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## EFFECTIVENESS OF KINESIOTHERAPY ASSOCIATED WITH HERBAL MEDICINAL PRODUCT IN THE PAIN PROFILE OF PATIENTS WITH FIBROMYALGIA: A RANDOMIZED, DOUBLE-BLIND CLINICAL TRIAL

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**Abstract:** Fibromyalgia (FM) is a chronic syndrome characterized by widespread musculoskeletal pain, often accompanied by fatigue, sleep disturbances, and emotional symptoms, compromising quality of life. Its prevalence varies between 2% and 5%, predominantly affecting women. Given the limitations of conventional treatments, this study evaluated the effects of a physiotherapeutic intervention associated with the topical application of OEAz—a substance recognized for its anti-inflammatory and muscle relaxant properties, although little studied in FM. This is a randomized, double-blind, controlled clinical study with women diagnosed with FM, divided into EG and CG, comparable in anthropometric data and baseline pain levels. The intervention consisted of kinesiotherapy sessions combined with topical application of OEAz in the EG; the CG received kinesiotherapy with placebo. To assess pain and the impact of FM, specific instruments were used: McGill Pain Questionnaire, Numerical Rating Scale (NRS), Fibromyalgia Impact Questionnaire (FIQ), and Chalder Fatigue Scale. The mean and standard deviation of pain levels were analyzed before and after the sessions to demonstrate the effectiveness of the intervention. The results showed a significant reduction in pain in the EG, with a decrease in NRS from  $7.40 \pm 2.70$  to  $3.33 \pm 1.88$ . In the CG, the reduction was smaller, from  $8.80 \pm 0.84$  to  $6.78 \pm 0.95$ . The difference between groups was statistically significant ( $p = 0.028$ ) and with a very large effect size ( $d = -2.32$ ) favorable to the EG. In the FIQ, there was an improvement in quality of life and a reduction in the impact on the EG, which went from severe to moderate after the intervention. Although the intergroup differences were not statistically significant, the clinical effect sizes indicated the relevance of the findings ( $d = -0.89$ ). Fatigue—a prominent symptom in FM—also decreased in the EG, with a drop of more than

30% between baseline and post-intervention ( $45.50 \pm 7.09$  to  $31.67 \pm 6.92$ ). Qualitative analysis of EG reports showed multifaceted improvements: sleep, anxiety, energy, and reduced medication use. In the CG, the reports were more modest. One participant stood out, having stopped using sedatives after 20 years, attributing the improvement to physical therapy. The sessions included multidisciplinary guidance on sleep hygiene, nutrition, and relaxation techniques, promoting adherence and positive results, reinforcing the biopsychosocial approach. It is evident that the combination of kinesiotherapy and topical application of OEAz may be effective in reducing painful symptoms and improving quality of life in FM. Despite the limited sample size, the protocol in the EG showed clinical superiority over the CG, suggesting the potential of OEAz as an adjunct in the management of chronic musculoskeletal pain. Future studies with a larger number of participants and longer follow-up are recommended to confirm the findings and deepen the understanding of the mechanisms involved.

**Keywords:** Fibromyalgia; Essential oil; Physical therapy; Chronic pain; Quality of life.

## INTRODUCTION

Fibromyalgia (FM) is described as a chronic syndrome characterized by widespread musculoskeletal pain, often associated with hyperalgesia, allodynia, fatigue, sleep disturbances, morning stiffness, and psychological symptoms such as anxiety, depression, and cognitive difficulties, including memory and reasoning difficulties. The pain, usually located in the cervical region, shoulders, limbs, and chest wall, can be considered a distinct clinical condition, being associated with disability, dysfunction, and decreased quality of life (Casanova-Rodríguez *et al.*, 2025; Assumpção & Matsutani, 2015).

According to the American College of Rheumatology, the diagnosis of FM is challenging due to the variation of its symptoms among individuals. Among the most common are widespread pain, severe fatigue, and sleep disturbances, with frequent reports of patients who do not feel refreshed after a night's rest. Other signs may include memory and concentration difficulties, depression, anxiety, migraines, digestive problems, irritable bladder, pelvic pain, and jaw pain. To confirm the diagnosis, laboratory and radiographic tests are used to rule out other conditions with similar symptoms, such as thyroid disorders or polymyalgia rheumatica (ACR, 2023).

Fibromyalgia syndrome (FMS) was first described in the 19th century as "muscular rheumatism," evolving under various names until the term "fibromyalgia" was introduced by Yunus *et al.* in 1981. In 1990, the American College of Rheumatology established diagnostic criteria based on tender points, and in 2010, Wolfe *et al.* proposed a more comprehensive approach, with severity and symptom scales. Today, both methods are considered complementary, contributing to a more accurate and comprehensive diagnosis (Assumpção & Matsutani, 2015; Melo, 2014).

The global prevalence of FM varies between 2% and 5% of the general population, with a significant predominance among women (Assumpção & Matsutani, 2015). The age group most affected depends on different studies, but in general, it is between 30 and 60 years (Melo, 2014; Da Silva *et al.*, 2023; Carvalho *et al.*, 2024). This context results in a considerable socioeconomic impact, increasing health-care costs and reducing productivity (Giorgi *et al.*, 2023; Salaffi *et al.*, 2022). In addition, Di Carlo *et al.* (2022 *apud* Giorgio *et al.*, 2023) indicated that patients over 71 years of age often experience worsening physical function compared to those in younger age groups.

The etiology and pathophysiology of FM are not yet fully understood, but studies indicate that its origin is related to disturbances in the central pain modulation mechanisms, dysfunctions in the hypothalamic-pituitary-adrenal axis, alterations in the immune system, and genetic predisposition (Zhang *et al.*, 2022; Assumpção & Matsutani, 2015; Melo, 2014). In addition, psychological factors such as anxiety, depression, and catastrophizing of pain have been correlated with symptom severity, impacting quality of life and increasing functional disability (Izquierdo-Alventosa *et al.*, 2020).

The treatment of FM combines pharmacological and non-pharmacological approaches. Medications such as analgesics, antidepressants, and anticonvulsants are commonly prescribed but may have side effects that compromise long-term treatment adherence (Assumpção & Matsutani, 2015; Melo, 2014). On the other hand, non-pharmacological interventions, such as therapeutic exercises, have shown significant efficacy in reducing symptoms and improving quality of life, especially when adapted to the individual conditions of patients (Soares, 2024; Giorgi *et al.*, 2023; Zhang *et al.*, 2022; Izquierdo-Alventosa *et al.*, 2020; Assumpção & Matsutani, 2015).

In addition, the use of medicinal plants has emerged as a complementary alternative. *Alpinia zerumbet* (Az), popularly known as colônia, has promising therapeutic properties. Studies indicate that this plant, abundant in northeastern Brazil, has muscle relaxant, antioxidant, antihypertensive, and anxiolytic actions, attributed to its bioactive components, such as terpinen-4-ol and 1,8-cineol (Bezerra *et al.*, 2000; Lahlou *et al.*, 2003; Santos *et al.*, 2011). This makes Az a possible adjuvant in the treatment of FM, especially in the management of muscle tension and pain reduction.

