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GUIDELINES

SIMFER guidelines on physical modalities for chronic primary pain management

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ABSTRACT

Chronic primary pain is a leading cause of disability worldwide and requires a multimodal management approach. Instrumental physical therapies are widely used in rehabilitation, although their effectiveness remains heterogeneous across conditions and modalities. The objective of this paper is to synthesize the evidence and recommendations from the 2026 Clinical Practice Guideline developed by the Italian Society of Physical and Rehabilitation Medicine (SIMFER) on the use of instrumental physical therapies in chronic primary pain (*i.e.*, complex regional pain syndrome, fibromyalgia, and primary bone marrow edema syndromes). The guideline was developed following the GRADE methodology. Systematic searches of Medline, Embase, and Cochrane Library were performed to identify systematic reviews and randomized controlled trials. Evidence was appraised in terms of risk of bias, inconsistency, indirectness, imprecision, and publication bias. Recommendations were formulated using the Evidence-to-Decision framework. The panel issued a conditional recommendation in favor of adding instrumental physical therapies to conventional treatment in patients with fibromyalgia, complex regional pain syndrome, and primary bone marrow edema syndromes. Evidence suggests modest to large improvements in pain and disability for specific modalities such as TENS, low-level laser therapy, and electromagnetic field therapy. However, overall certainty of evidence ranged from moderate to very low due to methodological limitations and heterogeneity. Adverse events were generally mild and transient, and patient acceptability was high. Instrumental physical therapies may be considered as adjunctive interventions within a multimodal rehabilitation approach for chronic primary pain. Despite encouraging findings, the low certainty of evidence highlights the need for high-quality trials with standardized protocols and long-term follow-up to strengthen future recommendations.

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KEY WORDS: Chronic pain; Physical therapy modalities; Rehabilitation; Guideline; Fibromyalgia.

Introduction

Chronic primary pain (CPP) is a distinct clinical condition recognized in the International Classification of Diseases 11th Revision (ICD-11) and defined as pain persisting or recurring for longer than three months, associated with significant emotional distress and/or functional disability, and not entirely explained by another medical condition.[1, 2] CPP represents a major public health issue and is associated with substantial impairment in physical functioning, psychological well-being, social participation, and quality of life. In recent years, increasing attention has been directed toward nociplastic pain mechanisms, central sensitization, and altered pain modulation processes underlying these conditions.[2]

The most clinically relevant CPP conditions are fibromyalgia and complex regional pain syndrome (CRPS). Fibromyalgia is characterized by chronic widespread pain associated with fatigue, sleep disturbances, cognitive symptoms, and psychosocial distress.[3] It affects approximately 2-3% of the general population and is considered a prototypical nociplastic pain condition. CRPS is a disabling regional pain disorder characterized by disproportionate pain, sensory abnormalities, autonomic dysfunction, trophic changes, and motor impairment, typically occurring after trauma or surgery.[4, 5] From an anatomo-pathological perspective, CRPS is sometimes associated with bone marrow lesions, which do not represent a clearly defined nosological entity but rather an imaging finding linked to heterogeneous conditions. Although less prevalent than fibromyalgia, CRPS is associated with severe disability and considerable healthcare burden.

Management of CPP requires a multimodal and biopsychosocial approach integrating pharmacological and non-pharmacological interventions.[6] However, pharmacological treatments often provide only partial symptomatic relief and may be associated with adverse effects limiting long-term adherence.[7] Consequently, rehabilitation interventions play a central role in the management of CPP.

Among non-pharmacological interventions, instrumental physical therapies are widely used in rehabilitation settings. These include electrotherapy, electromagnetic field therapy, laser therapy, cryotherapy, radiofrequency therapies, ultrasound, and vibration therapies. Their rationale is based on the modulation of nociceptive transmission, neuroinflammatory processes, muscle function, and central pain mechanisms.[8, 9] Despite their widespread use, evidence regarding their effectiveness remains heterogeneous, with variability across conditions, treatment protocols, and outcome measures.

To address this issue, the Italian Society of Physical and Rehabilitation Medicine (SIMFER) developed a national clinical practice guideline on the use of instrumental physical therapies in chronic primary pain.

Methods

Guideline development

This manuscript presents a focused synthesis of the SIMFER Clinical Practice Guideline on instrumental physical therapies for chronic primary pain. The guideline was developed according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology.[10]

The recommendation process involved a multidisciplinary panel including specialists in physical and rehabilitation medicine, rheumatology, methodology, physiotherapy, and patient representatives. Methodological support and evidence synthesis were provided by the team of the Laboratory of Methodology of Systematic Reviews and Guidelines production, Istituto di Ricerche Farmacologiche Mario Negri IRCCS (Milan, Italy).

