



## Multimodal Interventions for Managing Chronic Pain in Older Adults: A Randomized Controlled Trial in Primary Health Care Settings

Intervenciones multimodales para el manejo del dolor crónico en adultos mayores: un ensayo controlado aleatorizado en entornos de atención primaria de salud

Intervenções multimodais para o manejo da dor crônica em idosos: um ensaio clínico randomizado em unidades de atenção primária à saúde

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### Abstract

**Background:** Chronic musculoskeletal pain (CMSP) is a prevalent condition among older adults, which can significantly reduce functional capacity and quality of life. Multimodal interventions (MIs), combining aerobic, resistance, and balance exercises, are promising but understudied in primary healthcare settings. **Objective:** To evaluate the effectiveness of a 12-week MI program in reducing pain intensity and improving functional outcomes in older adults with CMSP. **Methods:** A randomized controlled trial was conducted with 113 participants (mean age:  $68.5 \pm 5.3$  years), randomly assigned to an experimental group (EG, n=57) or control group (CG, n=56). Pain intensity (Numeric Rating Scale), functional capacity (6-minute walk test; 6MWT), and lower-limb strength (30-second sit-to-stand test; 30 s-CST) were assessed at baseline and post-intervention. Data were analyzed using repeated-measures ANOVA, with effect sizes calculated for clinical relevance. **Results:** Pain intensity decreased by 2.53 points (95% CI: 2.34–2.72) in the EG, surpassing the MCID threshold of 1–2 points ( $p<0.0001$ ). Functional capacity improved by 23.87 meters (95% CI: 5.27–42.47) in the 6MWT, exceeding the MCID range of 14–30 meters ( $p<0.0001$ ). Lower-limb strength increased by 0.89 repetitions (95% CI: 0.15–1.26) in the 30 s-CST, representing meaningful progress despite falling short of the MCID threshold of 2 repetitions. Effect sizes were moderate to large for all outcomes. **Conclusion:** The multimodal intervention significantly reduced pain and enhanced functional capacity, demonstrating its clinical impact and practical utility for managing CMSP. Further research should assess the long-term impacts of MIs and explore implementation in diverse settings.

**Keywords:** Chronic Musculoskeletal Pain; Multimodal Intervention; Pain Management; Functional Capacity; Randomized Controlled Trial; Primary Health Care.

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## Resumen

**Introducción:** El dolor musculoesquelético crónico (DMSC) es una afección prevalente en adultos mayores que puede reducir significativamente la capacidad funcional y la calidad de vida. Las intervenciones multimodales (IM), que combinan ejercicios aeróbicos, de resistencia y de equilibrio, son prometedoras, pero se han estudiado poco en la atención primaria. **Objetivo:** Evaluar la eficacia de un programa de IM de 12 semanas para reducir la intensidad del dolor y mejorar los resultados funcionales en adultos mayores con DMSC. **Métodos:** Se realizó un ensayo controlado aleatorizado con 113 participantes (edad media:  $68,5 \pm 5,3$  años), asignados aleatoriamente a un grupo experimental (GE,  $n = 57$ ) o a un grupo control (GC,  $n = 56$ ). Se evaluaron la intensidad del dolor (Escala Numérica de Calificación), la capacidad funcional (prueba de marcha de 6 minutos; 6MWT) y la fuerza de las extremidades inferiores (prueba de bipedestación de 30 segundos; 30 s-CST) al inicio y después de la intervención. Los datos se analizaron mediante ANOVA de medidas repetidas, con tamaños del efecto calculados para su relevancia clínica. **Resultados:** La intensidad del dolor disminuyó en 2,53 puntos (IC del 95 %: 2,34-2,72) en el GE, superando el umbral de la MCID de 1-2 puntos ( $p < 0,0001$ ). La capacidad funcional mejoró en 23,87 metros (IC del 95 %: 5,27-42,47) en la prueba de 6 minutos, superando el rango de la MCID de 14-30 metros ( $p < 0,0001$ ). La fuerza de las extremidades inferiores aumentó en 0,89 repeticiones (IC del 95 %: 0,15-1,26) en la prueba de esfuerzo de 30 segundos (CST), lo que representa un progreso significativo a pesar de no alcanzar el umbral de la MCID de 2 repeticiones. La magnitud del efecto fue de moderada a alta en todos los resultados. **Conclusión:** La intervención multimodal redujo significativamente el dolor y mejoró la capacidad funcional, lo que demuestra su impacto clínico y utilidad práctica para el manejo del dolor musculoesquelético crónico (CMSP). Se recomienda que futuras investigaciones evalúen los impactos a largo plazo de los IM y exploren su implementación en diversos entornos.

