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Effect of Standard Physical Exercises for Non-specific Low Back Pain Combined with Multimodal Osteopathy Treatment on Pain Intensity and Functional Capacity: A Study Protocol for a Randomized Controlled Trial

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Aims: The aim of the proposed study is to determine the effect of a standard treatment for non-specific low back (CNSLBP) combined with multimodal osteopathy treatment on pain intensity and functional capacity.
Materials and Methods: This will be a blind randomized clinical trial, with 44 patients with CNSLBP, randomly assigned into two groups: Experimental group (EG) treated with therapeutic exercises and multimodal osteopathy treatment (n=22) and Control group (CG) treated with therapeutic exercises (n=22). Participants will receive treatment twice a week (total of 16 sessions). The primary outcome is pain, measured by numeric rating scale (NRS: score 0-11 points). Secondary outcomes are: Patient-specific functional scale (scored from 0 to 30), Oswestry Disability Questionnaire (ODQ), finger-to-floor distance test (FFD). Participants will be evaluated pre- and post-treatment and after 1 and 3 months (follow-up).
Results: Analysis will be by intention to treat using linear mixed models. Comparisons between groups before and after treatment will demonstrate whether osteopathy treatment exerts a supplementary effect on pain and functional capacity in patients with CNSLBP. The data will be published after the study is completed. The study will support the practice of evidence-based physical therapy for individuals with CNSLBP. This protocol was registered (NCT06566144) and received ethical approval (CAEE: 6.275.345).

Keywords: Chronic non-specific neck pain; physical therapy; exercise therapy; osteopathy.

1. INTRODUCTION

“Low back pain (LBP) is considered a common health condition in individuals, and it is associated with socioeconomic public health issues and high levels of work abstains” [1]. It is estimated that 70-85% of the population has had experience with LBP some time in life [2], being more common in 40 to 80 years old women [3]. “The most common form of this symptom is non-specific LBP, that is when the pathoanatomical cause of pain cannot be determined” [4]. “The symptoms stage has recently been reclassified, that is, acute under 6 weeks of duration and above as being chronic” [5].

“The chronic non-specific low back pain (CNSLBP) can be due to factors as biologic factors (genetics and biophysical) and psychosocial factors (depression, anxiety and catastrophizing)” [3]. “In this way, patients with this kind of dysfunction can present several clinical symptoms and different responses about the treatment offered” [6].

Regarding treatment, recent systematic reviews (SRs) have confirmed that oral non-steroidal anti-inflammatory drugs and serotonin-norepinephrine reuptake inhibitors (duloxetine) provide clinically significant pain reduction [7], however, only exercises show sustained benefits after treatment ends [8,5,7,9].

“Osteopathy has also shown good clinical responses as a non-pharmacological treatment to reduce pain index and disability scores in patients with chronic LBP” [10]. These results contribute to establishing a more robust evidence-based practice and stimulate its use in the treatment of chronic LBP symptoms.

In general, osteopathy, is a diagnostic and treatment approach based on the integrity of systems: musculoskeletal, neural, visceral, myofascial, and fluid, centered on the patient rather than the disease, which seeks to improve the function and mobility of body tissues through manual therapy [11]. This approach is characterized by the multimodal treatment that involves all the body structures and have a wide range of techniques that allows the therapist to apply them according to the patient needs [12].

However, although the results of a systematic metanalysis review strengthen evidence that osteopathy is effective in pain levels and functional status improvements in NSCLBP patients [10], it is important to highlight that the control groups used to compared with osteopathic treatment were constituted with several therapeutics modalities (Sham, no intervention, physiotherapy, exercise, active control group). Thus, those results do not clarify if the osteopathic treatment presents equal or superior effects to the clinical treatments previously recommended as an approach for those patients [5,7,9].

Therefore, considering that osteopathy can promote a positive clinical effect for individuals with CNSLBP, this study hypotheses that the use of a multimodal osteopathic treatment protocol can promote and additional effect in pain intensity, functional capacity in patients with nonspecific low back pain, treated with clinical interventions previously recommended [5,8].

