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Psychological Intervention in Adults with Difficult-to-Treat Migraine: Benefits of Applying MIDITRA Protocol

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A B S T R A C T

This study evaluated a tailored psychological intervention for refractory migraines, focusing on holistic well-being. Twenty-seven adult patients (24 females, 3 males) aged 23 to 70 (M= 48.33; SD=10.03) participated, assessing risk and protective factors and the intervention's impact on 23 completers. Through random assignment, participants were allocated to experimental or control groups. Results showed significant improvements post-intervention in the experimental group, including reduced disability and negative impact of headaches, and enhanced quality of life compared to baseline. They also had better outcomes in headache impact and quality of life compared to controls. Effect size analysis supported the intervention's efficacy, with improvements in positive affect, resilience, and depression. These findings emphasize the need for psychological interventions in migraine management, particularly for treatment-resistant cases. Enhanced physical and psychological parameters highlight the benefits of such interventions for patients facing substantial health challenge.

Intervención psicológica en adultos con migraña de difícil tratamiento: Beneficios de la aplicación del protocolo MIDITRA

Palabras clave:
Migrañas
Intervención psicológica
Salud mental
Calidad de vida
Catastrofización
Impacto negativo del dolor de cabeza
Discapacidad
Depresión
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Resiliencia

R E S U M E N

Este estudio evaluó una intervención psicológica adaptada para migrañas refractarias, centrada en el bienestar holístico. Participaron 27 pacientes adultos (24 mujeres, 3 hombres) de entre 23 y 70 años (M= 48,33; SD=10,03), y se evaluaron los factores de riesgo y protección y el impacto de la intervención en 23 participantes que la completaron. Mediante asignación aleatoria, los participantes fueron asignados a grupos experimentales o de control. Los resultados mostraron mejoras significativas post-intervención en el grupo experimental, incluyendo la reducción de la discapacidad y el impacto negativo de los dolores de cabeza, y la mejora de la calidad de vida en comparación con la línea de base. También obtuvieron resultados mejores en el impacto del dolor de cabeza y la calidad de vida en comparación con los controles. El análisis del tamaño del efecto respaldó la eficacia de la intervención, con mejoras en el afecto positivo, la resiliencia y la depresión. Estos hallazgos enfatizan la necesidad de intervenciones psicológicas en el manejo de la migraña, particularmente para los casos resistentes al tratamiento. La mejora de los parámetros físicos y psicológicos pone de relieve los beneficios de tales intervenciones para los pacientes que se enfrentan a un importante desafío para su salud.

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Migraines represent a neurological disorder characterized by recurrent episodes of moderate to severe headaches, which can significantly compromise the quality of life for those afflicted, lasting between 4 to 72 hours if left untreated. In addition to headache episodes, patients may experience other symptoms, with heightened sensitivity to external stimuli, nausea, and vomiting being the most common. Depending on the frequency of headache episodes, patients can be categorized into either chronic migraine (CM) or episodic migraine (EM). CM is diagnosed when headache pain occurs for 15 days or more per month for at least three months (AEMICE, 2021; González-Oria et al., 2019).

However, patients can also be differentiated based on their response to pharmacological treatment, leading to a distinction between those who respond well to treatment and those with difficult-to-treat migraines. The latter group is further categorized based on the number of failed treatment attempts, resulting in either resistant or refractory migraines. In the first case, multiple treatment attempts have failed, but effective treatment has eventually been found, while in the second case, effective treatment has remained elusive despite trying various options (Sacco et al., 2020).

Migraine ranks as the third most prevalent disease globally (15%), with a prevalence of 12% in Spain, and approximately 80% of the affected individuals are women aged 20 to 40 years. However, it is considered that this condition is both underdiagnosed and undertreated (AEMICE, 2021; Garrido et al., 2018; González-Oria et al., 2019).

Migraines not only significantly impact patients' physical health but also result in a substantial psychosocial burden. This condition profoundly affects various aspects of patients' lives, including physical, psychological, social, and occupational domains, potentially causing disability. In Spain, migraines are the leading cause of disability in adults under 50, with more than 50% experiencing severe or very severe levels of disability (Pérez, 2019). This disability manifests in numerous ways, reducing the overall quality of life. This reduction stems from both the direct physical symptoms and the indirect cognitive, psychological, and emotional symptoms, as well as limitations in recreational, occupational, and social activities (AEMICE, 2021). Furthermore, this diminished quality of life and high levels of disability exacerbate the severity of the disease, contributing to further patient deterioration (Leonardi et al., 2010; Raggi et al., 2011).

Comorbid mental health conditions, such as depression, anxiety, and distress, have been found to intensify the adverse effects of migraines, increasing disability, promoting chronicity, hindering treatment, and reducing adherence to potential future treatments (AEMICE, 2021; Buse et al., 2013; Novic et al., 2016). These conditions not only worsen the patient's state but can trigger crises, including sleep disturbances, changes in eating habits, and heightened stress (González-Oria et al., 2019; Kelman, 2007). Furthermore, cognitive impairments associated with these mental health disorders can modify and exacerbate the patient's psychological processes, particularly in pain catastrophizing, fear of pain, and pain acceptance (Lee et al., 2019). These altered cognitive processes can heighten the patient's perception and intensity of physical pain (Dahlke et al., 2017; Edwards, 2005; Roth et al., 2005), leading to a worsening cycle of the disease's impact.

There is evidence that psychological care combined with medical treatment enhances the quality of life for patients and their adherence to potential future treatments (Smith et al., 2021). Considering these factors, it becomes evident that migraines have a significant psychological impact, highlighting the need for psychological intervention in these patients (Dudeney et al., 2022).

However, as of now, no established protocol in Spain has been implemented in public health headache units (AEMICE, 2021; González-Oria et al., 2019).