Composition of the panel

The guideline was developed by a multidisciplinary panel comprising experts in physical and rehabilitation medicine, methodology, and health research, as well as representatives of scientific societies, allied health professionals, and patient organizations. The panel included clinicians with expertise in musculoskeletal rehabilitation and rheumatology, alongside a medical statistician, and representatives from the SIMFER, the Italian Society of Rheumatology (SIR), and the National Federation of Physiotherapists (FNOFI). Patient perspectives were ensured through the involvement of national associations, including the National Association of People with Rheumatic and Rare Diseases (APMARR) and Cittadinanzattiva.

A methodological working group affiliated with the Istituto di Ricerche Farmacologiche Mario Negri IRCCS (Milan, Italy) was responsible for evidence appraisal and synthesis, ensuring adherence to rigorous methodological standards. The panel operated under defined leadership roles, including a chair, co-chair, and a methodological chair. The guideline development process also included independent external reviewers with recognized expertise in rehabilitation and evidence-based medicine, including rep-

resentatives from the International Society of Physical and Rehabilitation Medicine (ISPRM) and the Cochrane Rehabilitation, Functioning, and Disability thematic group, who critically appraised the document prior to finalization.

Clinical question

The clinical question addressed in this manuscript was formulated according to the PICO framework as follows:

In individuals with chronic primary pain (fibromyalgia, primary bone marrow edema syndromes, and complex regional pain syndrome), is instrumental physical therapy, alone or in combination with conventional therapy, recommended compared with no treatment or conventional therapy alone?

• Population (P): individuals with chronic primary pain, specifically patients with fibromyalgia, primary bone marrow edema syndromes (transient osteoporosis and regional migratory osteoporosis), and complex regional pain syndrome (CRPS):

• intervention (I): instrumental physical therapies, including analgesic and muscle stimulation electrotherapy (NMES, TENS, PENS, interferential currents); electromagnetic field therapy; light- and laser-based therapies; exogenous and endogenous thermotherapy (diathermy); cryotherapy; contrast baths; radiofrequency therapies; therapeutic ultrasound, including low-intensity pulsed ultrasound (LIPUS); shockwave therapy (radial and focused); focal vibration therapy and whole-body vibration (WBV), administered alone or in addition to conventional therapy;

• comparator (C): sham intervention, no intervention, or conventional therapy. The guideline focuses on comparisons within the rehabilitation setting, in line with its scope and clinical questions. Pharmacological and psychological interventions, although relevant in the overall management of musculoskeletal pain, were not included as they fall outside the scope of this guideline;

• outcomes (O): pain, condition-related disability, and adverse events.

The panel identified and rated the relevance of outcomes through a structured voting process according to GRADE methodology. Outcomes were classified as critical, important, or not important for decision-making.

Literature search and study selection

A systematic literature search was conducted in Medline (PubMed), Embase, and the Cochrane Library (last updated February 20, 2025), without language restrictions. The search strategy focused exclusively on chronic primary pain conditions included in the PICO, namely fibromyalgia, CRPS, and primary bone marrow edema syndromes. Searches were designed to identify: systematic reviews and randomized controlled trials (RCTs) evaluating the effectiveness and safety of instrumental physical therapies; studies investigating patients' values and preferences, acceptability, feasibility, equity, costs, and cost-effectiveness. Initially, systematic reviews were searched and screened. When eligible systematic reviews had search dates preceding January 2024, updated searches for RCTs were conducted from the last available search date onward. Two reviewers independently screened titles, abstracts, and full texts for eligibility. Disagreements were resolved through discussion within the methodological group.

Certainty of evidence

The certainty of evidence was assessed according to the GRADE approach, considering risk of bias, inconsistency, indirectness, imprecision, and publication bias. The certainty of evidence was rated as high, moderate, low, or very low (Table I).

Evidence synthesis and formulation of recommendations

Evidence was summarized in structured evidence profiles reporting study characteristics, effect estimates, and certainty of evidence for all critical and important outcomes. Recommendations were formulated using the GRADE Evidence-to-Decision (EtD) framework,[11] considering:

TABLE I.—*Grading of the certainty of evidence.*

Certainty level	Definition	Implications
High	High confidence in the results	The true effect is very likely to be close to the estimated effect
Moderate	Moderate confidence in the results	The true effect is likely to be close to the estimated effect, but there is a possibility that it is substantially different
Low	Limited confidence in the results	Confidence in the effect estimate is limited: the true effect may be substantially different from the estimated effect
Very low	Very little confidence in the results	Confidence in the effect estimate is very limited: the true effect is likely to be substantially different from the estimated effect

balance between desirable and undesirable effects; certainty of evidence; patient values and preferences; acceptability; feasibility; equity; resource use. Recommendations were classified as strong or conditional, either in favor or against the intervention.