**Palabras-clave:** Dolor musculoesquelético crónico; Intervención multimodal; Manejo del dolor; Capacidad funcional; Ensayo controlado aleatorio; Atención primaria de salud.

## Resumo

**Introdução:** A dor musculoesquelética crônica (DMC) é uma condição prevalente entre idosos, que pode reduzir significativamente a capacidade funcional e a qualidade de vida. Intervenções multimodais (IMs), que combinam exercícios aeróbicos, de resistência e de equilíbrio, são promissoras, mas pouco estudadas em contextos de atenção primária à saúde. **Objetivo:** Avaliar a eficácia de um programa de IM de 12 semanas na redução da intensidade da dor e na melhora dos resultados funcionais em idosos com DMC. **Métodos:** Um ensaio clínico randomizado foi conduzido com 113 participantes (idade média:  $68,5 \pm 5,3$  anos), alocados aleatoriamente em um grupo experimental (GE,  $n=57$ ) ou grupo controle (GC,  $n=56$ ). A intensidade da dor (Escala Numérica de Avaliação), a capacidade funcional (teste de caminhada de 6 minutos; TC6M) e a força dos membros inferiores (teste de sentar e levantar em 30 segundos; TSC30) foram avaliadas no início e após a intervenção. Os dados foram analisados utilizando ANOVA de medidas repetidas, com tamanhos de efeito calculados para relevância clínica. **Resultados:** A intensidade da dor diminuiu em 2,53 pontos (IC 95%: 2,34-2,72) no grupo experimental, ultrapassando o limiar de diferença clinicamente importante mínima (DCIM) de 1-2 pontos ( $p < 0,0001$ ). A capacidade funcional melhorou em 23,87 metros (IC 95%: 5,27-42,47) no teste de caminhada de 6 minutos (TC6M), excedendo a faixa de DCIM de 14-30 metros ( $p < 0,0001$ ). A força dos membros inferiores aumentou em 0,89 repetições (IC 95%: 0,15-1,26) no teste de força de preensão manual de 30 segundos (30s-CST), representando um progresso significativo, apesar de não ter atingido o limiar de DCIM de 2 repetições. Os tamanhos do efeito foram de moderados a grandes para todos os desfechos. **Conclusão:** A intervenção multimodal reduziu significativamente a dor e melhorou a capacidade funcional, demonstrando seu impacto clínico e utilidade prática no manejo da dor crônica generalizada. Pesquisas futuras devem avaliar os impactos a longo prazo das intervenções multimodais e explorar sua implementação em diversos contextos.

**Palavras-chave:** Dor musculoesquelética crônica; Intervenção multimodal; Manejo da dor; Capacidade funcional; Ensaio clínico randomizado; Atenção primária à saúde.

## 1. Introduction

Chronic musculoskeletal pain (CMSP) is a leading cause of functional impairments among older adults, and is associated with substantial personal and societal costs (Adogwa, Reid, Chilakapati, & Makris, 2023). Older adults with CMSP present a considerably higher prevalence of

sarcopenia and risk of developing sarcopenia compared to older adults without CMSP (Chen, Wang, & Xu, 2023). Chronic musculoskeletal pain is also associated with substantial disability from reduced mobility, avoidance of social activities, falls, depression and anxiety, sleep impairment,

and isolation (Reid, Eccleston, & Pillement, 2015).

Although pharmacological modalities are recommended for this population, with multimodal characteristics, they can lead to polypharmacy, and therefore must be undertaken with caution due to the effects of pharmacokinetics and pharmacodynamics from commonly prescribed medications, that may generate side effects on cognitive function, myelination of nerves, and receptor density (Schwan, Sclafani, & Tawfik, 2019). For example, there is no evidence on the use of topical nonsteroidal anti-inflammatory drugs in chronic pain conditions (Derry, Conaghan, Da Silva, Wiffen, & Moore, 2016).

