

Intervenções não-farmacológicas sobre a dor crônica, limitações funcionais, qualidade de vida e de sono e saúde mental na fibromialgia: protocolo de revisão sistemática

Non-pharmacological interventions on chronic pain, functional limitations, quality of life and sleep, and mental health in fibromyalgia: systematic review protocol

Intervenciones no farmacológicas sobre el dolor crónico, limitaciones funcionales, calidad de vida y del sueño y salud mental en la fibromialgia: protocolo de revisión sistemática

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Como citar: Piedade CS¹, Santos EN², Santana LMA³, Pinheiro ES⁴, Silva GC⁵, Silva KSA⁶, Aguiar DS⁷, Paineiras-Domingos LL⁸. Intervenções não-farmacológicas na fibromialgia: protocolo de revisão sistemática. REVISA. 2026; 15(3): 41-48. Doi: <https://doi.org/10.36239/revisa.v15.n3.p1a11>

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Recebido: 13/01/2026
Aprovado: 27/03/2026

RESUMO

Objetivo: apresentar o protocolo de uma revisão sistemática que seja capaz de investigar a eficácia das abordagens não-farmacológicas na fibromialgia, considerando a dor crônica, limitações funcionais, desdobramentos emocionais e psicossociais, a qualidade de vida e do sono. Métodos: Protocolo de revisão sistemática registrado no PROSPERO (CRD420251175399). Bases consultadas: LILACS, PubMed, SciELO, PEDro database, Web of Science, Biblioteca Cochrane. Incluídos ensaios clínicos randomizados publicados entre 2015 e 2025. A qualidade metodológica dos estudos será avaliada por meio da ferramenta RoB 2. Os resultados serão organizados e apresentados através da sua síntese.

Descritores: Fibromialgia; Dor; Dor Crônica; Qualidade de Vida; Qualidade do Sono; Insônia; Depressão; Disfunção Motora; Estresse; Ansiedade; Fadiga Muscular

ABSTRACT

Objective: to present the protocol of a systematic review capable of investigating the effectiveness of non-pharmacological approaches in fibromyalgia, considering chronic pain, functional limitations, emotional and psychosocial outcomes, quality of life, and sleep. Methods: Systematic review protocol registered in PROSPERO (CRD420251175399). Databases consulted: LILACS, PubMed, SciELO, PEDro database, Web of Science, Cochrane Library. Included were randomized clinical trials published between 2015 and 2025. The methodological quality of the studies will be assessed using the RoB 2 tool. The results will be organized and presented through their synthesis.

Descriptors: Fibromyalgia; Pain; Chronic Pain; Quality of Life; Sleep Quality; Insomnia; Depression; Motor Dysfunction; Stress; Anxiety; Muscle Fatigue

RESUMEN

Objetivo: presentar el protocolo de una revisión sistemática capaz de investigar la eficacia de los enfoques no farmacológicos en la fibromialgia, considerando el dolor crónico, las limitaciones funcionales, las repercusiones emocionales y psicosociales, la calidad de vida y del sueño. Métodos: protocolo de revisión sistemática registrado en PROSPERO (CRD420251175399). Bases consultadas: LILACS, PubMed, SciELO, base de datos PEDro, Web of Science, Biblioteca Cochrane. Se incluyeron ensayos clínicos aleatorizados publicados entre 2015 y 2025. La calidad metodológica de los estudios será evaluada mediante la herramienta RoB 2. Los resultados se organizarán y presentarán a través de su síntesis.

Descriptores: Fibromialgia; Dolor; Dolor Crónico; Calidad de Vida; Calidad del Sueño; Insomnio; Depresión; Disfunción Motora; Estrés; Ansiedad; Fatiga Muscular

Introduction

Fibromyalgia is characterized as a chronic pain syndrome of multifactorial origin, whose main clinical manifestation consists of the presence of diffuse and persistent musculoskeletal pain in different regions of the body¹. However, its impacts extend beyond the painful experience, encompassing several functional limitations, such as sleep disturbances, especially non-restorative and fragmented sleep, intense fatigue, and impairment of cognitive functions. In addition, studies indicate a strong association between fibromyalgia and psychological disorders, particularly anxiety and depression, which may both intensify and be aggravated by the physical symptoms of the syndrome².