The study's objectives are to identify psychological and physical health profiles in adult patients diagnosed with difficult-to-treat CM (with a minimum of 6 months of diagnosis), scientifically validate and implement the efficacy and efficiency of an assessment and psychological treatment protocol for improving adaptation and psychological well-being in this population. Additionally, it seeks to promote the integration of the assessment and psychological intervention protocol generated in regular healthcare measures for CM patients.

The hypothesis posits that patients receiving the intervention will experience a reduction in migraine-related disability, less negative impact from headaches, improved quality of life, decreased pain catastrophizing, increased life satisfaction, heightened positive affect, diminished negative affect, reduced psychological stress, enhanced resilience, and lower levels of anxiety and depression.

Materials and Methods

Study Environment and Participant Involvement

A longitudinal experimental design with an inter-subject comparison was employed, comparing an experimental group (individuals receiving psychological treatment) and a control group (those without treatment) at two post-treatment time points. The method employed for the generation of allocation sequences was a computerised random number generator. The generation of the sequence was based on the process of simple randomisation, which is founded upon a single sequence of random allocations. Furthermore, an intra-subject analysis was conducted by comparing repeated measures to observe changes within the same individuals before (with two pre-treatment measurements) and after psychological treatment (with two post-treatment measurements).

Participants were recruited by neurologists from the Headache Unit of the IIS La Fe and referred to the principal investigator, accidental or convenience sampling was used. The inclusion criteria were as follows:

(1) Adults aged 18 or older, diagnosed with difficult-to-treat chronic migraines for over six months.

(2) Undergoing regular hospital follow-up in the neurology department of the University and Polytechnic Hospital La Fe.

(3) Completing the four evaluation sessions at T1, T2, T3, and T4.

(4) For the treatment group, attendance at a minimum of 80% of the psychological intervention sessions (8 out of 10).

Assessment and Intervention Protocol

MIDITRA constitutes an assessment and intervention protocol designed for application in adult patients diagnosed with chronic and difficult-to-treat migraines. It encompasses multiple psychological objectives. In T1, sociodemographic, psychological, clinical, and pharmacological data will be described. Sociodemographic data will not be collected in T2, T3, and T4. Instead, psychological, clinical, and pharmacological tests will be administered, and these assessments will also be described. In T3 and T4, an additional questionnaire will be included to evaluate treatment satisfaction among patients in the experimental group.

This protocol includes an individual session (T1) and 13 group sessions, ten of which will be dedicated to group psychological intervention for the experimental group. The four assessment

sessions will occur in T1, T2, T3, and T4. In the experimental group, these sessions are referred to as PRE1, PRE2, POST1, and POST2-FOLLOW-UP, while in the control group on the waiting list, they are referred to as PRE1, PRE2, PRE3, and PRE4.

Initially, subjects are randomized into two study groups: the experimental and the waiting list control group. The data collection process for the sample spanned a period of one year. Over the course of the study, the research protocol was implemented on three occasions. Each round entailed the administration of four assessments (in the control and experimental groups) and the implementation of the intervention programme in the experimental group. This was to ensure the feasibility of the study, given that only one psychologist was available to conduct both the assessments and the treatment. The initial sample size for each round of the protocol was 5 participants in the control group and 5 in the experimental group. It was initially anticipated that a total of 30 participants would be included in the study, comprising three batches of 10 individuals, with 5 participants in the control group and 5 in the experimental group. The final sample size was reduced to 27 participants, due to the occurrence of three experimental deaths among those who did not complete the entire study. The 30 participants were initially assigned to either the experimental or control groups and to one of three batches, based on their status as regular users of the hospital's headache unit.

In *PRE1*, participants from both groups receive individual explanations about the study, provide informed consent, and commit to confidentiality. They are also given the questionnaires to complete at that time. The average duration of this session is approximately 35-50 minutes. After ten weeks from this initial assessment, a second group assessment (*PRE2*) is conducted. During this assessment, participants from the experimental and control groups complete the questionnaires again, with an average session duration of 25-35 minutes.

Subsequently, the experimental group undergoes ten weekly group sessions of psychological treatment, with each session lasting between 90-120 minutes. After these ten weeks, a third group assessment and questionnaire administration (*POST1* and *PRE3*) are conducted for the experimental and control groups on the waiting list, with an average session duration of 25-35 minutes. Four weeks later, the final group assessment is carried out for both groups (*POST2-FOLLOW-UP* and *PRE4*) to assess the impact of time passage and the application of psychological treatment on the participants, with an average session duration of 25-35 minutes. Following this, the control group on the waiting list will receive psychological treatment.

This program provides patients with information, strategies, and tools to enhance both their physical and psychological well-being. MIDITRA consists of group therapy sessions designed to impart knowledge and strategies and to create a sense of unity and mutual support among patients, fostering a positive therapeutic environment. Table 1 shows the major areas the program will focus on, along with the sessions outlined in each module and the objectives to be covered.

Assessment Tools

Except for the last questionnaire, all instruments were administered at the four assessments (T1, T2, T3, and T4). The final questionnaire was exclusively completed by patients in the experimental group at T3 and T4.

Degree of Disability: The Migraine Disability Assessment Scale (MIDAS) was employed to assess disability related to headache pain in daily activities. Regarding psychometric properties, the reliability scores in the original study, an internal consistency analysis was conducted using Cronbach's α, which yielded a score of 0.76 in the USA and 0.73 in the UK. Additionally, the Pearson test-retest correlation was analyzed, resulting in a value of 0.80 in the USA and 0.83 in the UK (Stewart et al., 1999; Lipton et al., 2001). The tool accurately captures the extent of disability caused by migraines, showing strong construct validity. MIDAS has been shown to correlate significantly with other indicators of migraine-related disability, including headache days and medication use, reinforcing its concurrent validity. Test-retest reliability has been found to be strong, with patients demonstrating consistent MIDAS scores when their migraine status remains unchanged over time. Reliability scores are reported to be above 0.70, ensuring that the questionnaire produces stable results under similar conditions. In our sample, we were unable to consistently assess effectiveness due to the fact that some questions were relate to work, and over 80% of our sample are unable to work due to migraines. Regarding questions pertain to household chores and leisure activities, our patients emphasized that their social lives are so limited that they do not engage in these activities, not because of pain, but because they already avoid them or do not organize activities for fear of having a migraine.

