CLINICAL STUDY PROTOCOL & STATISTICAL ANALYSIS PLAN

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OFFICIAL STUDY PROTOCOL TITLE

Effects of Instrument-Assisted Soft Tissue Mobilization, Deep Friction Massage, and Sham Instrument-Assisted Soft Tissue Mobilization on Electromyographical Activation, Pain and Function in Non-Specific Low Back Pain

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This official document contains the full trial protocol and statistical analysis plan submitted for public registration on ClinicalTrials.gov. All trial procedures comply with ethical guidelines and institutional standards.

Effects of Instrument-Assisted Soft Tissue Mobilization, Deep Friction Massage, and Sham Instrument-Assisted Soft Tissue Mobilization on Electromyographical activation, Pain and Function in Non-Specific Low Back Pain

Abstract

Background: Non-specific low back pain (NSLBP) is one of the leading causes of disability worldwide and is associated with substantial physical, psychological, and socioeconomic burdens. Instrument-Assisted Soft Tissue Mobilization (IASTM) has demonstrated beneficial effects on pain, disability, and range of motion in individuals with NSLBP. However, it remains unclear whether these effects are attributable to the instrument itself, soft tissue mobilization mechanisms, or placebo-related factors. Furthermore, no previous study has directly compared IASTM with Deep Friction Massage (DFM) in lower back, despite their shared therapeutic principles.

Objective: To compare the effects of IASTM, DFM, and sham IASTM on pain, disability, lumbar range of motion, pressure pain threshold, psychological status, and electromyographical activation in individuals with NSLBP.

Methods: This assessor-blinded, three-arm randomized controlled trial will recruit 66 participants aged 18–60 years with NSLBP. Participants will be randomly assigned to IASTM, DFM, or sham IASTM groups. All groups will receive a standardized four-week rehabilitation program consisting of two sessions per week, including hot pack application, stretching, strengthening exercises, and cryotherapy. Outcome measures will be collected at baseline, immediately after the first treatment session, and after four weeks. Primary outcomes include pain intensity (VAS), disability (ODI), lumbar range of motion and surface electromyography (sEMG). Secondary outcomes include pressure pain threshold (PPT), and psychological status (HADS). Data will be analyzed using linear mixed models under an intention-to-treat framework.

Conclusion: This study will provide evidence regarding the comparative effectiveness of IASTM, DFM, and sham IASTM, helping to clarify the specific therapeutic contribution of instrument-assisted soft tissue mobilization in the management of NSLBP.

Introduction

Low Back Pain (LBP) continues to rank the world's top disease in terms of Years Lived with Disability (YLDs), with an estimated number of people suffering from it at 619 million worldwide in 2020 and 628.8 million in 2021 (1,2). However, the Age Standardized Prevalence Rate (ASPR), Incidence Rate (AIR), and YLDs rate of the disorder have slightly decreased since 1990 because of reduced occupational ergonomic risk factors and a decrease in smoking rates (1,3). Nonetheless, its absolute number has increased sharply because of population expansion and aging. Thus, 266 million newly diagnosed cases of the disorder were reported in 2021, with Central Europe demonstrating the highest ASPR of the illness and East Asia having the lowest values (2). LBP is always more widespread among females, and its prevalence increases with age. The highest prevalence was observed at the age of 80–84, while the maximum number of cases occurred between 50 and 54 (1,4). According to the projection, 843 million people would be suffering from LBP by 2050, with the largest increase expected to happen in Asia and Africa (1). The three modifiable risk factors occupational

ergonomic factors, high Body Mass Index (BMI), and smoking account for 38-39% of the LBP-related YLDs (1,2).

Pathophysiology and Clinical Characteristics Non-Specific Low Back Pain (NSLBP), also known as "mechanical LBP," refers to pain localized between lower ribs and gluteal folds for at least 12 weeks with no pathological causes (5). It involves several physiological processes such as nociceptive mechanisms, nerve damage, and central sensitization. One of the current models of the condition is based on a concept of the myofascial unit, which includes muscles, fasciae, nerves, lymphatics, and blood vessels (6). Persistent nociceptive stimulus from somatic or visceral origin leads to the development of central sensitization in the spine and antidromic release of inflammatory neuropeptides and induction of neurogenic inflammation, which, in turn, provokes fascial densification, reduced ability to glide, and stasis, thus causing pain (6). Clinically, NSLBP manifests itself in a form of deep, diffuse, aching pain, with its symptoms depending on the source of the problem: discogenic, zygapophyseal joint, sacroiliac joint, or lumbar muscle strain (5). Neurological examination in this case usually results in negative outcomes. Psychological factors play an important role in the manifestation of the problem. Thus, patients with NSLBP demonstrate higher prevalence of such symptoms as sleep disturbance, anxiety, and depression, and the presence of the latter makes pain worse (7). Furthermore, there are clinical differences between the patient groups, e.g., those young females who have mild lumbar scoliosis suffer from unilateral pain in comparison to those who do not have this abnormality, with lower pain intensity and asymmetry of the paraspinal muscles (8).