The aim of the proposed study is to determine the effect of a standard treatment for CNSLBP combined with multimodal osteopathy treatment on pain intensity and functional capacity.

2. MATERIALS AND METHODS

2.1 Design

A randomized controlled clinical trial will be carried out conducted after being approved by the Ethics Committee of Nove de Julho University (process nº: 6.275.345). All individuals were properly informed regarding the objectives and procedures and signed a statement of informed consent prior to testing. Fig. 1 displays the flowchart of the study.

2.2 Sample Size

The minimally clinically important difference, assessed by the NPRS, for the treatment of chronic LBP is ≥ 2 [13]. Therefore, for this study, a minimally clinically important difference of 2.0 with a standard deviation of 2.5 on the NPRS was considered, with $\alpha = 0.05$ (5% chance of Type I error) and $1-\beta = 0.95$ (95% power). The estimated number of participants required was 19 individuals. Considering a potential 20% dropout rate, 22 individuals per group were included in the study (total of 44 participants). The calculation was performed using G*Power software [14].

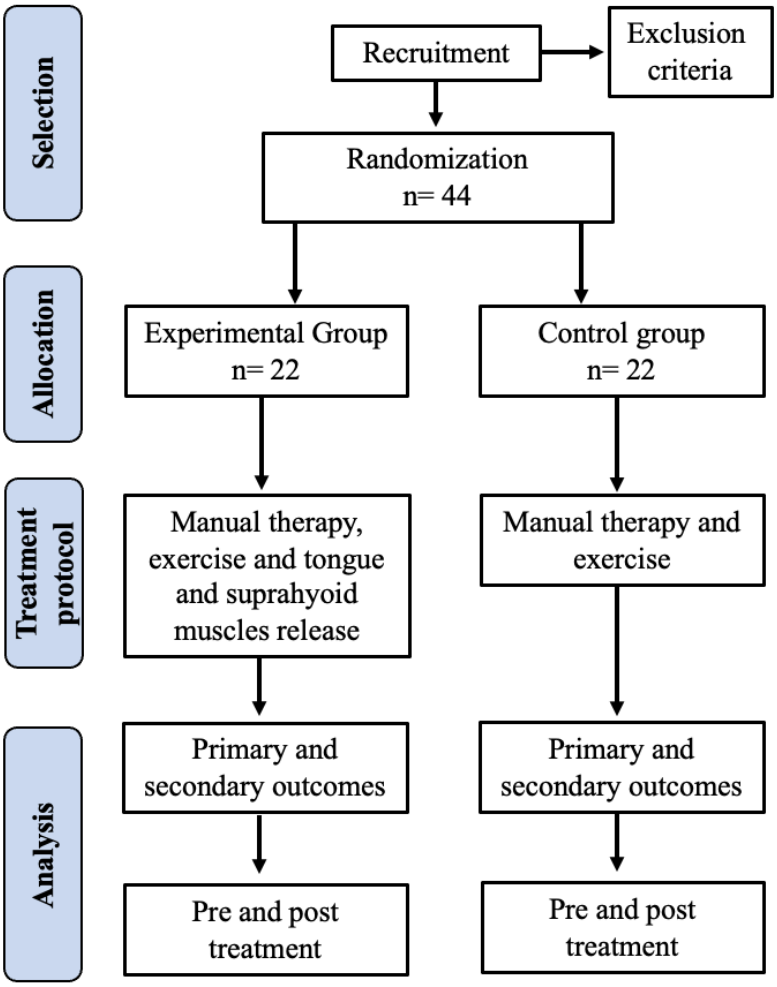

Fig. 1. Study flow diagram. (Figure source: authors)

2.3 Participants

Forty-four individuals within an age range of 18–70 years will be accepted for both groups. The participants will be recruited from a waiting list of patients at the Teaching Clinic of the Brazilian College of Osteopathy. Those who report chronic low back pain as the main complaint will be asked to undergo a screening process to determine whether they meet the eligibility criteria.