Headache Impact: The Headache Impact Test (HIT-6) is a self-report questionnaire that generates an overall score reflecting the negative impact of headache pain. HIT-6 has demonstrated strong construct validity, meaning it effectively measures what it is intended to: the impact of headaches on a person's life. HIT-6 scores have been found to correlate strongly with other validated tools such as the Migraine Disability Assessment (MIDAS), further supporting its use in clinical practice. High HIT-6 scores are associated with more severe headache disability and a greater impact on quality of life.HIT-6 has shown good internal consistency, with Cronbach's alpha values typically ranging from 0.80 to 0.90, meaning that the questionnaire's items consistently measure the same underlying construct—headache impact. The test-retest reliability of HIT-6 has been found to be high, indicating that patients' scores are stable over time when their headache condition remains unchanged. In the original study, a reliability analysis was conducted, yielding an internal consistency (Cronbach's alpha) of 0.89 in the initial assessment and 0.90 in the subsequent assessment, with an intraclass correlation of 0.89. Furthermore, the test-retest reliability of the total sample was 0.78 (Kosinski et al., 2003). Authors (Martin et al., 2004) conducted the Spanish validation, resulting in a Cronbach's alpha of 0.87. The sample was tested for reliability, and a Cronbach's alpha of 0.83 was obtained.

Quality of Life: The Migraine-Specific Quality of Life Questionnaire (MSQ) is a self-assessment tool that measures the quality of life specifically for individuals with migraines by evaluating their daily functioning. The MSQ demonstrates strong construct validity by accurately assessing how migraines affect daily life, emotional well-being, and social functioning. The tool has been validated in multiple studies by showing significant correlations with migraine frequency, intensity, and duration, which confirms that it effectively measures the intended construct: migraine-related quality of life. In its Criterion Validity, MSQ has been compared with other tools, such as the SF-36 (Short Form Health Survey), to assess its validity. It has shown significant correlations with general quality of life measures, indicating that it captures a specific yet comprehensive picture of how migraines impact patients compared to broader health surveys. The MSQ has been found to have high internal consistency, with Cronbach's alpha values typically ranging from 0.85 to 0.92, which indicates that the questionnaire items are reliably measuring the same underlying construct across different migraine populations. Studies have shown that the MSQ has excellent test-retest reliability, meaning that patients tend to score similarly on the questionnaire

Table 1.
Summary of the MIDITRA program. Sessions and objectives.

MIDITRA PROGRAM		
Module	Session	Objectives
Adjustment to the illness	1	Understand the illness and its symptoms. Assess beliefs, concerns, or fears related to the illness. Reflect on pain experiences and pain-related behaviors in their life. Encourage participation by considering the need to improve their quality of life. Provide information about the intervention program's goals and reach a consensus on individual objectives.
Self-esteem/self-concept	2	Promote self-awareness and self-reflection. Encourage the development of personal identity with a foundation of positive self-esteem as a predictor of the degree of psychological adjustment in individuals with chronic illnesses. Foster cognitive and behavioral patterns that support a positive self-image and prevent the stigma associated with illness.
	3	Learn to promote the skills that enhance self-efficacy, motivation, and a sense of mastery. Promote positive language to achieve more favorable thoughts and behaviors. Acquire tools and practices that foster positive self-esteem.
Emotional self-regulation	4	Explain that chronic illnesses and their treatment can lead to the onset of emotional problems and a deterioration in the quality of life. Recognize the potential for developing depressive symptoms when dealing with a chronic illness. Define depression and offer guidance on its prevention.
	5	Foster a resilient attitude to facilitate the acquisition of appropriate habits and behaviors. Promote positive emotions that can alleviate daily painful situations. Teach emotional skills to enhance well-being and emotional intelligence.
	6	Understand that fear/anxiety are often associated with chronic illnesses, which can reduce well-being. Identify and manage anxiety symptoms associated with everyday situations in individuals with chronic illnesses. Promote a calm and positive attitude when dealing with setbacks caused by fear. Teach anxiety/fear control strategies and fear management.
Decision-making and problem-solving	7	Explain what constitutes appropriate decision-making and problem-solving. Understand how developmental milestones, life stressors, and a chronic illness impact decision-making and problem-solving.
	8	Conceptualize stress and its factors. Explain the potential responses to stress in specific situations. Define stress control techniques. Teach fundamental coping skills and cognitive strategies.
Social skills	9	Recognize the impact of chronic illnesses on social relationships. Identify the ways in which the illness has influenced their social relationships and their sense of belonging to a group. Understand the support that family and friends can provide in managing the illness and its treatment. Receive training in social skills.
	10	Define assertiveness, positive communication, and active listening. Examine the role of communication in personal relationships. Develop effective communication skills with family and healthcare professionals. Acknowledge the importance of communication in intimate relationships. Acquire tools for fostering positive communication.

when their migraine status remains consistent over time, ensuring the tool's reliability in repeated measures. Authors as Martin et al., (2000) analyzed its reliability, finding that Cronbach's alpha ranged from 0.86 to 0.96 for its dimensions. The sample was tested for reliability, and a Cronbach's alpha of 0.93 was obtained.