Management Guidelines The current international management guidelines of NSLBP promote non-pharmacological management as the first-line treatment approach with a focus on multimodal active interventions (9,11). The main type of intervention in question is exercise therapy, including general aerobic exercise and strengthening. It is also highly recommended to conduct various mind-body practices such as Pilates and yoga. There is strong evidence that the latter is superior to any inactive therapy and especially helpful in relieving pain and disability caused by chronic NSLBP (10,12). Such interventions as adapted physical exercise (McKenzie method, motor control exercises) and multidisciplinary biopsychosocial rehabilitation combining physical activity, psychological interventions, and ergonomics are among the most successful ones (10,11). Manual Therapy, e.g., spinal manipulation and mobilization, is recommended only as an adjuvant to exercise therapy (9,11). In contrast, passive approaches, including electrotherapy (TENS, ultrasound, laser), mechanical traction, lumbar corset, and bed rest are rejected (9,11,12). Patient education is highly recommended with an accent on keeping active, reassurance, and dealing with fears related to movement (9,11). CBT is suggested for patients with chronic NSLBP who have psychosocial risk factors, i.e., yellow flags (11,12). Moreover, recent studies prove the usefulness of Kinesio taping for managing acute pain but fail to demonstrate the effectiveness of this method in the long-term course of the treatment (12).

The deep friction massage (DFM) therapy, also called Cyriax friction massage or transverse friction massage, is considered as a specific type of soft tissue technique that was developed by Dr. James Cyriax. This treatment aims to keep the mobility of the ligament, tendon, and muscle, and inhibit or break down scar adherence and adhesion (24). This technique is commonly used for various musculoskeletal pathologies (25).

This approach is done by using deep transverse pressures across the direction of the affected tissue with the goal of creating traumatic hyperemia in order to eliminate the metabolites that cause pain and restore functional movement (27). Various empirical studies have shown that DFM is effective in reducing pain for different painful disorders. For instance, DFM is found to be related to the improvement of pain, which is due to an analgesic effect that can last up to 24 hours; however, active release techniques have been proven to result in better grip strength improvement (24). As for myofascial pain syndrome, the application of DFM leads to a greater pain decrease than that from dry needling with improved cervical range of motion (26). A study on the treatment of adhesive capsulitis suggests that deep transverse friction massage has proven to significantly relieve pain and increase range of motion, particularly in the short term (27). Although DFM therapy is common, there are some authors who recommend the need for updating the parameters of the technique in view of the fact that its value has not been proven by all studies (25).

Instrument-Assisted Soft Tissue Mobilization (IASTM) refers to a form of manual therapy intervention involving hard instruments specifically manufactured from stainless steel or plastic to apply pressure to muscles, fascia, tendons, and ligaments. It originated from cross-friction massage and also shares some historical basis with gua sha, where specially made instruments allow practitioners to perform more invasive manipulations while minimizing the effort exerted during manual therapy (13,14,15). The suggested mechanisms include stimulation of fibroblasts proliferation, increased collagen synthesis, better blood flow, and promotion of inflammation necessary to induce tissue healing (13,14). According to the clinical trial results, an average improvement in the range of motion (ROM) of 10.7% and decreased joint stiffness (6.2%) can be achieved through just one session of IASTM through decreasing myofascial sliding resistance (16). For individuals with chronic neck pain, IASTM leads to pain relief and improved proprioception through increased fascial movement, improved local circulation, and decreased ischemia (17). There are data demonstrating the effectiveness of IASTM for the enhancement of soft tissue mobility and ROM especially of the ankle and shoulder joints (14). The findings from a systematic review and meta-analysis suggest moderate certainty evidence about IASTM as an efficient intervention for pain relief in musculoskeletal disorders and low certainty evidence for enhancing functioning in such disorders, particularly in chronic neck pain and cervicogenic headaches (18). Moreover, IASTM presents some ergonomic benefits to practitioners due to reduced physical loads from the manipulation procedure and possible prevention of musculoskeletal disorders related to work with hands (15).

