Study Title:	**A novel treatment for nonspecific chronic low back pain Using Multi Angular Isometric Lumbar Exercise (MAILE): Randomized Clinical Trial.**
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Synopsis

The study aims to evaluate the effectiveness of Multi Angular Isometric Lumbar Exercise (MAILE) in comparison to traditional lumbar stabilization and core stability treatments for managing nonspecific chronic low back pain (NCLBP). MAILE is designed to specifically target the Lumbo-Pelvic Hip complex with the goal of improving pain levels, stability, strength, and overall function.

Objectives of the study are to assess several key outcomes:

Pain Intensity: Measuring the level of pain experienced by patients.

Functional Disability: Evaluating the impact of NCLBP on daily activities and overall function.

Functional Stability: Assessing the stability of the Lumbo-Pelvic Hip complex during movement.

Muscle Strength: Determining the strength of muscles within the targeted region.

By examining these outcomes, the research seeks to determine whether MAILE offers superior benefits and greater cost-efficiency compared to conventional treatments for patients with NCLBP and motor control dysfunction. If successful, MAILE could provide a more effective and economical approach to managing this common and debilitating condition. This Randomized Clinical Trial (RCT) will be conducted across multiple outpatient clinics within the Hamad Medical Corporation (HMC). The study will involve 98 patients diagnosed with non-specific chronic low back pain (NCLBP), who will be randomly assigned to one of two groups: the Multi Angular Isometric Lumbar Exercises (MAILE) group or the Core Stability group. Both groups will follow tailored exercise programs over a three-week period.

The MAILE group will focus on exercises designed to enhance lumbar stability and core strength through multi-angular isometric lumbar exercises performed at various angles. These exercises aim to target the deep stabilizing muscles of the lumbar spine, promoting overall spinal stability and reducing pain. The Core

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Stability group will engage in exercises that emphasize the activation and strengthening of the core muscles, which play a crucial role in maintaining spinal stability and function.

The outcomes of this trial will help determine the effectiveness of MAILE compared to traditional core stability exercises in managing NCLBP, potentially guiding future therapeutic strategies.

The study will evaluate the impact of the interventions on several critical factors, including pain, functional ability, muscle activation, and core stability. By assessing these outcomes, the research aims to identify a more effective and economical approach to managing nonspecific chronic low back pain (NCLBP). The goal is to determine whether Multi Angular Isometric Lumbar Exercise (MAILE) offers superior benefits compared to traditional lumbar stabilization and core stability treatments, potentially leading to improved patient outcomes and cost-efficiency in managing NCLBP.

1. Abbreviations and Acronyms

Multi Angular Isometric Lumbar Exercise (MAILE); Core stability exercise (CSE); Low back pain (LBP). Nonspecific chronic low back pain (NCLBP); years lived with disability (YLD); Visual Analogue Scale (VAS); Oswestry Disability Index (ODI); Activities of Daily Living (ADL); transverse abdominus (TrA); abdominal drawing-in maneuver (ADIM); internal oblique (IO); external oblique (EO); Chronic Mechanical Low Back Pain (CMLBP); standard deviation (SD); interquartile range (IQR); Pressure Biofeedback Unit (PBU); Posterior Superior Iliac Spine (PSIS); Magnetic Resonance Imaging (MRI); Body Mass Index (BMI); International Classification of Disease (ICD); International Classification of Functioning, Disability, and Health (ICF);

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2. Introduction / Background

Low back pain (LBP) is defined as pain and discomfort localized below the costal margin and above the inferior gluteal folds, with or without referred leg pain (1). It is a common complaint worldwide, affecting both genders and most age groups, with about one in four adults seeking care within a sixmonth period. Although most recent-onset LBP episodes settle, only about one in three resolves completely over a 12month period. Additionally, about three in five cases will recur in an ongoing relapsing pattern, and about one in ten do not resolve at all (2).

Nonspecific chronic low back pain (NCLBP) affects a significant portion of the adult population, often leading to disability and reduced quality of life. Among the various contributing factors, weakness and dysfunction of the lumbar musculature play a critical role in the persistence and exacerbation of symptoms. While traditional exercise approaches such as dynamic strengthening and stretching exercises have shown some efficacy, they often fail to adequately target the deep stabilizing muscles of the lumbar spine or may not be suitable for all patients, particularly those with pain or instability. (3) Multi-Angular Isometric Lumbar Exercises (MAILE) present a novel approach to addressing these challenges by allowing for the isometric contraction of lumbar muscles at multiple angles, which is hypothesized to improve overall lumbar stability and strength without the risks associated with dynamic movements. Previous research has demonstrated the effectiveness of isometric exercises in enhancing muscle strength and joint stability; however, the application of MAILE in populations with NCLBP has not been thoroughly investigated (4). This study aims to explore the efficacy of MAILE in improving lumbar

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muscle function and reducing pain in individuals with NCLBP, thereby filling a critical gap in the current evidence and potentially informing future clinical practice."

Epidemiology

Low back pain (LBP) is well recognized as a public health problem. The Global Burden of Disease Study 2016 reported LBP in the top of years lived with disability (YLD) contributing 57.6 million (40.8–75.9 million) of total YLDs, largely because of aging and increasing world population. In low- and middleincome nations, LBP has risen by more than 50% since 1990. (5). Estimates of the point prevalence vary from 12-33% and lifetime prevalence varies from 11-84% (6). The Pathophysiology of patients with LBP is not well understood. In Germany, about 70% of adults have at least one episode of back pain per year
(7), meaning that the mechanism is unclear. Given how little we know about the underlying causes of LBP; it is not surprising that a gold standard treatment does not currently exist.

Prevalence of back pain in the middle east

Nonspecific chronic low back pain (NCLBP) is a pervasive health issue, with a particularly high prevalence in the Middle East. In Saudi Arabia with a prevalence rate ranging from 18.8% to 53.5%. The specific statistics—24.1% of workers reporting reduced working hours, 29.2% experiencing limitations in activities, and 15.3% being absent from work—underscore the substantial burden LBP places on both individuals and the workforce in the region. (8)

In 2013, a cross-sectional survey conducted in Qatar investigated the epidemiology of low back pain

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(LBP) within the primary healthcare setting. The study revealed that LBP had a significant prevalence,

affecting approximately 59.2% of the 2,180 subjects surveyed. This finding underscores the high incidence of LBP in the region, highlighting the need for effective preventive and therapeutic measures in primary care to manage this widespread health issue. (9)

Recurrent low back pain

Because low back pain is often recurrent in nature, exclusive use of temporal definitions to describe its course has been challenged in the literature (10). The primary argument is that when low back pain is recurrent, the time to improvement from a single episode does not accurately describe outcomes. This is not purely an academic issue, as the prognosis of low back pain changes when the influence of recurrence is considered of patients with acute low back pain who were followed for 1 year, 65% reported 1 or more additional episodes (11). In that same study, 2 months was the median time to another episode of low back pain and 60 days was the median total duration of low back pain in the year. Other studies have reported lower, but still substantial, recurrence rates ranging from 20% to 35% over a period of 6 to 22 months (12).