Catastrophizing: The Pain Catastrophizing Scale (PCS) measures pain catastrophizing through rumination, magnification, and helplessness of patients. A reliability analysis was conducted using Cronbach's alpha, yielding coefficients of 0.91 for the rumination scale, 0.75 for the extension scale, and 0.87 for the helplessness scale, in addition to a total index of 0.93 (Osman et al., 1997). In the validation of the Spanish sample conducted by García et al. (2008), the internal consistency of the PCS was analysed, resulting in scores exceeding 0.70 for Cronbach's alpha for both the overall scale and the subscales. Specifically, Cronbach's alpha for the total scale was 0.79, 0.82 for the rumination subscale, 0.74 for the magnification subscale and 0.80 for the helplessness subscale. The test-retest reliability was 0.84 for the total scale, 0.86 for the rumination subscale, 0.82 for the magnification subscale and 0.83 for the helplessness subscale (García et al., 2008). In the present study, the reliability of the data was assessed through the implementation of Cronbach's alpha, which yielded a value of 0.94.

Life Satisfaction: The Satisfaction with Life Scale (SWLS) assesses individuals' overall life satisfaction. In the original study by Diener et al. (1985), the questionnaire was validated, resulting in a Cronbach's alpha score of 0.87 and a test-retest correlation coefficient of 0.82. In the study where the scale was validated with a Spanish adult sample, yielding a Cronbach's alpha of 0.88 (Vázquez et al., 2013). The sample was tested for reliability, and a Cronbach's alpha of 0.89 was obtained.

Affectivity: The Positive and Negative Affect Schedule (PANAS) measures positive and negative affectivity. The PANAS has demonstrated robust psychometric properties, as evidenced by the high alpha coefficients observed in both the original validation (0.88 for PA and 0.87 for AN) (Watson et al., 1988) and the Spanish validation (Sandín et al., 1999). In the latter, the alpha coefficients for the male and female groups were 0.89 (PA) and 0.91 (AN) and 0.87 (PA) and 0.89 (AN), respectively. The high Cronbach's alpha

coefficients obtained for both scales (AP and AN) indicate that the scale exhibits a high degree of internal consistency and can be considered a reliable instrument. In the present study, reliability tests were conducted, resulting in a Cronbach's alpha of 0.892 for AP and 0.940 for AN.

Stress: The Perceived Psychological Stress Scale (EEP-10) evaluates perceived psychological stress in everyday situations and stressful circumstances. In the Spanish validation study (Remor, 2006), a validity analysis was conducted, resulting in the following data: with regard to internal consistency, as indicated by Cronbach's alpha, the 14-item version yielded a score of 0.81, while the short 10-item version obtained a score of 0.82. With respect to test-retest reliability, the correlations were 0.73 for the 14-item version and 0.77 for the 10-item version, with p=0.000. The sample was tested for reliability, and a Cronbach's alpha of 0.77 was obtained.

Resilience: The Brief Resilient Coping Scale (BCS) assesses an individual's overall resilience. In the original study, the internal consistency, as measured by Cronbach's alpha, was 0.69, and the test-retest reliability was 0.71 ($p < 0.001$). In the Spanish validation conducted (Moret-Tatay et al., 2015), a Cronbach's alpha of 0.86 was obtained. The sample was tested for reliability, and a Cronbach's alpha of 0.81 was obtained.

Emotional Symptomatology: The Hospital Anxiety and Depression Scale (HADS) was designed to measure mood in non-psychiatric hospital patients. In Terol-Cantero et al. (2015) reviewed the use of the HAD scale in Spanish samples and concluded that it exhibited good internal consistency, with scores ranging from 0.80 to 0.86 on the anxiety subscale and from 0.80 to 0.87 on the depression subscale. However, they noted that in one study involving healthy patients, the score was 0.71, which was below the generally accepted range. It is noteworthy that in a few isolated studies, the scores were observed to be somewhat higher, reaching as high as 0.90. Reliability tests were conducted on our sample, resulting in a Cronbach's alpha of 0.70 (anxiety) and 0.819 (depression).

Treatment Satisfaction: The Treatment Satisfaction Scale (CRES-4) aims to measure patients' satisfaction with the therapy received. The Spanish adaptation conducted by (Nielsen et al., 2004). The sample was tested for reliability, and a Cronbach's alpha of 0.80 was obtained.

Participants

The study commenced in October 2022 and conclude in December 2023. The principal investigator making initial contact with the patients. During this contact, the study's procedures were explained, informed consent was provided, and the first individual assessment was conducted.

Initially, 30 potential patients were contacted as candidates for inclusion in the study. However, after applying the inclusion criteria, the initial sample consisted of 27 adult patients diagnosed with migraine who are being followed up in the Neurology Service of the Hospital Universitario y Politécnico de La Fe in Valencia (Spain).

The initial sample of 27 patients was analysed and the results are presented below. The age of the patients ranged from 23 to 70 years, with a mean age of 48.33 years (*SD*=10.038). Regarding gender, many of the patients were female (88.9%), with 24 of the 27 patients under study being female and the remaining 3 (11.1%) being male. Regarding the origin of the patients, 96.3% (26 patients) were Caucasian, while one patient (3.7%) was African. In terms of education, two patients (7.4%) have not completed basic education, eight patients (29.6%) have completed basic education, ten patients (37%) have completed high school or vocational training, and seven patients (25.9%) have completed higher education. However, all patients have been in school for at least ten years, with an average of 15.07 years of schooling. Regarding the employment status of the patients, only four of them, representing 14.8% of the sample, were in employment at the time of the evaluation. Three of them were civil servants, and one had a permanent contract. The patients who were not working covered a variety of situations, including unemployment, paid or unpaid employment, sick leave due to migraines, total or partial incapacity, retirement, student status, or housewife status. The marital status of the patients was diverse, with 55.6% of them being married. This included 15 patients who were single (3.7%), 2 who were divorced (7.4%), 2 who were widowed (7.4%), 1 who was separated (3.7%), and 4 who were living with a partner (14.8%). Additionally, the patients were queried as to whether they had resided with a family member who was afflicted with a chronic physical ailment. It was observed that 44.4% of them had done so, which equates to 12 individuals.

The patients were initially distributed between the research groups, with 15 in the experimental group and 12 in the control group. The distribution was random and carried out prior to any contact with the patients. After applying the exclusion criteria, the final study sample consisted of 11 subjects in the experimental group and 12 subjects in the control group.