For some years it has been known that multimodal interventions (MIs), which integrate aerobic, resistance, balance, and flexibility exercises, have a positive effect on falls prevention, as described by Baker et al. (Baker, Atlantis, & Fiatarone Singh, 2007). However, Baker et al. (Baker et al., 2007) also concluded that there were limited data available suggesting the effects of MIs on physical, functional, and quality of life outcomes. Nowadays, MIs including exercise rehabilitation combined with usual medical care are prescribed as efficacious therapeutic options to decrease disabilities in older adults with CMSP (Kechichian et al., 2022).

Older adults with CMSP in Brazil are normally managed in Primary Health Care (PHC) (Honorato Dos Santos De Carvalho, Rossato, Fuchs, Harzheim, & Fuchs, 2013). Despite the existence of customized assessments and treatments for this population in PHC, implementing new approaches and technologies is still a challenge due to the absence of comprehensive training programs for managing CMSP (McEwen et al., 2023). In this context, physical activity and exercise represent a real strategy to reduce gaps in care. Therefore, physical activities (Morcillo-Muñoz et al., 2021), such as MIs, should be continuously available as one of the many priorities in an evidence-based approach for the health system. MIs represent a systematic approach to incorporate into the comprehensive management strategies of the PHC, decreasing the knowledge gaps, improving the quality of care, and contributing to reducing a critical societal and personal burden of aging in Brazil (Torres, Da Silva, Ferreira, Mendes, & Machado, 2019). Considering the above, the current study aimed to analyze efficacy of an MI exercise program.

## 2. Materials and Methods

### 2.1. Study design and settings

This study followed a parallel, randomized, controlled, single-blind trial design, conducted in accordance with the Consolidated Standards of Reporting Trials

(CONSORT) guidelines (Merkow, Kaji, & Itani, 2021). The trial was carried out in Basic Health Units (BHUs), between March and June 2022. BHUs were selected based on their multidisciplinary focus on older adults with chronic musculoskeletal pain (CMSP), and the study protocol received ethical approval (Ethics Committee at the Faculty of Health and Technology Science, University of Brasília, CAAE n° 97587018.0.0000.8093).

## 2.2. Participants

A non-probabilistic sampling method was used. For recruitment, three BHUs were invited to enroll participants. These BHUs were selected for their expertise in the multidisciplinary treatment of older adults with CMSP. The staff in the BHUs initially introduced the study to the patients who received a call from the principal researcher. Through these calls, the principal investigator initiated participant recruitment by assessing key eligibility criteria

The calls were possible considering the existence of an electronic registration system containing the families living in the territory covered by BHU. After the initial contact, the potential participants were scheduled for a face-to-face meeting to confirm the eligibility criteria. Medical history and physical examinations were conducted for all individuals to assess

eligibility, in the presence of an independent researcher, who was blinded to group allocation. Furthermore, all participants were examined by a medical examination, including an EEG, to exclude pathologic conditions. After these steps, written informed consent was obtained by the same competent subjects who applied the eligibility criteria. All participants received the research-related information with sufficient time to consider their participation.

Participants were considered eligible if they were adults aged 60 years or older, with nociceptive CMSP lasting more than three months, affecting multiple body sites, and capable of standing without assistance. Exclusion criteria included severe cardiovascular conditions, fibromyalgia, recurrent falls (two or more in the previous 12 months), severe pain (7-10 on the Numeric Rating Scale), supervised physical exercise in the previous six months, sensory deficits, or psychiatric disorders. Recruitment was conducted through telephonic outreach and face-to-face eligibility assessments, by trained researchers using standardized tools, including the Mini-Mental State Examination (MMSE) and Geriatric Depression Scale (GDS-15). Participants provided written informed consent in compliance with ethical standards.