The hip has long been identified as a potential source of contributor to low back dysfunction, and impairments in hip mobility have been found to be associated with the presence of low back pain.(13,14.15.16.17&18) It has been suggested that altered movements of the hip and spine may contribute to the development of low back pain, as they may alter the loads placed on the lumbar facets

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and posterior spinal ligaments(19). Several authors have described restricted hip mobility in patients with low back pain as an indicator of positive response to interventions targeting the hip. (20,21,22,23,24&25) Some early evidence demonstrates successful incorporation of interventions targeting the hip into a more comprehensive treatment program for patients with lumbar spinal stenosis. (26 & 27) Though research in this area is developing, clinicians may consider including examination of the hip and interventions targeting identified hip impairments for patients with low back pain.

So, we should concern all those chains connected and named as lumbopelvic hip complex in designing the component of the needed exercise to promote maximum stability and the unity of the complex. From this point we designed exercise connect the hip pelvic and lumbar component with different angels.

While individuals in all strata of society commonly experience low back pain, its prevalence does appear to vary based on factors such as sex, age, education, and occupation. Women tend to have a higher prevalence of low back pain than men, although the differences reported vary in magnitude. (28, 29, 30 & 31) An increase in age is also associated with higher prevalence of low back pain. The more severe forms of low back pain continue to increase with agenda the overall prevalence increases until ages 60 to

65. (32) Lower educational status is associated with increased prevalence of low back pain (33, 34, 35 & 36) as well as a longer episode duration and worse outcome (37).

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Significance of the problem:

MAILE is an effective treatment which produces short-term improvement in global recovery and activity for people with nonspecific chronic low back pain (NCLBP). Improvement in pain intensity, muscle strength functional stability and disability were demonstrated in group of patients with low back pain suffering from a degenerative disc disease, osteoarthritis of lumbar spine, Spondylolysis, and spondylolisthesis in addition significantly it reduces symptoms in people with hyper mobility.

There is evidence that MAILE can give rapid relief of low back pain without the need to extensive muscle exercise and thereby may be as effective as current treatments without the need for a prolonged physiotherapy regime.

Back pain is a common musculoskeletal ailment related to vertebral mal alignment (38). To distribute the body's load during ortho grade movement and other daily activities, human vertebrae form normal curvatures from the cervical to the pelvis and sacrum. However, inclination or declination of sagittal lumbar lordosis can lead to excessive load being applied on vertebral joints and intervertebral discs; resulting in nerve root compression, disc degeneration, and inflammation of joint capsules (39, 40) Christie et al. (41) reported increased Lumbosacral angles in patients with chronic back pain. In addition, more than 80% of patients with back pain have limited range of motion, lumbar flexion, flexor muscle weakening, and imbalance of muscle strength (42 & 43). Research findings have also verified the association between chronic back pain and vertebral instability caused by lumbar muscular atrophy (44).

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Therefore, strengthening lumbar muscles and increasing lumbar flexibility are important objectives of lumbar pain treatment (45). Exercise can help strengthen muscles and maintain asymptomatic lumbar lordosis (46). Specifically, lumbar stabilization exercises can provide therapeutic benefits in the treatment of chronic back pain (47) through the adjustment of vertebral segments and an increase in dynamic stability and lumbar muscle strength (48 & 49).

The research in trunk control has made important contributions to the understanding of neuromuscular reorganization in back pain and injury. As long four decades ago it was shown that motor strategies change in injury and pain. (50). The CS (core stability) studies confirm that such changes take place in motor control of the trunk muscles of patients who suffer back injury and pain.

However, these findings combined with general beliefs about the importance of abdominal muscles for a strong back, and influences from “Pilates” have promoted several misunderstandings in CS training (51). Staying active could improve clinical outcomes and reduce the personal and social impact of back pain, as proposed by Waddel (52), based on a motor control exercises program. The main aim of this program is to re-establish the impairment or deficit in motor control around the neutral zone of the spinal motion segment by restoring the normal function of the local stabilizer muscles.

Stabilization exercise program has become the most popular treatment method in spinal rehabilitation since it has shown its effectiveness in some respects related to pain and disability. However, some studies have reported that specific exercise programs reduce pain and disability in chronic but not in acute low back pain, although it can be helpful in the treatment of acute low back pain by reducing recurrence rate (53).

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Yet, there are no comparative RCT studies that compare the clinical outcomes of core stability and lumbar stabilization exercises and with the outcomes of MAILE exercise. Thus, this study compares the effects of each type of exercise on pain scale, functional disability, functional stability, and lumbar muscle strength in patients with chronic back pain.

The purpose of the study is to assess the effectiveness of MAILE (Multi Angular Isometric Lumbar Exercise) exercises targeting the Lumbo-Pelvic Hip complex compared to a standard exercise program that emphasizes lumbar stabilization and core stability exercises (CSE). This comparison aims to evaluate their efficacy in treating patients with Nonspecific Chronic Low Back Pain (NCLBP) who also exhibit motor control dysfunction. By comparing these two approaches, the study seeks to determine which intervention yields better outcomes in terms of pain reduction, functional improvement, and overall management of NCLBP with motor control dysfunction.

The hypothesis suggests that there will be significant differences between the two experimental groups in pain intensity, functional disability, functional stability, lumbar muscle strength, and the effectiveness of MAILE Exercise of Lumbo-Pelvic Hip complex compared to a control group of lumbar stabilization and core stability exercises in treating patients with Nonspecific Chronic Low Back Pain (NCLBP) with motor control dysfunction. This implies that the MAILE Exercise intervention is expected to yield superior outcomes in terms of pain reduction, improved functional ability and stability, increased muscle strength, and overall effectiveness compared to the control group intervention.

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Rationale for the Study

To date, no studies have been published on the effectiveness of MAILE, providing a strong impetus to conduct this research. By filling this gap in literature, the study will offer new insights into the management of NCLBP, potentially establishing MAILE as a superior treatment option. The findings will contribute valuable evidence to the scientific community and may lead to improved clinical practices in the management of NCLBP.

3. Objectives

1. **Pain Intensity Comparison:** To compare the reduction in pain intensity between patients undergoing multi-angular isometric lumbar exercises (MAILE) and those performing lumbar stabilization and core stability exercises (CSE).