The following will be the inclusion criteria: chronic low back pain in the region between the 12th rib and the gluteal fold, with a minimum duration of 6 weeks [5] with or without referral of pain in the lower limbs [15]. It was considered CNSLBP when no specific cause was detectable, such as infection, neoplasia, metastasis, osteoporosis, rheumatoid arthritis, fracture, inflammatory process or radicular syndrome [4,16]. As baseline pain, a minimum intensity score of 3 out of 10 (0 = no pain, 10 = most intense pain) was considered and verified by the Numerical Pain Rating Scale (NPRS) [17].

The following will be the exclusion criteria: i) previous history of spinal disorders (local trauma, cauda equina syndrome, spinal canal stenosis, congenital abnormalities tumor); ii) inflammatory or infectious diseases (rheumatoid arthritis, fibromyalgia and vertebral osteomyelitis); iii) previous lumbar spine surgery; iv) pregnant women; v) regular opioid analgesics (≥2 times per week) or opioid patches; vi) receiving disability benefits for back pain or even for another health reason; vii) previous injections for back pain, such as facet joint blocks, nerve root or epidural steroid injection in the previous year; viii) having undergone physical therapy, massage, acupuncture, or any other therapeutic intervention for back pain in the previous two weeks; ix) osteopathy techniques that are not used as a treatment for low back pain; x) Neuropathic pain tested with Lasegue and Valsalva clinical tests and DN4 (Douleur Neuropathique) evaluation.

The participants will be allocated to the experimental group (EG, n=22) or control group (CG, n=22) (Fig. 1). The randomization of the volunteers to the different groups using a drawing with two opaque envelopes – one containing the letter A (EG) and the other containing the letter B (CG). The envelopes were chosen by the volunteer on the day of data collection. As 22 individuals will be determined for each group after one of the groups was complete, the criterion for the other group became the consecutive order of arrival.

2.4 Blinding

An independent researcher will perform the following procedures [18]: Evaluator 1 - screening of the participants with inclusion and exclusion criteria; Evaluator 2 - questionnaires administration and participants clinical evaluation before and pre- and post-treatment; Evaluator 3 - participants randomized allocation to EG or CG; Evaluator 4 - administration of both treatment protocols; Evaluators 5 - processing of data on lumbar range of motion and statistical data analysis. Evaluators 1 and 5 will also be blinded to group allocation and type of treatment.

2.5 Evaluation Procedures

The tests will be performed in a single session pre-treatment and then post-treatment, thirty days follow-up and ninety days follow-up. The clinical characteristics of individuals will be assessed by a physical therapist with at least 5 years of experience through the following instruments: i) Numerical Pain Rating Scale (NPRS; 0 to 10 points) [19]; ii) Oswestry Disability Questionnaire (ODQ; 0 to 50 points; no disability (0 to 4), mild disability (5 to 14), moderate disability (15 to 24), severe disability (25 to 34), and complete disability (35 to 50) [19]; iii) Finger-to-floor distance (FFD) [20]; iv) Patient-Specific Functional Scale (PSFS; 0 to 10 points) [21]; v) STarT Back Screening Tool (SBST; 9-item questionnaire; three risk groups (low, medium, and high) [22].

2.6 Outcome Measures

Primary Outcome: Changes in pain intensity, assessed using the NPRS (Numerical Pain Rating Scale). This is an 11-point scale where 0 means "no pain" and 10 means "worst possible pain" [15]. NPRS outcome measures will be evaluated pre- and post-treatment and after 1 and 3 months (follow-up).

Secondary Outcomes: (measures conducted pre- and post-treatment)

1) Oswestry Disability Questionnaire (ODQ): Used to measure disability caused by low back pain [19]. The ODQ is a 10-item scale with higher numbers indicating greater disability. The questionnaire is self-report

and includes the following groups of questions: pain intensity and its effect on personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and travelling. Each subscale contains 6 questions and to each question a score from zero to four is assigned. The levels of disability are determined according to the total score as: no disability (0 to 4), mild disability (5 to 14), moderate disability (15 to 24), severe disability (25 to 34), and complete disability (35 to 50). For no disability only advice on lifting, sitting, and exercise is given, and for mild disability conservative treatment is indicated. Patients with moderate disability need detailed investigation while individuals with severe disability require intervention. Completely disabled people are either bed-bound or are exaggerating their symptoms.

