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**Original Article** 

# Effects of meditation associated with education in neurosciences of pain in adults with fibromyalgia: A randomized controlled trial\*

Lucas Pelegrini Nogueira de Carvalho<sup>1,2</sup>

https://orcid.org/0000-0002-5027-2042

Lílian Silva Araújo<sup>2</sup>

https://orcid.org/0000-0002-6267-7573

Maria do Perpétuo Socorro Lage Avelar<sup>3</sup>

https://orcid.org/0000-0002-4061-7908

Karina Gramani Say<sup>2</sup>

https://orcid.org/0000-0002-2451-8109

**Objective**: to analyze the influence of meditation associated with pain neuroscience education in pain perception, sleep and functional capacity of adults with fibromyalgia. **Method**: this is an experimental, controlled, randomized study whose participants were divided into two groups: mindfulness group and mindfulness group and education in pain neuroscience. **Results**: improvements were observed in some variables related to pain, functional capacity, anxiety, depression, sleep quality and catastrophization. 270/5000. There was no difference in the intergroup comparison, but there were differences in the intra-group comparison. **Conclusion:** mindfulness-based interventions and education in pain neurosciences proved to be effective in improving the condition of patients with fibromyalgia. Clinical trial register: REBEC RBR-58pgs4

**Descriptors**: Elderly; Aging; Chronic Pain; Fibromyalgia;

Sleep; Mindfulness; Health Education.

## How to cite this article

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<sup>\*</sup> This article refers to the call "Mindfulness and other contemplative practices".

<sup>&</sup>lt;sup>1</sup> Universidade de São Paulo, Escola de Enfermagem de Ribeirão Preto, PAHO/WHO Collaborating Centre for Nursing Research Development, Ribeirão Preto, SP, Brazil.

<sup>&</sup>lt;sup>2</sup> Universidade Federal de São Carlos, Departamento de Gerontologia, São Carlos, SP, Brazil.

<sup>&</sup>lt;sup>3</sup> Sarvananda Casa de Yoga, São Carlos, SP, Brazil.

# Efeitos da meditação associada a educação em neurociências da dor em adultos com fibromialgia: ensaio clínico controlado e randomizado

**Objetivo:** analisar os efeitos do *mindfulness* associado com educação em neurociências da dor na percepção da dor, sono e capacidade funcional de adultos com fibromialgia. **Método:** tratase de um estudo experimental controlado e randomizado cujos participantes foram divididos em dois grupos: grupo *mindfulness* e grupo *mindfulness* e educação em neurociência da dor. **Resultados:** foram observadas melhorias de algumas variáveis relacionadas à dor, na capacidade funcional, ansiedade, depressão, qualidade do sono e na catastrofização. Não houve diferença na comparação intergrupos, porém existiram diferenças na comparação intra-grupos. **Conclusão:** intervenções baseadas na prática de *mindfulness* e educação em neurociências da dor se mostraram eficazes na melhora do quadro de pacientes com fibromialgia. Registro do Ensaio clínico: REBEC RBR-58pgs4.

Descritores: Idoso; Dor Crônica; Fibromialgia; Sono; Atenção Plena; Educação em Saúde.

# Efectos de la meditación asociada con la educación en neurociencia del dolor en adultos con fibromialgia: un ensayo clínico aleatorio controlado

**Objetivo:** analizar los efectos de la atención plena asociada con la educación en neurociencias del dolor sobre la percepción del dolor, el sueño y la capacidad funcional de los adultos con fibromialgia. Método: este es un estudio experimental, controlado, aleatorizado cuyos participantes se dividieron en dos grupos: grupo de atención plena y grupo de atención plena y educación en neurociencia del dolor. **Resultados:** se observaron mejoras en algunas variables relacionadas con el dolor, la capacidad funcional, la ansiedad, la depresión, la calidad del sueño y la catastrofización. No hubo diferencias en la comparación intergrupal, pero sí hubo diferencias en la comparación intragrupo. **Conclusión:** las intervenciones basadas en la práctica de la atención plena y la educación en neurociencias del dolor demostraron ser efectivas para mejorar la condición de los pacientes con fibromialgia. Registro del ensayo clínico: REBEC RBR-58pgs4

**Descriptores:** Ancianos; Dolor Crónico; Fibromialgia; Sueño; Atención Plena; Educación para la Salud.

### Introduction

The world and Brazil have undergone an intense population aging<sup>(1-2)</sup>. As a consequence of changes in the age structure of the population and advances in health sciences, the phenomenon called epidemiological transition can be observed. It refers to the process of reducing infectious diseases and to the increase in chronic-degenerative diseases<sup>(1)</sup>. Chronic diseases interfere with the functional capacity of the individuals affected, in addition to impairing the independence and quality of life of older adults<sup>(3)</sup>. In addition, many conditions are accompanied by pain, with chronic pain being one of the main complaints<sup>(4)</sup>.