There is ample evidence confirming the use of Instrument-Assisted Soft Tissue Mobilization (IASTM) for chronic and non-specific low back pain (NSLBP) management in providing patients with pain relief, reduction of disability, and increase in the range of movements of the lumbar spine (19,20,21). A four-week protocol including IASTM and conventional physiotherapy resulted in better outcomes than conventional physiotherapy alone in terms of pain reduction and disability improvement (19). Treatment of NSLBP patients using IASTM for two weeks led to significant improvement in the ROM in both lumbar flexion and extension (20). When compared to Kinesio-Taping (KT) technique, IASTM showed even better results with respect to pain (39.7% vs. 33.8%), disability (53.1% vs. 44.7%), and responder rate (93% vs. 77%) (21). In addition, a combination of IASTM and cupping therapy for one session provided immediate and

prolonged effects until one week later (23). Mechanistically, IASTM increases local bioimpedance that suggests decreased myofascial water content which might promote easier fascia gliding (22).

Notwithstanding the abundance of research studies on the effectiveness of Instrument Assisted Soft Tissue Mobilization (IASTM) for patients with NSLBP [19,20,21], certain limitations are still evident in existing literature. First of all, most previous studies did not compare IASTM directly with placebo control interventions [19,21,23]. As a result, it becomes impossible to identify whether observed improvement is caused by the instrument, mechanical effects of mobilization, or placebo influence. Moreover, even though IASTM relies on principles of Cyriax deep friction massage (DFM) [13,14,15]. To address the current lack of direct comparative data between instrument-assisted soft tissue mobilization (IASTM), deep friction massage (DFM), and sham IASTM, well-designed randomized controlled trials are required to assess their outcomes in patients with non-specific low back pain (NSLBP).

Null Hypothesis (H0) There will be no significant differences among Instrument-Assisted Soft Tissue Mobilization (IASTM), Deep Friction Massage (DFM), and sham IASTM in terms of pain reduction and functional improvement in patients with non-specific low back pain.

Alternative Hypothesis (H1) There will be significant differences among Instrument-Assisted Soft Tissue Mobilization (IASTM), Deep Friction Massage (DFM), and sham IASTM in terms of pain reduction and functional improvement in patients with non-specific low back pain.

Research Objectives

This randomized controlled trial primarily compares the effects of Instrument-Assisted Soft Tissue Mobilization (IASTM), Deep Friction Massage (DFM), and sham IASTM on pain intensity, functional disability, and paraspinal muscle activation in individuals with chronic non-specific low back pain (NSLBP). Specifically, the study aims to:

1. Determine whether IASTM provides superior therapeutic benefits over placebo by comparing it with sham IASTM.
2. Directly compare the effectiveness of IASTM against DFM.
3. Evaluate secondary outcomes, including lumbar range of motion (ROM), pressure pain threshold (PPT), and psychological status.

Methodology

This research is going to use a prospective, assessor-blinded, parallel-group randomized controlled trial (RCT) design in order to investigate the effects of IASTM, DFM, and sham IASTM on pain and functional results of patients suffering from NSLBP. Prior to the start of data collection, ethical approval will be sought from the Ethics Committee of Imam Abdulrahman Bin Faisal University, while the trial itself will be registered at an appropriate clinical trial registry (not avalible).

Participant recruitment will be performed via advertisements at physiotherapy outpatient clinics. In order to participate in the trial, patients should be between 18 and 60 years old, be diagnosed with NSLBP [19]. Participants with a history of spinal surgery,

spinal fracture, malignancy, inflammatory spinal diseases, neurological deficit, severe osteoporosis, pregnant women, and people having serious skin conditions will be excluded from participation [19]. Participants will be selected from low back pain classifications most consistent with mechanical and musculoskeletal dysfunction according to the APTA Clinical Practice Guidelines, including Acute and Subacute Low Back Pain with Mobility Deficits, Acute, Subacute, and Chronic Low Back Pain with Movement Coordination Impairments, and Acute Low Back Pain with Related (Referred) Lower Extremity Pain. These classifications are characterized primarily by nociceptive and movement-related impairments that are potentially responsive to manual therapy and soft tissue interventions. In contrast, individuals classified as having Chronic Low Back Pain with Related Generalized Pain or Low Back Pain with Related Cognitive or Affective Tendencies will be excluded. These classifications are associated with central nervous system sensitivity, altered pain processing, psychological factors, and features of central sensitization (nociplastic pain), which may not respond primarily to peripheral soft tissue interventions. Excluding these presentations will improve the homogeneity of the study sample and allow a more accurate evaluation of the specific effects of Instrument-Assisted Soft Tissue Mobilization and Deep Friction Massage on pain, disability, and neuromuscular function in individuals with non-specific low back pain [39].