2. **Functional Disability Comparison:** To evaluate and compare the effectiveness of MAILE versus lumbar stabilization and CSE in reducing functional disability caused by non-specific chronic low back pain (NCLBP).

3. **Functional Stability Comparison:** To assess and compare the improvement in the stability of the Lumbo-Pelvic Hip complex between the two exercise groups.

4. **Muscle Strength Comparison:** To measure and compare the changes in muscle strength in the targeted region between patients practicing MAILE and those following a lumbar stabilization and CSE regimen.

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4. Indicate if this is a retrospective data review

- ☐ **Retrospective Chart/data Review** *N/A*
- **Provide the date range of the chart review**
  N/A

5. Study Methodology

The study is designed as a **Randomized Controlled Clinical Trial (RCT)** aimed at evaluating the effectiveness of multi-angular isometric lumbar exercises (MAILE) versus core stability exercises (CSE) in patients with non-specific chronic low back pain (NCLBP).

Participants:

Sample Size: 98 patients (using effect size of 0.6 standard deviations, then for power 80% and alpha of 5%, the sample size per arm is 44 and with 10% loss to follow up then sample size per arm is 49 (so total of 98)

- **Inclusion Criteria:** Patients aged 18–60 years diagnosed with NCLBP by orthopedic doctors, general physicians, or neurologists.
- **Exclusion Criteria:** Patients with specific pathologies causing low back pain, history of lumbar surgery, or other significant comorbidities.

Randomization:

- **Randomization Method:** Stratified randomization will be used to allocate participants into two intervention groups (49 patients per group).

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- **Allocation Concealment:** In this study, allocation concealment ensures the integrity of randomization and maintain unbiased group allocation. Allocation concealment will be performed by an eligibility evaluator who is a physiotherapist involved in screening patients to stratified randomization, and he/she refers the patient to treating physiotherapist with an

opaque, sealed envelope, after opening the envelope, the treating physiotherapist will know the patient's group assignment.

Blinding:

- **Blinding of Assessors:** The outcomes will be assessed by a physiotherapist who will be blinded to the intervention groups.
- **Maintaining Blinding:** Assessors will remain blinded to group assignments throughout the study. To ensure this, the following measures will be implemented:
- **Rigorous Protocols:** Adherence to strict protocols for intervention and assessment.
- **Independent Assessors:** Use of independent assessors for baseline and outcome measurements.
- **Separation of Roles:** Clear delineation of roles between those administering the interventions and those assessing outcomes.
- **Monitoring Adherence:** Regular monitoring of adherence to blinding procedures to promptly address any issues and uphold the study's integrity.

Group 1: 49 patients who will receive MAILE technique.

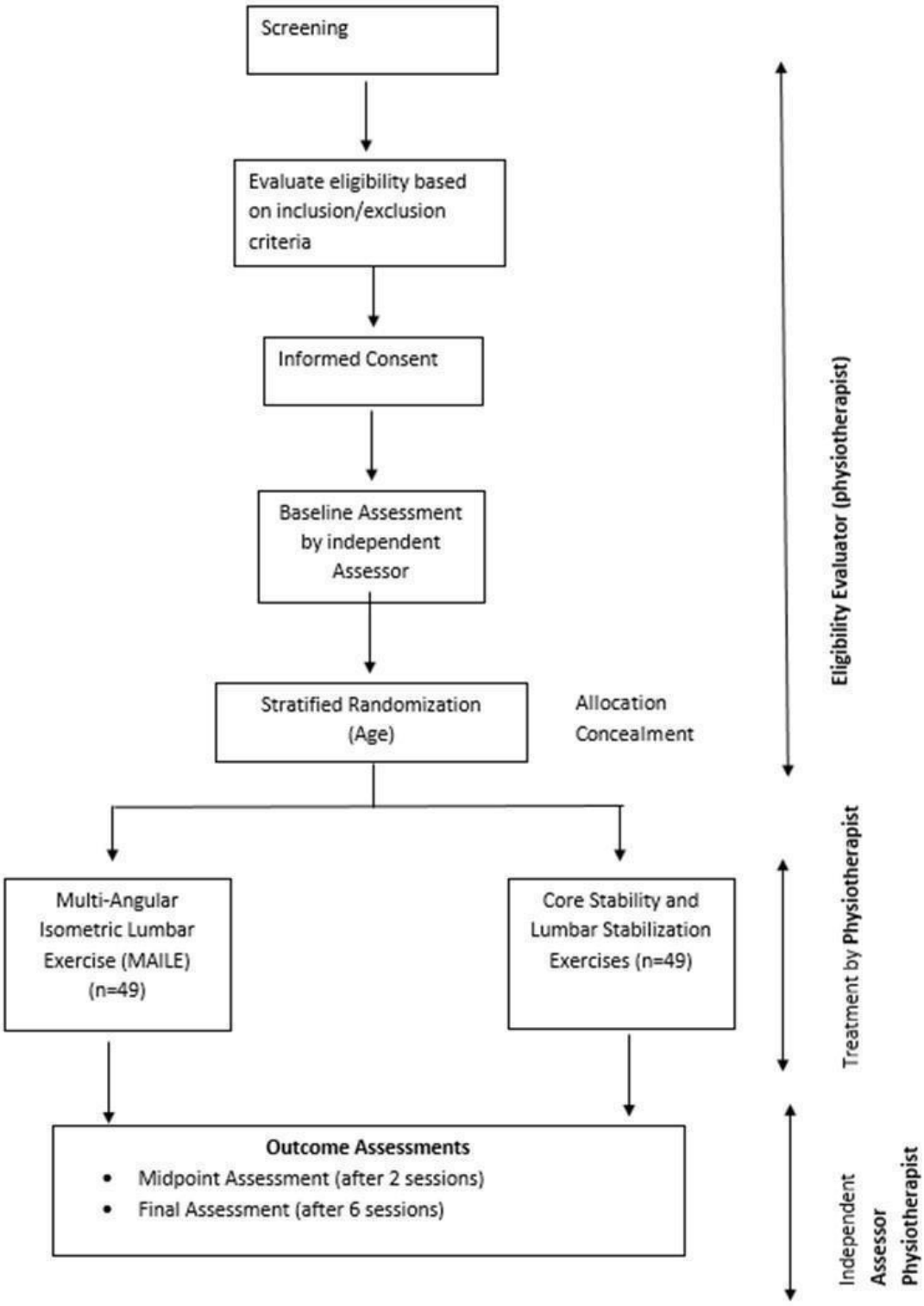
Group 2: 49 patients who will receive Core Stability & Lumbar Stabilization Exercise (control group).