*Alpinia zerumbet* belongs to the *Zingiberaceae* family and is often confused with the genus name. The *Alpinia* genus includes about

230 recognized species, and Az is known in Brazil as “colônia” and “flor-da-redenção” (Van *et al.*, 2021). Introduced to the country in the 19th century, it was taken to the Botanical Garden of Rio de Janeiro and associated with the signing of the Golden Law, as it was said to be the flower presented to Princess Isabel on that occasion (Brazil, 2014). Its leaves have distinct microscopic characteristics, such as paracytic stomata and oil cells, which contribute to its therapeutic properties (Brazil, 2014). Traditionally, the plant has been used to treat various conditions, including hypertension, inflammation, and cardiovascular disorders (Chan *et al.*, 2024; Nishidono & Tanaka, 2024). Its bioactive compounds, such as 1,8-cineol and terpinen-4-ol, have antimicrobial, anti-inflammatory, and antioxidant properties (Van *et al.*, 2021). In addition, its chemical composition varies according to the region, influencing its therapeutic properties (Santos *et al.*, 2011).

Studies indicate that Az has low toxicity, with a LD50 greater than 5 g/kg and no genotoxicity when consumed as tea (Santana, 2009). However, compounds such as terpinen-4-ol, linalool, and  $\beta$ -caryophyllene demonstrate cytotoxic activity against cancer cells, inducing cell death and interrupting the cell cycle (Van *et al.*, 2021). Clinical studies suggest that the plant's essential oil may be effective in reducing blood pressure and managing muscle spasticity and osteoarthritis, despite some reported gastrointestinal effects (Brazil, 2014). In a clinical trial with fibromyalgia patients, the essential oil demonstrated safety, improving quality of life but without a significant impact on anxiety and pain (Melo, 2014). However, further studies and clinical trials are needed to confirm its therapeutic applications and reinforce its potential as a herbal medicinal product (Chan *et al.*, 2024).

Scientific literature has already extensively documented the benefits of light to modera-

te exercise in reducing FM symptoms such as pain, insomnia, muscle stiffness, and anxiety, provided that it is performed regularly (Casanova-Rodríguez *et al.*, 2025; Soares, 2024; Carvalho *et al.*, 2024; Giorgi *et al.*, 2023; Da Silva *et al.*, 2023; Zhang *et al.*, 2022; Izquierdo-Alventosa *et al.*, 2020; Assumpção & Matsutani, 2015; Marques *et al.*, 2015; Lirio & Mattos, 2013). However, a paradox arises in this context: after exercising, especially when not performed under the guidance of a qualified professional, the patient may experience local pain and discomfort, which tends to aggravate symptoms, hindering treatment (Pessoa *et al.*, 2023; Da Silva *et al.*, 2023). The need to exercise to improve clinical condition, as it would play an essential role in reducing pain sensitivity, according to SBR (2022), contrasts with the experience that movement can aggravate symptoms, creating a vicious cycle that leads patients to avoid physical activity, known as kinesiophobia, which, in the long term, further worsens the symptoms associated with FM.

The challenge, therefore, is to seek alternatives to minimize peri- and post-kinetic discomfort in patients with FM, given that catastrophizing pain is a striking feature of the disease. This causes patients to experience a much higher level of post-exercise physical suffering than expected for people without the condition, who only feel the usual muscle pain from training, which is easily tolerated (Matsutani, 2015).

Studies indicate that initial exercise may lead to a slight intensification of symptoms in fibromyalgia patients; however, continuous and prolonged training provides significant improvements (Pessoa *et al.*, 2023). Despite the widely recognized benefits of physical exercise in the management of FM, many patients give up therapy before realizing its positive effects. In this scenario, the hypothesis is that the use of a phytotherapeutic agent that helps reduce pain and promotes muscle rela-

xation before exercise, with effects that last for a significant period, could contribute to more fluid and comfortable movement. Thus, the intention is to control exacerbated symptoms during the early stages of regular exercise, reducing the chances of dropout, until the benefits of therapeutic exercise become evident.

Considering the significant impact of FM on patients' quality of life and the demand for more effective and accessible treatments, this research aims to investigate the effectiveness of non-pharmacological interventions, including physical exercise protocols associated with the topical use of *Alpinia zerumbet* essential oil (OEAz), on symptoms and quality of life in women with FM. Although there is a limited number of studies directly linking OEAz to pain reduction, several studies have shown its relaxing effects on muscles in cases of spastic hypertonia attributed to intramuscular calcium modulation (Cândido *et al.*, 2017a; Cândido *et al.*, 2017b; Maia *et al.*, 2016; Cândido *et al.*, 2012a; Cândido *et al.*, 2012b; Cândido *et al.*, 2012c) and in knee osteoarthritis (Brazil, 2014). This modulation reduces the availability of calcium in muscle cells, decreasing excitability and excessive contraction, which promotes muscle relaxation. In addition, OEAz has anti-inflammatory and antioxidant properties that may contribute to reducing the production of local pro-inflammatory mediators, reducing the inflammatory process and pain sensitivity (Brazil, 2014; Melo, 2014). In patients with fibromyalgia, characterized by hypersensitivity to pain and muscle fatigue, these actions have the potential to indirectly aid in the control of post-exercise pain, minimizing muscle stress and promoting functional recovery and comfort after physical activity.

Therefore, the objective of this research is to contribute to the advancement of the therapeutic management of this chronic condition.

This research has the following objectives:

- To evaluate the effectiveness of therapeutic exercises associated with the administration of a topical herbal medicinal product for pain reduction in patients with fibromyalgia after 12 weeks of treatment;
- Investigate the difference in pain perception between the experimental and control groups;
- Analyze the quality of life and associated symptoms, such as fatigue and muscle stiffness, of the female participants in the study;
- Verify the evolution of muscle strength in the research participants;
- Compare the results of both groups in terms of adverse effects and benefits after completing the protocols.

## METHODOLOGY

This is a controlled, double-blind, randomized, single-center, prospective clinical trial with a quantitative-qualitative approach. Twelve female participants were included, regardless of the time since their fibromyalgia diagnosis, who were members of the Gente de Fibro Group and residents of the municipality of Cachoeirinha, RS, where the headquarters of the Cesuca University Center is located. The participants were selected by simple random sampling, with a refusal rate of 16.7%. All participants signed an Informed Consent Form (ICF), which presented all relevant information about the study, formalizing their participation and authorizing the disclosure of the results obtained.

The research was approved by the Research Ethics Committee (CEP) of the Cesuca University Center, under number 5,318,790, and registered on the Brazil Platform under number 56827122.6.0000.5665. The trial was conducted in accordance with the ethical guidelines and standards for research involving human subjects established in Resolutions No. 251/1997 and No. 466/2012 of the National Health Council (CNS) of the Ministry of Health.