External review

The draft recommendations underwent independent external review by two experts in physical and rehabilitation medicine and evidence-based medicine. Reviewers evaluated clarity, consistency, methodological rigor, and applicability of the recommendations through a structured assessment process. All reviewers completed conflict of interest declarations.

All suggested revisions were reviewed by the panel and incorporated into the final document when deemed appropriate. All external reviewers completed a declaration of conflicts of interest.

The external review process was conducted through a structured questionnaire, which included four statements for each recommendation under evaluation. Reviewers were asked to indicate their level of agreement using a 3-point scale: (1) disagree, (2) uncertain, and (3) agree.

The four statements were as follows:

- the recommendation is clearly formulated with respect to the intervention, the comparator, and the target population;
- the recommendation is formulated in a way that facilitates documentation and measurement of adherence;
- the strength of the recommendation is consistent with my knowledge and assessment of the evidence;
- the rating of the certainty of the evidence is consistent with my knowledge and assessment of the evidence.

An optional open-ended question was also included to allow reviewers to provide additional comments on each recommendation.

Updating procedure

The final document produced by the Panel in 2025 is published online in full, in Italian, on the website of the Istituto Superiore di Sanità (https://www.iss.it/documents/20126/10776488/LG_C0050_SIMFER_Terapie+fisiche+strumentali.pdf).[12]

Given the continuous evolution of scientific knowledge and the expected availability of new relevant evidence, an update of the guideline is planned within two years. In particular, bibliographic searches will be updated from the date of the last search to the time of the update, and newly identified studies relevant to the clinical question will be assessed for potential inclusion.

Applicability

The recommendations were developed to ensure direct applicability to the Italian population, translating the available scientific evidence into practical guidance for the use of instrumental physical therapies in the management of CPP.

Resource implications

An assessment of costs and resource use was conducted to inform the recommendations and evaluate their potential impact on healthcare resources.

Monitoring indicators

The panel identified the following operational indicator to monitor the implementation of the recommendations: prevalence of the use of instrumental physical therapies in chronic primary pain conditions (*i.e.*, fibromyalgia, CRPS, and bone marrow edema syndromes)

Results

Recommendation

In individuals with chronic primary pain (fibromyalgia, primary bone marrow edema syndromes, and CRPS), the panel suggests the use of instrumental physical therapies in addition to conventional therapy.

- strength of recommendation: conditional in favor;
- certainty of evidence: variable across interventions (see subgroup considerations).

Subgroup considerations

- The panel suggests the use of TENS in combination with other interventions in patients with fibromyalgia (conditional recommendation in favor, moderate certainty of evidence);
- the panel suggests the use of low-level laser therapy (LLLT) in combination with other interventions in patients with fibromyalgia (conditional recommendation in favor, low certainty of evidence);
- the panel suggests the use of pulsed electromagnetic field therapy (PEMF) in combination with other interventions in patients with CRPS (conditional recommendation in favor, moderate certainty of evidence);
- the panel suggests the use of TENS in combination with other interventions in patients with CRPS (conditional recommendation in favor, low certainty of evidence).

Implementation considerations

Patient selection

Implementation should be based on clearly defined inclusion criteria, particularly with regard to diagnosis.

- Fibromyalgia: patients diagnosed according to validated clinical criteria and presenting with documented disability; instrumental physical therapies may complement exercise programs and psychological support.
- CRPS: patients diagnosed according to validated clinical criteria; instrumental physical therapies should be considered within a multimodal approach.

Integration into rehabilitation pathways

Instrumental physical therapies should be incorporated into multimodal rehabilitation programs that include therapeutic exercise, patient education, and psychological support. Their use as stand-alone interventions is not recommended, whereas their combination with other treatments may enhance acceptability and clinical benefit.

Communication

Patients should be actively involved in shared decision-making processes. Clear communication is essential to explain expected benefits, limitations of the evidence, and potential adverse effects.

Equity and access

Efforts should be made to ensure equitable access across the national healthcare system, minimizing regional disparities and clearly defining essential levels of care.

Research priorities

Future research should focus on high-quality studies with larger sample sizes and longer follow-up periods. Further investigations on cost-effectiveness and patient preferences are also needed.