Due to its multisystemic nature, the disease generates important clinical and psychosocial repercussions, significantly compromising the functionality and quality of life of affected individuals.

In the epidemiological context, fibromyalgia has an estimated worldwide prevalence ranging from 0.2% to 4.7% of the population. In Brazil, it is estimated that approximately 2.5% of the population is affected by the syndrome, with an unequal distribution between the sexes². The condition is more frequent in women, who account for approximately 90% of diagnosed cases. Despite this female predominance, scientific evidence demonstrates that fibromyalgia may also occur in men, older adults, adolescents, and children, reinforcing the need for clinical investigation regardless of the individual's age or sex^{2,3}.

Socioeconomic aspects also influence the manifestation and severity of the syndrome. Fibromyalgia is frequently observed in women living in contexts of social, economic, and political vulnerability^{4,5}. Research indicates that women younger than 60 years tend to present more intense and disabling symptoms. From a clinical and pathophysiological perspective, women have a greater predisposition to developing generalized chronic pain when compared to men, as well as a higher probability of presenting increased sensitivity at multiple anatomical points evaluated during physical examination^{3,6,7}. This condition of central sensitization contributes to explaining both the high prevalence of fibromyalgia among women and the epidemiological differences observed in several studies worldwide.

The symptoms of fibromyalgia are varied and involve both pain and alterations in different body systems. The main manifestation is generalized musculoskeletal pain, which usually affects regions such as the neck, lower back, shoulders, and joints, and is related to increased pain sensitivity caused by alterations in the central nervous system⁸. In addition, the presence of intense and persistent fatigue is common, as well as sleep disorders, including insomnia and the sensation of non-restorative sleep, in addition to association with anxiety and depression, which are factors contributing to the worsening of pain⁹.

The syndrome may also cause cognitive difficulties, known as "brain fog," which affect memory, attention, and concentration¹⁰. In addition to these symptoms, there is increased sensitivity to external stimuli, such as touch, light, noise, and strong odors, which may increase discomfort and significantly impact patients' quality of life¹¹.

Physical exercise may be used as a non-pharmacological strategy for the treatment of fibromyalgia. Among the most commonly used modalities, aerobic exercise stands out,

as it reduces pain, fatigue, and depression, in addition to promoting improvements in health, quality of life, and physical fitness among patients with fibromyalgia¹².

In this context, studies identify acupuncture as another effective method. This technique has the ability to stimulate the release of endorphins and enkephalins by the body, modulating pain perception through the action of neurotransmitters¹³. Thus, in the Brazilian context, the National Policy on Integrative and Complementary Practices (PNPIC)¹⁴, established in 2006 and incorporated into the Unified Health System (SUS), expanded health promotion actions and the lines of care directed toward patients with fibromyalgia¹⁵.

Among the approaches included in this policy are acupuncture, traditional Chinese medicine, homeopathy, and several complementary therapies. These practices have been used as alternatives in the management of chronic pain syndromes and psychiatric disorders¹⁶.

Given the above, this protocol aims to present a proposal for a systematic review capable of investigating the effectiveness of non-pharmacological approaches in addressing the functional limitations of the syndrome, in addition to examining factors related to chronic pain, emotional and psychosocial outcomes, quality of life, and sleep patterns in this population. It is expected that this study will provide a comprehensive overview of the clinical course of fibromyalgia, offering support for more accurate clinical management aligned with the real needs of affected individuals.

Methodology

This is a systematic review protocol, publicly registered in the International Prospective Register of Systematic Reviews (PROSPERO) under registration number CRD420251175399. Through this protocol, it is intended to use a methodological strategy to ensure research transparency and avoid duplication of efforts, including a description of the problem of interest, the inclusion criteria, the search strategies, the information sources, and the procedures for data analysis and presentation.

The entire structure of this protocol was developed in accordance with the documentary recommendations of the **Joanna Briggs Institute (JBI)**¹⁷ and The Cochrane Collaboration¹⁸.

The systematic review, in turn, will be structured according to the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 checklist¹⁹.