Following the provision of written informed consent and completion of baseline assessments, eligible participants will be randomly assigned in a 1:1:1 allocation ratio to one of three intervention groups: (1) Instrument-Assisted Soft Tissue Mobilization (IASTM), (2) Deep Friction Massage (DFM), or (3) sham IASTM. Randomization will be performed using a computer-generated random sequence prepared by an independent researcher who is not involved in participant recruitment, treatment administration, outcome assessment, or data analysis. Allocation concealment will be ensured through the use of sequentially numbered, opaque, sealed envelopes (SNOSE). Each envelope will contain a single group assignment according to the pre-generated randomization sequence and will be opened only after completion of the baseline assessment. This procedure will minimize the risk of selection bias and maintain the integrity of the allocation process. A total of 66 participants will be enrolled in the study and allocated equally across the three intervention arms, resulting in 22 participants per group. The allocation ratio of 1:1:1 will ensure balanced group sizes and facilitate valid comparisons between interventions. Due to the nature of the interventions, blinding of the treating physiotherapists will not be feasible. However, outcome assessors and data analysts will remain blinded to group allocation throughout the study to reduce detection and analysis bias. The randomization code will remain concealed until completion of the statistical analyses. The rehabilitation program in all three groups will take four weeks and will involve two sessions per week [19].

Patients in the IASTM group will be treated with the help of D shaped stainless-steel IASTM instruments with sweep and fan movements being made across the lumbar paraspinal muscles and adjacent myofascial structures under moderate pressure [29]. During the treatment, the area under work will be coated with a lubricant, while the tool will be used at a certain angle to the tissues (30°-60°) [14]. All participants will receive a standardized exercise and education program based on the recommendations of the American Physical Therapy Association (APTA) Clinical Practice Guidelines for low back pain. The exercise program will consist of stretching and strengthening exercises

targeting impairments commonly associated with mobility deficits, movement coordination impairments, and referred lower extremity pain. The stretching component will include static stretches for the hamstrings, hip flexors, piriformis, gluteal muscles, and lumbar paraspinal muscles. Each stretch will be held for 30 seconds and repeated three times bilaterally. The strengthening component will focus on trunk coordination, stabilization, and muscular endurance. Exercises will include abdominal drawing-in, abdominal bracing, pelvic tilts, bridging, quadruped arm-leg raises (bird-dog), and modified plank exercises. Participants will perform 2–3 sets of 10–15 repetitions for each exercise, with progression based on individual tolerance and performance. In addition, all participants will receive standardized patient education emphasizing the favorable prognosis of non-specific low back pain, the importance of maintaining normal daily activities, avoiding prolonged bed rest, adopting active coping strategies, and gradually returning to work and physical activities. Education will also include information regarding the resilience of the spine, basic pain neuroscience concepts, and the importance of improving function and activity levels rather than focusing solely on pain reduction [39]. The exercise and education program will be delivered equally to all study groups throughout the intervention period to ensure consistency across treatment arms. [14]. This standard rehabilitation program, which will be common to all participants irrespective of their assignment to either of the three groups (IASTM, friction massage, or sham IASTM) will consist of stretching exercises, strengthening exercises, patient education.

Participants in the DFM group will undergo manual deep transverse friction massage according to Cyriax [25] with deep pressure being applied across the fiber orientation of affected tissues using standardized rhythmic transverse movements, limited to only six sweeps. Sham IASTM group participants will have an imitation of the real IASTM procedure, using the same tool and treatment positioning but without applying therapeutic pressure necessary for effective tissue mobilization [14].

Outcome measures

Outcome measures will be collected at baseline before treatment initiation (T0), immediately after the first intervention session (T1), and at Week 4 following completion of the intervention period (T2). The primary outcomes will be pain intensity, assessed using the Visual Analogue Scale (VAS); functional disability, assessed using the Oswestry Disability Index (ODI); lumbar range of motion (ROM), assessed using an inclinometer; and neuromuscular function, assessed using surface electromyography (sEMG). The secondary outcomes will include psychological functioning, assessed using the Hospital Anxiety and Depression Scale (HADS), and pressure pain threshold (PPT), assessed using a pressure algometer.

Pain

The assessment of pain intensity was done with the help of Visual Analog Scale (VAS), which is an accepted and proven instrument to measure pain in musculoskeletal diseases. The VAS was comprised of a horizontal line that had a length of 100 mm between two points, labeled "no pain" and "worst pain imaginable." Patients had to indicate how severe their pain was by marking the scale. Scores were calculated by determining the distance from the "no pain" point to the mark, expressed in millimeters.