## INCLUSION CRITERIA AND GROUP ALLOCATION

The inclusion criteria defined for the study were: female patients with a confirmed diagnosis of FM through proof of previous treatment for the condition, aged between 30 and 70 years, with no ethnic restrictions, and who were members of the Gente de Fibro group. Exclusion criteria included patients with untreated inflammatory or endocrinological rheumatic diseases; neurological, chronic renal, or infectious conditions; glaucoma; urinary retention; coronary heart disease, arrhythmias, or congestive heart failure; pregnant or lactating women; patients with hypersensitivity to AZ or its components; as well as those with bleeding, hyperestrogenemia, or blood pressure below 100/60 mmHg.

Eligible participants were randomly assigned to one of two research groups: Experimental Group (EG) and Control Group (CG). The registration and randomization process was conducted in partnership with the Cesuca Pharmacy Course and was carried out by a faculty member independent of the research team. An automated system based on probabilistic decisions was used, ensuring an impartial and reproducible process, which reduced possible biases in the distribution of groups. The generation of the allocation list allowed the formation of two balanced and comparable groups. In addition, the participation of an external professional ensured double blinding, so that both the collaborators and the researchers were unaware of the allocation to the groups.

## RESEARCH DESIGN

To conduct the research, the participants were divided into two weekly schedules (2:30 p.m. and 4:00 p.m.), with two sessions per week over 12 consecutive weeks, totaling 24 meetings. The interventions took place at the Cesuca Physical Therapy Teaching Clinic, a

structured environment for supervised practice, with strict control of procedures. The allocation of time slots was based on the participants' availability, with the possibility of mixed composition between the groups (CG and EG) in each shift, but without prior control of this variable.

For each participant, an individual bottle containing the topical solution corresponding to their group (experimental or control) was prepared, properly coded and stored to ensure the double-blind protocol. This process was conducted with the support of a professor from the Pharmacy Course, who had no direct involvement in the collections. The substance was applied to the skin, respecting the dosage proportional to body weight (0.05 ml for every 7 kg), approximately 15 minutes before the start of physical activities, during the measurement of vital signs.

The application sites were defined in the initial anamnesis of each session, when the participants indicated the Numerical Rating Scale (NRS) and the specific pain points at that moment. If more than three painful points were reported, the participant herself selected the three main sites to receive the application of the substance previously assigned to her.

The formulation used in the EG consisted of 67% sunflower oil (Dersani) and 33% OEAz (Falcão *et al.*, 2021; Melo, 2014), while the CG received a subtherapeutic solution with 2% OEAz in sunflower oil—a proportion established based on preliminary tests conducted by the researchers themselves, with the aim of equalizing the aroma between the solutions. The solutions were handled at the Ceuca School Pharmacy Handling Laboratory, with quality control and faculty guidance, following strict technical guidelines to determine the density and number of drops based on each patient's body weight.

The main phase of the sessions was structured in a circuit, with progressive exercises

aimed at developing strength, localized muscle endurance, and cardiorespiratory capacity. The stations included warm-up, resistance/isometric exercises for the upper and lower limbs and trunk/core/abdomen, as well as aerobic stimuli such as treadmill, adapted walking, and shuttle run. The perceived load, execution time, and complexity of the movements were adjusted weekly according to individual tolerance. Intensity was monitored by estimated HR (40–70% of HRmax) and subjective perception of effort (Borg). The sessions ended with stretching and breathing exercises aimed at recovery and relaxation.

### DATA COLLECTION INSTRUMENTS

A series of questionnaires and tests were administered at different times during the 24 kinesiotherapy sessions. These instruments were selected to assess the patients' quality of life, FM-associated symptoms, pain intensity, and muscle strength. Quality of life was measured using the Fibromyalgia Impact Questionnaire (FIQ), which examines nine domains, such as physical function, pain, and fatigue. To quantify pain, the McGill Pain Questionnaire (Br-MPQ) was used, which assesses the sensory, affective, and cognitive dimensions of pain. Muscle strength was assessed using the 30-second chair sit-to-stand test (TSL30s) for the lower limbs and the handgrip strength test using a dynamometer for the upper limbs. The Numerical Rating Scale (NRS) and Borg Scale were also used for continuous monitoring of pain and perception of physical effort during the exercise protocol in the sessions. Finally, each patient received a diary at the introductory meeting, in which they were asked to record any perceived changes on a daily basis, including possible side effects.

The table below shows the frequency of application of the instruments and scales used throughout the study, detailing the specific moments when each was used to assess the different aspects of the participants.

Instrument/Scale	Evaluates	In the 24 sessions	Before session 1	After session 12	After session 24
Borg	Perceived effort	X	-	-	-
Chalder	Physical and mental fatigue	-	X	X	X
NRS	Pain	X	-	-	-
Br-MPQ	Pain	-	X	X	X
Handgrip Dynamometer	Upper limb muscle strength	-	X	X	X
FIQ	Quality of life	-	X	X	X
TSL30s	Lower limb muscle strength	-	X	X	X

**Table 1** – Frequency of application of instruments and scales

Source: Prepared by the author, 2025.

## EXTRACTION PROCESS OF ALPINIA ZERUMBET ESSENTIAL OIL

According to the Brazilian Health Regulatory Agency (Anvisa), the essential oil of *Alpinia speciosa* and *A. zerumbet* is predominantly extracted by hydrodistillation using the Clevenger apparatus, with extraction times ranging from 3 to 8 hours (Brazil, 2014).

For this research, *Alpinia zerumbet* essential oil (OEAz) was extracted from selected leaves and flowers from a sustainable plantation located in Trajano de Moraes (RJ), Brazil, cultivated in a syntropic system and in a favorable environment, at an altitude of about 1,000 meters. The collection prioritized young shoots, as they have a higher concentration of volatile compounds. Distillation was carried out with natural mineral water, over low heat for about 5 hours from the start of hydrolate collection, with strict temperature and pressure control to ensure purity and preserve the volatile properties of the oil. The process took place in September and December 2024. At the end process, the essential oil was collected directly from the separation funnel, minimizing contamination risks, and stored in appropriate containers to ensure its integrity until final use.

## STATISTICAL ANALYSIS

For statistical analysis of the data, GNU PSPP software, version 2.0.0-g5b54d1, was used, an open source program for statistical

data analysis, functionally equivalent to SPSS.

The literature recommends caution when applying parametric tests to small samples ( $n < 30$ ), due to the limitation of these tests in detecting deviations from normality in this context. Therefore, considering the small sample size, we opted to use non-parametric statistical tests, which do not require the assumption of normality, ensuring greater robustness and reliability in the results (Magalhães & Mendes, 2024; Guimarães, 2015).