Structure of the Research Question

Aiming to identify studies that evaluate aspects related to myocardial or peripheral revascularization surgery, with a racial focus identifying Black patients; to present the main clinical outcomes reported in the studies, such as complications, mortality, and associated comorbidities; to identify levels of functional capacity and quality of life; and to discuss the implications of the findings for cardiovascular rehabilitation, for understanding healthcare delivery, and for ensuring racial equity in health, the research question guiding this review was structured based on the PICO strategy, namely (P = Population; I = Intervention; C = Context; O = Outcomes; and S = Type of studies to be analyzed in this review (studies))¹⁷. The information representing each criterion can be identified in **Table 1**.

Table 1- Structure of the research question. Salvador, BA, Brazil, 2025

Population	Adults (over 18 years of age) diagnosed with fibromyalgia
Intervention	Non-pharmacological interventions
Context	-----
Outcomes	At least one of the following: type and level of pain, functional limitations, mental health, quality of life, sleep quality, anxiety, depression, and stress.
Type of studies	Randomized clinical trials

Inclusion and Exclusion Criteria

The inclusion criteria for studies in this review will consider: (a) studies investigating adults (≥ 18 years) diagnosed with fibromyalgia; (b) studies published and available in English, Spanish, and Portuguese. The adopted time frame will correspond to the period from December 2015 to October 2025.

Studies investigating adults (≥ 18 years) diagnosed with fibromyalgia without pain and functional limitations, and adults (≥ 18 years) diagnosed with associated chronic and clinical conditions will be excluded.

Search Strategies

The main databases to be searched are: Latin American and Caribbean Health Sciences Literature (LILACS) and PubMed. Other important or specialized databases that will be searched include: SciELO, the PEDro database, Web of Science, and the Cochrane Library.

The search strategy will follow the three-step process recommended by the JBI17, consisting of: the first step, identification of keywords and construction of a logical search framework, based on knowledge of the field, initially guiding the research with the development of specific search strategies for each database. The second step involves conducting the search itself in each specific database, as described in the protocol. The third step involves reviewing the reference lists of all retrieved studies for subsequent evaluation and inclusion of additional studies.

The following descriptors extracted from the Health Sciences Descriptors (DeCS) platform or the Medical Subject Headings (MeSH) will be used, combined with the Boolean operators "AND" and "OR" to generate the search strategy: fibromyalgia AND chronic pain OR quality of life OR sleep quality AND functional limitation OR anxiety OR depression AND non-pharmacological treatment / fibromyalgia AND chronic pain OR quality of life OR sleep quality AND functional limitation OR anxiety OR depression AND non-pharmacological treatment. Each search strategy formulated for the respective databases will be described at the end of the systematic review.

Study Selection and Data Extraction

After the searches, all retrieved studies will be exported to Rayyan Web20 for the identification and exclusion of duplicates, followed by the organization of publications and study selection according to the eligibility criteria, through the reading of the respective titles and abstracts by two independent reviewers.

Study Assessment

To assess the quality of the selected studies, the Cochrane Risk of Bias 2 (RoB-2) assessment tool^{21,22} will be used.

The data will be assessed independently by at least two individuals (or a person/machine combination), with a process in place to resolve disagreements.

Additional information will not be requested from the study investigators if the necessary information is unclear or unavailable in the study publications/reports.

Data Analysis, Synthesis, and Presentation

The systematic review will gather as its main outcomes the type and level of pain, functional limitations (fatigue), and quality of life. Additional outcomes will include sleep quality (sleep disorders) and mental health (depressive and anxiety symptoms).

All extracted data will be organized into Tables (1, 2, and 3).

Table 1 will present the characteristics of the studies (authors, year of publication, study population [gender, race/ethnicity, age, functional profile], study objective, methodology, and the conclusion of each study). Table 2 will present the main results, and Table 3 will present the secondary outcomes.

Acknowledgments

The authors thank the Research Group "Health of the Black Population and Chronic Diseases," UFBA/CNPq for all the support.

Financial Support

The authors declare that they received no financial support.

Conflict of Interest

The authors declare that there is no conflict of interest.

Data Availability Statement

The data from this study are stored by the authors, and data sharing is not available.

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