High scores indicated more severe pain sensations. The VAS scale is a reliable and valid measurement tool, and the minimal clinical difference is estimated at 12 mm [30].

Disability

Oswestry Disability Index (ODI) was used as the measure to determine the level of physical disability experienced due to CLBP. ODI refers to a reliable and valid self administered questionnaire consisting of 10 items covering various aspects of daily activity performance on a 0-to-5-point scale [31]. A change of 10 points on the Oswestry Disability Index (ODI; 0–100 scale) was considered the minimal clinically important difference (MCID), representing a clinically meaningful improvement in disability among individuals with low back pain [28]. Increasing totals reflect an increasing level of disability. In ODI scoring system, 0%-20% reflects minimal disability, 21%-40% reflects moderate disability, 41%-60% reflects severe disability, 61%-80% reflects cripple or handicap, and 81%-100% reflects total disability. ODI has been found to be highly reliable and valid in measuring physical disability due to CLBP [32]. The Arabic version of the ODI adapted for the Saudi population has demonstrated excellent psychometric properties, including outstanding test–retest reliability (ICC = 0.99), good internal consistency (Cronbach's α = 0.886), and strong construct validity [37]. In addition, the Saudi Arabic version showed excellent feasibility and acceptability, requiring approximately 3.4 minutes to complete with no missing responses reported. Therefore, the Arabic ODI is considered a reliable and valid instrument for evaluating disability in Arabic-speaking individuals with chronic low back pain [37]. The Oswestry Disability Index (ODI) was used to assess functional disability, with a reduction of ≥10 points considered the minimal clinically important difference (MCID) [38].

Range of motion

Lumbar range of motion (ROM) will be assessed using Bubble inclinometer, a non invasive instrument widely used to quantify spinal mobility. Measurements will be obtained for lumbar flexion, extension, and lateral flexion using standardized anatomical landmarks. The T12 and S1 spinous processes will be used as reference points for flexion and extension measurements, while the T12 spinous process will serve as the reference point for lateral flexion assessment. Participants will be instructed to perform maximal movement within each plane of motion, and each measurement will be repeated three times, with the average value used for analysis to improve reliability and minimize measurement error. Previous research using the Baseline Bubble Inclinometer (Model 10602; Fabrication Enterprise Inc., USA) demonstrated excellent reliability for lumbar ROM assessment, with within-day ICC values ranging from 0.770 to 0.982, between-day ICC values ranging from 0.835 to 0.977, and SEM values ranging from 0.38° to 1.20°. Therefore, inclinometry is considered a reliable method for evaluating lumbar mobility and monitoring treatment outcomes [33].

Neuromuscular function

Kinematic and functional performance will be assessed using surface electromyography (sEMG) to evaluate paraspinal muscle activation during lumbar movement. Bilateral muscle activity of the thoracic erector spinae (TES), lumbar erector spinae (LES), and lumbar multifidus (LMU) will be recorded using a wireless surface electromyography system (Trigno™ Wireless EMG System, Delsys Inc., Natick, Massachusetts, USA). Prior

to electrode application, the skin will be prepared by light abrasion and cleansing with alcohol to reduce impedance. Disposable Ag–AgCl surface electrodes will be placed bilaterally with an inter-electrode distance of 20 mm. Electrode placement will be standardized at 5 cm lateral to the T9 spinous process for TES, and 2 cm lateral to the L2 and L5 spinous processes for LES and LMU, respectively [36]. The sEMG signals will be sampled at 2000 Hz, band-pass filtered between 10 and 500 Hz, full-wave rectified, and processed using root mean square (RMS) amplitude analysis. Muscle activation data will be normalized to a submaximal voluntary contraction (sMVC) obtained during a standardized prone trunk extension task. The average bilateral RMS amplitude will be used for statistical analysis, with higher values indicating greater paraspinal muscle activation and neuromuscular function. Previous studies have demonstrated excellent reliability for paraspinal sEMG measurements, with intraclass correlation coefficients (ICC) ranging from 0.872 to 0.996 [36].

Pain pressure threshold

The PPT test was performed using the hand-held digital algometer, which is a valid and reliable method of pain sensitivity quantification. The examination was conducted bilaterally on the lumbar paraspinal muscles using the Wagner FDX-25 digital algometer, with the application rate set to a constant 50 kPa per second. When subjects experienced the sensation of pressure changing into pain, a measurement was made. Three separate readings were recorded on both sides, with one minute separating each test, and the mean value was used for analysis [30]. PPTs were assessed over the erector spinae muscles, 2.5 cm lateral to the spinous process of the most painful lumbar segment using a pressure algometer [40].