The data were organized in a spreadsheet, with adequate coding and categorization of variables. For intragroup comparisons, the paired Wilcoxon test was used, and for intergroup comparisons, the Mann-Whitney test was used. In addition to statistical significance, Cohen's *d* was calculated to quantify the magnitude of intragroup differences in the post-intervention. This measure, based on the difference between means, complements the analysis by indicating the strength of the effect, regardless of the p-value, providing greater clarity to the interpretation of the results (Holmes *et al.*, 2023; Espírito-Santo & Daniel, 2015).

All statistical analyses were conducted exclusively in the aforementioned version of PSPP, following the methodological assumptions recommended in the scientific literature for experimental designs with repeated measures.



## RESULTS AND DISCUSSION

Twelve collaborators were initially included in the study, with the intervention carried out over twelve weeks in the first half of 2025, totaling 24 sessions distributed regularly in two weekly meetings. The participants' adherence was considered satisfactory, with most attending 75% or more of the sessions. No collaborators were excluded due to low attendance; however, one participant was excluded in the tenth week due to an injury that occurred during an outdoor activity, resulting in five members in the CG and six in the EG.

The data collection instruments were applied at three different times, as shown in Table 1, with the intermediate tests being used only for monitoring and control purposes. The initial anthropometric characteristics of the CG and EG, used to describe the sample, are shown in Table 2.

### CHARACTERIZATION OF THE SAMPLE

The data in Table 2 show that CG and EG had similar means in height ( $1.57 \pm 0.03$  m and  $1.54 \pm 0.05$  m), weight ( $88.10 \pm 10.06$  kg and  $81.83 \pm 12.44$  kg), BMI ( $35.81 \pm 4.18$  and  $34.80 \pm 6.09$  kg/m<sup>2</sup>), age ( $55.20 \pm 8.87$  and  $59.50 \pm 4.64$  years) and baseline NRS ( $8.80 \pm 0.84$  and  $7.40 \pm 2.70$ ), with no statistically significant differences. The variables showed good internal homogeneity, absence of *outliers* within the groups, and coefficients of variation below 20%, which favors comparability between the groups.

Throughout the twelve weeks of physiotherapy intervention, anthropometric data indicated a slight reduction in the participants' body weight, which directly impacted their BMI. The average reduction in BMI was 1.76% in the total sample, with the CG showing a 2.29% decrease and the EG showing a 1.32% decrease.

After the final tests, the CG showed a re-

duction in BMI sufficient to reclassify it from Grade II Obesity to Grade I Obesity, according to WHO (2025) parameters, while the EG remained in the Grade I Obesity classification. According to Álvarez-Nemegyei *et al.* (2022), fat mass volume can negatively influence the severity of fibromyalgia. At the time of the intervention, only one patient in the EG had a BMI within the eutrophic range; the other participants remained classified between Obesity Grade I and II, distributed between the groups.

### FIBROMYALGIA IMPACT QUESTIONNAIRE

The Fibromyalgia Impact Questionnaire (FIQ, adapted by Marques *et al.*, 2006) is widely used in clinical practice and research to assess the impact of FM on quality of life.

In this study, in the total score, both the CG ( $73.81 \pm 12.14$ ) and the EG ( $78.24 \pm 9.52$ ) presented scores compatible with severe FM impact, according to the classification proposed by Marques (2015), evidencing significant clinical impairment of the collaborators.

In the EG, a statistically significant reduction was observed between the pre- and post-intervention moments ( $p < 0.05$ ). However, this difference was not significant when comparing groups. The mean scores in the EG showed significant reductions in the following domains: pain (from 8.67 to 5.08;  $-41.4\%$ ), fatigue (from 8.50 to 6.17;  $-27.4\%$ ), anxiety (from 8.50 to 3.67;  $-56.8\%$ ), depression (from 9.25 to 3.58;  $-61.3\%$ ), and total score (from 78.24 to 50.52;  $-35.4\%$ ). These results suggest relevant clinical positive effects of the intervention applied in this group.

Despite the lack of statistical significance between the groups, Cohen's *d* values indicated clinically relevant effects in favor of EG, with magnitudes considered very large in the domains of anxiety ( $d = -1.50$ ) and depression ( $d = -1.57$ ); large in the domains of pain ( $d = -0.99$ ) and total score ( $d = -0.89$ ); and

Variable	Control group (n=5)	Experimental Group (n=6)	p<0.05
Age (mean±SD)	55.20±8.87	59.50±4.64	0.647
Height (mean±SD)	1.57±0.03	1.54±0.05	0.407
Pre-weight (mean±SD)	88.10±10.06	81.83±12.44	0.537
Post-weight (mean±SD)	87.03±10.08	81.65±12.89	0.562
Pre-BMI (mean±SD)	35.81±4.18	34.80±6.09	1.000
BMI_post (mean±SD)	34.99±3.88	34.34±6.07	0.958
Baseline_NRS (mean±SD)	8.80±0.84	7.40±2.70	0.390
Education	Complete elementary (1); High school completed (2); Incomplete higher education (1); Higher education completed (1)	Incomplete elementary education (1); Complete elementary education (2); Complete secondary education (1); Incomplete higher education (2)	
Comorbidities	HAS (1); Osteoarthritis (4); Others (3)	ASD (2); DM (1); Asthma (1); Osteoarthritis (3); Stroke (1); Others (3)	
Medications	Antidepressants (4); Anticonvulsants and neuromodulators (4); Anxiolytics and hypnotics (2); Analgesics and anti-inflammatories (including NSAIDs) (4); Antihypertensives/Cardiovascular (2); Diuretics (1); Thyroid hormone (1); Dietary supplements (1); Immunosuppressants/Rheumatological (0); Other medications (1)	Antidepressants (7); Anticonvulsants and neuromodulators (6); Anxiolytics and hypnotics (2); Analgesics and anti-inflammatories (including NSAIDs) (5); Antihypertensives/Cardiovascular (5); Diuretics (0); Thyroid hormone (3); Dietary supplements (3); Immunosuppressants / Rheumatological (3); Other medications (6)	

**Table 2** – Characterization of participants according to anthropometric data, education level, medication use, and comorbidities

Source: Survey data (2025).

Domain	CG_pre	EG_pre	CG_post	EG_post	p value	Cohen's d post
Pain (5)	9.40±1.34	8.67±2.04	8.00±2.85	5.08±3.01	0.082	-0.99
Fatigue (6)	9.40±1.08	8.50±1.84	8.70±1.48	6.17±4.23	0.309	-0.77
Anxiety (9)	9.40±1.34	8.50±1.76	7.90±1.95	3.67±3.37	0.054	-1.50
Depression (10)	8.90±2.46	9.25±1.17	8.60±2.07	3.58±3.87	0.065	-1.57
Total	73.81±12.14	78.24±9.52	69.14±13.19	50.52±25.10	0.201	-0.89

**Table 3** – Fibromyalgia Impact Questionnaire – FIQ: pre- and post-intervention between groups

Source: Survey data (2025).