Patients and the treating physiotherapist will not be blinded to the types of exercises. However, we have ensured that the outcome assessment will be conducted by an independent assessor (physiotherapist) who will

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not be aware of the participants' group assignments (MAILE or Core Stability). Please refer to the flowchart outlining the study process, which clearly differentiates the roles of the Eligibility Evaluator (physiotherapist), treating physiotherapist, and the independent outcome assessor (physiotherapist).

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Data Collection Methods:

Initial Data Collection (Baseline Measurement):

Timing: Before the start of the treatment.

Method: Participants will undergo comprehensive assessment including surveys, physical examinations, and performance tests.

Tools: Standardized questionnaires (e.g., Visual Analog Scale for pain, Oswestry Disability Index for functional disability), physical assessment tools, and strength measurement devices.

Midpoint Assessment:

Timing: After two sessions of the treatment.

Method: Participants will be reassessed using the same standardized tools and methods as the initial data collection to ensure consistency.

Tools: Repeat of the initial assessment tools to evaluate changes in pain, functional disability, and muscle strength.

Final Assessment:

Timing: After six sessions of the treatment (end of the intervention phase).

Method: A final comprehensive assessment will be conducted using the same tools and methods as the previous data collection points.

Tools: Final use of the initial assessment tools to determine the overall impact and effectiveness of the intervention.

Data Collection Procedures:

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Pre-Intervention: Initial baseline measurements will be taken in a controlled environment to ensure consistency.
During Intervention: Midpoint assessment after two sessions will be conducted to track early changes.

Post-Intervention: Final assessment after the completion of six sessions to measure the overall impact of the intervention.

Supervision: All data collection sessions will be supervised by trained investigators to ensure accuracy and reliability of the data.

Documentation: Data will be recorded on standardized forms and entered into a secure database by authorized personnel.

Ensuring Data Integrity:

Consistency: Using the same tools and procedures for all assessments.

Training: Ensuring all investigators are trained in the data collection methods and tools.

Audits: Conducting regular data audits to check for accuracy and completeness.

By following these data collection methods, the study aims to ensure that data is gathered consistently and accurately, providing a reliable basis for evaluating the effectiveness of the MAILE intervention compared to traditional core stability exercises.

6. Study Population and Study Setting/ Location

The sample for the study will be selected from patients receiving treatment at the Department of Orthopedic Physiotherapy outpatient clinic at Hazm Mebaireek General Hospital, the outpatient physiotherapy clinics at Al khor Hospital, Female Bin Omran Outpatient physiotherapy Qatar Rehabilitation Institute, Physiotherapy Outpatient Al Wakrah Hospital and Aisha bint Hamad al - Attiyah

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Hospital outpatient physiotherapy all of which are part of the Hamad Medical Corporation in Qatar. These clinics provide care for a diverse population of patients with various musculoskeletal conditions, including chronic low back pain. Selecting participants from these clinics ensures access to a broad range of individuals who may benefit from the interventions being studied.

Inclusion criteria:

All patients will be selected for this study with the following criteria:

The International Classification of Disease (ICD) diagnosis of spinal instabilities and the associated International Classification of Functioning, Disability, and Health (ICF) diagnosis of chronic low back pain with movement coordination impairments is made with a reasonable level of certainty when the patient presents with the following clinical findings. Chronic, recurring low back pain that is commonly associated with localized and referred lower extremity pain intermittently.

Presence of one or more of the following:

- Low back and/or low back–related lower extremity pain that worsens with sustained end-range movements or positions.
- Lumbar hypermobility with segmental motion assessment
- Mobility deficits of the thorax and lumbopelvic/hip regions
- Diminished trunk or pelvic region muscle strength and endurance
- Movement coordination impairments while performing community/work-related recreational or occupational activities.

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- Pain related to the low back (lower lumbar region, L4/L5 and/or L5/S1 region), this benchmark was determined by the examining physician through subjective complaint and description, as well as objectively, using inspection, palpation, motion assessment, and standard orthopedic and neurologic tests such as Kemp's, Milgram's, Yeoman's, straight leg raise, and Valsalva maneuver.

- Must have had more pain free days than days with low back pain in the past year. Low back pain is more than 3 months (pain felt between T12 and the gluteal fold) Age ranged from 18 - 60 years.

- Positive prone instability test

- Presence of aberrant movements with motion testing Straight leg raises greater than 91°.

- BMI ranges from 20- 30.

- Patients willing and able to participate in an exercise program safely and without cognitive impairments that would limit their participation.

Exclusion criteria:

- Radiculopathy: Assessed by examining physicians using patient history, standard screening tests, and detailed orthopedic /neurologic evaluations.

- Cauda Equina Symptoms: Presence of perianal numbness or loss of bowel/bladder control, as evaluated by the examining physician.

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- Spine Deformity: Including current spinal fractures, spinal infections, or spinal tumors.
- Severe Osteoporosis: Current history of severe osteoporosis.
- Prior Lumbar Spine Surgery: Any previous lumbar spine surgery.
- Pregnancy: Pregnant individuals are excluded.
- Psychiatric Illness or Cognitive Impairment: Conditions such as dementia or Alzheimer's.
- Substance Abuse: Known current substance abuse.
- Medication Use:
    - Current use of anticoagulants or corticosteroids.
    - History of steroid use at a dosage of 7.5 mg or more for over six months.
- Trauma: Recent or relevant trauma history.
- Lever Use Restrictions: Patients experiencing pain or neurological symptoms during body positioning or lever application for the technique should not be treated.
- Cardiac Conditions: Patients with cardiac conditions are excluded.
- Cancer Patients: Individuals with cancer are excluded.
- Other Medical History: Includes history of back surgery, rheumatologic disorders, or spine infections.

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These criteria are designed to minimize risks and ensure the appropriateness of participants for the intended intervention or study.

7. Study procedures

In the study, 98 patients referred to from orthopedic doctors, general physicians, neurology doctors, and primary health care doctors, diagnosed with Nonspecific Chronic Low Back Pain after lumbar spine assessment, will be included. These patients will be randomly assigned to one of two treatment groups:

MAILE group and the Core Stability group will engage in exercises focusing on a range of muscle groups associated with lumbar stability and core strength. These exercises are designed to target specific muscles to improve overall function, stability, and reduce pain in patients with Nonspecific Chronic Low Back Pain.

MAILE Group and Core Stability Group - Patients in these groups will perform exercises focusing on: Erector spinae, Multifidus, Longissimus spinalis, Deep transverse spinalis, Rotators brevis & longus, Intertransversarii, Latissimus dorsi, Rectus abdominis, Transverse abdominis, External & internal oblique, Quadratus lumborum, Psoas major & Iliacus, Iliocostalis, Pelvic floor musculature, and Diaphragmatic musculature

These exercise programs are tailored to target specific muscle groups related to lumbar stability and core strength, with the aim of improving overall function and reducing pain in patients with Nonspecific Chronic Low Back Pain.