Psychological status

Depression is more prevalent among individuals with chronic low back pain and is associated with greater pain intensity, disability, medication use, and unemployment, highlighting the importance of routine depression screening in this population [39]. Hospital Anxiety and Depression Scale (HADS), which is a tool used to assess psychological status, particularly anxiety and depression, was applied in the current study. HADS Arabic version consists of 14 items that are categorized into two domains: anxiety and depression, scored on a scale from 0 to 3. Scores that are higher indicate more psychological distress, while a score above 11 signifies clinical importance of the symptoms. The validity, reliability, and responsiveness of HADS Arabic have been found to be appropriate in assessing psychological status. Subjects answered the questionnaire independently in a silent environment before being assessed, and their anxiety and depression scores were separately calculated [34]. MCID for HADS has been estimated at about 1.5 [35].

Sample Size

A priori sample size calculation was performed based on the primary outcome of pain intensity measured using a 100-mm Visual Analogue Scale (VAS). The calculation was informed by the minimally clinically important change (MCIC) for chronic low back pain, which has been reported as 20 mm on a 100-mm VAS by Ostelo and de Vet [28]. To estimate variability, data were obtained from a previous randomized clinical trial involving individuals with chronic low back pain conducted by Rajfur et al. [41]. Based

on the baseline VAS standard deviations reported across treatment groups, a pooled standard deviation of 1.46 points was calculated and subsequently converted to 14.6 mm to correspond with the 100-mm VAS metric. Using these estimates, the standardized effect size was calculated as the ratio of the MCIC to the pooled standard deviation, yielding a Cohen's d of 1.37. However, because MCIC values are intended to reflect the smallest clinically meaningful improvement rather than the expected treatment effect, reliance on the MCIC-derived effect size may overestimate the true intervention effect and consequently underestimate the required sample size. Therefore, a more conservative moderate effect size (f = 0.25), consistent with Cohen's recommendations for ANOVA-based designs [42], was adopted for the final sample size estimation.

Sample size estimation was performed using GPower software (version 3.1.9.7; Heinrich-Heine University Düsseldorf, Germany). As the primary analysis will be conducted using linear mixed-effects models (LMMs), and GPower does not directly support sample size estimation for LMMs, a repeated-measures ANOVA with a within between interaction was used as an accepted approximation for the group × time interaction effect. The calculation assumed a moderate effect size (f = 0.25), an alpha level of 0.05, statistical power of 90% (1−β = 0.90), three treatment groups, and three assessment time points. A correlation of 0.50 among repeated measurements was assumed, consistent with commonly adopted practice in repeated-measures sample size estimation when prior estimates are unavailable, together with a nonsphericity correction factor of 1.0. Based on these assumptions, the minimum required sample size was estimated to be 55 participants. To account for an anticipated attrition rate of 15%, the final target sample size was increased to 66 participants, resulting in 22 participants per group (IASTM, DFM, and sham IASTM).

Statistical Analysis

All statistical tests will be performed using the IBM SPSS Statistics software, Version 29.0, (IBM Corp., Armonk, NY, USA). The analyses will follow the principles of intention-to-treat analysis. Descriptive statistics will be calculated for all baseline measures and demographics. Means and standard deviations will be used for continuous variables, whereas frequencies and percentages will be calculated for categorical variables. For the primary and secondary outcomes, LMMs will be applied to explore the effects of group, time point, and their interaction on each outcome measure, such as pain intensity, disability, range of motion, and pressure pain threshold. Random intercepts corresponding to individual participants will be included to control for correlations of outcomes measured repeatedly from the same subjects. Baseline measures can be included as covariates depending on each model.

Whereas Group × Time interactions are statistically significant, post-hoc analysis for pairwise comparisons will be carried out with Bonferroni correction for multiple testing. Statistical significance level is set at $p < 0.05$. Effect size will be calculated to interpret the clinical significance of the findings in addition to the p-value and 95% confidence interval. In cases of missing values, appropriate multiple imputation techniques will be applied.