Domain	CG_pre	EG_pre	CG_post	EG_post	p value	Cohen's d post
Physical symptoms	27.20±5.02	26.50±3.62	19.20±5.67	17.00±4.00	0.520	-0.46
Mental symptoms	18.60±3.21	19.00±4.20	16.00±3.94	14.67±3.50	0.409	-0.36
Total	45.80±7.98	45.50±7.09	35.20±8.87	31.67±6.92	0.230	-0.45

**Table 4** – Chalder Fatigue Questionnaire: pre- and post-intervention between groups

Source: Research data (2025).

medium in the domain of fatigue ( $d = -0.77$ ). According to Bennett *et al.* (2009), a minimum reduction of 14% in the total QIF score is already considered clinically relevant. In the present study, the CG showed a reduction of only 6.33% in the total impact of FM, while the EG showed a reduction of 35.42%—that is, approximately 2.5 times higher than the established criterion, indicating a significant clinical effect of the intervention with OEAz compared to the placebo group. In addition, the EG went from a severe classification ( $78.24 \pm 9.52$ ) to a moderate classification ( $50.52 \pm 25.10$ ), according to Marques (2015).

Particularly in the domain of depression, a substantial difference was observed: the CG showed a reduction of only 0.30 points (from  $8.90 \pm 2.46$  to  $8.60 \pm 2.07$ ), while the EG had a reduction of 5.67 points (from  $9.25 \pm 1.17$  to  $3.58 \pm 3.87$ ), representing an 18.9-fold improvement. These data suggest that topical use of OEAz may have enhanced the reduction of depressive symptoms in the EG, producing clinically relevant gains, especially considering the high prevalence of depression symptoms among patients with fibromyalgia, corroborating the findings of Melo (2014), who found statistical significance ( $p < 0.01$ ) in the symptom of depression in patients treated with OEAz compared to the control group.

## CHALDER FATIGUE TEST

Fatigue — one of the most prevalent symptoms in fibromyalgia (Casanova-Rodríguez *et al.*, 2025; Marques, 2015) — was assessed using the Chalder Fatigue Questionnaire (CFQ), which evaluates physical and mental symptoms, consisting of 14 items and with a total score of 56 points. The higher the total score, the more severe the fatigue (Marques, 2015).

According to table 4 there was a significant reduction in physical symptoms in both groups (CG:  $p = 0.043$ ; EG:  $p = 0.026$ ), but no significant difference between them in the

post-test ( $p = 0.520$ ), with a small to medium effect favorable to the EG ( $d = -0.46$ ). For Mental Symptoms, no significant differences were observed intra- or between groups (CG:  $p = 0.109$ ; EG:  $p = 0.273$ ; between groups:  $p = 0.409$ ), with a small effect also in favor of the EG ( $d = -0.36$ ). The total score showed a significant reduction in both groups (CG:  $p = 0.043$ ; EG:  $p = 0.028$ ), with no significant difference between them ( $p = 0.230$ ), with a small to medium effect favoring the EG ( $d = -0.45$ ).

In percentage terms, the EG showed a 35.84% reduction in physical symptoms and a 30.65% reduction in the total score, reinforcing the magnitude of the changes observed, even in the absence of intergroup statistical significance.

Complementing the quantitative data, subjective reports of general well-being among participants indicated a higher frequency of positive expressions in the EG, such as “very good,” “improved,” and “I felt good.” In the CG, although the reports were also positive, they highlighted aspects related to social interaction and coping with pain. Only one participant in the EG reported no improvement (“same”). Expressions directly linked to reduced physical and mental fatigue were identified, such as “more energy,” “alert,” and “lively,” indicating consistency between the subjective data and the results of the Physical Symptoms and Total domains of the Chalder questionnaire.

The effect sizes indicate small to moderate clinical relevance in favor of the EG, especially in physical symptoms and total score. Despite the lack of statistical significance between groups, the findings reinforce the importance of considering both clinical effects and participants’ subjective perceptions when evaluating interventions for fibromyalgia.

The quality of life of these patients is often impaired by pain, fatigue, and functional limitation. Although it is not known whether this worsening is a cause or consequence of

symptom intensification, interventions that act on any of these variables tend to benefit the others (Carvalho *et al.*, 2024). According to Silva *et al.* (2022), there is a lack of studies on exercise and fatigue in fibromyalgia patients, and the existing have methodological limitations, although they suggest improvement in this symptom. In this scenario, the results of the EG indicate that the reduction in fatigue may be related both to functional improvement and to a possible adjuvant effect of OEAz, contributing to the clinical evolution observed.

### GRIP STRENGTH TEST – DYNAMOMETER

The handgrip test was included in the study because it is the most frequently cited instrument for assessing muscle strength and endurance in patients with fibromyalgia, according to a review of protocols conducted by Santos *et al.* in 2014 (20/88 studies analyzed). Although no specific protocols were adopted for strengthening the finger flexor muscles—the focus of the test—several therapeutic activities required their isometric or dynamic activation during functional exercises. Given this, there was an expectation of modest improvement, confirmed by a gain of more than 20% only in the MSE of the CG (28.57%).

In the intragroup statistical analysis of handgrip strength, both groups showed an increase in the mean values from pre- to post-intervention, but without statistical significance and with effect sizes ranging from insignificant to small (Table 5). On the right side (RS), the CG went from  $14.80 \pm 2.95$  to  $18.20 \pm 6.98$  ( $p=0.345$ ;  $d=0.17$ ) and the EG from  $16.33 \pm 2.73$  to  $19.17 \pm 4.22$  ( $p=0.075$ ). On the left side (LS), the CG ranged from  $14.00 \pm 2.35$  to  $19.60 \pm 5.55$  ( $p=0.080$ ) and the EG from  $16.33 \pm 2.58$  to  $18.33 \pm 4.27$  ( $p=0.246$ ;  $d=-0.26$ ). The intergroup comparison in the post-intervention did not indicate a statisti-

cally significant difference (RD  $p=0.406$ ; LE  $p=1.000$ ).

Carvalho *et al.* (2024) reported limited effects of strength training on fibromyalgia, with only one of the two studies showing statistical significance. Although the current protocol was not specific for strength, the results showed an effect of similar magnitude. Cigarán-Méndez *et al.* (2022) identified a negative correlation between handgrip strength and pain, and a positive correlation with quality of life, associating lower strength with worse outcomes.

Although the handgrip findings do not show clinical significance, modest muscle strengthening may contribute to pain reduction, as well as improvements in quality of life and functionality (Carvalho *et al.*, 2024; Pessoa *et al.*, 2023).

The superior performance of the CG compared to the EG may be related to the absence of the phytotherapeutic agent product OEAz, since the modulation of  $Ca^{2+}$  channels affects sarcomere recruitment and muscle contractility. Although the EG may have reported lower pain perception—which tends to favor more fluid exercise execution and functional performance—the lower muscle fiber activation may have limited the strength gains observed in this group in the handgrip test. The entry of calcium ions into muscle cells is essential for contraction, and strength gains depend on the progressive recruitment of motor units, whose reduction can compromise muscle adaptation (Guyton & Hall, 2021).