## 2.3 Randomization and Blinding

Participants were randomly assigned to the experimental group (EG) or control group (CG) using block randomization, with a block size of eight, following recommendations for clinical trials (Efird, 2010). Block randomization ensures balanced group sizes by dividing participants into blocks, each containing an equal number of allocations to the EG and CG. For a block size of eight, each block included four allocations to the EG and four to the CG, arranged in random sequences (e.g., EG, CG, CG, EG, CG, EG, EG, CG). The block sequences were pre-generated by an independent researcher and assigned sequentially as participants enrolled in the study. Participants and intervention providers were blinded to group allocation. Randomization was implemented using sealed, opaque, and consecutively numbered envelopes to ensure allocation concealment, managed by an independent researcher to minimize bias.

#### *2.4 Interventions*

The experimental group (EG) received an MI program supervised by qualified physical education professionals. The MI included progressive resistance exercises, balance training, and aerobic activities, delivered twice weekly over 12 weeks at outdoor areas of the BHU. Each session consisted of a warm-up (light walking), strength and coordination exercises

using elastic bands and cones, and a cool-down phase with stretching. Sessions lasted 40 to 50 minutes, and exercise loads were adjusted using the OMNI-Resistance Exercise Scale (Colado et al., 2018). The control group (CG) received a multidisciplinary pain education program consisting of three 60-minute group sessions, along with active static stretching exercises performed twice weekly. Stretching targeted major muscle groups, and adaptations were made for older participants (Neil-Sztramko et al., 2022).

#### *2.5 Outcomes*

Primary outcomes included pain intensity, assessed using the Numeric Rating Scale (NRS) on a 0-10 scale (Farrar, Young, LaMoreaux, Werth, & Poole, 2001), and global perception of change, measured with the Patient Global Impression of Change Scale (PGICS), validated for Portuguese-speaking populations (Domingues & Cruz, [s.d.]). Secondary outcomes were functional capacity measures assessed with the Six-Minute Walk Test (6MWT) (Agarwala & Salzman, 2020) and the 30-Second Chair Stand Test (30 s-CST) (Jones, Rikli, & Beam, 1999). Each test was performed in 3 trials, and the highest value was used for statistical analysis. Outcome assessors were blinded to group allocation to minimize bias (Poolman et al., 2007).

#### *2.6 Sample size calculation*

A pilot analysis, conducted with proportional randomization blocks and a minimum of 12 participants per block, provided an estimated effect size of 0.28. Using this effect size, with a 95% confidence interval and 80% statistical power to detect group-by-time interaction differences, the required sample size was determined to be 104 participants (52 per group). To account for potential dropouts, the final sample size was adjusted to 113 participants. The sample size calculation was performed using G\*Power 3.1.9.6.

## 2.7 Statistical analysis

The assumptions of normality and homogeneity of variables were investigated using the Kolmogorov-Smirnov test and Bartlett test, respectively. Categorical variables were expressed as absolute and proportion values, and continuous variables as means with 95% confidence interval (95% CI). The baseline values between groups of the 30-Second Chair Stand Test were compared using Welch's t-test, which is appropriate for data with unequal variances, as identified by the F-test for homogeneity of variances ( $p=0.0137$ ). The results indicated a statistically significant difference between the groups at baseline. Therefore, we used the one-way ANOVA chance score between the baseline and post-treatment ("ANOVA-Change") to investigate statistical differences observed between groups. This approach

ensures that any variability due to initial differences is neutralized, allowing us to focus on the true effects of the intervention. Considering that the PGICS outcome was assessed only after the 12-week intervention, the unpaired  $T$  test with Welch correction was used.

According to the homogeneity of baseline assessment for primary (NRP) and secondary outcomes (6MW), the repeated measures two-way ANOVA was used with a 95% CI design with a mixed effects model and fit full model (pre-post [repeated measures] two arms [GE vs. CC]). The hypothesis of interest was the group-by-time interaction at an *a priori* alpha level of 5% ("ANOVA-RM"). When a significant difference was observed, the Bonferroni post hoc test was performed.

The ES values with 90% CI were calculated with Cohen's  $f$  statistic to estimate the strength of the interaction index for ANOVA. The ES of Cohen's  $f$  statistics were interpreted as follows: 0.10 to 0.25 = small; 0.26 to 0.40 = medium;  $\geq 0.41$  = large. The statistical analyses were performed using Prism 9 software (version 9.0.0).