The International Association for the Study of Pain (IASP) classifies pain as an "unpleasant, sensitive and emotional experience, associated or not with real harm or potential injuries in the tissues and related to individual memory, to the expectations and emotions of each person", which can be divided into acute - which occurs suddenly - or chronic - duration of 6 months or more.

The prevalence of chronic pain in the Brazilian population ranges from 29.3 to 73.3%<sup>(5)</sup>. Such prevalence is one third higher in women than in men; moreover, it is more prevalent among individuals over 65 years old when compared to those under 44<sup>(6)</sup>. Despite not being a normative factor for senescence, chronic pain is associated with chronic-degenerative diseases that can appear in this period of life<sup>(7-9)</sup>.

Some undesirable outcomes of chronic pain are related not only to the negative perception of health, but also to psychological, biological and spiritual well-being<sup>(10)</sup>. Other conditions arising from the chronic pain process would be dependence on activities of daily living, limitations in social life, changes in sexuality, economic imbalance, hopelessness and depression, factors that, when considered together, directly interfere with quality of life<sup>(4,11-13)</sup>.

In this context, fibromyalgia, a disease characterized by diffuse and chronic musculoskeletal pain also associated with other psychological disorders, such as anxiety, depression and sleep disorders, is highly associated with chronic insomnia and non-restorative sleep: 76 to 90% of the fibromyalgia patients report non-repairing sleep, while this prevalence is of 10% to 30% in normal individuals<sup>(14)</sup>.

Many factors contribute to the onset of the disease - genetics, infections, autoimmune diseases, lifestyle or emotional distress - but the neural alteration caused by the harmful behavior must be highlighted, as it generates greater brain connectivity in the regions that are responsible for the modulation and evaluation

of harmful stimuli and areas also responsible for interceptive awareness and bodily sensations, which results in greater awareness of nociceptive processes and generates the chronicity of painful processes<sup>(14-15)</sup>. The literature reveals that the prevalence of fibromyalgia varies between 0.2% and 6.6% of the population, ranging from 2.4% to 6.8% among women<sup>(16)</sup>.

Given the current scenario, studies suggest that *mindfulness*-based interventions demonstrate good results in the treatment of diseases such as fibromyalgia, anxiety disorders, cancer, and hypertension, among other diseases, since it improves symptoms such as pain, anxiety and depression, in addition to promoting the sensation of well-being<sup>(11,17-18)</sup>.

Mindfulness can be defined as a practice that integrates the mind and the body mainly aiming to reduce stress but, above all, the orientation of the conscience to the present moment and without judgments<sup>(19)</sup>. Other authors also point out that the meditation process focused on mindfulness is to be attentive to the processes that occur in the present moment, contemplating experiences with attitudes of curiosity in subtle nuances of daily life, feeling, perceiving and accepting everyday facts in a non-reactive way, being in control with our brain, connectivity and control of our subjective well-being<sup>(20)</sup>.

The practice of meditation can be a safe and effective therapeutic intervention, promoting health and improving quality of life, providing: improved pain acceptance, better management of stressful situations, decreased aggression in psychiatric patients, and improved quality of life and self-efficacy(19). This is because meditation provides a reduction in the activity of the sympathetic nervous system, inducing less neural activation, which reduces the work of the brain mechanisms that are responsible for sensitizing the brain regions by influencing painful processes(21) and, as a consequence, the increased action of the parasympathetic nervous system, reflecting in a better functioning of neuroendocrine, metabolic and neural functions, increasing the concentration of melatonin, serotonin, gamma-aminobutyric acid (GABA) and the decrease in cortisol and norepinephrine(15).

Although interest in alternative forms of treatment is growing, studies on meditation are scarce, especially with the older adult population. There is evidence that the analgesic effects of the meditative practice can be significant after eight weeks of intervention<sup>(22)</sup>.

In addition, the lack of knowledge on the part of the patients about their disease can result in an obstacle in their treatment, as it creates poorly adaptive behaviors and strategies for coping with pain, such as hypervigilance and disassociation of lifestyle behaviors with the pain condition<sup>(22-23)</sup>. It is believed that the practice of Education in Neurosciences of Pain (ENP) can contribute to a better classification of pain from the perspective of the patients regarding knowledge of pain, catastrophic thinking, fear prevention, depression, anxiety, stress, attitudes and pain behaviors, and use of the health services<sup>(24-26)</sup>. The goal of the therapy is to describe how the nervous system acts by sensitizing peripheral and central nerves and how brain processing interprets tissue information and neural activation, which results in the ability to model pain and that this representation does not always happen in a true manner<sup>(27)</sup>.