2) Finger-to-floor distance (FFD): Used to assess lumbar mobility in flexion [20].
3) Patient-Specific Functional Scale (PSFS): Patients were asked to identify up to three important activities they were having difficulty with or were unable to perform due to their condition (e.g., low back pain). The assessment was conducted using an 11-point scale (ranging from 0 "unable to perform activity" to 10 "able to perform activity at pre-injury level") [21].
4) Prognostic Risk Assessment: The risk of poor prognosis among participants with low back pain, influenced by physical and psychosocial factors, was evaluated using the STarT Back Screening Tool (SBST). The SBST is a 9-item questionnaire that stratifies patients with low back pain into three risk groups (low, medium, and high) that represent their prognosis regarding disability [22].

2.7 Statistical Analysis

The data will be organized and tabulated using the Statistical Package for the Social Sciences (SPSS, v.19.0), with the significance level set at 5% ($p < 0.05$). The normality of data distribution will be verified by the Shapiro-Wilk test. Descriptive statistics will be used to characterize the participants and the groups (EG and CG) will be compared using either the independent t-test or the Mann-Whitney test. Linear mixed models considering intention to treat analysis in case of dropouts will be used to analyze the treatment effect [23]. Differences between groups (treatment effect) and respective 95% confidence intervals will be calculated.

2.8 Interventions

Participants will be treated at the School Clinic of the Brazilian College of Osteopathy. The CG will only receive the standard treatment for CNSLBP [5,8] (Table 1). The EG will undergo the same treatment as the CG, along with a multimodal osteopathy protocol previously suggested by other authors [12,24]. All patients will undergo sixteen 40-min standard treatment sessions twice a week. The participants in the EG will undergo an additional 40-min with a multimodal osteopathy protocol in sessions 1, 2, 3 and 4 leading to a total of 160 min in these sessions. Table 1 displays a summary of the techniques used in both treatments as well as the respective specifications, as suggested by previous studies. Before the start of each session, a warm-up will be performed by walking on a treadmill for 10 minutes.

2.8.1 Standard treatment for chronic low back pain

The treatment to be used in the study is in accordance with the latest guidelines for chronic LBP [5,8]. A warm-up will be performed by walking on a treadmill (Total Health® - RX6) for 10 minutes, followed by 3 sets of 10 to 15 repetitions of exercise: bridge, cat, abdominal, straight leg raising, and oyster (Fig. 2), and 3 sets of 30 to 60 seconds of each isometric exercise (front plank and side plank, [Fig. 2]), where the therapist will assess the optimal amount of repetitions for each individual. The rest period between sets will be 40 seconds, and the rest period between exercises will be 1 minute. The total duration of the session will be 40 minutes [8,25,26].

2.8.2 Multimodal osteopathy protocol

The experimental group (EG) will receive the standard treatment for low back pain twice a week, as the control group (CG), and osteopathy treatment, which will be administered by a professional with experience in the field, every 15 days, for 8 weeks, totaling 4 sessions. The duration of the osteopathy sessions will be 40 minutes.

For osteopathy treatment, techniques such as soft tissue release, joint mobilizations, cranial sutures mobilizations, and visceral mobilizations will be utilized. Each technique will be applied until the therapist feels the tissue release in the treated area. The protocol was defined based on

the anatomical, neurophysiological, and autonomic relationships between the structures to be treated and the lumbar spine [12,24]. Multimodal osteopathic interventions used in this treatment protocol are displayed in Fig. 3.