This study implemented a Full ITT (FITT) analysis, meaning that all randomized participants were included in the analysis and analyzed as randomized (McCoy, 2017). No missing data were observed for primary or secondary outcomes.

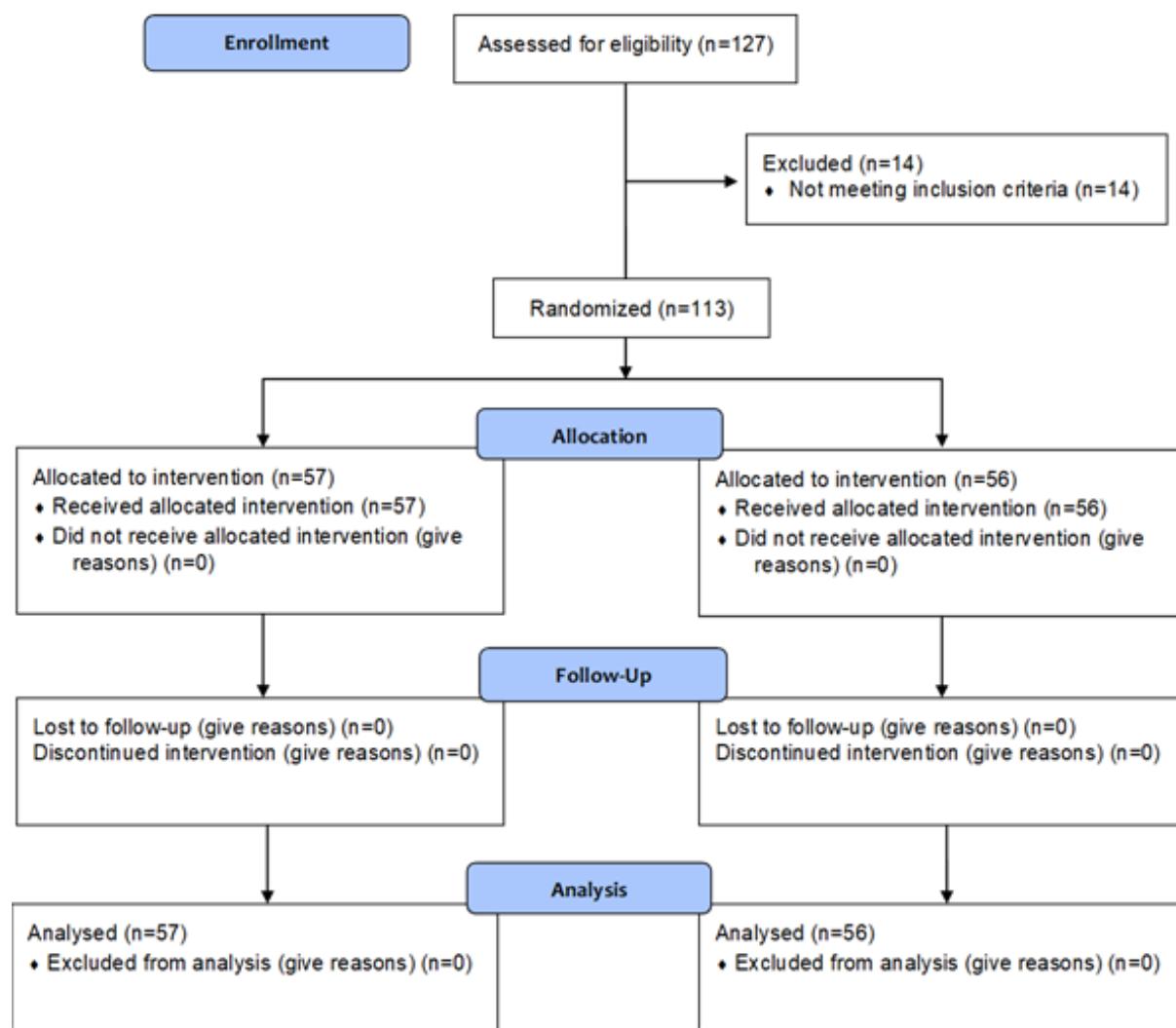


Figure 1 - CONSORT flow diagram.