Evidence on efficacy and safety

An initial bibliographic search was conducted up to February 1st, 2025, in Medline (PubMed), Embase, and the Cochrane Library, without language restrictions and limited to systematic reviews. After duplicate removal, 298 records were identified. Eleven systematic reviews were retrieved in full text as potentially relevant, and two additional reviews were identified through other sources.

After assessing overlap among primary studies included in the reviews, five systematic reviews were ultimately considered.[13-17] These reviews were used as sources to identify primary studies meeting the inclusion criteria, which were subsequently retrieved in full text. Four reviews addressed fibromyalgia[13-16] and one addressed complex regional pain syndrome (CRPS).[17] No systematic reviews were identified for bone marrow edema syndromes.

Subsequently, three additional searches were conducted to identify RCTs in the same databases up to February 20, 2025: without date limits for bone marrow edema syndromes, from 2021 onward for CRPS, and from 2018 onward for fibromyalgia, in order to capture studies published after the search dates of the included systematic reviews.

For fibromyalgia, 380 records were identified after duplicate removal; 27 studies were assessed in full text, and 22 were included. For CRPS, 73 records were identified; nine studies were assessed in full text, and eight were included. No studies were identified for bone marrow edema syndromes (Figure 1, 2, 3, 4).

Synthesis of evidence – desirable effects

Cryotherapy

Systemic cryotherapy in patients with fibromyalgia showed clinically relevant effects. One RCT reported a large reduction in pain (SMD=-1.17, 95% CI: -1.72 to -0.61) and a very large improvement in disability (SMD=-2.05, 95% CI: -2.69 to -1.42).[18] However, the certainty of the evidence was very low, as results were derived from a single small study.

Transcutaneous electrical nerve stimulation (TENS)

TENS demonstrated a moderate reduction in pain (SMD=-0.64, 95% CI: -0.94 to -0.34, moderate certainty) and a small improvement in disability (SMD=-0.45, 95% CI: -0.65 to -0.26, high certainty) in fibromyalgia[19-21] In CRPS, TENS showed a large effect on pain reduction (SMD=-1.95, 95% CI: -2.84 to -1.06) and a small effect on disability (SMD=-0.40, 95% CI: -1.13 to 0.32), with low certainty of evidence.[22]

Neuromuscular electrical stimulation (NMES)

NMES showed very large effects on pain (SMD=-3.91, 95% CI: -5.06 to -2.77) and disability (SMD=-1.32, 95% CI: -1.92 to -0.73) in fibromyalgia. However, the certainty of evidence was low to very low due to small sample sizes and high risk of bias.[23, 24]