The study will examine both the MAILE Group and the Core Stability Group to determine if the exercises created differences in terms of pain intensity (measured with a visual analog scale), functional disability

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(assessed using the Oswestry Disability Questionnaire), and transverse abdominus muscle activation capacity (measured with a Pressure Biofeedback Unit = PBU). Additionally, core stability will be assessed through various tests including the Single Leg Balance Test, Single Leg Squat Test, and Three-Plane Core Tests.

The program will span over 3 weeks, participants attending 30-minute sessions twice a week. By evaluating these outcomes and parameters, the study aims to determine the effectiveness of both exercise programs in improving pain, functional disability, muscle activation capacity, and core stability in patients with Nonspecific Chronic Low Back Pain.

Treatment procedure:

Group I:

Participants in this group will be treated with Multi Angular Isometric Lumbar Exercise (MAILE).

Group II:

Participants in this group will follow a graded exercise program that emphasizes lumbar stabilization and core stability exercises.

MAILE should be prescribed to individuals who:

Experience Chronic or Recurrent Low Back Pain: Especially those whose pain episodes do not completely resolve over time and tend to recur in an ongoing relapsing pattern.

Need Targeted Lumbar Strengthening: Individuals who require specific strengthening of the lumbar muscles to improve stability and support for the lower back.

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Can Tolerate Isometric Exercises: Patients who can perform isometric exercises, which involve muscle contractions without joint movement, at various angles.

Have Minimal Acute Inflammation or Injury: Those who do not have significant acute inflammation, recent lumbar spine injuries, or conditions that might not aggravated by isometric exercises.

Are Cleared by a Healthcare Provider: Individuals who have been assessed and cleared by a healthcare professional to ensure that MAILE is appropriate for their specific condition and overall health status.

It is essential for patients to receive a thorough evaluation to determine the suitability of MAILE for their particular case of low back pain.

MAILE is likely to benefit patients who exhibit the following predictors:

Age Group: Up to 60 years old.

Greater General Flexibility: Hamstring length greater than 90 degrees.

Positive Prone Instability Test: Indicates lumbar spine instability.

Presence of Aberrant Movement: During spinal range of motion, including painful arc of motion, abnormal lumbopelvic rhythm, and using arms on thighs for support.

Postpartum Women: Expecting a good response to the MAILE program.

Positive Posterior Pelvic Pain Provocation (P4) Test: Also known as the thigh thrust test.

Positive Active Straight Leg Raises: Indicating potential instability or weakness.

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Positive Pain Provocation with Palpation of PSIS Region: Pain persists greater than 5 seconds after palpation of the long dorsal sacroiliac ligament (54).

Positive Pain Provocation with Palpation of Pubic Symphysis: Pain persists greater than 5 seconds after palpation (55).

Positive Trendelenburg Sign: Indicates weakness in the gluteus Medius muscle, which may contribute to instability and lower back pain.

Patients meeting these criteria are more likely to experience beneficial outcomes from the MAILE program, as these factors suggest specific characteristics of low back pain that are well-suited to the targeted isometric exercises provided by MAILE. **Instrumentation for Spinal Assessment and Treatment The following tools will be used during the study:**

Pain Assessment:

Visual Analogue Scale (VAS):

Pain will measure through a 10 cm VAS. Participants will be asked to indicate along the VAS anchored with none and most severe pain imaginable the amount of pain they were currently feeling regarding the experimental pain task they were about to experience. VAS has been used to measure pain in other studies and have demonstrated sound psychometric properties.

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Visual Analogue Scale (VAS) for Measuring Pain

The Visual Analogue Scale (VAS) is a widely used tool for measuring subjective experiences, such as pain (56). Here's a detailed explanation of how it can be used to measure pain in the context of an experimental pain task:

The VAS is a straight horizontal line, typically 10 centimeters long.

The ends of the line are labelled with descriptive anchors:

Left End (0 cm): "None" indicating no pain.

Right End (10 cm): "Most severe pain imaginable" indicating the highest level of pain.

Procedure:

Participants are asked to place a mark on the line at the point that represents their current level of pain.

The position of the mark along the line represents the participant's pain level quantitatively.

Functional Disability Assessment:

Oswestry Disability Index (ODI) Overview

The Oswestry Disability Index (ODI) is a well-established tool used to assess perceived disability in patients suffering from low back pain. Originally developed by Fairbank et al., (57) the ODI has been widely adopted and modified for various applications. Here's a detailed explanation:

The index comprises 10 items.

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Activities of Daily Living (ADL): 8 items focus on daily activities such as personal care, lifting, walking, sitting, standing, sleeping, sex life, and social life.

Pain: 2 items specifically address pain intensity and its impact.

Scoring:

Each item is scored on a scale from 0 to 5.

The scores are summed to yield a total raw score.

The total score is then converted to a percentage to represent the level of disability.

Calculation: Total Score = (Sum of Item Scores / Maximum Possible Score) x 100.

For example, if the sum of item scores is 25 out of a possible 50, the percentage score would be:

Total Score = (25 / 50) × 100 = 50 %

Total Score = (50 / 25) × 100 = 50% **Interpretation**

of Scores 0-20%:

Minimal disability.

21-40%: Moderate disability.

41-60%: Severe disability.

61-80%: Crippling back pain.

81-100%: Patients are either bed-bound or have an exaggeration of symptoms.

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Lumbar Muscle Strength Assessment:

Pressure Biofeedback Assessment Tool

The Pressure Biofeedback Assessment Tool is used to evaluate the activation and control of the transverse abdominus (TrA) muscle during the abdominal drawing-in maneuver (ADIM). This method assesses core stability and motor control without compensatory movements from other muscles. (58, 59 & 60) **Testing Procedures**

Patient Positioning:

Position: Patients are positioned in a supine hook-lying position (lying on their back with knees bent and feet flat on the ground).

Purpose: This position helps isolate the transverse abdominus muscle and minimize the involvement of other muscles.

Instructions for ADIM: Patients are instructed to "Take a breath in and, as you exhale, gently draw your navel in toward your spine. "Cue to Draw In “Gently”: Emphasis is placed on a gentle contraction to avoid over-aggressive force generation and to prevent changes in pelvic or spinal position, which would engage compensatory muscles like the rectus abdominis, internal oblique (IO), external oblique (EO), or erector spinae.

Repetitions: Subjects perform five practice repetitions.

Feedback: During these trials, the examiner provides verbal and tactile feedback to correct errors such as breath holding, pelvic tilt, or bracing.