### 3. Results

#### 3.1 Baseline characteristics of the sample and flow of participants

The CONSORT flow diagram (Figure 1) summarizes the flow of participants through the study. Both the experimental group (EG) and control group (CG) were predominantly composed of females, with proportions of 87.72% in the EG and 89.29% in the CG. The prevalence of falls in the previous year was notably low in both groups, at 1.75% in the EG and

1.78% in the CG. Participants in both groups were classified as overweight according to BMI criteria.

The knee was the most prevalent pain site, affecting 55.74% of participants in the EG and 57.14% in the CG. Cognitive function scores showed values above the traditional cut-off values (Melo & Barbosa, 2015), indicating no cognitive impairments in either group. Similarly, depressive symptoms showed normal values, with no

evidence of clinically significant depression (Santiago-Bravo, Sudo, Assunção, Drummond, & Mattos, 2019).

Baseline characteristics, including age, BMI, functional capacity, pain levels, and psychological measures, were not significantly different between groups ( $p > 0.05$ ), ensuring the comparability of participants at the start of the intervention.

### *3.2 Primary outcomes*

A significant interaction effect ( $p < 0.0001$ ) indicated a reduction in pain scores in the EG compared to the CG, with a difference between groups of 2.53 points (95% CI: 2.34 to 2.72). This reduction was associated with a large ES of 0.50. The PGICS analysis indicated a mean difference between groups of 0.91 points (95% CI: 0.63 to 1.18;  $p < 0.0001$ ), in favor to the EG (mean = 6.17 [-123 to 0.52 - 99%CI]) when compared to the CG (mean 5.28 [-1.25 to -0.52 - 99%CI]), indicating an improved self-perception of treatment effectiveness, with a medium effect size of 0.28.

### *3.3 Secondary outcomes*

For the 6MWT, the mean difference between groups showed an increase of 23.87 meters (95% CI: 5.27 to 42.47;  $p < 0.05$ ) in favor of the EG. This improvement was associated with a large ES of 0.43. For the 30 s-CST, the mean difference demonstrated a reduction of 0.93 repetitions (95% CI: -1.784

to -0.09;  $p = 0.03$ ) in favor of the EG. The effect size, calculated as 0.34, represents a medium effect.

## **4. Discussion**

The current study showed that the multimodal intervention led to significant improvements in pain intensity, functional capacity, and lower-limb strength in older adults with CMSP.

The EG demonstrated a reduction in pain intensity of 2.53 points (95% CI: 2.34-2.72), which exceeds the minimum clinically important difference (MCID) threshold of 1-2 points (Salaffi, Stancati, Silvestri, Ciapetti, & Grassi, 2004).

The MCID is used to interpret the relevance of treatment effects (Olsen et al., 2018), as the smallest difference in score in the outcome of interest which participants perceive as beneficial. These results may be attributed to exercise-induced mechanisms, as exercise and regular physical activity decrease pain excitability and improve inhibition in the central nervous system (Sluka, Frey-Law, & Hoeger Bement, 2018).

In practice, our results on pain reduction are in concordance with the vast majority of the literature on exercise prescription, in which matching exercise to fitness level parameters is fundamental (Rice et al., 2019). In this line the present study observed that the MI led to hypoalgesia in older adults with CMSP.

**Table 1.** Between-group comparisons for primary and secondary outcomes.

Outcomes	EG (n = 57)	CG (n = 56)	Interaction p-value	ES
<b>NRS (score: 0-10)</b>				
Baseline	4.96 (4.58 to 5.34)	4.74 (4.39 to 5.09)		
Post-intervention	1.91 (1.54 to 2.28)	2.72 (2.42 to 3.03)	< 0.0001 **	0.50
<b>6MWT (meters)</b>				
Baseline	375.1 (357.1 to 393)	377.7 (361.4 to 394.0)		
Post-intervention	440.6 (412.2 to 469.1)	393.5 (378.8 to 408.2)	0.03**	0.43
<b>TLS30 (repetitions)</b>				
Baseline	10.51 (9.58 to 11.43)	9.57 (9.07 to 10.07)		
Post-intervention	12.32 (11.28 to 13.35)	10.48 (10.97 to 9.99)	0.006**	0.34

Data presented as mean and 95% confidence interval; \*\* group-by-time interactions ( $p \leq 0.05$ ); EG: Experimental Group; CG: Control Group; ES: Effect Size. NRS: numeric rating pain; 6MWT: 6-minute walk test; TLS30s: Sit and Stand from a chair test.

