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Effects of Three Sessions of Diaphragmatic Myofascial Release on Pain, Balance, and Quality of Life in Patients with Chronic Nonspecific Low Back Pain (A Regional Interdependence Model): Protocol of a Randomized Clinical Trial

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ABSTRACT

Background: Chronic nonspecific low back pain (CNLBP) is a prevalent cause of disability, despite advancements in management. The diaphragm, a key respiratory muscle crucial for adjusting intra-abdominal pressure and maintaining lumbar spine stability, often exhibits dysfunction in chronic LBP. Improving diaphragm function may yield positive effects on chronic LBP. Therefore, the main aim of the present study is to assess the addition of myofascial release of the diaphragm to traditional treatment on pain, balance, and quality of life in patients with chronic nonspecific LBP.

Methods: A prospective, double-blind, randomized controlled clinical trial will include 24 participants with CNLBP, randomly assigned to a control group (sham diaphragm myofascial release) or an interventional group (diaphragm myofascial release). All patients will receive three sessions of either the main release or sham interventions, followed by the application of Transcutaneous Electrical Nerve Stimulation (TENS). Outcome measures will be assessed at baseline, after the third session (post-treatment), and after one week (follow-up). Pain will be measured using the Visual Analogue Scale (VAS), disability using the Roland-Morris Questionnaire, static balance via the single-leg stance test, dynamic balance using the functional reach test, lumbopelvic mobility via the tip-to-floor test, and chest expansion with a tape measure. This study is the first to investigate the effects of diaphragm myofascial release in individuals with chronic low back pain. Considering the diaphragm's potential role in postural control and interdependence of body regions, this intervention may offer benefits beyond pain relief, including improved balance and function. The randomized controlled design enhances the reliability of findings. Although blinding and objective diaphragm assessment were limited, the results may support the inclusion of this safe and simple technique as an adjunct in managing chronic LBP.

Results: Repeated measures ANOVA will be used for data analysis after collection.

Conclusion: This trial will examine the effects of diaphragm myofascial release compared with sham diaphragm myofascial release on pain, balance, chest expansion, lumbopelvic mobility, and disability in individuals with chronic nonspecific LBP. Potential implications for clinical practice and future research will be discussed, and the limitations of the study will also be considered.

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Introduction

Low back pain (LBP), affecting approximately 23% of adults, ranks among the top five reasons for physician visits, with about 11–12% of individuals experiencing disability worldwide [1]. According to European guidelines, low back pain is characterized by the presence of pain in the region between the last ribs and the inferior gluteal creases, with or without referral to the lower limbs [2]. The most prevalent form of low back pain is known as "chronic non-specific low back pain," which lacks a specific identifiable pathology [3]. Low back pain can be categorized based on the duration of symptoms: "acute" for symptoms lasting less than 6 weeks, "sub-acute" for symptoms lasting more than 6 weeks but less than 12 weeks, and "chronic" for symptoms persisting for more than 12 weeks [4]. More than 80% of health expenses are related to low back pain, impacting over 7 million American adults who experience limitations in their activities of daily living due to chronic low back pain [5]. This condition not only leads to a reduced quality of life but also results in increased disability [6].

Previous studies have indicated that individuals with low back pain differ from healthy subjects in terms of lumbar fascia properties [7]. Research on lumbar myofascial release has shown positive outcomes for patients with chronic non-specific low back pain [8-13]. Many studies on low back pain focus primarily on the lumbar region; however, previous research has also demonstrated that the respiratory system influences low back pain [14, 15]. The diaphragm plays a crucial role in lumbar stabilization [16]. This dome-shaped muscle descends during inspiration, adjusting intra-abdominal pressure to help stabilize the lumbar spine [17]. Dysfunction of the diaphragm—whether related to mobility, strength, or endurance—can adversely affect lumbar spine function [18]. While some studies have demonstrated restrictions in diaphragm mobility, limited research has focused on strategies to improve diaphragm mobility in patients with chronic non-specific low back pain [19-21].

Myofascial release has been identified as an effective treatment for reducing disability caused by low back pain [22]. This technique involves applying low-load, prolonged stretches to the fascial tissue to restore its optimal length, potentially leading to reductions in both pain and disability [22, 23]. The literature indicates that fascia plays a crucial role in transmitting force, serving as a conduit for nerves and vessels, and providing proprioceptive input due to its abundant innervation [23, 24]. Fascia is a key structure in maintaining balance, primarily by providing normal proprioception. Due to its abundance of proprioceptors, fascia can detect internal and external stimuli, enabling the control of motor responses. It allows individuals to perceive the position of their body parts in space, even with their eyes closed [25]. It has been demonstrated that static balance is impaired in patients with chronic non-specific low back pain [26]. As is well known, balance relies on three key subsystems: visual, vestibular, and proprioceptive [26-28]. Although the role of the diaphragm has been discussed in chronic low back pain, no research to date has investigated the effects of diaphragm myofascial release on chronic non-specific low back pain. The present study explores the impact of diaphragm myofascial release on pain, balance, and disability in patients with low back pain.