As it is a method of good resolution and low cost, ENP becomes an alternative for the economy of the public health system. In this perspective, the use of this method has been a promising strategy to face the problems that are found today in the health area, increasingly showing the bidirectional exchange of knowledge, in which the professional with technical knowledge passes this knowledge on to the patient, who brings popular alternatives closer to reality to deal with his problems.

Therefore, this study aimed to verify the effects of the *Mindfulness* practice associated with the practice of education in neurosciences of pain on the perception of pain in adults diagnosed with fibromyalgia living in a city in the inland of São Paulo. In addition to this variable, the effects of these interventions on sleep, mood and functional capacity of the studied sample were analyzed.

#### Method

#### Study participants and location

This is a controlled and randomized clinical trial, whose participants were people aged 40 years old or older diagnosed with fibromyalgia and treated at the Unified Health System in São Carlos, São Paulo, Brazil. The individuals were randomly allocated in two groups: *Mindfulness* and Education in Neurosciences of Pain Group (MENPG), whose participants underwent both interventions, and in the active control group, whose intervention was the practice of *mindfulness* (MG).

The inclusion criteria were the following: being 40 years old or older, having a medical diagnosis of fibromyalgia, with pain intensity classified as moderate or severe using the Numerical Pain Rating Scale, 0 being considered painless, from 1 to 3 mild pain, 4 to 6 moderate pain, and 6 to 10 severe pain. Individuals who showed signs of cognitive decline by scoring below the cut-off point in the Mini Mental State Examination (MMSE) were excluded – in the case of participating older adults;

having hip or knee limitations, or difficulties in performing movements at ground level; practicing physical activity regularly, corresponding to more than 150 minutes of physical activity weekly; having some acute emotional involvement (an event in the last 5 months leaving the person emotionally vulnerable, such as deaths, accidents and other personal and emotional issues); self-reported obsessive compulsive disorder (OCD); and being under fibromyalgia treatment or undergoing it for less than 3 months. In addition, participants who had more than 25% of absences in the interventions (the equivalent to 3.25 absences) were discontinued.

#### Instruments, data collection and analysis procedures

There were two evaluations (pre- and postintervention) on a previously scheduled day and time. They took place at the School Health Unit of the Federal University of São Carlos (Universidade Federal de São Carlos, UFSCar), in a private environment free from interference. The evaluators were members of the LADORFE (Laboratório de Estudos em Dor e Funcionalidade no Envelhecimento) group. The following was used for data collection: a sociodemographic questionnaire, specifically designed for this study, followed by a numerical scale for the classification of pain intensity, assessment of mental status by the Mini Mental State Examination (MMSE) and specific questions of the exclusion criterion, questions regarding the intensity, location and impact of pain through the Brief Pain Inventory, assessment of functional capacity using the Katz Index of Independence in Activities of Daily Living and Lawton's Instrumental Activities of Daily Living Scale, assessment of sleep quality using the Pittsburgh Scale, screening for depressive symptoms using the Geriatric Depression Scale (GDS), a questionnaire to assess the impact of fibromyalgia on the patient's life (FIQ- impact of fibromyalgia), an anxiety assessment scale (Hospital Anxiety and Depression Scale - HAD), assessment of the degree of catastrophization regarding rumination, learned helplessness and magnification using the Pain Catastrophization Scale, assessment of kinesiophobia, and the approach to pain and its intensity using the Tampa Scale for Kinesiophobia (TSK).

The data were analyzed using descriptive and quantitative statistical analysis in inter- and intra-group comparisons. First, to verify normality, all the data were submitted to the Shapiro-Wilk's test. Subsequently, the Mann-Whitney's U test was used for inter-group analysis, and Wilcoxon's for intra-group analysis. The significance level for both was  $p \leq 0.05$  and, for the analyses, STATISTICA 7.0 was used.

#### Intervention

The MENPG was submitted to Education in Neurosciences of Pain classes, which focused on learning the neurobiology and neurophysiology of painful processes. The ENP meetings lasted 30 minutes each and were held for 3 weeks. After the ENP protocol was completed, the MENPG was then submitted to mindfulness practices, which were carried out at the School Health Unit (Unidade Saúde Escola, USE), located within the Federal University of São Carlos (UFSCar), in partnership with qualified instructors for the development of the *mindfulness* program. The meetings took place twice a week, lasting 1 hour and having 13 sessions. The MG met the same criteria and protocols that were applied in the MENPG, the meditative practices had the same characteristics and duration, although this group was not submitted to Education in Neurosciences of Pain classes.

The intervention in Education in Neurosciences of Pain aimed to establish an educational action in which it could present the neurobiology of painful processes and making understand and answer the main doubts, why they occur, and what measures help or worsen the condition of patients with chronic pain. The intervention was applied by a member of the LADORFE trained to apply the intervention.