### 30-SECOND SIT-TO-STAND TEST (TSL30S)

The TSL30s was used to assess lower limb strength and was chosen in conjunction with the handgrip test, which measures upper limb muscle strength, thus comprising the assessment of strength in the appendicular limbs of the participants. The TSL30s was the third most used test in the assessment of muscle

Upper limb	CG_pre	EG_pre	CG_post	EG_post	p value	Cohen's d post
Right	14.80±2.95	16.33±2.73	18.20±6.98	19.17±4.22	0.406	0.17
Left	14.00±2.35	16.33±2.58	19.60±5.55	18.33±4.27	1.000	-0.26

**Table 5** – Upper limb strength test: pre- and post-intervention between groups  
Source: Survey data (2025).

Unit	CG_pre	EG_pre	CG_post	EG_post	p value	Cohen's d post
Number of repetitions	9.60± 1.52	14.17±2.48	15.00±3.24	18.00± 2.97	0.140	0.97

**Table 6** – Lower limb strength test: pre- and post-intervention between groups  
Source: Research data (2025).

Domain	CG_pre	EG_pre	CG_post	EG_post	p value	Cohen's d post
IAD	3.00±0.71	2.67±1.03	2.20±1.48	1.33±1.51	0.391	-0.58
Total	55.20±8.38	56.00±7.62	49.00±12.41	45.33±10.31	0.714	-0.33

**Table 7** – McGill Pain Questionnaire scores: pre- and post-intervention between groups  
Source: Research data (2025).

Domain	Group	n	Mean±SD	Mann-Whitney test	Cohen's d post
NRS_baseline	CG	5	8.80±0.84	U=8.50; Z= -0.86; p=0.390	-0.70
	EG	5	7.40±2.70		
NRS_I	CG	5	6.78±0.95	U=2.00; Z= -2.19; p=0.028	-2.32
	EG	5	3.33±1.88		
NRS_F	CG	5	4.03±1.12	U=3.00; Z= -1.99; p=0.047	-1.17
	EG	5	1.74±1.53		
NRS_+1	CG	5	2.34±0.81	U=5.00; Z= -1.57; p=0.116	-1.04
	EG	5	1.14±1.42		

**Table 8** – Numerical Rating Scale (NRS): baseline, initial, final, and one day later  
Source: Research data (2025).

strength and endurance in patients with fibromyalgia, as identified in the literature review conducted by Santos *et al.* (2014), which analyzed 88 articles and theses on the subject.

Both groups showed a significant increase in the number of repetitions from pre- to post-test, showing statistical relevance within the groups (Table 6). The CG increased from an average of  $9.60 \pm 1.52$  repetitions to  $15.00 \pm 3.24$  ( $p=0.043$ ), while the EG went from  $14.17 \pm 2.48$  to  $18.00 \pm 2.97$  repetitions ( $p=0.027$ ). Although the comparison between the groups in the post-test did not show a statistically significant difference ( $p=0.140$ ), the effect size was considered large ( $d=0.97$ ), favoring the CG.

Although the therapeutic plan used in this study did not specifically aim to increase muscle strength, but rather to improve overall physical condition—including cardiorespiratory aspects—the significant gain in lower limb strength observed in absolute terms may be related to the participants' history of physical inactivity, often motivated by previous painful experiences associated with physical exercise. This assumption is in line with Lirio and Mattos:

The hypothesis we suggest is that patients with fibromyalgia had, at the beginning of the study, muscle strength limitations resulting from the disease and that strength training enabled rehabilitation, allowing for better performance in the other assessments, thus enabling a significant increase in muscle strength (Lirio & Mattos, 2013, p. 65).

Even so, the results obtained indicate that both groups showed significant improvement in lower limb muscle strength after the intervention, with a more favorable clinical and functional trend for the CG. The improvement in muscle strength may reflect benefits in secondary outcomes, such as quality of life, functionality, general health, and physical and mental aspects, as highlighted by Carvalho *et al.* (2024), who emphasize the positive impact of muscle strengthening on multiple dimen-

sions relevant to patients with fibromyalgia.

As already mentioned in the previous subitem, which addresses muscle strength testing in the upper limbs, the superior performance of the CG compared to the EG could be related to the application of OEAz, since the modulation of  $Ca^{2+}$  channels can significantly interfere with sarcomere recruitment and muscle contractility. Despite the likely reduction in pain in the EG favoring better functional performance, the modulation of  $Ca^{2+}$  channels may have limited the recruitment of motor units and, consequently, muscle strength gains in the TSL30s (Guyton & Hall, 2021).

### MCGILL PAIN QUESTIONNAIRE (BR-MPQ)

Pain was the guiding symptom of this study, constituting the main parameter for evaluating the effectiveness of the proposed treatment. According to Roenn *et al.* (2010), chronic pain is associated with a higher mortality rate, and studies indicate that patients with widespread pain have an increased risk of death. Our initial hypothesis was that the pain characteristic of fibromyalgia, often exacerbated by functional training and therapeutic exercises (Matsutani *et al.*, 2015), could be alleviated with the topical application of the herbal medicinal product *Alpinia zerumbet*. Two instruments were used to directly measure pain: the McGill Pain Questionnaire, which assesses qualitative and sensory aspects of the pain experience, and the more subjective NRS, which quantifies perceived intensity. In addition to these, other instruments applied in the study, such as the QIF, allowed an indirect assessment of the pain component by reflecting on the interference of pain in the daily activities and quality of life of the participants.

In the McGill Questionnaire (Table 7), intragroup analysis revealed that the EG showed a statistically significant reduction in the Current Pain Intensity (CPI) domain, whose

mean decreased from  $2.67 \pm 1.03$  to  $1.33 \pm 1.51$  ( $p=0.038$ ), representing a reduction of 1.34 points (-50.19%). In the CG, there was no statistically significant reduction in this domain, although a trend toward improvement was observed, reducing from  $3.00 \pm 0.71$  to  $2.20 \pm 1.48$  (a reduction of 0.80 points; -26.67%;  $p=0.157$ ). These data suggest that guided physical activity, even without the use of phytotherapeutic agent, can contribute to pain relief in patients with fibromyalgia, which is in line with the conclusions of Carvalho *et al.* (2024) and Giorgi *et al.* (2023).

In the intergroup comparison, no statistically significant differences were observed between CG and EG in any domain evaluated ( $p>0.05$ ), possibly due to the small sample size. However, the effect size in the IAD domain was moderate (-0.58), favoring the EG.