The functional capacity (6MWT) results indicated a 23.87-meter improvement in EG, exceeding the MCID threshold (14.0 to 30.5) reported by Crouch et al. (Bohannon & Crouch, 2017). In the available literature, there is limited direct evidence investigating the effects of MI exercise programs on specific improvements in functional capacity measured by the 6MWT among older adults with MSCP. While direct comparisons are limited, the present study demonstrated that MI exercise programs have the potential to improve functional capacity in older adults with chronic musculoskeletal pain, as measured by the 6MWT.

Lower-limb strength gains (30 s-CST) showed a mean increase of 0.89 repetitions (95% CI: 0.15-1.26) in favor of the EG. Minimum clinically important differences for older people with CMSP have not yet been published in the literature. A study investigating a 12-week MI exercise program,

which included supervised sessions twice weekly, demonstrated significant improvements in physical function among older adults. Participants in the intervention group showed an average increase of 2.4 repetitions in the 30CST compared to the control group, indicating increases in lower limb strength and endurance. This finding suggests that even in populations with significant health challenges, multimodal exercise can effectively improve lower limb functionality (Mikkelsen et al., 2022). Furthermore, another study evaluating a 16-week multimodal exercise program for individuals with dementia reported positive outcomes in lower limb strength. The program, which combined various exercise modalities, led to improvements in the modified 30CST, reflecting gains in lower extremity function. These findings underscore the versatility and efficacy of multimodal exercise interventions across diverse older adult populations (Barisch-

Fritz, Trautwein, Scharpf, Krell-Roesch, & Woll, 2022).

Regarding the effect sizes observed in the present study, the large and medium effect sizes in primary and secondary outcomes reflect the clinical relevance of these findings and demonstrate the potential use of MIs in primary care settings. Effect size is a crucial measure to complement statistical significance, providing a clearer picture of the practical impact of the intervention on patients' lives. This study also highlights a feasible condition for implementing MIs in PHC settings, addressing critical barriers to CMSP management, such as accessibility and resource constraints. By delivering structured exercise programs in PHC environments, healthcare providers can offer cost-effective, scalable solutions to reduce the reliance on specialized care. This approach also aligns with global efforts to shift toward non-pharmacological interventions for chronic pain management, reducing the risks associated with opioid use, such as dependence and adverse effects.

Some limitations of the current study need to be presented: the lack of long-term follow-up limits insights into the sustainability of these benefits over time. Furthermore, the lack of an active gold-standard control group, such as supervised physiotherapy or other established non-pharmacological interventions, limits the contextualization of the observed results.

Finally, the predominantly female sample (>85%) reduces generalizability to male populations. These limitations highlight areas for future research, including extended monitoring periods, the inclusion of different active comparators, and cost-effectiveness evaluations.

## 5. Implications of Physiotherapy Practice

The findings of this study indicate that a 12-week fitness program that includes walking, muscular strengthening, and balancing training can considerably reduce chronic pain and enhance physical function in older people. These improvements were not only statistically significant, but also clinically relevant. The study found that physiotherapists working in public primary care settings can effectively administer this type of program despite low resources. It provides a safe, low-cost alternative to pharmaceuticals, allowing older people to become more self-sufficient and active in daily life. This method emphasizes the importance of physiotherapy in controlling chronic pain through movement, particularly in aging populations where polypharmacy and restricted access to specialized treatment are prevalent concerns.

## 5. Conclusion

The results of the current study demonstrated the efficacy of multimodal interventions in reducing pain intensity and improving functional outcomes among older adults with chronic musculoskeletal pain. The results highlight clinically meaningful

improvements, as evidenced by effect size values and minimum clinically important difference thresholds. Considering the gaps in primary care services, the MI exercise program represents a valuable addition to aid in addressing the challenges faced by the Brazilian health system.

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We state that all authors have made substantial contributions to all the following: the conception and design of the study, acquisition of data, analysis and interpretation of data, drafting the article or revising it critically for important intellectual content and final approval of the version to be submitted.

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