Recruitment

Initially, neurologists will be responsible for recruitment, which will take place in the hospital during routine patient visits. Participants will be asked to complete a battery of questionnaires on their psychological and physical health statuses in 4 sessions. The outcome measures will be collected by the medical and psychological specialists.

Statistical Methods

Reliability will be assessed using Cronbach's alpha to determine the internal consistency of the questionnaires. To describe participant profiles, descriptive analyses will include frequencies, percentages, means, medians, and standard deviations. Correlation analysis will be conducted using Spearman's rank correlation test.

Prior to selecting a statistical approach, we evaluated the prerequisites for implementing a mixed ANOVA. Initially, we conducted normality tests on the dependent variables at each level of the independent variables. The findings revealed a notable deviation from the normality assumption, which, coupled with the limited sample size, undermined the reliability of the mixed ANOVA results. To evaluate the efficiency and benefits of the treatment protocol, non-parametric tests for comparing means will be employed. For within-subject analysis, the Wilcoxon signed-rank test will be utilized, while for inter-subject analysis, the Mann-Whitney U test will be applied. The effect size will be evaluated using Cohen's d.

Ethics and dissemination

Each participant received information about the aim and procedures of the study and provided written consent for participation. Consent and assent were obtained by the medical specialist. The data were confidential and anonymized and used solely for the study's objectives (27 April 2016 Data Protection Act (GDPR)). Numerical codes linked each participant's identification information. The data collected were stored in a locker in the place of work of the principal investigator, and electronic data were protected by a password on the university network computer.

Any protocol amendments were registered at *ClinicalTrials.gov*(NCT05658185). we got the support of the university's research ethics committee and Polytechnic Hospital La Fe of Valencia (Ref: 2022-600-1).

Results

General information on pre-intervention physical and pharmacological status: descriptive data

With regard to medication intake, it can be observed that 59.2% of patients consume tranquillisers on a daily basis, either one or more in the same day. This is equivalent to 16 of the 27 patients. The consumption of analgesics is higher, with 25 of the patients (92.6%) consuming them daily. Similarly, 19 of the patients consume daily sleeping medication, equating to 70.3% of the total sample. The consumption of stimulants is lower and is linked to the presence of other illnesses, with only 6 of them (22.2%) consuming them daily. The daily intake of antidepressants is also high, being 77.8%, equating to 21 of the patients. Ten patients (37%) take medication for heart problems or blood pressure. Finally, five patients take opioids on a regular basis, which represents 18.5% of the total number of patients.

Regarding the specific issue of migraines, the period since diagnosis ranged from 48 to 3 years, with an average of 21.93 years. The duration of treatment ranged from 45 to 2 years, with an average of 19.22 years. The number of hospital admissions due to migraines ranged from zero to fifty, with an average of 4.93. Notably, only eight patients (29.6%) had not been admitted on any occasion.

The patients perceived the level of disability caused by migraines at the time of the initial evaluation to range between 5 and 10 on a scale of 0 to 10 disability. Of the patients, 88.9% (24 patients) scored 8 or above, while 44.4% (12 patients) scored a disability of 10. In terms of the number of days per month on which patients experienced pain, the range was between nine and 30 days, with an average of 25.67 days. On average, patients needed to take medication for 22.70 days. The type of medication taken during the crisis could be triptans, anti-inflammatory drugs, anaesthetics, a combination of two or all three, or no medication. A total of 55.6% of patients reported taking triptans during crises, 3.7% took anti-inflammatory drugs, 3.7% took anaesthetics, 33.3% took a combination of drugs, and 3.7% took no medication, indicating that none of the treatments were effective. Despite the observation of 85.2% of patients that the treatment was effective, 14.8% did not notice any improvement. Among the patients who did observe some improvement, 23 of them reported an improvement ranging from 4 to 9 on a scale of 0 to 10, with an average of 6.43. The intensity of pain experienced by patients during migraine attacks ranged from 6 to 10 on a scale of 0 to 10, with an average of 8.85. It is noteworthy that 70.3% of patients rated their pain as 9 or 10.

When queried about the family history of migraines, 21 patients (77.8%) reported a family history, 5 patients (18.5%) indicated no history, and 1 patient (3.7%) was unsure. Additionally, the patients were queried as to whether the migraines were related to menstruation. Of the 27 patients, 10 (37%) indicated that there was a relationship, while 17 (63%) stated that there was not. It is noteworthy that in our study, only three men were included, resulting in a greater number of women (14) who stated that there was no relationship than men (10) who did.

With regard to the patients' habits, 17 (63%) consumed caffeine, while 10 (37%) did not. The number of coffees consumed per week among those who consumed caffeine ranged from one to 24, with an average of 11.94. With respect to tobacco consumption, seven patients (25.9%) were identified as smokers, while the remaining 20 (74.1%) did not smoke. However, four of the 20 patients were former smokers. The number of cigarettes smoked per week by patients who smoke ranged from 20 to 140, with a mean of 77.29 cigarettes. In contrast, the number of patients who consume alcohol is lower, with only three individuals (11.1%) reporting alcohol consumption. These individuals consume one or two alcoholic drinks per week.

In relation to other diagnosed medical illnesses, 55.6% of the patients have another pain disorder or chronic illness, equating to 15 patients. When queried about the most prevalent conditions, seven patients (25.9%) were diagnosed with fibromyalgia and chronic fatigue, five patients (18.5%) had irritable bowel syndrome, three patients (11.1%) had asthma, and 21 patients (77.8%) exhibited sleep disturbances.

Regarding psychological treatment, 15 patients (55.6%) reported having experienced psychological problems in the past, and the same number of patients reported having such problems at the time of the study.