Table 1. Exercises osteopathy protocol

Standart treatment for chronic low back pain	
Exercises Sessions 1 to 16	Bridge Cat Frontal plank Lateral plank Abdominal Straight leg raising Pelvis abduction (“Oyster’’)
Multimodal Osteopathic treatment for chronic low back pain	
Exercises Sessions 1 to 4	4º Ventricle release (CV-4) Suboccipital release Diaphragm functional release Renal fascia release Jejunum and ileum release Cecum release Sigmoid release DOG technique Pelvis global technique
Exercises Sessions 1 to 16	Bridge Cat Frontal plank Lateral plank Abdominal Straight leg raising Pelvis abduction (‘’Oyster’’)

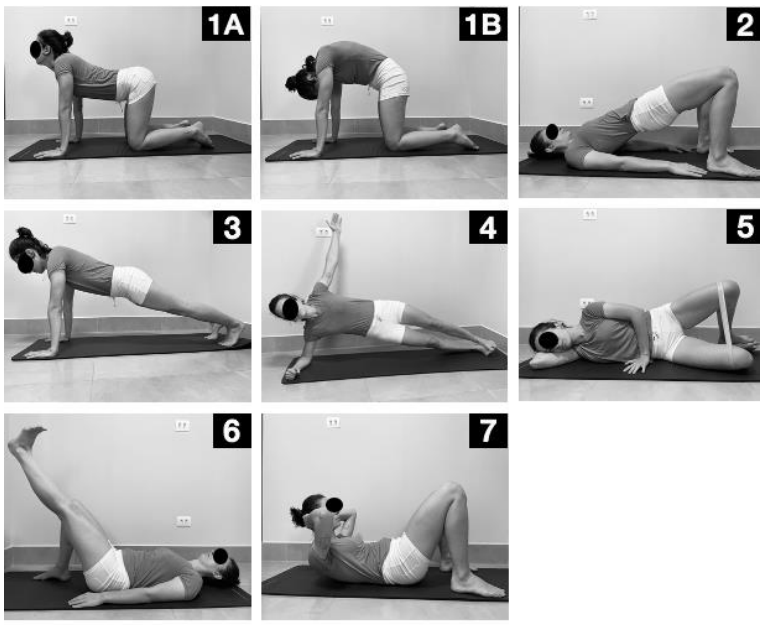

Fig. 2. Standard treatment for chronic low back pain: Exercises. Sessions 1 to 16. 1A and 1B – Spine mobilization (‘’Cat’’); 2 – Bridge exercise; 3 – Frontal plank; 4 – Side plank; 5 – Pelvis abduction (‘’Oyster’’); 6 – Straight leg raising; 7- Abdominals. The exercises will be performed according to the participant’s condition and will not cause pain. (Figure source: authors)