For the practice of mindfulness, a protocol adapted from the practice of mindfulness based stress reduction (MBSR) was developed(28). The protocol consisted of a practice in 13 sessions, each meeting lasting 1 hour. Due to the characteristics of the participants, in this adaptation of the protocol there was no immersion day. The practice was based on training the mind and aspects of attention anchored in some cognitive activity or breathing itself. The technique also consisted of training to stop being less reactive to the negative emotions of the day as well as conditioning the moments of happiness to small pleasures and learning to stimulate gratitude and compassion. We emphasize that the professors were qualified to apply the method and that they were blind volunteers during the study, that is, they did not know which of the participants had attended Education in Neurosciences of Pain classes.

### Ethical aspects

The requirements of Resolution 466/2012 regulated by the National Health Council, which deals with research involving human beings were respected. Only adults and older adults who agreed to participate and signed the Free and Informed Consent Form took part in this study. This study was approved by the

Ethics Committee of Research in Human Beings of the Federal University of São Carlos (opinion number: 2,848,109).

### **Results**

Figure 1 shows the flowchart of the progression of this study. The intervention took place in two stages: one in the second semester of 2018 and another at the beginning of the first semester of 2019. The recruitment of participants took place through dissemination on social media such as Facebook, Radio UFSCar, city newspapers, pamphlets, posters, and oral dissemination in waiting rooms of Basic Health Units (BHUs). At the first moment, we evaluated 15 volunteers who expressed interest in participating in the project, of which 9 were included as they met the research criteria. Of these, 5 were excluded either for dropping out or for exceeding the limit of absences stipulated at the time of the intervention. In the second part of the study, 92 individuals expressed an interest to participate; 39 of them were evaluated and 36 were included. At the end, 21 volunteers were discontinued from the study either for dropping out or for exceeding the limit of absences stipulated at the time of the intervention. The reasons why some volunteers gave up were the following: health problems, both of the participants and of the participants' relatives; environmental adversities such as the difficulty of transportation and/or financial difficulty to reach the place where the research was carried out; in addition to unfamiliarity with the practice, which, for consisting of a mental training and a learned cognitive capacity, takes into account subjective and intrinsic aspects of the participants.

The data of the MENPG members (n=7) are shown in Table 1. All the participants were female, with a mean age of 58.5 years old (± 12.84), and with a mean score of 7.5 (± 1.98) on the Numerical Pain Rating Scale. Five of the participants were married, one single and one widow; two had incomplete high school, two had complete high school, two with complete elementary school and one with complete higher education. In the MG (n=12), eleven participants were female. The mean age of this group was 54 years old (± 7.22), and the mean score on the Numerical Pain Rating Scale was 6.25 (± 1.71). Of the participants, eight were married, two single and two divorced. Regarding schooling, two had incomplete elementary school, three had complete high school, five had complete higher education and two had postgraduate degrees. The MG data are shown in Table 1.

#### Research flowchart First application moment Second application moment of the research of the research (September to December 2018) (February to April 2019) Project disclosure Project disclosure (September to October 2018) (January to February 2019) Assessment of the Research Subjects Assessment of the Research Subjects for the MENPG and MG groups for the MENPG group (January 5th to February 30th, 2019) (October 8th to October 19th, 2018) Total of interested: 92 Total of interested: 15 Total of assessments: 39 Total of assessments: 15 Included: 36 (15 in the MENPG group Included: 9 and 21 in the MG group) Excluded: 6 Excluded: 3 Intervention in ENP Intervention in ENP for the MENPG group for the MENPG group (October 15th, 17th and 19th, 2018) (January 30th to February 13th, 2019) Intervention in Meditation Intervention in Meditation (October 22nd to (February 15th to December 3<sup>rd</sup>, 2018) April 9th, 2019) Dropouts: 5 participants Dropouts: 21 participants MENPG: 3 participants MENPG: 4 participants MG: 1 participant MG: 11 participants Remaining: 4 participants Remaining: 15 participants Reassessment of the research subjects Reassessment of the research subjects (December 4th to December 13th) (April 10th to April 25th) Data analysis and production of the results and discussion

\*MENPG - Mindfulness and Education in Neurosciences of Pain Group; †ENP = Education in Neurosciences of Pain; †MG = Meditation Group

(May and June)