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General information on the psychological state prior to the intervention: Descriptive data

The MIDAS questionnaire categorizes all patients as grade IV, indicating severe disability, as their score exceeded 21 points. The majority of patients (21, 77.8%) exhibited clinically significant levels of catastrophization, with a mean score of 43 (SD=12.71). The quality of life of the patients was low, with only 4 patients (14.8%) scoring more than 20 points (response range 0-100). It is observed that more than 60% of the patients do not even reach the level of slightly satisfied.

Patients exhibited a lower mean of positive affect than the general population, which is 32.74 with a standard deviation of 8.31. Conversely, they exhibited a higher mean of negative affect than the general population mean of 20.08 with a standard deviation of 7.62. Patients exhibited high levels of stress, with 81.48% of them scoring in the medium or high range. Additionally, 77.78% of the patients exhibited low resilience, with none of them scoring in the high range. In the case of anxiety, the mean score indicated a probable case of significant clinical anxiety. In the case of depression, the data indicated a mean score that pointed to a clinical problem in depression.

Between-subjects analysis: comparison of pre-treatment means of the control and treatment groups

A comparison analysis of the means of the pre-treatment scores obtained by the patients in the control and experimental groups was conducted to verify that there were no significant differences between the samples of the two groups, thus ensuring that the samples were comparable. After performing the Mann-Whitney U test, it was confirmed that there were no statistically significant differences between the means of the two groups, thereby accepting the null hypothesis of homogeneity of the sample.

Table 2.
Comparison of mean scores at different points in time in the control group.

	T1	T2	T3	T4	Z(T1-T2)	Z(T2-T3)	Z(T2-T4)
	M (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)			
Degree of disability	68.50 (27.73)	70.58 (21.94)	65.92 (23.15)	69.17 (17.08)	-0.542	-1.214	-1.021
Negative impact of headache	72.83(6.13)	72.58 (4.78)	72.58 (5.73)	72.75 (5.14)	-0.703	-0.060	-0.460
Catastrophisation	36.83 (10.30)	36.42 (12.99)	36.25 (11.53)	36.17 (10.78)	0.000	-0.401	-0.276
Quality of life	10.42 (10.81)	10.01 (5.72)	10.95 (11. 02)	14.88 (14.93)	-0.918	-0.204	-1.020
Satisfaction with life	10.25 (4.11)	13.75 (5.34)	3.08 (1.88)	3.00 (1.48)	-1.357	-0.368	-0.189
Positive affect last week	20.50 (6.36)	21.50 (6.05)	19.67 (6.50)	21.00 (6.42)	-0.629	-1.419	-0.312
Overall positive affect	32.33 (8.95)	29.33 (7.57)	29.50 (8.46)	25.00 (6.62)	-0.446	-0.275	-1.64
Negative affect last week	29.50 (8.88)	28.83 (9.80)	26.92 (8.65)	30.33 (11.19)	-0.256	-0.802	-0.938
Overall negative affect	25.00 (5.63)	27.17 (8.57)	23.42 (8.17)	24.08 (8.88)	-0.590	-0.934	-0.971
Psychological stress	3.08(0.70)	2.92 (0.69)	2.67 (0.65)	2.75 (0.87)	-1.000	-1.342	-0.816
Resilience	10.17 (5.04)	9.33 (3.96)	10.33 (4.29)	10.08 (4.14)	-0.777	-1.612	-1.420
Anxiety	11.00 (4.49)	10.75 (4.16)	10.67 (3.45)	10.92 (5.50)	-0.268	0.000	-0.091
Depression	14.92 (3.55)	14.25 (3.55)	13.58 (2.78)	14.17 (3.71)	-1.039	-1.140	-0.154

Note. $^{***}p \leq .001$ $^{**}p \leq .01$ $^{*}p \leq .05$.

Within-subject analysis: Comparison of mean scores at different points in time in the control and experimental groups

In order to perform the analyses described below, the non-parametric Wilcoxon test was employed to measure the means separately for each group at the different time points.

Control group

Table 2 illustrates the variation in means between the scores obtained by the control group at T1 and T2, both pretreatment measurements. Despite the deterioration of the patients in most of the variables, the variations between the two pretreatment evaluations did not show statistically significant differences in any of the variables analyzed. The variation of means between the scores obtained by the control group at T2 and T3. T2 represented the pre-treatment period, while T3 represented the post-treatment period. Despite the observed variations, they were deemed to be minimal and not clinically significant. For the variation of means between the scores obtained by the control group at T2 and T4, the former representing the initial pre-treatment period and the latter representing the subsequent follow-up assessment conducted after a period of time following the conclusion of the intervention, there were no statistically significant changes observed in the control group. The means of the variables analyzed remained relatively stable over time.

Experimental group

Table 3 illustrates that the mean scores of the experimental group at T1 and T2, both pre-treatment measures, exhibited minimal changes for the majority of variables, with the exception of quality of life, general positive affect, and anxiety. Upon analysis, it can be observed that the mean score for the quality-of-life variable decreased from 27.91 (T1) to 14.94 (T2). Similarly, the mean score for general positive affect exhibited a decline, from 36 (T1) to 23.73 (T2) while the mean scores for anxiety decreased from 12.45 (T1) to 10.64 (T2).

Upon examination of the variation in means between the scores obtained by the experimental group at T2 and T3, it was observed that while there was an increase in the means of the variables, only four variables demonstrated statistically significant differences: degree of disability, negative impact of headache, catastrophizing, and quality of life. In terms of the degree of disability, there was a

Table 3.
Comparison of mean scores at different points in time in the experimental group