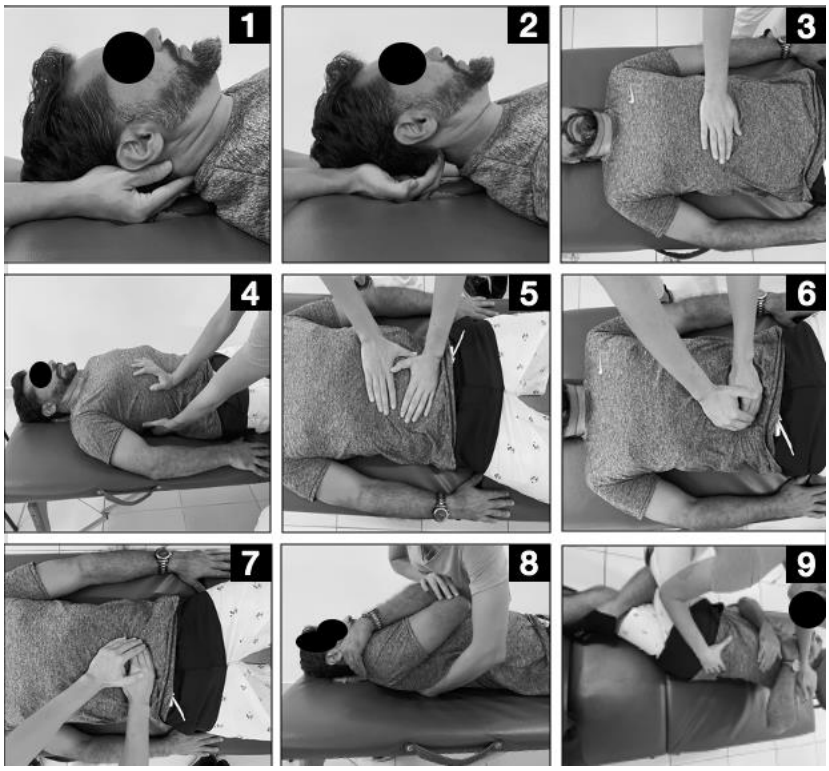

Fig. 3. Intervention: Multimodal osteopathic intervention. Sessions 1 to 4. 1 – CV-4 fourth ventricle release; 2 – Suboccipital release; 3 – Diaphragm functional release; 4 – Renal fascia release; 5 – Jejunum and ileum indirect release; 6 – Cecum release; 7 – Sigmoid release; 8 – DOG technique; 9 – Pelvis global technique. (Figure source: authors).

3. DISCUSSION

Recent Systematic reviews [10,11] and clinical trials [18,27] have shown promising effects about the Osteopathic treatment in individuals with CLBP. However, the adopted approaches were with isolated techniques for treatment. No evidence was found about the clinical effects of a multimodal treatment for this dysfunction.

Thus, this study aims to demonstrate the use of multimodal osteopathic approach, encompassing all your didactic divisions and applying the osteopathic concept similar to the daily clinical use. The results of this clinical trial will support evidence-based practices in osteopathic field and could contribute to decision making process about therapeutic modalities to be use as a treatment for CNSLBP. The data will be published after the study is completed.

4. CONCLUSION

This protocol study may contribute to new research possibilities, including multimodal osteopathic treatment combined with other therapeutic techniques in patients with low back pain. After the results of this future study are published, the proposed therapeutic approach may be integrated into clinical practice as a complement to conventional therapy for low back pain, expanding the therapeutic options available to healthcare professionals and patients.

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

The author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during the writing or editing of this manuscript 3.

CONSENT

As per international standard or university standard, patient(s) written consent has been collected and preserved by the authors.

ETHICAL APPROVAL

Eligible participants will receive full information on the objectives and procedures to be carried

out in the study, and those who agreed to participate must signed a statement of informed consent, in accordance with the Declaration of Helsinki 1975 and Resolution 466/12 of the National Health Council. This study received approval from the Ethics Committee of the Nove de Julho University (process nº: 6.275.345) and is registered with ClinicalTrials.gov (NCT06566144).