Figure 1 - Flowchart of the research development, São Carlos, SP, Brazil, 2020

Table 1 - Characterization of the MENPG\*. São Carlos, SP, Brazil, 2020

Code	Age (years old)	Gender	Schooling	Marital status	Numerical Pain Rating Scale	Katz Scale	Lawton Scale	
C1	70	Fem <sup>†</sup>	CES <sup>‡</sup>	Single	9	Dependent on 1 BADLs§ Partially Dep		
C2	51	Fem <sup>†</sup>	IHSII	Married	9			
C3	81	Fem <sup>†</sup>	IHSII	Widow	7	Dependent on 1 BADLs§	Independent	
C7	52	Fem <sup>†</sup>	CHS <sup>¶</sup>	Married	8	-	-	
C8	61	Fem <sup>†</sup>	CHE**	Married	5	Dependent on 1 BADLs§	Independent	
C14	49	Fem <sup>†</sup>	CES‡	Married	5	-	-	
C15	46	Fem⁺	CHS¶	Married	10	-	-	
Code	Age (years old)	Gender	Schooling	Marital status	Katz Scale	Lawton Scale		
C4	57	Fem <sup>†</sup>	IES <sup>††</sup>	Married	-		-	
C5	57	Fem <sup>†</sup>	CHE**	Married	-		-	
C6	50	Fem <sup>†</sup>	CHE**	Married	-		-	
C9	57	Fem <sup>†</sup>	PG§	Single	-		-	

(to be continued...)

Table 1 - continuation

Code	Age (years old)	Gender	Schooling	Marital status	Katz Scale	Lawton Scale
C10	54	Fem <sup>†</sup>	CHS¶	Married	-	-
C11	53	Fem <sup>†</sup>	CHS¶	Married	-	-
C12	44	Fem <sup>†</sup>	CHS <sup>¶</sup>	Married	-	-
C13	59	Fem <sup>†</sup>	CHE**	Divorced	-	-
C16	64	Fem <sup>†</sup>	CHE**	Divorced	Independent in all BADLs <sup>§</sup>	Independent
C17	64	Fem <sup>†</sup>	IES††	Single	Independent In all BADLs§	Independent
C18	48	Male	CHE**	Married	-	-
C19	41	Fem <sup>†</sup>	PG <sup>‡‡</sup>	Married	-	-

\*MENPG = Mindfulness and Education in Neurosciences of Pain Group; \*Fem = Female; \*CES = Complete Elementary School; \*BADL = Basic Activities of Daily Life - Note that not all patients were older adults; therefore, not all were submitted to instruments developed for the older adult population; \*IHIS = Incomplete High School; \*CHS = Complete High School; \*\*CHE = Complete Higher Education; \*IES = Incomplete Elementary School; \*FG = Post-Graduation

There was a significant difference between the groups at the pre-intervention moment in the variable measured by the Fibromyalgia Impact Questionnaire - FIQ (p=0.02), but not in the post-intervention assessment. Table 2 shows the results of the pre- and post-intervention assessments and the p-values for the analyses conducted. It can be observed that the groups had no significant differences and that the results of the post-intervention evaluations had a better expression.

In the Brief Pain Inventory, a significant difference was found for the "worst pain in the last 24 hours" (p=0.03), "average pain" (p=0.04) and "interference of pain in mood" (p=0.02) variables. Table 4 shows the pre- and post-intervention values for the aforementioned instrument.

Intra-group analyses were also carried out. As shown in the table below, the MENPG group showed significant differences in the points of pain (p=0.017),

milder pain in the last 24 hours (p=0.017), pain interference in general activities (p=0.027) and pain interference in sleep (p=0.02) variables for the Brief Pain Inventory. There was also a difference in the FIQ result (p=0.017) and in the catastrophizing and kinesiophobia variables (p=0.017). Table 4 shows the results of the pre- and post-intervention analysis for the MENPG. Regarding the analysis of the MG, a significant difference was observed for the following variables: points of pain (p=0.002), pain interference in general activities (p=0.018), pain interference in mood (p=0.034), pain interference in walking (p=0.024), pain interference at work (p=0.003), interference in relationships (p=0.010) and pain interference in sleep (p=0.005) in the Brief Pain Inventory, as well as in the fibromyalgia impact questionnaire (p=0.007), in the symptoms of anxiety (p=0.001) and depression (p=0.02). Table 4 shows the results of the assessments for the MG.