	T1	T2	T3	T4	Z (T1-T2)	Z (T2-T3)	Z (T2-T4)
	M (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)			
Degree of disability	79.80 (14.37)	82.67 (11.31)	69.82 (22.84)	67.09 (19.19)	-0.534	-2.023*	-2.207*
Negative impact of headache	70.47 (5.11)	71.73 (5.13)	67.09 (4.87)	69.91 (5.11)	-1.386	-2.552**	-0.949
Catastrophisation	38.40 (10.13)	39.40 (12.77)	29.27 (15.81)	31.45 (12.75)	-1.337	-2.299*	-2.493**
Quality of life	16.67 (12.93)	14.19 (12.04)	29.58 (16.28)	29.58 (19.84)	-2.805**	-2.669**	-2.501**
Satisfaction with life	10.93 (4.51)	10.13 (4.07)	3.00 (1.67)	3.36 (1.43)	-1.134	-1.294	-2.154*
Positive affect last week	24.33 (7.83)	20.53 (6.56)	25.27 (8.82)	23.64 (9.67)	-1.582	-0.765	-0.178
Overall positive affect	34.80 (9.26)	25.60 (9.00)	28.09 (8.03)	29.55 (6.85)	-2.627**	-1.340	-1.790
Negative affect last week	33.47 (8.51)	30.73 (10.53)	26.64 (9.05)	28.91 (8.43)	-0.534	-0.664	-0.579
Overall negative affect	30.80 (9.97)	30.60 (11.93)	31.55 (10.83)	28.64 (9.52)	-0.970	-0.358	-0.445
Psychological stress	2.73 (0.70)	3.07 (0.59)	2.91 (0.54)	2.73 (0.65)	-1.134	-0.577	-1.342
Resilience	12.53 (2.36)	10.53 (3.34)	13.18 (3.82)	13.18 (3.57)	-1.248	-1.486	-1.970*
Anxiety	13.60 (4.07)	11.20 (3.39)	11.45 (4.76)	10.27 (4.52)	-2.140*	-0.666	-0.085
Depression	11.73 (3.69)	12.93 (4.08)	11.00 (4.92)	11.09 (3.89)	-1.566	-0.655	-0.804

Note. $^{**}p \leq .001$ $^{**}p \leq .01$ $^{*}p \leq .05$.

Table 4.
Comparison of mean scores at different points in time in the experimental group.

	Control Group T3	Experimental Group T3	Control Group T4	Experimental Group T4	Z(T3) (Control-Experimental)	d	Z(T4) (Control-Experimental)	d
	M (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)				
Degree of disability	65.92 (23.15)	69.82 (22.84)	69.17 (17.08)	67.09 (19.19)	-0.063	0.17	-0.186	0.11
Negative impact of headache	72.58 (5.73)	67.09 (4.87)	72.75 (5.14)	69.91 (5.11)	-2.289*	1.03	-1.333	0.55
Catastrophisation	36.25 (11.53)	29.27 (15.81)	36.17 (10.78)	31.45 (12.75)	-1.26	0.50	-0.894	0.40
Quality of life	10.95 (11. 02)	29.58 (16.28)	14.88 (14.93)	29.58 (19.84)	-2.652**	1.34	-1.818	0.84
Satisfaction with life	3.08 (1.88)	3.00 (1.67)	3.00 (1.48)	3.36 (1.43)	-0.063	0.04	-0.659	0.25
Positive affect last week	19.67 (6.50)	25.27 (8.82)	21.00 (6.42)	23.64 (9.67)	-1.571	0.72	-0.556	0.32
Overall positive affect	29.50 (8.46)	28.09 (8.03)	25.00 (6.62)	29.55 (6.85)	-0.401	0.17	-1.390	0.68
Negative affect last week	26.92 (8.65)	26.64 (9.05)	30.33 (11.19)	28.91 (8.43)	-0.062	0.03	-0.154	0.14
Overall negative affect	23.42 (8.17)	31.55 (10.83)	24.08 (8.88)	28.64 (9.52)	-2.069*	0.85	-1.017	0.50
Psychological stress	2.67 (0.65)	2.91 (0.54)	2.75 (0.87)	2.73 (0.65)	-1.033	0.40	-0.203	0.02
Resilience	10.33 (4.29)	13.18 (3.82)	10.08 (4.14)	13.18 (3.57)	-1.299	0.70	-1.675	0.80
Anxiety	10.67 (3.45)	11.45 (4.76)	10.92 (5.50)	10.27 (4.52)	-0.342	0.19	-0.124	0.13
Depression	13.58 (2.78)	11.00 (4.92)	14.17 (3.71)	11.09 (3.89)	-1.547	0.65	-1.706	0.81

Note. ***$p \leq .001$ **$p \leq .01$ *$p \leq .05$ d de Cohen = TE pequeño ≈ 0,20; TE moderado ≈0,50; TE grande≈ 0,8.

notable decline from 80.45 (T2) to 69.82 (T3). Similarly, the negative impact of headache exhibited a reduction from 71.64 (T2) to 67.09 (T3). In those of catastrophizing, there was a decrease from 38.91 (T2) to 29.27 (T3), while in those of quality of life, there was an increase from 14.94 (T2) to 29.58 (T3).

Finally, regarding the variation of means between the scores obtained by the experimental group at T2 and T4, the first being pre-treatment and the second follow-up after a period of time following the end of the intervention, it is important to note that although all the means of the variables improved, statistically significant changes were only found in the variables of degree of disability, catastrophizing, quality of life, life satisfaction, and resilience. The mean scores for the degree of disability variable decreased from 80.45 (T2) to 67.09 (T4), those for catastrophizing decreased from 38.91 (T2) to 31.45 (T4), and those for quality of life increased from 14.94 The mean score for satisfaction with life increased from 2.27 (T2) to 3.36 (T4), while resilience increased from 10.64 (T2) to 13.18 (T4). These findings indicate an improvement in the patients.