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Objective: Ensure correct technique and proper engagement of the transverse abdominus.

Testing Phase:

ADIM Contraction: Subjects are asked to maintain the ADIM contraction for 10 seconds.

No Visual Feedback: Subjects are not allowed to see the pressure gauge to prevent any bias or altered performance.

Rest Period:

After the five practice trials, subjects rest for 2 minutes before the actual measurement.

Functional Stability Assessment: (Core Stability) (61)

Single leg balance test, Single leg squat test & three plane core test

Single Leg Balance Test

The Single Leg Balance Test is a straightforward, yet effective clinical assessment used to evaluate a patient's balance, stability, and proximal core strength. Here's a detailed explanation of the test: **Procedure**

Initial Position:

The patient stands with feet hip-width apart on a flat, stable surface.

Test Execution:

The patient is asked to lift one leg off the ground, bending the knee of the non-weight-bearing leg. No additional verbal cues are given to ensure that the patient naturally adopts a comfortable and stable posture.

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Observation:

The examiner observes the patient's posture and any compensatory movements. Indicators of Proximal Core Weakness

Trendelenburg Posture:

If the pelvis drops on the side of the lifted leg, it indicates inhibition of quadratus lumborum on the nonweight bearing side and weakness in the gluteus Medius muscle on the weight-bearing side. This is known as a Trendelenburg sign.

Limb Rotation:

Internal Rotation: The weight-bearing leg rotates inward, suggesting weakness in the external rotators and abductors of the hip.

External Rotation: The weight-bearing leg rotates outward, indicating potential weakness in the internal rotators or other stabilizing muscles.

Balance and Stability:

Swaying: Excessive swaying or inability to maintain the position indicates poor balance and possible core instability.

Foot Movement:

Repeated need to place the lifted foot back on the ground to maintain balance suggests insufficient core and lower extremity strength.

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Interpretation

Normal Result: The patient can maintain a stable, upright posture on one leg for at least 30 seconds without significant deviations.

Abnormal Result: Presence of Trendelenburg posture, significant internal or external rotation of the weight-bearing limb, or inability to maintain balance indicates potential proximal core weakness or lower extremity muscle imbalance.

Single Leg Squat Test

The Single Leg Squat Test is a more advanced evaluation following the Single Leg Balance Test, providing a dynamic assessment of balance, strength, and movement quality. Here's how the test is performed and interpreted:

Procedure

Starting Position:

The patient stands with feet hip-width apart on a flat, stable surface.

The patient lifts one leg off the ground, bending the knee of the non-weight-bearing leg.

Test Execution:

The patient is asked to perform repetitive partial squats (quarter to half squats) on the weight-bearing leg. No additional verbal cues are provided to ensure a natural and self-directed movement pattern.

Observation:

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The examiner observes the quality of movement, focusing on deviations, control, and symmetry.

Indicators of Proximal Core Weakness and Movement Quality

Trendelenburg Posture:

Pelvis Drop: Similar to the Single Leg Balance Test, a Trendelenburg sign (pelvis drop on the side of the lifted leg) indicates weakness in the gluteus Medius on the weight-bearing side and potential inhibition of the quadratus lumborum on the non-weight-bearing side.

This deviation may become more apparent during the dynamic movement of the squat.

Knee Alignment:

Medial Knee Collapse (Valgus): The knee moves inward, suggesting weak hip abductors and external rotators.

Lateral Knee Movement (Varus): The knee moves outward, indicating imbalance or instability.

Trunk Stability:

Forward Lean: Excessive forward lean can indicate weak core muscles or compensatory strategies to maintain balance.

Lateral Trunk Shift: The trunk shifts sideways, suggesting weak lateral stabilizers or compensatory movement.

Foot Stability:

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Arch Collapse (Pronation): The foot excessively rolls inward, suggesting weak intrinsic foot muscles and poor overall stability.

Supination: The foot excessively rolls outward, indicating imbalance.

Control and Symmetry:

Smooth, Controlled Movement: Indicates good proximal strength and stability.

Jerky, Uncontrolled Movement: Suggests poor neuromuscular control and potential weakness.

Interpretation

Normal Result: The patient performs the squats with minimal deviations, maintaining good alignment and control throughout the movement.

Abnormal Result: Significant deviations such as a Trendelenburg posture, medial or lateral knee movement, excessive trunk lean, or foot instability indicate proximal core weakness, hip muscle imbalances, or poor neuromuscular control.

Three-Plane Core Testing

Three-plane core testing is a comprehensive assessment used to evaluate core strength and stability across different planes of motion. This test involves specific movements in the sagittal, frontal, and transverse planes, each designed to target different muscle groups and assess their functional capabilities.

Here's a detailed explanation of the testing procedure and its significance:

Procedure

General Setup:

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The patient stands 8 cm away from a wall.

Each test progresses from bilateral weight-bearing to single-leg stance to increase difficulty.

Sagittal Plane Testing - Initial Position:

The patient stands facing away from the wall with feet flat on the ground.

Movement:

The patient will be instructed to slowly lean backward until their head just barely touches the wall.

The movement starts with both feet on the ground, progresses to partial weight-bearing on each leg, and ultimately to single-leg standing.

Muscle Activation:

Eccentric Activation: Abdominals, quadriceps, hip flexors.

Concentric Activation: Hip extensors, spine extensors.

Frontal Plane Testing - Initial Position:

The patient stands on one side of their body 8 cm away from the wall.

Movement:

The patient stands on the inside leg (the leg closer to the wall) and slowly leans their shoulder towards the wall until it just barely touches. Repeat on the other side to test both sides of the body.

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Muscle Activation:

Eccentric Strength: Quadratus lumborum, hip abductors, long spinal muscles (on the side away from the wall).

Transverse Plane Testing - Initial Position:

The patient stands 8 cm away from the wall.

Movement:

The patient progresses from bilateral weight-bearing to single-leg stance.

They alternately touch one shoulder and then the other to the wall, maintaining a controlled rotational movement.

Muscle Activation:

Muscles Involved: Abdominal muscles, hip rotators, spine extensors.

Progressive Testing Approach

Bilateral Weight-Bearing: Starting position for initial assessment of core stability.

Partial Weight-Bearing: Increases demand on core muscles by shifting weight.

Single Leg Stance: Further challenges core stability and balance, isolating muscle function on each side.

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7.1 Study Duration and Timelines

Please make sure to provide timelines either in a table or bullet points.

The expected duration of the study will be two years. The study will start immediately after the MRC approval. We estimate the number of patients to be screened from all sites involved is approximately 250 to 300.