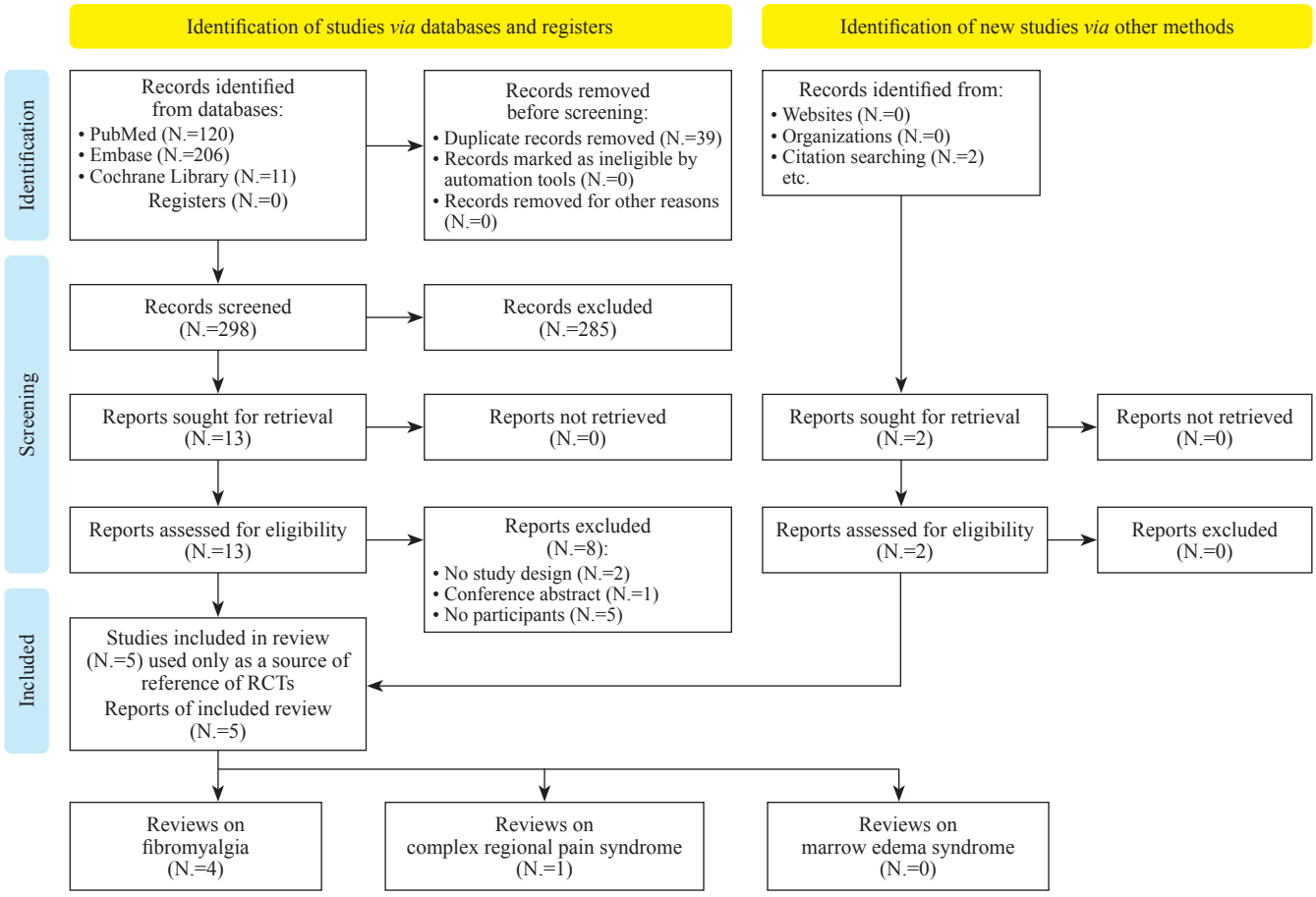

Figure 1.—PRISMA flow diagrams for systematic reviews for fibromyalgia, CRPS, and bone marrow edema syndromes.

Monopolar dielectric radiofrequency

Radiofrequency therapy demonstrated large reductions in pain (SMD=-0.91, 95% CI: -1.45 to -0.38) and disability (SMD=-0.83, 95% CI: -1.36 to -0.3), with low certainty of evidence, in fibromyalgia.[25]

Pulsed electromagnetic fields (PEMF)

In fibromyalgia, PEMF resulted in a non–clinically relevant reduction in pain (SMD=-0.19, 95% CI: -0.54 to 0.16m moderate certainty) and disability (SMD=0, 95% CI: -0.34 to 0.35).[26] In CRPS, electromagnetic field therapy showed a small reduction in pain (SMD=-0.46, 95% CI: -0.83 to -0.09 moderate certainty)[27-29]

Low-level laser therapy (LLLT)

LLLT demonstrated large effects on pain reduction (SMD=-1.67, 95% CI: -2.15 to -1.18) and disability (SMD=-1.62, 95% CI: -2.07 to -1.18), with low certainty of evidence, in fibromyalgia.[30, 31]

Whole-body vibration (WBV)

Whole-body vibration showed large reductions in pain (SMD=-1.60, 95% CI: -2.41 to -0.79) and disability (SMD=-1.54, 95% CI: -2.34 to -0.74) in fibromyalgia; however, the certainty of evidence was very low due to small sample sizes and high risk of bias.[32]

Undesirable effects

Undesirable effects of instrumental physical therapies in fibromyalgia and CRPS were generally trivial or mild and transient, including skin irritation, local pain, tingling, muscle stiffness, headache, or discomfort. Most studies reported no adverse events, and no serious adverse events were described.