**Table 2 -** Comparison of the performance of the meditation and pain neuroscience group and the meditation group in the pre- and post-intervention assessments. São Carlos, SP, Brazil, 2020

	Groups							
Evaluation instruments		Pre-evaluation		Post-evaluation				
	MENPG*	MG <sup>†</sup>	р	MENPG*	MG <sup>†</sup>	Р		
FIQ‡	69.42 ± 8.75	55.44 ± 13.01	0.02	31.95 ± 18.94	33.42 ± 20.85	0.75		
HAD <sup>§</sup>	8.57 ± 1.90	10.75 ± 3.72	0.14	5.85 ± 3.80	7.33 ± 4.03	0.65		
Anxiety	7.85 ± 5.52	8.5 ± 3.23	0.55	3 ± 3.55	6.41 ± 3.72	0.06		
Depression	13.42 ± 2.57	11.41 ± 5.45	0.58	6.57 ± 3.69	7.08 ± 4.39	0.96		
Sleep quality	27.28 ± 9.46	23.66 ± 12.69	0.75	12.85 ± 9.80	11.33 ± 9.34	0.71		
Catastrophization	43 ± 7.34	41.36 ± 9.03	0.61					
Kinesiophobia								

<sup>\*</sup>MENPG = Mindfulness and Education in Neurosciences of Pain Group; 'MG = Meditation Group; 'FIQ = Fibromyalgia Impact Questionnaire; <sup>§</sup>HAD = Hospital Anxiety and Depression Scale

**Table 3** - Comparison of the performance of the MENPG\* and MG<sup>†</sup> groups for the Brief Pain Inventory in the pre- and post-intervention assessments. São Carlos, SP, Brazil, 2020

	Groups					
		Before				
	MENPG*	MG <sup>†</sup>	p-value	MENPG*	MG <sup>†</sup>	p-value
Points of pain	40.42 ± 5.12	11 ± 8.28	0.22	36.91 ± 11.01	13.16 ± 11.91	0.82
Worst pain (24h)	8.57 ± 1.81	5.71 ± 2.62	0.03	6.08 ± 1.83	4.25 ± 3.04	0.36
Milder pain (24h)	5.14 ± 2.34	2.85 ± 2.41	0.36	3 ± 1.53	1.91 ± 2.10	0.20
Average Pain	7.14 ± 2.34	5 ± 2.38	0.04	4.75 ± 1.48	3.5 ±2.71	0.17
Pain at the moment	5.85 ±2.79	2.14 ± 3.18	0.71	$3.66 \pm 2.01$	1.66 ± 2.38	0.96
Pain relievers	4.42 ± 2.14	4 ± 2	0.07	5.66 ± 2.26	6 ± 1.77	0.52
Interference in: General activities	8.71 ± 1.49	3 ± 4.04	0.58	6.5 ± 2.61	2.66 ± 2.41	0.31
Mood	4 ± 4.04	2 ± 2.88	0.02	7.54 ± 1.63	2.58 ± 2.84	0.38
Walking	7 ± 3.41	$4.42 \pm 3.99$	0.65	$5.75 \pm 2.34$	$2.66 \pm 3.28$	0.65
Work	$6.85 \pm 3.07$	$4.42 \pm 3.30$	0.96	$6.5 \pm 2.46$	3.16 ± 2.69	0.31
Relationship status	5 ± 4.86	1 ± 1.91	0.92	$5.33 \pm 3.39$	1.58 ± 2.02	0.38
Sleep	8.85 ± 1.67	$3.28 \pm 4.34$	0.71	6.41 ± 3.98	2 ± 2.33	0.65
Ability to enjoy life	7.57 ± 2.87	2.14 (±3.93)	0.49	6.25 ± 3.41	2.91 ± 3.02	0.44

<sup>\*</sup>MENPG = Mindfulness and Education in Neuroscience of Pain Group; †MG = Meditation Group

**Table 4 -** Intra-group analysis of the MENPG\* and  $MG^{\dagger}$  groups for pre- and post-intervention assessments. São Carlos, 2020