Regarding the total score of the McGill Pain Questionnaire, both groups showed a trend toward improvement, although without statistical significance. In the CG, the mean score decreased from  $55.20 \pm 8.38$  to  $49.00 \pm 12.41$ , representing a reduction of 6.20 points, equivalent to 11.23% ( $p=0.080$ ). In the EG, the mean decreased from  $56.00 \pm 7.62$  to  $45.33 \pm 10.31$ , a decrease of 10.67 points, or 19.05% ( $p=0.075$ ). Intergroup analysis also did not identify statistical significance ( $p=0.714$ ), although the effect size was small (-0.33), still favorable to the EG.

The reduction in pain scores in the IAD and total domains, observed more significantly in the EG, may be related to the muscle relaxant and anti-inflammatory action of OEAz, attributed to the modulation of  $Ca^{2+}$  channels, and the modulation of the inflammatory response (Van *et al.*, 2021; Brasil, 2014; Melo, 2014).

## NUMERICAL RATING SCALE (NRS)

The NRS was applied at four different times throughout the intervention (Table 8): on the first day (Baseline\_NRS), recorded once to

represent “pure” pain; before the start of each session (NRS\_I) and immediately after each session (NRS\_F) — both collected in all 24 sessions —; and on the day after the session (NRS\_+1), the latter recorded via WhatsApp message from the second week of treatment. The objective of NRS\_+1 was to assess the maintenance of pain relief over a longer period of time, but also between sessions. This sequential application of the scale was intended to capture both the immediate and residual effects of the physiotherapy intervention and the topical application of the herbal medicinal product.

The MFSL participant was kept in the main analyses to preserve the statistical and clinical representativeness of the EG, but was considered an outlier in the specific NRS analyses due to relevant visual and numerical discrepancies in relation to the group (SILVA, 2023). Her response pattern was atypical, not following the trend of pain reduction observed in the group (e.g., NRS\_+1: mean EG = 1.14; MFSL = 7.57), which could compromise the estimation of the prolonged effect of the herbal medicinal product. The exclusion of this single participant was methodologically justified and supported by the literature on the management of outliers.

At baseline, the EG had a mean pain score of  $7.40 \pm 2.70$  and the CG  $8.80 \pm 0.84$ , with no statistically significant difference ( $p=0.390$ ), indicating homogeneity between the two groups at the start of the study.

Before the sessions (NRS\_I), both groups showed a significant reduction in pain compared to baseline ( $p=0.043$ ). The EG decreased from  $7.40 \pm 2.70$  to  $3.33 \pm 1.88$  (55% reduction), while the CG decreased from  $8.80 \pm 0.84$  to  $6.78 \pm 0.95$  (23% reduction). The mean pain was significantly lower in the EG ( $p=0.028$ ), with a very large effect size ( $= -2.32$ ), indicating greater efficacy of the intervention associated with OEAz.

Immediately after the exercises (NRS\_F), both groups maintained a significant reduction in pain compared to the beginning of the session ( $p=0.043$ ). The EG reduced from  $3.33\pm 1.88$  to  $1.74\pm 1.53$  (48% reduction), and the CG from  $6.78\pm 0.95$  to  $4.03\pm 1.12$  (41% reduction). Pain was significantly lower in the EG ( $p=0.047$ ), with a large effect size ( $= -1.17$ ), suggesting a greater analgesic effect with the association with OEAz.

On the day after the session (NRS\_+1), both groups maintained a significant reduction in pain compared to baseline ( $p=0.043$ ). The EG reduced from  $7.40\pm 2.70$  to  $1.14\pm 1.42$  (85% reduction), and the CG from  $8.80\pm 0.84$  to  $2.34\pm 0.81$  (73% reduction). Although the difference between the groups was not statistically significant ( $p=0.116$ ), the effect size was large ( $= -1.04$ ), indicating a favorable trend for the EG in maintaining analgesia.

The specialized literature has already established that physical exercise, in its various forms, is the gold standard in the non-pharmacological treatment of chronic pain associated with fibromyalgia (Santos *et al.*, 2022; SBR, 2022; Oliveira & Claro, 2020; Matsutani, 2015). Among these modalities, aerobic exercise stands out for its essential role in reducing pain sensitivity. Neira *et al.* (2024) observed positive effects of both ground-based therapy (GBT) and aquatic therapy (AT), with the latter being slightly superior to GBT in reducing pain. Complementarily, Da Silva *et al.* (2023), in an integrative review, emphasize that resistance training is a viable strategy in the therapeutic approach to fibromyalgia, promoting pain reduction and improving quality of life in women affected by the syndrome. Soares (2024) also contributes to this body of evidence by highlighting that kinesiotherapy favors tissue oxygenation and local blood circulation, helping to reduce contractures and muscle pain. These findings reinforce the importance of well-structured and personalized

physiotherapeutic interventions focused on the combination of therapeutic modalities to maximize clinical benefits in pain management in patients with fibromyalgia.

The findings of NRS\_I ( $p=0.028$ ) and NRS\_F ( $p=0.047$ ) demonstrated, in a statistically significant manner, superior performance of the EG compared to the CG, most likely due to the association with topical application of OEAz. Although systematic literature searches did not identify clinical studies directly investigating the relationship between topical OEAz use and pain reduction in patients with fibromyalgia, it is suggested that this improvement is mainly related to the muscle relaxant and anti-inflammatory properties of the phytotherapeutic agent. Clinical evidence in populations with spasticity indicates that OEAz has a muscle relaxant effect possibly mediated by calcium channel blockade (Cândido *et al.*, 2017a; Cândido *et al.*, 2017b; Maia *et al.*, 2016; Cândido & Xavier-Filho, 2012; Santos *et al.*, 2011). Furthermore, a well-conducted animal model study, classified as moderate on the PEDro scale, demonstrated that OEAz, rich in compounds such as terpinen-4-ol and cineol—recognized for their anti-inflammatory and antioxidant properties and ability to modulate L-type calcium channels—reduced inflammation in the acute phase after tenotomy in rats (Santos-Júnior *et al.*, 2017). Such mechanisms may promote muscle relaxation by modulating  $Ca^{2+}$  channels and acting on the inflammatory response associated with exercise-induced muscle microlesions, indirectly contributing to the analgesic effects observed in the present study. Thus, the hypothesis that OEAz has complementary therapeutic potential in chronic musculoskeletal pain conditions is reinforced.

Analysis of the temporal evolution of pain between NRS\_+1 and NRS\_I (i.e., pain one day after a session until the moment before the next session) revealed a clinically rele-



vant pattern. In the CG, there was significant reinstallation of pain, with an increase from  $2.34 \pm 0.81$  to  $6.78 \pm 0.95$ , approaching the baseline value (77%). In the EG, this increase was more modest, from  $1.14 \pm 1.42$  to  $3.33 \pm 1.88$  (45% of baseline). This difference suggests a possible cumulative effect of OEAz on pain modulation and exercise-induced inflammatory response, favoring the maintenance of relief between sessions.