The certainty of evidence regarding adverse effects was

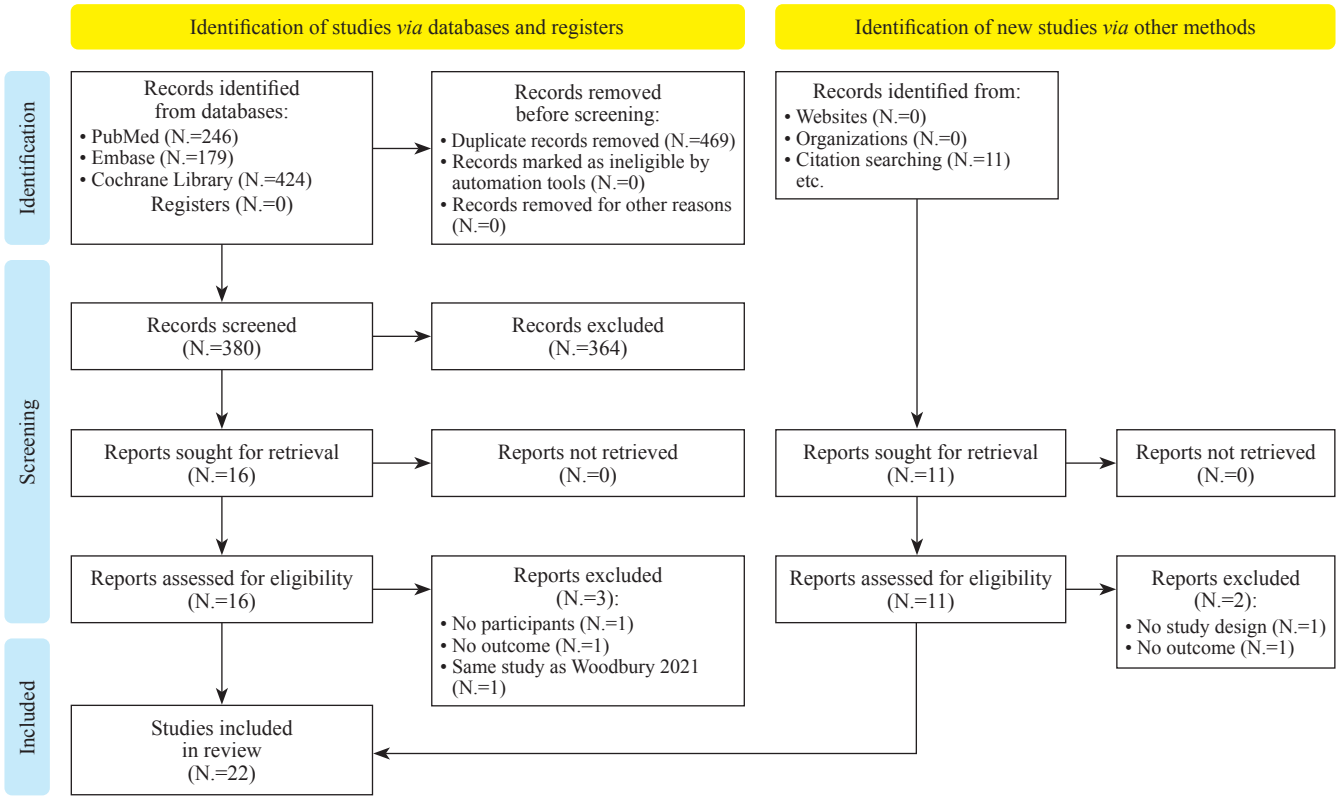

Figure 2.—PRISMA flow diagrams for RCTs for fibromyalgia.

low, as only a subset of studies systematically reported these outcomes; however, the overall direction of evidence is reassuring.

Overall certainty of the evidence

Overall, the certainty of the evidence was judged to be low, ranging from moderate to very low depending on the intervention and condition. The main limitations were imprecision of estimates, risk of bias (including performance, detection, and attrition bias), and inconsistency across studies.

Patients values and preferences

A bibliographic search was conducted in PubMed and Embase up to February 22nd, 2025. After duplicate removal, 809 records were identified; five studies were assessed in full text, and one was included.

Patients with fibromyalgia showed good acceptability of instrumental physical therapies. In particular, the study by Taylor *et al.*[33] evaluated acceptability of non-pharmacological treatments and found that the ratio between perceived benefits and side effects was greater than 1 for most interventions, indicating that patients generally perceived benefits to outweigh limitations. Acceptability was particularly high for TENS, cryotherapy, and LLLT, which were considered safe and well tolerated.

No data were available regarding values and preferences in patients with CRPS.

Balance of effects

The panel judged that the balance between desirable and undesirable effects favors instrumental physical therapies.

Costs and resource use

A bibliographic search conducted in PubMed and Embase up to January 19th, 2025 identified 201 records; no studies were included.

Costs were therefore estimated based on national reimbursement tariffs in 2025. The panel considered that, overall, the use of instrumental physical therapies compared with conventional therapy alone is associated with negligible additional costs or savings.