7.2 **Informed Consent**

*a) How people will be **NOTIFIED OR APPROACHED** to consider being a research subject in this study?*

- Patients referred from an orthopedic doctor, General Physicians, Neurology doctors after assessment of their lower back and diagnosed as nonspecific chronic low back pain will be approached for participation in the study

b) Describe the CONSENT PROCESS procedures (When, Where, How, by Whom).

- Treating physiotherapist will assess the patient who come for physiotherapy treatment in Hazm

Mebaireek General Hospital, the outpatient physiotherapy clinics at Al khor Hospital, Female Bin Omran Outpatient Physiotherapy Qatar Rehabilitation Institute, Physiotherapy Outpatient Al Wakrah Hospital and Aisha bint Hamad al - Attiyah Hospital outpatient physiotherapy.

. Based on the inclusion/exclusion criteria, the physiotherapist will obtain the informed consent form face to face if the patient is eligible to include in the study.

c) Describe HOW LONG potential participants will have to decide on study participation and for how long the subjects will participate in the study after signing consent form.

- Patients can decide participation in the study prior to starting the physiotherapy sessions for their low back pain. After signing the consent form participants will be in the study at least for 3 weeks, i.e. until they complete their physiotherapy sessions

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d) *Describe how subjects will be SCREENED FOR ELIGIBILITY for the study and what will be planned screening number.*

Patients referred from an orthopedic doctor, General Physicians, Neurology doctors after assessment of their lower back and diagnosed as nonspecific chronic low back pain will be approached for participation in the study. We estimate the number of patients to be screened from all sites involved is approximately 250 to 300. Finally, 98 participants will be included in the study.

e) *Describe below how subjects will be ENROLLED into the research study.*

through informed consent, triage therapist will select the patient of NCLBP

f) *Describe below how participants will be COMPENSATED (if applicable) for their participation in the research study.*

No compensation

7.3 **Subject Withdrawal/ Withdrawal of Consent**

If subject is withdrawn from the study, data collected will not be used for the stud

7.4 **Risk**

Expected Risks:

Participants may experience fatigue or exhaustion related to physical activity, temporary dizziness or lightheadedness during or after exercise, and potential skin irritation or sores from the use of exercise equipment

Physical Risks:

The exercises involved in the study may cause temporary muscle soreness or discomfort. There is also a risk of strain or injury, but this is expected to be minimal and similar to the risks associated with standard physiotherapy exercises.

Psychological Risks:

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Participating in the study may cause some stress or anxiety, especially if you are worried about the exercises or their effectiveness.

Privacy Risks:

While we take measures to protect your privacy, there is a minimal risk of unauthorized access to your personal information. We will use codes to identify your data instead of your name to minimize this risk.

Legal, Social, and Economic Risks:

There are no anticipated legal, social, or economic risks associated with participation in this research.

Pregnancy Risks:

If you are pregnant or planning to become pregnant, please inform the research team immediately. the exercises involved in this research might pose a risk to you or your fetus. You should not become pregnant while participating in this study.

Unpredictable Risks:

There might be risks that we cannot predict at this time. If any new risks are identified during the study, we will inform you immediately.

7.5 **Bio-Specimens & Sample Collection**

Data will be discarded and there is no collection of specimens in this study

7.6 **Admission, transfer, discharge**

The procedures related to research will be performed in outpatient clinics. No admission, transfer or discharge applied.

7.7 **Outcomes**

Pain measurement based on Visual Analogue Scale (VAS)

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Functional disability based on Oswestry Disability Index (ODI)
Measurement of stability based on Single leg balance test, Single leg squat test & three plane core test

Measuring strength and strength based on Pressure Biofeedback Assessment Tool

7.8 **Data Collection, Management &**

Confidentiality Initial Data Collection (Baseline

Measurement):

This will be conducted before the start of the treatment.

To establish initial measurements and provide a comparison point for subsequent assessments.

Midpoint Assessment:

Conducted after two sessions of treatment.

To evaluate early changes and the initial effectiveness of the intervention.

Final Assessment:

Conducted after six sessions of the treatment.

To assess the overall impact and effectiveness of the intervention after the complete treatment period.

Data Management:

Data will be collected using standardized forms and protocols to ensure consistency and reliability.

The data will be entered into a secure, password-protected database by the lead PI or designated research team members.

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Regular audits will be conducted to verify the accuracy and completeness of the data entries.

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Confidentiality:

All data collected will be kept confidential and used solely within the study group for research purposes.

Participants' identities will be anonymized using unique codes to protect their privacy.

Access to the data will be restricted to the principal investigators and authorized study personnel.

All data will be stored securely, with electronic data protected by encryption and physical data stored in locked cabinets located in the research site offices involved.

Participants will be informed about the confidentiality measures and their rights regarding data privacy as part of the informed consent process.

a) Please indicate below HOW study data will be collected for the proposed research.

☒ *Study Forms* ☐ *Study Database* ☐ *Study Web-Based/App* ☐ *Other* Data Collection Sheet

Data will be collected and de-identified, codes will be used to cover patient identifiers such as Name, HC no., DOB. Any link between code and identifier will be deleted at the end of the data collection and anonymized data will be kept for at least 5 years after study completion.

b) Describe below WHERE (Facility and Department) and HOW the study data is physically stored.

We will store the physical forms and documents related to the study in each following facilities, Outpatient Physiotherapy Clinic, Hazm Mebariek general hospital (HMGH), the outpatient physiotherapy clinics at Al khor Hospital, Female Bin Omran Outpatient Physiotherapy Qatar Rehabilitation Institute, Physiotherapy Outpatient Al Wakrah Hospital and Aisha bint Hamad al - Attiyah Hospital outpatient physiotherapy. The de-identified password protected and coded data on a hard drive will be kept in the Outpatient Physiotherapy Clinic, Hazm Mebariek general hospital (HMGH).

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c) *Describe below WHO controls access to the study data*

Lead PI

d) *Describe below WHO has access to the study data.*

Lead PI and designated research team members

e) *Describe below HOW the study data is accessed.*

The de-identified password protected and coded data on a hard drive will be kept in the Outpatient Physiotherapy Clinic, Hazm Mebariek general hospital (HMGH) and will be accessible only for Lead PI and designated research team members.

f) *Will subject identifiers be shared outside of HMC? If YES describe below WHOM the study data is shared* No

8. Study monitoring/Data Safety Monitoring Board (DSMB)

N/A

9. Statistical Consideration and Data Analysis

Analysis Plan:

The statistical analysis for this study will be conducted using a comprehensive and systematic approach to ensure the reliability and validity of the results. The analysis will involve the following steps:

1. **Descriptive Statistics:**

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- Descriptive statistics will be used to summarize the baseline characteristics of the study participants. This will include mean, standard deviation, median, and interquartile range for continuous variables, and frequencies and percentages for categorical variables.