Kinesiotherapy plays a crucial role in pain modulation and the resolution of inflammatory processes. Body movement promotes increased lymphatic flow, facilitating the removal of inflammatory substances and cellular debris from the interstitial space, which contributes to a decrease in inflammation and consequent reduction in pain (Guyton & Hall, 2021). In addition, stimulation of A- $\beta$  nerve fibers during kinesiotherapy activates inhibitory circuits in the central nervous system, reducing the transmission of nociceptive stimuli in the spinal cord. This mechanism is in line with the Gate Control Theory of pain, which suggests that the activation of non-nociceptive sensory fibers can block the conduction of pain impulses, attenuating the perception of pain (Melzack & Wall, 1965).

## ADVERSE EFFECTS AND BENEFITS

During the preliminary meeting, notebooks were distributed to the participants for daily recording of their perceptions about the treatment, including physical sensations, adverse effects, perceived benefits of the activities performed, and any changes in medication use. The participants were instructed to note both improvements and possible worsening. The notebooks were collected on the day of the final tests, photographed for documentation, and returned to the participants. Although not all participants kept consistent records, relevant qualitative notes were identified in seven notebooks—four from the EG and three from

the CG. These records were analyzed through thematic categorization, using keywords such as pain, sleep, energy, well-being, and medications, which were used to structure the interpretation of the data below.

Analysis of the reports and clinical information from the EG participants reveals a general improvement in multiple aspects related to pain, sleep, energy, and well-being. A reduction in medication use was observed in some participants (BGMX, LSBS) and an improvement in pain and physical symptoms (EJMS, MRSV). Sleep quality also showed progressive improvement, reflecting more energy and a better disposition for daily activities, as reported by MESX: “sleep, more cheerful.” In addition, the positive psychological impact was evident, with reports of improved mood and decreased anxiety (LSBS), which contributed to a general state of well-being and increased motivation to continue treatment. For example, BGMX highlighted that her “mood improved” and that she “gets out of bed better, without pain.”

BGMX also posted the following comment on the WhatsApp group one day after the third session of the survey: “I don’t have any [pain], I’m not taking any medication, and today we managed to [wash] my toes with greater ease. I didn’t feel any pain in my spine. I’m very, very happy (sic).”

The overall assessment of the EG collaborators indicates that all would recommend continuing treatment, demonstrating satisfaction with the results achieved.

In the CG, although some participants reported improvement in pain and mood (MTCA, MAJG, MLFS), the changes were less significant and, in some cases, accompanied by the suspension of important medications, such as melatonin (MMJX), which may have influenced sleep quality. The energy reported was variable, but there was recognition of the positive impact of physical therapy in coping with psychological symptoms, such as depression and social phobia, as evidenced

by MCAD's report: "leaving home to go to physical therapy helps me with social phobia and depression." The impact of treatment on mood and mobility was also highlighted, although some physical symptoms, such as pain and fatigue, remained more intense than in the EG, consistent with the analyses of specific instruments (QIF and Chalder).

In general, the EG showed a more consistent evolution, not only in pain control and sleep quality, but also in aspects related to energy, psychological well-being, and functional capacity. An emblematic case was that of collaborator MFSL, who had been using Gardenal (phenobarbital), a sedative used to control seizures, for about 25 years. After a recent medical recommendation to gradually discontinue the medication, MFSL experienced unpleasant symptoms such as insomnia, feeling "asleep while awake," headaches, and dizziness, which led her to resume use at a reduced dose. However, during physical therapy treatment, the patient surprisingly managed to go several days without the medication, associating this fact directly with the physical therapy sessions, and eventually stopping its continuous use. This experience highlights the therapeutic potential of physical intervention in the symptoms of fibromyalgia, in addition to its positive influence on emotional state and sense of autonomy, reinforcing adherence and motivation for treatment. The MFSL report also highlights the importance of biopsychosocial care, showing how physical therapy can contribute to reducing the use of chronic medications and significantly improving quality of life, even in complex and prolonged clinical cases.

## FINAL CONSIDERATIONS

This study evaluated the effect of physiotherapy intervention, through kinesiotherapy associated with topical application of OEAz in patients with FMS, showing adequate comparability between the CG and EG. Despite

the limited sample size, the homogeneity of the anthropometric variables gave robustness to the analyses. Recent studies have shown that movement, through guided therapeutic exercises, is considered the gold standard in the treatment of the syndrome, with a focus on improving functional performance. This principle was evidenced in both groups in the present study, which showed improvement in several domains evaluated, including pain. However, a predominance of clinical improvement was observed in the group that used OEAz, suggesting a potential additional benefit of this intervention. The application of NRS demonstrated a significant reduction in pain levels before and after the sessions in the EG, with evidence of a prolonged effect, suggesting synergy between kinesiotherapy and the anti-inflammatory and muscle relaxant properties of OEAz.

Specific instruments for assessing the impact of fibromyalgia and fatigue indicated a statistically significant reduction in painful and emotional symptoms in the EG, despite the absence of statistical significance in intergroup comparisons, with relevant clinical effect sizes. Handgrip strength showed a tendency to improve in both groups, with a predominance in the CG. This result can be explained by the effect of the essential oil on the EG, which, by modulating intracellular calcium channels, reduces the release of calcium necessary for the interaction between actin and myosin, limiting muscle contraction. Thus, the muscle relaxation promoted by the oil may have decreased the recruitment of motor units, resulting in a smaller gain in strength in the EG compared to the CG. These findings indicate the need for studies with larger samples for confirmation.

Qualitative reports reinforced the multifaceted benefits of the combined intervention, including decreased anxiety and reduced medication use, corroborating the quantitative

data. These results indicate that the combination of kinesiotherapy and OEAz is a viable and effective approach for reducing symptoms and improving quality of life in patients with fibromyalgia.

Future investigations with larger samples and prolonged protocols are recommended to consolidate the observed effects and clarify the pathophysiological mechanisms involved. In summary, the protocol applied in the EG demonstrated clinical superiority in several aspects, reaching almost nineteen times that found in the CG in terms of depression, highlighting the potential of OEAz as an adjuvant in the management of chronic musculoskeletal pain associated with fibromyalgia.

During the physical therapy sessions, it was observed that the incorporation of guidelines based on complementary knowledge favored the clinical response of the patients, even without the direct involvement of other professionals. Strategies such as encouraging mindfulness, recommendations related to he-

althy habits (such as maintaining regular meal times, good hydration, and moderation in the consumption of stimulants), and strict adherence to medication appeared to contribute to improvements in sleep quality, pain control, and willingness to exercise. In addition, attentive and empathetic listening, without judgment or intervention during the participants' reports, proved effective in reducing emotional tension and stress levels. It was often noted that some patients choked up or teared up when sharing their experiences, highlighting the emotional burden associated with fibromyalgia and the therapeutic potential of acceptance. These observations reinforce the importance of a biopsychosocial approach in the treatment of the syndrome, suggesting that care can be enriched by integrated knowledge, contributing significantly to the overall well-being of patients.

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