Method

Study Design

This study will be a double-blinded, randomized controlled trial, with the assessor and the patients blinded. The trial will include two groups: an intervention group and a sham intervention group. The study was registered in the Iranian Registry of Clinical Trials (https://irct.behdasht.gov.ir/trial/67486, on February 28, 2023). It has been approved by the Ethics Committee in Research at the Tehran Faculty of Rehabilitation Sciences (Approval ID: IR.TUMS.FNM.REC.1401.119). This study protocol will follow the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) to guide reporting of the study's findings (Appendix 3). Participant enrollment will be conducted by posting study advertisements on social media until the required sample size is achieved. All measurements will be conducted at the Laboratory of the School of Rehabilitation, Tehran University of Medical Sciences (TUMS).

Participants

Individuals diagnosed with chronic non-specific low back pain by a physician will be recruited. The diagnosis of non-specific low back pain typically involves excluding other specific or severe conditions such as nerve root compression, spondylolisthesis, spinal infection, and cauda equina syndrome [1]. Participants with chronic non-specific low back pain, as diagnosed by a physician, will be recruited through advertisements in clinics and social media platforms affiliated with Tehran University of Medical Sciences and physiotherapy clinics in Tehran.

Inclusion criteria

The inclusion criteria for participant selection include individuals aged 18–40 who have had pain lasting for more than three months, experience discomfort between the lower ribs and the gluteal crease, do not radiate pain below the gluteal crease, present non-radicular pain, lack neurological signs, and have no history of surgery in the thoracic or lumbar regions.

Conversely, exclusion criteria include individuals currently undergoing other treatments for low back pain and those exhibiting signs of fracture or infection in the low back region.

Randomization, Allocation, and Blinding

The target population will comprise 24 participants with chronic non-specific low back pain. This sample size was calculated based on data from our previous pilot study involving four patients with non-specific low back pain who underwent diaphragm myofascial release. The variables assessed in the pilot study were pain intensity (VAS) and chest expansion. Participants who sign the consent form will be randomly allocated in a 1:1 ratio. Randomization will be performed using the "Random Allocation Software."

Participants in the intervention group will receive diaphragm myofascial release. In contrast, those in the sham intervention group will experience identical hand placement, but the physiotherapist will not apply any force to release the diaphragm muscle. A single physiotherapist will administer the intervention. However, a second physiotherapist will conduct baseline outcome measurements, assessments at the third session, and follow-up evaluations blinded to group assignments. The assessor involved in outcome evaluations will remain blinded throughout the study and will not have access to information regarding whether a participant belongs to the intervention or sham group.

Intervention

The physical therapist will employ two diaphragm myofascial release techniques. In the first technique, the participant will lie supine on the table while the therapist stands above. The therapist will place their hypothenar and the three medial fingers to target the cartilaginous parts of ribs 7–10 on both sides. During the participant's inhalation, the therapist will apply cranially and laterally directed force to the lower ribs to facilitate their elevation. During exhalation, the therapist will use resistance against rib movement. This technique will be repeated for two sets, with ten repetitions per set [29].

In the second technique, the participant will lie prone, and the therapist's hands will be placed on the posterior side of the lower ribs and the popliteal region on the same side. During exhalation, the therapist will move their hands away from each other without sliding them on the participant's skin, and the force will be discontinued during inhalation. This technique will be performed for one minute on each side [30].

In the sham intervention group, the physical therapist will use the exact hand placements as in the intervention group; however, no force will be applied in any direction. This will control for the placebo effects of touch in both groups. In both groups, conventional Transcutaneous Electrical Nerve Stimulation (TENS) will be applied to the low back region for 20 minutes, with an electrical current frequency of 100 Hz and a pulse duration of 200 µs [31]. The treatment will be administered over three sessions, and participants will be instructed to refrain from receiving other therapies during the study period. The study will be discontinued if a participant reports worsening pain during or between sessions.

Outcome Measures

The outcome measures for this study are essential for evaluating the multiple dimensions of chronic non-specific low back pain. The Visual Analogue Scale (VAS) quantifies pain intensity, offering insight into the subjective experience of pain. The Roland Morris Low Back Pain and Disability Questionnaire captures the multifaceted nature of pain-related disability. The Finger Tip to Floor Distance Test assesses lumbopelvic mobility, while the Single-Leg Stance and Functional Reach Tests evaluate static and dynamic balance. Chest expansion measurements provide information on respiratory function. These measures offer a comprehensive assessment of how chronic non-specific low back pain affects pain, disability, mobility, and functional capacity. These measurements will be recorded at baseline, during the third session, and one week after the third session.

Pain Intensity

Pain intensity will be assessed using the VAS, where scores range from 0, indicating "no pain," to 10, representing "the worst pain imaginable." A paper-based visual analogue scale will be used to measure pain intensity [32].