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Appendixes

Appendix 1. Consent Form for Participants in the Randomized Controlled Trial

INFORMED CONSENT STATEMENT
Project Title: Effects of Instrument-Assisted Soft Tissue Mobilization (IASTM), Deep Friction Massage (DFM), and Sham IASTM on Pain and Function in Non-Specific Low Back Pain.
Principal Investigator: Mohammad Faiz Alahmari Affiliation: College of Applied Medical Sciences, Imam Abdulrahman Bin Faisal University
1. Invitation to Participate You are invited to participate in a research study conducted over four weeks. You have been selected because you have non-specific low back pain. The study compares three physiotherapy approaches: IASTM, DFM, and sham IASTM.
2. Study Procedures If you agree to participate, you will be randomly assigned to one of three groups: IASTM, DFM, or sham IASTM. You will receive two sessions per week for four weeks. Each session may include hot pack preparation, the assigned intervention, stretching, strengthening exercises, and cryotherapy.
Assessments will be conducted at baseline (T0), immediately after the first session (T1), and at week 4 (T2). Outcomes include pain intensity, pressure pain threshold, disability, lumbar range of motion, psychological status, and exploratory lumbar muscle activity using non-invasive surface EMG.
3. Risks and Discomforts Risks are limited and similar to routine physiotherapy. You may feel temporary soreness, mild discomfort, skin sensitivity, or fatigue after treatment. All procedures will be performed by trained personnel with safety precautions.
4. Benefits You may experience reduced pain, improved function, and improved lumbar mobility. Your participation may also help improve physiotherapy evidence for non-specific low back pain.
5. Confidentiality Your information will be kept confidential and identified by participant code only. Data will be used for research purposes only.
6. Voluntary Participation Participation is voluntary. You may refuse or withdraw at any time without any effect on your healthcare.
7. Questions and Contact Information Mohammad Faiz Alahmari Phone: 0547210987 Email: 2250700002@iau.edu.sa
8. Consent Statement By signing below, you confirm that you have read and understood the information, had the opportunity to ask questions, and voluntarily agree to participate.
Participant Name: _____ Participant Signature: _____ Date: _____ Researcher Signature: _____ Date: _____

Appendix 2. Demographic Data and Initial Screening Sheet

Section 1: Demographic Information	Value
Participant ID	
Name	
Age (18-60 years)	
Sex	☐ Male ☐ Female
Occupation	
Mobile number	
Height (cm)	
Weight (kg)	
BMI	
Dominance	☐ Right ☐ Left

Section 2: Clinical History	Response
Duration of low back pain	_____ weeks/months (must be >12 weeks)
Pain location	☐ Lumbar ☐ Lumbosacral ☐ Other: _____
Pain type	☐ Dull ☐ Sharp ☐ Radiating ☐ Other: _____
Previous episodes	☐ Yes ☐ No
Current medications (e.g., analgesics)	☐ Yes ☐ No Specify: _____
Previous physiotherapy for low back pain (last 6 months)	☐ Yes ☐ No
Red flags reported	☐ Yes ☐ No Specify: _____

Section 3: Inclusion Criteria (Tick if YES)	YES
Age between 18 and 60 years	☐
Diagnosed with non-specific low back pain (NSLBP)	☐

Section 4: Exclusion Criteria (Tick if YES)	YES
History of spinal surgery	☐
Spinal fracture	☐
Malignancy/cancer	☐
Inflammatory spinal disease	☐
Neurological deficit or radiculopathy requiring medical referral	☐
Severe osteoporosis	☐
Pregnancy	☐
Serious skin condition in the lumbar treatment area	☐
Any other contraindication to manual therapy/IASTM	☐

Eligibility Decision	Details
Decision	☐ Eligible ☐ Not Eligible
Reason if not eligible	
Assessor signature	
Date	

Appendix 3. Data Collection Sheet (RCT)

Study Information	Value
Study title	Effects of IASTM, DFM, and Sham IASTM on Pain and Function in Non-Specific Low Back Pain
Participant ID	
Group allocation	☐ IASTM ☐ DFM ☐ Sham IASTM
Assessor	
Date	

Section 1: Baseline Characteristics (T0 Only)	Value
Age (years)	
Gender (M/F)	
Height (cm)	
Weight (kg)	
BMI	
Occupation	
Dominant hand (R/L)	
Pain duration (weeks/months)	
Previous episodes (Y/N)	
Medication use (Y/N)	
Previous physiotherapy (Y/N)	

Time points: T0 = Baseline; T1 = Immediately after first session; T2 = Week 4

2.1 Pain Intensity (VAS 0-10)	T0	T1 (Post-first session)	T2 (Week 4)
Score			

2.2 Pressure Pain Threshold (PPT) - Lumbar Paraspinals (kPa)	T0	T1 (Post-first session)	T2 (Week 4)
Right lumbar paraspinals			
Left lumbar paraspinals			
Mean value			

2.3 Disability (ODI)	T0	T1 (Post-first session)	T2 (Week 4)
ODI raw score /50			
ODI percentage (%)			
Disability category			