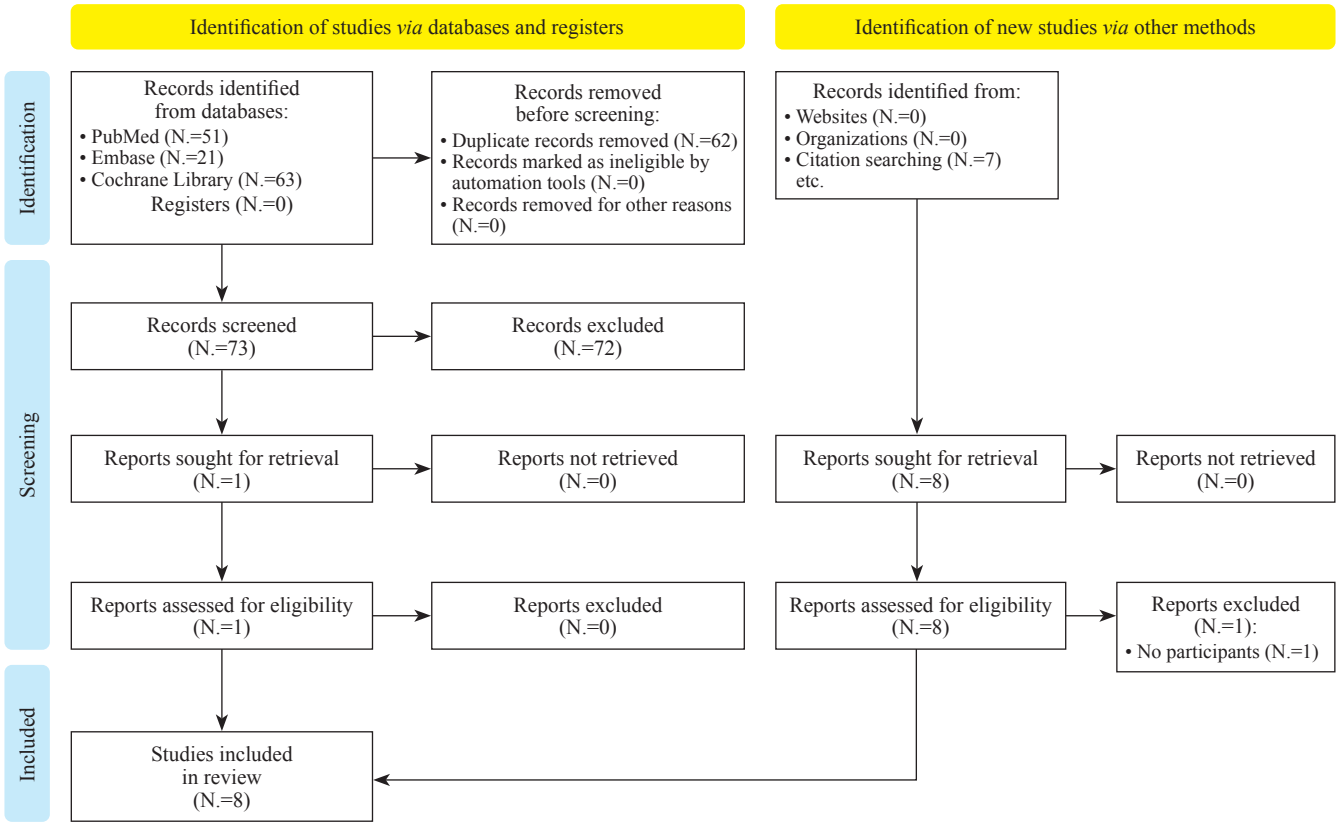

Figure 3.—PRISMA flow diagrams for RCTs for CRPS.

Cost-effectiveness

A bibliographic search conducted up to February 14th, 2025 (176 records identified) did not yield any eligible studies on cost-effectiveness.

Equity

A bibliographic search conducted up to February 22nd, 2025 (809 records identified) did not identify any relevant studies.

The panel considered that the availability of instrumental physical therapies within the National Health Service (public and accredited private providers) is likely to improve equity by enhancing access to care and reducing out-of-pocket expenses.

Acceptability

Three studies were included.[31, 33, 34] In fibromyalgia, acceptability was generally high. The study by Taylor *et al.*[33] showed that most non-pharmacological interventions had an acceptability ratio >1 (range 0.60-9.65), indicating that perceived benefits outweighed disadvantages.

TENS, cryotherapy, and LLLT were perceived as safe, well tolerated, and effective, with a favorable balance between efficacy and comfort. Whole-body vibration and radiofrequency therapy also showed positive acceptability, although evidence was limited.

In CRPS, acceptability was also good, with mild and transient side effects that did not negatively affect patient perception. For bone marrow edema syndromes, no direct data were available; however, the lack of alternative treatments suggests a likely favorable patient preference.

Feasibility

A bibliographic search conducted up to February 22, 2025 (809 records identified) did not identify any studies specifically assessing feasibility.

The panel considered that feasibility may vary across the national territory, as geographical factors may limit access to rehabilitation centers (*e.g.*, long travel distances or the need for assistance).