Intersubject analysis: comparison of post-treatment means of the control and treatment groups

Table 4 presents a comparison of the control and treatment groups at T3, the first post-treatment evaluation. The table reveals that the group means exhibit certain variations that favor the experimental group. However, only statistically significant changes were observed in the variables of negative impact of headache, quality of life, and general negative affect. The mean of the headache negative impact variable for the experimental group is 67.09, while that of the control group is 72.58. This indicates that the experimental group experienced a more detrimental impact of headache than the control group. Similarly, the mean of the quality-of-life variable revealed that the experimental group exhibited the most favorable conditions, with a mean of 29.58, while the control group had a mean of 10.95. However, we observed a higher mean in the general negative affect in the patients of the experimental group, with 31.55, while those of the control group was 23.42. Furthermore, the effect size at T3 was calculated using Cohen's d. It was observed that the effect size when comparing the data between the experimental and control group was especially large in the variables negative impact of headache, quality of life, positive affectivity in the last week, resilience, and moderate in the variables catastrophizing and depression. This indicates that the treatment performed had a significant impact on the experimental group, resulting in healthier measures.

Secondly, the comparison of means of the control group and the experimental group at T4, follow-up evaluation, can be observed. Upon analysis of the variables, a slight improvement was observed in the experimental group. However, these differences were not deemed clinically significant when assessed through mean comparison analysis.

¡Analysis of satisfaction of treatment by patient: Descriptive data

In the evaluation of T3 and T4, patients in the experimental group were administered an additional questionnaire, the CRES-4, with scores ranging from 0 to 100, with the exception of the last variable, which is the total variable and ranges from 0 to 300. In the four variables, the higher the score, the better. It is important to note that in the third variable, the perception of emotional change, a score below 50 indicates a worsening of the patient's mood. Table 5 presents the results for T3, which show a high degree of satisfaction

Table 5.
The perceived satisfaction of the experimental group with MIDITRA at T3 and T4 will be evaluated.

	T3		*T4*			
	M	*SD*	*M*	*SD*	*Min*	*Max*
Satisfaction with the treatment	76.36	21.57	89.09	16.40	0	100
Solution of the problem	85.45	9.34	83.64	12.06	0	100
Perception of emotional change	62.50	9.68	60.23	9.38	0	100
Effectiveness of treatment according to the patient	224.32	37.15	232.96	32.62	0	300

with the treatment, a high perception of improvement in their problems, a medium-high perception of emotional change, and a high consideration that the treatment is effective in the eyes of the patient.

With regard to the mean scores of the questionnaire at T4, which indicated a higher level of satisfaction with the treatment than at T3, there was a slight decrease in the perception of solutions to their problems and an emotional change. However, the results remained positive. Additionally, there was an increase in the efficacy of the treatment according to the patients. In conclusion, at both time points, the patients provided favourable ratings of the treatment.

Discussion

This research aims to examine the physical and psychological status of patients with difficult-to-treat chronic migraines and analyze the effects of applying a specific psychological intervention protocol.

Physical and psychological profile of these patients showed that they cannot maintain gainful employment due to their condition. Moreover, medication usage is remarkably high, with all participants consuming medication daily, including tranquilizers, analgesics, pain medications, and antidepressants. These findings align with scientific literature related to these variables, which indicate a low quality of life and a high degree of disability (Leonardi et al., 2010; Raggi et al., 2011), along with a high prevalence of comorbid mental illnesses, such as anxiety and depression (AEMICE, 2021; Buse et al., 2013; Novic et al., 2016). These comorbid disorders, combined with the experience of chronic pain, can impact cognitive processes, making patients more susceptible to stress (Huber & Henrich, 2003), leading to catastrophic thinking, greater fear of pain, poor pain acceptance (Lee et al., 2019), and an intensified perception of baseline physical pain (Dahlke et al., 2017; Edwards, 2005; Roth et al., 2005).

Concerning treatment, both intra-subject and inter-subject improvements are observed in all aspects in the experimental group upon completing the treatment and compared to the control group. These findings support existing research (Dudeney et al., 2022; Lee et al., 2019; Probyn et al., 2017), which highlights the need for psychological treatments for these patients and the resulting benefits on their physical and mental health.

At the intra-subject level, significant improvements are observed in favor of the experimental group regarding disability level, negative impact of headaches, catastrophizing, quality of life, positive affect over the last week, resilience, and depression. In contrast, for the control group, scores remain relatively stable over time, with potential fluctuations, primarily showing deterioration in patients but without significant changes towards improvement.

Analyzing inter-subject group comparisons, the initial random assignment of patients to groups showed no differences in any variables. However, post-treatment evaluations reveal differences in variables favoring improvements in the experimental group. With treatment, the variations that may indicate population-level improvements include variables related to the negative impact of headaches, catastrophizing, quality of life, positive affect, resilience,

Our objective was to promote psychological assessment and intervention as regular healthcare measures for patients with chronic migraines. The study highlights the benefits of this protocol for patients who express satisfaction with it.

This research presents the potential benefits of implementing an assessment and psychological treatment protocol for patients with difficult-to-treat migraines, their families, and society as a whole, both in psychological and economic terms.

Scientific literature suggests that improving socioemotional competencies can enhance well-being and emotional symptoms, resulting in reduced levels of aggression, anxiety, and depression. These competencies are linked to improved social skills, communication abilities, increased social support, and better psychological adjustment. Therefore, this assessment and intervention protocol could enhance socio-emotional skills, self-management, self-efficacy, and, consequently, the physical and mental health of patients with difficult-to-treat migraines.

While this study underscores the advantages of the treatment for patients, further research is imperative. It is imperative that further studies be conducted to elucidate the necessity for the implementation of protocols such as the one presented in our study on larger samples of patients. This would facilitate a more comprehensive analysis of its benefits on physical and psychological health, as well as a greater generalisation of the results. It is further recommended that such research should be followed up over time, as this is an essential aspect of tracking the maintenance of changes over time.

The present study represents an initial investigation aimed at developing a psychological assessment and treatment protocol and evaluating its efficacy on a pilot sample. Among the limitations of our work is the relatively small sample size. To gain a more comprehensive understanding of the treatment's efficacy, it is essential that future research expands the study's application to a larger patient population, including both new and follow-up cases. Additionally, future investigation in this field could benefit from comparative studies examining the impact of pharmacological treatment optimisation without psychological intervention, as well as the potential benefits of combining this approach with psychological intervention.

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