Low Back Pain Disability

Low back pain-related disability will be evaluated using the Roland Morris Low Back Pain and Disability Questionnaire, which consists of 24 items. Participants will select the items that reflect the disabilities they have experienced due to low back pain. This questionnaire is considered a reliable and sensitive tool for assessing disability in individuals with low back pain [33].

Lumbopelvic mobility

Lumbopelvic mobility will be assessed using the Finger Tip to Floor Distance Test, a valid and reliable measure. During this test, participants will attempt to touch the floor with their fingers while standing without bending their knees. The physical therapist will then measure the distance between the tip of the third finger and the floor using a standard tape measure [34].

Static Balance

Static balance will be assessed using a chronometer while the participant stands on one leg with arms crossed, aiming to maintain balance. The physical therapist will stop the chronometer if the participant loses balance, with a maximum time limit of 45 seconds. The test will be conducted six times—three times with eyes closed and three times with eyes open. The mean time for static balance with eyes closed and open will be calculated separately. This test is recognized as a valid and reliable measure of static balance [35].

Dynamic Balance

The Functional Reach Test, a reliable and valid measure, will be utilized in this study to assess dynamic balance. During this test, the participant will stand by a wall with the toes of both feet behind a line. The physical therapist will instruct the participant to flex the shoulder to 90 degrees and reach forward as far as possible without bending the knees or moving the feet. The physical therapist will then measure the reach distance using a tape measure [36].

Chest Expansion

While in a short sitting position, the physical therapist will instruct the participant to perform maximal inhalation and exhalation, respectively. The physical therapist will then measure chest expansion at the level of the xiphoid process using a tape measure [30].

Data Collection and Sources of Data

Twenty-four volunteers meeting the study criteria will participate in this research and be randomly assigned to either the intervention or sham intervention group. One physical therapist will administer treatment, while outcome assessments at baseline, the third session, and the follow-up session will be conducted by another physical therapist who is blinded to group assignments. Participant recruitment commenced in April 2023, and data collection is ongoing. Changes in outcome measures before and after treatment for each group and differences between groups will be statistically analyzed and reported. We anticipate releasing our results in the fall of 2024.

Statistical Analysis

We determined the sample size based on our pilot study, resulting in 24 participants [12 in each group), calculated using G*Power with an effect size of 0.6. Four patients with low back pain were involved in our pilot study, and we measured chest expansion and pain intensity in these individuals.

Statistical analysis will be conducted using IBM SPSS Statistics for Windows, version 25. Outcome measures will be presented as means, standard deviations, and 95% confidence intervals. The Kolmogorov–Smirnov test will be employed to assess the normality of the data. If the data meet the normality assumption, we will use the independent samples t-test to compare differences between the intervention and sham groups. Repeated-measures ANOVA will be applied to evaluate the intervention's effectiveness over time (baseline, post-treatment, and follow-up). A significance level of 0.05 will be considered statistically significant. If the data do not meet the assumptions of parametric tests, non-parametric alternatives or transformations will be considered, depending on the dataset's characteristics and recommendations from statistical experts.

Discussion

To our knowledge, no study has explored the effectiveness of diaphragm myofascial release in individuals with low back pain (LBP). Chronic LBP is a debilitating condition, with its prevalence increasing worldwide. [37]. According to the regional interdependence model, areas remote from the site of pain may influence the painful region [38]. The diaphragm, a primary respiratory muscle, can exhibit dysfunction in individuals with chronic LBP [18]. Diaphragmatic excursion tends to be restricted in these patients [20]Therefore, improving diaphragm muscle

excursion may positively affect LBP characteristics, which encompass not only pain but also factors such as balance and disability. Understanding these broader implications is crucial for comprehensively addressing the complex nature of chronic LBP.

Since managing chronic LBP remains a challenge in healthcare, the introduction of effective adjunctive treatment options is highly valuable. Myofascial release is considered a very safe method. Therefore, we designed a study to evaluate the effects of diaphragm myofascial release on LBP. Myofascial release helps elongate and soften connective tissue, increasing its length and width through the realignment of collagen crystals [39].

In the sham intervention group, the physical therapist will use the exact hand placements as in the intervention group, but no directional force will be applied. This approach is intended to control for the placebo effects of touch in both groups.

The strength of this study lies in its design as a double-blinded randomized controlled trial, ensuring a rigorous and unbiased assessment of the intervention's effects. Blinding both participants and assessors reduces potential biases, thereby enhancing the reliability of the study findings. Exploring the economic implications and cost-effectiveness of incorporating diaphragm myofascial release into the management of chronic LBP could further support its practical utility in healthcare settings.

This study has some limitations. Double or triple blinding is not feasible, and laboratory-based assessment of diaphragm function is not included.

Conclusion

This study will provide evidence regarding the effectiveness of diaphragm myofascial release compared to sham diaphragm myofascial release in addressing pain, balance, chest expansion, and disability in patients with chronic non-specific LBP.

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Author Contributions

All authors have made significant contributions to the study design, data collection, management, analysis, and interpretation; the writing of the report; and the decision to submit the report for publication. All authors have read and approved the final manuscript as submitted.

Conflict of interest: None declared

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