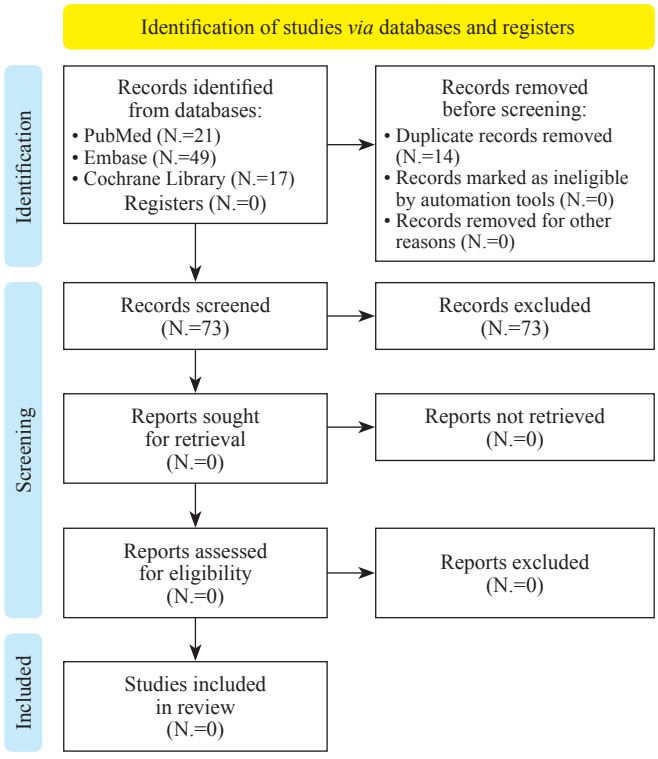

Figure 4.—PRISMA flow diagrams for RCTs for bone marrow edema syndromes.

Conclusions

This guideline synthesis supports the use of instrumental physical therapies as adjunctive interventions within a comprehensive, multimodal rehabilitation strategy for chronic primary pain, including fibromyalgia and CRPS. The panel issued a conditional recommendation in favor of their use, reflecting a favorable balance between desirable and undesirable effects, good patient acceptability, and minimal safety concerns.

However, the overall certainty of the evidence remains low, mainly due to heterogeneity in study design, small sample sizes, and variability in treatment protocols and outcome measures. These limitations restrict the generalizability of findings and highlight the need for cautious interpretation in clinical practice.

Instrumental physical therapies should not be used as stand-alone treatments but rather integrated with exercise therapy, patient education, and psychological interventions, in line with a biopsychosocial model of care. Individualization of treatment, appropriate patient selection, and shared decision-making are essential to optimize outcomes.

Future research should prioritize high-quality randomized controlled trials with standardized intervention protocols, adequate sample sizes, and long-term follow-up. Additionally, studies addressing cost-effectiveness, feasibility, and patient preferences are needed to further inform clinical and policy decisions.

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Conflicts of interest
Matteo Franchi reported research support related to reimbursement for attending conferences or educational activities. Alessandro Picelli reported having received research funding from organizations with commercial interests related to the guideline topic. Panel members abstained from voting on the strength of recommendations in cases where they were authors of one or more studies considered for the recommendation or when they had received direct or indirect funding from companies related to the intervention under evaluation. The remaining authors certify that they have no conflict of interest with any financial organization regarding the material discussed in this manuscript.

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Data availability
No data are available because this study did not generate any datasets.

Ethical approval
The authors confirm that this article does not report any studies involving human participants conducted by the authors. The authors confirm that this article does not report any studies involving embryos, gametes, and human embryonic stem cells conducted by the authors. The authors confirm that this article does not report any studies involving animals conducted by the authors.

Authors' contributions
Giovanni Iolascon and Antimo Moretti conceived and coordinated the guideline project; Silvia Minozzi and Marien Gonzalez Lorenzo provided methodological supervision and conducted evidence appraisal and synthesis according to the GRADE methodology; Matteo Franchi contributed to the statistical and methodological aspects of the guideline development process; Andrea Bernetti, Giovanna Beretta, Antonella Celano, Alessandro DE SIRE, Silvia Galeri, Nicolò Girolimetto, Angelo G. Mazzali, Anna M. Moretti, Tiziana Nicoletti, and Alessandro PICELLI contributed to the development of the clinical questions, interpretation of the evidence, formulation of recommendations, and expert revision of the manuscript; Francesca Gimigliano and Carlotte Kiekens contributed to the external review and critical appraisal of the document; Giovanni Iolascon and Antimo Moretti drafted the first version of the manuscript. All authors contributed to manuscript revision and critically reviewed the content for important intellectual aspects. All authors read and approved the final version of the manuscript.

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