The personal Information about potential and enrolled participants will be collected, shared, and maintained by the study researchers in order to protect confidentiality before, during, and after the trial.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. Hartvigsen, J, Hancock MJ, Kongsted A, Louw Q, Ferreira ML, Genevay S, Hoy D, Karppinen J, Pransky G, Sieper J. What low back pain is and why we need to pay attention. Lancet. 2018;391:2356–2367.
2. Kahere M, Hlongwa M. A scoping review on the epidemiology of chronic low back pain among adults in Sub-Saharan Africa. 2022:1–22.
3. Knezevic NN, Candido KD, Vlaeyen JWS, Van Zundert J, Cohen SP. Low back pain. Lancet 2021;398:78–92.
4. Maher C, Underwood M, Buchbinder R. Non-specific low back pain. Lancet. 2016;389:736-747.
5. George SZ, Fritz JM, Silfies SP, Schneider MJ, Beneciuk JM, Lentz TA, et al. Interventions for the management of acute and chronic low back pain: Revision 2021. J Orthop Sports Phys Ther. 2021; 51:CPG1–60. Available:https://doi.org/10.2519/jospt.2021.0304.
6. Kent P, Keating J. Do Primary-care clinicians think that nonspecific low back pain is one condition? Spine (Phila Pa 1976). 2004;29:1022–31.
7. Kolber MR, Ton J, Thomas B, et al. PEER systematic review of randomized controlled trials: Management of chronic low back pain in primary care. Can Fam Physician. 2021;67(1).
8. Gianola S, Bargeri S, Del Castillo G et al. Effectiveness of treatments for acute and subacute mechanical non-specific low back pain: A systematic review with network meta-analysis. Br J Sports Med. 2022;56:41-50.
9. Owen PJ, Miller CT, Mundell NL, Verswijveren SJJM, Tagliaferri SD, Brisby H, et al. Which specific modes of exercise training are most effective for treating low back pain? Network meta-analysis. Br J Sports Med. 2020;54:1279–87.
10. Dal Farra F, Risio RG, Vismara L, Bergna A. Effectiveness of osteopathic interventions in chronic non-specific low back pain: A systematic review and meta-analysis. Complement Ther Med. 2021; 56:102616.
11. Franke H, Franke JD, Fryer G. Osteopathic manipulative treatment for nonspecific low back pain: A systematic review and meta-analysis. BMC Musculoskelet Disord. 2014;15.
12. Bortolazzo GL, Pasin Neto H, Bicalho E. Osteopatia: Um conceito global e integrativo. Piracicaba: Editora dos Editores. 2019;344.
13. Suzuki H, Aono S, Inoue S, Imajo Y, Nishida N, Funaba M, et al. Clinically significant changes in pain along the Pain Intensity Numerical Rating Scale in patients with chronic low back pain. Plos One. 2020;15:1–16.
14. Faul F, Erdfelder E, Lang AG, Buchner A. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods. 2007;39(2):175–91.
15. Buchbinder R, Hartvigsen J, Dan C, et al. What low back pain is and why we need to pay attention. Lancet. 2018a;391:2356–67.
16. Buchbinder R, Hartvigsen J, Dan C, et al. What low back pain is and why we need to pay attention. Lancet. 2018b;391:2356-2367.
17. Ferreira-Valente MA, Pais-Ribeiro JL, Jensen MP. Validity of four pain intensity rating scales. Pain. 2011;152:2399–404. Available:https://doi.org/10.1016/j.pain.2011.07.005.
18. Silva ACO, Godinho MM, Biasotto-Gonzalez DA, Politti, F. The effect of tongue and suprahyoid muscles release in the treatment of chronic non-specific neck

pain: Study protocol for a randomized controlled trial. International Journal of Osteopathic Medicine. 2020;38: 25-30.
19. Vigatto R, Alexandre NMC, Filho HRC. Development of a Brazilian Portuguese Version of the Oswestry Disability Index. Spine (Phila Pa 1976). 2007;32:481–6.
20. Perret C, Poiraudeau S, Fermanian J, Lefèvre Colau MM, Mayoux Benhamou MA, Revel M. Validity, reliability, and responsiveness of the fingertip-to-floor test. Arch Phys Med Rehabil 2001; 82:1566–70.
21. LOP C, CG M, J L, PH F, ML F, GC P, et al. Clinimetric testing of three self-report outcome measures for low back pain patients in Brazil: Which one is the best? Spine (Phila Pa 1976). 2008;33:2459–63.
22. Pilz B, Vasconcelos RA, Marcondes FB, Lodovichi SS, Mello W, Grossi DB. The Brazilian version of STarT Back Screening Tool - translation, cross-cultural adaptation and reliability TT - Versão brasileira do STarT Back Screening Tool - tradução, adaptação transcultural e confiabilidade. Brazilian J Phys Ther. 2014;18:453–61.
23. Twisk JWR. The problem of evaluating the magnitude of tracking coefficients. Eur J Epidemiol. 2003;18:1025–6.
24. De Oliveira Meirelles F, De Oliveira Muniz Cunha JC, Da Silva EB. Osteopathic manipulation treatment versus therapeutic exercises in patients with chronic nonspecific low back pain: A randomized, controlled and double-blind study. J Back Musculoskelet Rehabil. 2020;33:367–77.
25. Sipaviciene S, Kliziene I. Effect of different exercise programs on non-specific chronic low back pain and disability in people who perform sedentary work. Clin Biomech. 2020;73:17–27.
26. Kim B, Yim J. Core stability and hip exercises improve physical function and activity in patients with non-specific low back pain: A randomized controlled trial. Tohoku J Exp Med. 2020;251:193–206.
27. Licciardone JC, Moore S, Fix K, Blair LG, Ta K. Osteopathic manipulative treatment of patients with chronic low back pain in the United States: A retrospective cohort study. J Osteopath Med. 2023;123:259–67.

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