MENDOi-blast	A	Dt		MOIIIt	A	D	
MENPG variables*	Assessment	Reassessment	р	MG <sup>IIII</sup> variables <sup>†</sup>	Assessment	Reassessment	р
Points of pain	40.42 ± 5.12	11 ± 8.28	0.01	Points of pain	36.91 ± 11.01	13.16 ± 11.91	0.00
Worst pain	8.57 ± 1.81	5.71 ± 2.62	0.12	Worst pain	6.08 ± 1.83	$4.25 \pm 3.04$	0.05
Milder pain	5.14 ± 2.34	$2.85 \pm 2.41$	0.01	Milder pain	3 ± 1.53	1.91 ± 2.10	0.24
Average pain	$7.14 \pm 2.34$	5 ± 2.38	0.12	Average pain	4.75 ± 1.48	$3.5 \pm 2.71$	0.18
Pain at the moment	5.85 ±2.79	2.14 ± 3.18	0.06	Pain at the moment	3.66 ± 2.01	1.66 ± 2.38	0.06
Pain relievers†	4.42 ± 2.14	4 ± 2	0.34	Pain relievers	5.66 ± 2.26	6 ± 1.77	0.06
Int activ‡	8.71 ± 1.49	$3 \pm 4.04$	0.02	Int activ‡	6.5 ± 2.61	2.66 ± 2.41	0.01
Int mood <sup>§</sup>	4 ± 4.04	2 ± 2.88	0.28	Int mood <sup>§</sup>	7.54 ± 1.63	2.58 ± 2.84	0.03
Int walking <sup>∥</sup>	7 ± 3.41	$4.42 \pm 3.99$	0.07	Int walking <sup>  </sup>	5.75 ± 2.34	2.66 ± 3.28	0.02
Int work¶	$6.85 \pm 3.07$	$4.42 \pm 3.30$	0.17	Int work¶	$6.5 \pm 2.46$	3.16 ± 2.69	0.00
Int relat**	5 ± 4.86	1 ± 1.91	0.06	Int relat**	$5.33 \pm 3.39$	1.58 ± 2.02	0.01
Int sleep††	8.85 ± 1.67	$3.28 \pm 4.34$	0.02	Int sleep††	6.41 ± 3.98	2 ± 2.33	0.00
Int ab <sup>‡‡</sup>	7.57 ± 2.87	$2.14 \pm 3.93$	0.06	Int ab <sup>‡‡</sup>	6.25 ± 3.41	2.91 ± 3.02	0.13
FIQ <sup>§§</sup>	69.42 ± 8.75	31.95 ± 18.94	0.01	FIQ <sup>§§</sup>	55.44 ± 13.01	33.42 ± 20.85	0.00
Anxiety	8.57 ± 1.90	$5.85 \pm 3.80$	0.15	Anxiety	$10.75 \pm 3.72$	$7.33 \pm 4.03$	0.00
Depression	$7.85 \pm 5.52$	$3 \pm 3.55$	0.10	Depression	$8.5 \pm 3.23$	6.41 ± 3.72	0.02
Catastrophization	27.28 ± 9.46	12.85 ± 9.80	0.01	Catastrophization	23.66 ± 12.69	11.33 ± 9.34	0.00
Kinesiophobia	$43 \pm 7.34$	43.71 ±10.59	0.75	Kinesiophobia	41.36 ± 9.03	43.66 ± 8.95	0.12
Sleep	13.42 ± 2.57	6.57 ± 3.69	0.01	Sleep	11.41 ± 5.45	$7.08 \pm 4.39$	0.00

<sup>\*</sup>MENPG = Mindfulness and Education in Neurosciences of Pain Group; \*Int activ = Interference of pain in general activities; \*Int mood = Interference of pain in mood; "Int walking = Interference of pain in walking; \*Int work = Interference of pain at work; \*\*Int relat = Interference of pain in relationships; \*Int sleep = Interference of pain in sleep; \*Int ab = Interference with the ability to enjoy life; \*SFIQ = Fibromyalgia Impact Questionnaire; ||||MG = Meditation Group

### **Discussion**

The present study aimed to analyze the effects of the therapy based on the Mindfulness method with an association with the Education in Neurosciences of Pain on the interference of pain, functional capacity, mood and sleep of adults and older adults with Fibromyalgia in a city in the inland of São Paulo. For this, the research relied on the longitudinal and quantitative analysis of two intervention groups: the MG (Meditation Group) and

the MENPG (Meditation and Education in Neurosciences of Pain Group). The results obtained suggest that both interventions have a positive impact on the fibromyalgia symptoms, functional capacity, mood and sleep levels of people affected by this disease.

The results of intra-group comparisons suggest that the proposed interventions benefited the participants with improvements in most of the variables studied. The *Mindfulness*-based intervention associated with the education in neurosciences of pain proved to be effective

in reducing the perception of pain and its interference in general activities and in sleep, in the questionnaire on the impact of fibromyalgia on catastrophization and quality of sleep. The group that participated only in the *Mindfulness*-based intervention, on the other hand, showed not only the improvement in the variables mentioned for the previous group, but also improved in the score of the anxiety and depression symptoms.

No significant differences were observed after the interventions when the groups were compared. However, as improvements were observed in the intra-group analyses, we can infer that, in general, the interventions provide benefits, but their effects do not differ.

Mindfulness is currently gaining prominence in the field of neuroscience for its contributions, including at the brain level (29-30). Research studies involving Mindfulness-based interventions have shown considerable improvements in the levels of insomnia, depression, anxiety and management of fibromyalgia, which suggests an important role in cognitive theories of sleep and in poorly adaptive behaviors in relation to pain(15,30-31). In line with the literature, our study demonstrated such benefits.

Studies that show the impact of Mindfulness-based therapies on the physical and psychological symptoms of fibromyalgia show that attention levels are associated with lesser impacts of the disease, which can result in positive results in the sleep, relationship with pain and relationship with disease variables<sup>(32)</sup>. Although a specific scale was not used to assess the participants' attention, this study demonstrated that they had not only improved sleep, but also the perception of pain interference in relationships, as well as the perception of pain itself.

