting the inclusion criteria described above, all participants underwent an initial psychological intake interview to assess their clinical and motivational suitability for the program. Based on the outcome of this interview, it was mutually agreed to include them in the MBSR intervention.

Chronic migraine with MOH was defined as headache occurring on 15 or more days per month for more than 3 months, with regular overuse of acute headache medication for more than 3 months, according to ICHD-3 criteria. Tension-type headache with analgesic overuse was similarly diagnosed based on ICHD-3 guidelines, with documentation of analgesic intake exceeding recommended limits.

All participants were undergoing treatment at the Regional Headache Center, R. Dulbecco Hospital, Catanzaro, Italy. The research was conducted in collaboration with the hospital healthcare staff. The overall duration of the study was 10 months, from April 2024 to February 2025. Each group participated in a training program consisting of 8 sessions, distributed over 8 weeks. The meetings were held weekly, and each session followed a specific sequence of activities. During the implementation of the MBSR protocol, no participants dropped out of the study. All individuals completed the full cycle of sessions as planned. Moreover, adherence to the home practice was consistently high: each participant regularly engaged in the assigned exercises, following the program's guidelines. This represents a significant aspect of the study, as it highlights not only the participants' interest and motivation but also the feasibility and acceptability of the MBSR program within the selected sample. Consistent adherence – both during in-person sessions and at home – provides a solid basis for reliably assessing the intervention's effectiveness.

Here is a brief description of the 8 sessions:

Session 1. A pre-test assessment was conducted, followed by psychoeducation on headaches and their triggers, such as stress, diet, exercise, and circadian rhythms. The concept and benefits of mindfulness were introduced, with emphasis on mindful presence. The session included a brief mindful breathing practice, and participants shared their feelings and expectations for the program.

Session 2. The concept of mindfulness was further explored both theoretically and practically, with a distinction made between formal and informal practices. Participants practiced mindful breathing and body-scan meditations, followed by a sharing of physical and emotional sensations.

Session 3. The focus was on perception and the role of past expe-

periences in shaping stress responses. Participants reflected on their own experiences and engaged in mindful breathing and body scan exercises.

Session 4. The session addressed stress reactivity from physiological and psychological perspectives, including psychoeducation on stress and its triggers. Participants identified their main stressors and practiced body scan meditation.

Session 5. Continued exploration of the link between stress and headache attacks, focusing on the role of thoughts, especially rumination, in generating stress. Functional analysis of thoughts, emotions, and behaviors was introduced. Participants practiced mindful breathing meditation.

Session 6. The theme was communication, with emphasis on communication styles and assertiveness, and how ineffective communication can interfere with mindfulness practice. The session concluded with a body scan practice.

Session 7. The emphasis was on integrating mindfulness into daily life, and participants were encouraged to step out of their comfort zones. The final practice was the "mountain meditation".

Session 8. The last session was dedicated to sharing experiences, emotions, changes, and future hopes. The importance of maintaining mindfulness practice over time was stressed. A final assessment was conducted, and participants described the value of the program using three adjectives.

Each participant underwent pre- and post-treatment assessment using the following psychological tests:

- i) HADS, a self-report questionnaire consisting of 14 items divided into two subscales of 7 items each: one for anxiety and one for depression. It was designed to assess the emotional state of patients with physical illnesses, minimizing the influence of somatic symptoms typical of traditional psychiatric scales; (26)
- ii) MAAS, a 15-item scale developed to measure a central component of mindfulness: the ability to be fully present and aware of what is happening in the moment, without judgment. The scale has demonstrated good psychometric properties and measures a specific quality of consciousness related to various aspects of self-regulation and psychological well-being. After summing the responses, higher scores indicate a greater level of openness and attention to the present moment, *i.e.*, a higher predisposition to mindfulness; (27)
- iii) SF-36, a 36-item questionnaire used to evaluate quality of life and perceived health. It explores eight domains: physical functioning, physical role limitations, bodily pain, general health, vitality, emotional role limitations, mental health, and social functioning. It assesses physical, psychological, and social well-being. The scores provide a comprehensive overview of the patient's health and can be used to monitor changes over time or compare different groups. (28)

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