2.4 Lumbar Range of Motion (Degrees)	T0	T2 (Week 4)
Flexion		
Extension		
Right lateral flexion		
Left lateral flexion		

2.5 Psychological Status (HADS)	T0	T2 (Week 4)
Anxiety score		
Depression score		

2.6 Exploratory Neuromuscular Function (sEMG)	T0	T2 (Week 4)
Right erector spinae activation		
Left erector spinae activation		
Right multifidus activation		
Left multifidus activation		
Muscle activity symmetry/index		

Section 3: Treatment Adherence	Attended (✓/✗)	Notes
Week 1 - Session 1		
Week 1 - Session 2		
Week 2 - Session 1		
Week 2 - Session 2		
Week 3 - Session 1		
Week 3 - Session 2		
Week 4 - Session 1		
Week 4 - Session 2		

Section 4: Adverse Events	Description
Date	
Severity	☐ Mild ☐ Moderate ☐ Severe
Action taken	
Outcome	

Section 5: Notes / Comments
Assessor Signature: _____ Date: _____

Appendix 4: Hospital Anxiety and Depression Scale. A: Anxiety question, and D: Depression question:

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:
Total score: Depression (D) _____ Anxiety (A) _____
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

Appendix 5: Oswestry Disability Index (ODI)

Section 1—Pain intensity

- ☐ I have no pain at the moment.
- ☐ The pain is very mild at the moment.
- ☐ The pain is moderate at the moment.
- ☐ The pain is fairly severe at the moment.
- ☐ The pain is very severe at the moment.
- ☐ The pain is the worst imaginable at the moment.

Section 2—Personal care (washing, dressing, etc.)

- ☐ I can look after myself normally without causing extra pain.
- ☐ I can look after myself normally but it causes extra pain.
- ☐ It is painful to look after myself and I am slow and careful.
- ☐ I need some help but manage most of my personal care.
- ☐ I need help every day in most aspects of self-care.
- ☐ I do not get dressed, I wash with difficulty and stay in bed.

Section 3—Lifting

- ☐ I can lift heavy weights without extra pain.
- ☐ I can lift heavy weights but it gives extra pain.
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed, eg. on a table.
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
- ☐ I can lift very light weights.
- ☐ I cannot lift or carry anything at all.

Section 4—Walking

- ☐ Pain does not prevent me walking any distance.
- ☐ Pain prevents me from walking more than 1 mile.
- ☐ Pain prevents me from walking more than ½ mile.
- ☐ Pain prevents me from walking more than 100 yards.
- ☐ I can only walk using a stick or crutches I am in bed most of the time.

Section 5—Sitting

- ☐ I can sit in any chair as long as I like.
- ☐ I can only sit in my favorite chair as long as I like.
- ☐ Pain prevents me sitting more than one hour.
- ☐ Pain prevents me from sitting more than 30 minutes.
- ☐ Pain prevents me from sitting more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

Section 6—Standing

- ☐ I can stand as long as I want without extra pain.
- ☐ I can stand as long as I want but it gives me extra pain.
- ☐ Pain prevents me from standing for more than 1 hour.
- ☐ Pain prevents me from standing for more than 3 minutes.
- ☐ Pain prevents me from standing for more than 10 minutes.
- ☐ Pain prevents me from standing at all.

Section 7—Sleeping

- ☐ My sleep is never disturbed by pain.
- ☐ My sleep is occasionally disturbed by pain.
- ☐ Because of pain I have less than 6 hours sleep.
- ☐ Because of pain I have less than 4 hours sleep.
- ☐ Because of pain I have less than 2 hours sleep.
- ☐ Pain prevents me from sleeping at all.

Section 8—Sex life (if applicable)

- ☐ My sex life is normal and causes no extra pain.
- ☐ My sex life is normal but causes some extra pain.
- ☐ My sex life is nearly normal but is very painful.
- ☐ My sex life is severely restricted by pain.
- ☐ My sex life is nearly absent because of pain.
- ☐ Pain prevents any sex life at all.

Section 9—Social life

- ☐ My social life is normal and gives me no extra pain.
- ☐ My social life is normal but increases the degree of pain.
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests (e.g., sports).
- ☐ Pain has restricted my social life and I do not go out as often.
- ☐ Pain has restricted my social life to my home.
- ☐ I have no social life because of pain.

Section 10—Travelling

- ☐ I can travel anywhere without pain.
- ☐ I can travel anywhere but it gives me extra pain.
- ☐ Pain is bad but I manage journeys over two hours.
- ☐ Pain restricts me to journeys of less than one hour.
- ☐ Pain restricts me to short necessary journeys under 30 minutes.
- ☐ Pain prevents me from travelling except to receive treatment.