In addition, the researchers<sup>(33)</sup> emphasize the importance of developing well-structured mechanisms and approaches, detecting common influential factors and how the association of the practice linked to other therapies can have different results. The frequency of practices and affinity are also noteworthy as they can directly influence the results that the practice can offer<sup>(11,15,32-33)</sup>. These considerations justify the discontinuity of the participants who had absences above the pre-established limits.

The literature recognizes that a biopsychosocial treatment for pain chooses to use cognitive, emotional and behavioral skills, understood by comprehensive strategies that meet the levels of pain complexity and a holistic view of the patient, and contribute to the reduction of pain and suffering<sup>(11)</sup>. Therefore, considering the perspective that fibromyalgia has multiple factors influencing pain, strategies such as the ENP have been gaining recognition to mitigate the psychological and also physical effects of the disease. Despite the literature showing improvements in pain, disability and

levels of catastrophization, the difference in results from the different doses applied is still questioned. In this study, the intervention with neurosciences of pain for the MENPG lasted three weeks and we did not observe significant differences when comparing it with the MG. A number of studies suggest that higher dosages may lead to a decrease in pain intensity in patients with fibromyalgia followed-up over three months<sup>(34-35)</sup>.

The ENP applied in isolation<sup>(35)</sup> does not demonstrate a viable intervention for the modification of these variables. The authors emphasize the importance of the way in which the application of the technique must be conducted, which should involve a specialized clinician and provide training to the education provider, which would result in a better experience for the patient. For this reason, this work proposed to apply such an intervention together with the practice of the *Mindfulness*-based intervention.

In our study, we observed the discontinuity of some participants, who reported non-adaptation to the practice of *Mindfulness*. In this sense, better adherence and engagement for those who have an affinity for the practice of meditation helps these individuals to remain in the intervention programs<sup>(33)</sup>. According to the authors, this provides a better adaptation of the practice in the participants' daily lives.

The feelings and disconnection and fragmentation that often accompany suffering and the encouragement to release the prisons from our own habits and thoughts, which includes changes in life habits and the intention to cultivate compassion for life, predicted in the bases of meditation mechanisms focused on compassion, emphasizing improving feelings of connection, belonging and less rigid standards<sup>(33)</sup>.

As additional results, the experience of group practice provided greater understanding and acceptance among the individuals, which can contribute to greater sharing of experiences, sociability and reflections on the participants' daily lives, providing the experience of describing feelings and emotions and collective acceptance.

As a limitation, we mention the non-evaluation of the multiple facets of *Mindfulness*, which can be important for the integral understanding of the patient's condition and to attend to possible difficulties that the patient may encounter with the technique. In addition, the participants' level of attention was not assessed. Finally, the difficulty of reaching the practice site may have been a barrier to the participants.

## Conclusion

This study aimed to analyze the effects of the *Mindfulness*-based therapy and if associated with Education in Neurosciences of Pain, which in turn

consists of reconceptualizing pain and by exposing knowledge about pain neurobiology, in patients with fibromyalgia in the inland of São Paulo. As a result, we could notice that the meditative technique has good efficacy, attenuating the symptoms of chronic pain, functional capacity and psychological symptoms. Although the literature points out the beneficial effects of education in neurosciences of pain on catastrophic thoughts and kinesiophobia, in this research it was not possible to notice statistically significant differences in inter-group analyses. However, significant improvements were observed in the intra-group analyses for both interventions, which suggests that both the Mindfulness intervention and the association of Mindfulness with pain neuroscience can be beneficial for patients with fibromyalgia.

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#### **Author's Contribution**

Study concept and design: Lucas Pelegrini Nogueira de Carvalho, Lílian Silva Araújo, Maria do Perpétuo Socorro Lage Avelar, and Karina Gramani Say. Obtaining data: Lílian Silva Araújo and Maria do Perpétuo Socorro Lage Avelar. Data analysis and interpretation: Lucas Pelegrini Nogueira de Carvalho, Lílian Silva Araújo and Karina Gramani Say. Statistical analysis: Lílian Silva Araújo and Karina Gramani Say. Drafting the manuscript: Lucas Pelegrini Nogueira de Carvalho, Lílian Silva Araújo and Karina Gramani Say. Critical review of the manuscript as to its relevant intellectual content: Lucas Pelegrini Nogueira de Carvalho, Maria do Perpétuo Socorro Lage Avelar, and Karina Gramani Say. Others (Application of the mindfulness technique): Maria do Perpétuo Socorro Lage Avelar.

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Corresponding Author:
Karina Gramani Say
E-mail: kagramanis@yahoo.com.br
bhttps://orcid.org/0000-0002-2451-8109