2. **Baseline Comparison:**

   - Independent samples t-tests and Mann-Whitney U test will be performed for comparing continuous variables between the two intervention groups, whereas chi-square tests and Fisher's exact test will be used for categorical variables.

3. **Primary Outcomes Analysis:**

   - The primary outcomes include pain intensity, functional disability, functional stability, and muscle strength.
   - **Pain Intensity:** Measured using a visual analog scale (VAS). Analysis will be conducted using independent samples t-tests to compare changes in pain intensity between the two groups.
   - **Functional Disability:** Measured using the Oswestry Disability Index (ODI). Independent samples t-tests will also be used to compare functional disability changes between the two groups.
   - **Functional Strength:** Measuring strength based on Pressure Biofeedback Assessment Tool.

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- **Functional Stability and Muscle Strength:** Assessed using Single Leg Balance Test, Single Leg Squat Test, and Three-Plane Core Tests. Independent samples t-tests will be utilized to analyze changes between the groups.

4. **Hypothesis Testing:**

- The hypothesis suggests significant differences between the MAILE group and the core stability group in terms of pain intensity, functional disability, functional stability, and muscle strength. Two tailed tests will be employed, with a significance level set at $p < 0.05$.

10. Adverse Event Reporting

In this randomized controlled trial (RCT), the primary aim is to compare the outcomes of multi-angular isometric lumbar exercises (MAILE) and core stability exercises (CSE) in terms of pain intensity, functional stability, functional disability, and muscle strength. The study has been designed in a way that the interventions both MAILE and CSE are unlikely to pose significant risks to participants, minimizing the likelihood of adverse events.

However, should any adverse events occur—whether they are related or unrelated to the interventions—these will be thoroughly documented and analyzed separately for each group. This approach ensures that any potential complications or unexpected outcomes are appropriately addressed and accounted for, maintaining the study's integrity and ensuring participant safety throughout the trial.

Anticipated AEs related to the research may include, but are not limited to:

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- Musculoskeletal Pain or Discomfort: Increased pain or discomfort in the back, hips, or other areas targeted by the exercises.
- Muscle Strain or Sprain: Overuse injuries due to exercise interventions.
- Fatigue or Exhaustion: General fatigue or tiredness resulting from physical activity.
- Dizziness or Lightheadedness: Temporary dizziness or lightheadedness during or after exercise sessions.
- Skin Irritation or Pressure Sores: Potential skin irritation or sores from exercise equipment or positions.

11. Ethical Consideration

The study will be conducted in full conformance with principles of the "Declaration of Helsinki", Good Clinical Practice (GCP) and within the laws and regulations of MOPH in Qatar.

12. Sponsor, Funding & Collaborator Information

Funding is requested from MRC

13. Dissemination of Results and Publication policy

The findings of the study will be presented in national and international conferences and will be published in peer-reviewed international journals. Any publication (including presentations, posters, and manuscripts) resulting from the approved research activity will acknowledge the Medical Research Center of Hamad Medical Corporation.

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15. Appendices

a. Evaluation of Core stability

A comprehensive assessment of movement deviations and core stability, often conducted in healthcare or physical therapy settings. Here's a breakdown of the assessment protocol outlined:

Single Leg Balance Test:

This test evaluates postural deviations and proximal core stability. The presence of Trendelenburg's sign, where the pelvis on the unsupported side drops when standing on one leg, may indicate a deficit in proximal core stability. If the balance is assessed as very poor, further testing may be discontinued.

Bilateral Single Leg Squat Test:

Following a successful single leg balance test, the next step is to assess bilateral single leg squat maneuver. This test helps identify postural deviations such as a large valgus moment at the knee, which could indicate weak abductors of the lower extremity.

Three-Plane Core Strength Test:

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This test evaluates core strength in all planes of motion. It involves a series of progressive exercises, starting from a closed chain double leg stance to partial weight bearing, and finally to single leg stance in sagittal and frontal planes.

Sagittal Plane Evaluation:
The patient stands about 8cm from a wall facing away from it. They are instructed to lean backward, keeping both feet on the ground, until their head just barely touches the wall. This movement loads the abdominals, hip flexors, and quadriceps eccentrically, while activating the spine and hip extensors concentrically.

Frontal Plane Evaluation:

Similar to the sagittal plane test, the patient stands about 8cm from a wall, but this time with one side facing the wall. They are asked to touch their inside shoulder just barely to the wall. This test assesses lateral stability and activates the muscles responsible for stabilizing the body in the frontal plane.

These assessments help healthcare providers identify weaknesses or deficits in core stability and movement patterns, allowing for targeted interventions and exercise programs to improve overall function and reduce the risk of injury.

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b. Pressure Bio feedback assessment tool

The pressure biofeedback unit is a valuable tool used in assessing lumbar spine strength and core stability. Here's a step-by-step description of the testing procedure:

1. **Positioning:** Patients are positioned in a supine hook-lying position, which means lying on their back with knees bent and feet flat on the surface.
2. **Placement of the Pressure Biofeedback Unit:** The pressure biofeedback unit is placed under the lumbar spine region.
3. **Inflation of the Unit:** The unit is inflated to a specific pressure level, typically 40 mmHg, using air-filled reservoirs.
4. **Testing Procedure:** Subjects are instructed to perform the abdominal drawing-in maneuver, which involves gently pulling the navel toward the spine to engage the deep abdominal muscles, particularly the transverse abdominis.

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5. **Duration of Contraction:** Subjects are asked to maintain the contraction for a specific duration, often 10 seconds. This helps assess the endurance and control of the deep abdominal muscles.

6. **Practice Trials:** Subjects are allowed 5 practice repetitions of the maneuver. During these practice trials, they receive verbal and tactile feedback from the examiner to correct any errors, such as breath holding, pelvic tilt, or bracing. This feedback helps ensure proper technique and engagement of the targeted muscles.

7. **Blinding**: Subjects are not allowed to see the pressure gauge of the biofeedback unit at any time during the testing procedure to prevent bias in their performance.

8. **Rest Period:** After the practice trials, subjects are given a rest period of 2 minutes to minimize fatigue and allow for recovery.

9. **Measurement:** The measurement for the study is taken after the rest period. This measurement likely involves assessing the pressure reading on the biofeedback unit, which indicates the level of lumbar spine movement or stability achieved during the abdominal drawing-in maneuver.

This testing procedure helps evaluate the ability of individuals to effectively engage their deep abdominal muscles to stabilize the lumbar spine, which is crucial for maintaining proper posture and preventing back pain or injury.

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