20th March 2025

Study Protocol

Title:

Comparative Analysis of Different Physiotherapy Interventions on Anterior Pelvic Tilt in Subjects with Non-Specific Low Back Pain: A Randomized Controlled Trial

5. METHODOLOGY

7.1 Study Design: This study will be a randomized controlled trial (RCT) with multiple treatment arms.

7.2 Sampling Technique: Convenient Non-Probability Sampling technique will be used to select the sample. Selected participants will be randomly assigned to any of the intervention groups.

7.3 Sample Size Calculation: Sample size will be calculated through G Power software by using primary outcome measure. The estimated size is 80-100 participants. Each group shall consist of 20-25 participants approximately.

7.4 Study Setting: Study will be conducted at Department of Rehabilitation at National Hospital, Bahawalpur, Punjab, Pakistan.

7.5 Sample Selection Criteria:

INCLUSION CRITERIA:

1. Age: Participants must be between 20 and 40 years old.
2. Gender: Both genders, Male and Female have equal chance of selection as participant in the study.
3. Diagnosis: Participants must have a confirmed diagnosis of non-specific low back pain (NSLBP), altered lumbar posture, restricted range of motion of lumbar spine due to muscular spasm etc., altered anterior pelvic tilt angle by a qualified healthcare professional, based on standardized diagnostic criteria (e.g., clinical examination, imaging studies).
4. **Confirmation of Anterior Pelvic Tilt (APT):** Participants exhibiting APT confirmed through physical assessment by a trained examiner. This confirmation will involve the use of standardized measures such as digital inclinometers or goniometers.
5. Severity: Participants should have mild to moderate symptoms of non-specific low back pain (NSLBP) specially pain, as determined by the assessing healthcare provider.
6. **Physical Capability:** Participants who are physically capable of performing the prescribed exercises and interventions without significant limitations.

7. **Consent:** Participants who provide informed consent to participate in the study after receiving detailed information about the study objectives, procedures, potential risks, and benefits.
8. **Compliance:** Participants who are willing and able to comply with the study procedures, including attending scheduled sessions, adhering to the intervention protocols, and completing required assessments.
9. **No Concurrent Treatment:** Participants who have not undergone any concurrent treatments specifically targeting APT or low back pain during the study period to avoid confounding effects.

EXCLUSION CRITERIA:

1. **Trauma or Fracture:** Individuals with a history of trauma or fracture around the pelvic and lumbar region, as this may significantly affect the participant's ability to perform the prescribed exercises and interventions and confound study outcomes.
2. **Orthopedic or Neurological Surgery:** Participants with a history of orthopedic or neurological surgery related to the pelvic or lumbar region, as this may impact the participant's musculoskeletal function and response to the interventions.
3. **Malignancy:** Individuals with a diagnosis of malignancy, as this may introduce confounding variables and complicate the interpretation of study outcomes.
4. **Autoimmune Disorders:** Participants with autoimmune disorders affect musculoskeletal function, as these conditions may influence the participant's response to interventions and introduce variability in study outcomes.
5. **Referred or Radiating Visceral Pains:** Individuals experiencing referred or radiating visceral pains, as these symptoms may indicate underlying pathologies requiring specific treatment and may confound the assessment of APT and NSLBP.
6. **Gait Abnormalities and Neurological Disorders:** Participants with gait abnormalities or neurological disorders affecting musculoskeletal function, as these conditions may influence the participant's ability to perform exercises and interventions and confound study outcomes.

7. **Congenital and Developmental Disorders:** Individuals with congenital or developmental disorders affecting musculoskeletal function, as these conditions may introduce variability in study outcomes and complicate the interpretation of results.
8. **Pregnancy:** Pregnant individuals will be excluded from the study due to the potential risks associated with certain physiotherapy modalities and the need for specialized considerations in this population.
9. **Contraindications:** Participants with contraindications to specific physiotherapy modalities included in the study protocol (e.g., contraindications to electrotherapy) will be excluded to ensure participant safety.
10. **Inability to Attend Sessions:** Participants who are unable to attend scheduled physiotherapy sessions due to logistical constraints (e.g., transportation issues, scheduling conflicts) will be excluded.
11. **Cognitive Impairment:** Participants with significant cognitive impairment or communication difficulties that may impede their ability to understand and follow study instructions will be excluded.
12. **Participation in Other Research:** Participants who are currently participating in other research studies involving treatment interventions for MPS and/or radiculopathy will be excluded to avoid potential confounding effects on outcomes and treatment adherence.

These inclusion and exclusion criteria are designed to ensure the safety of participants, minimize confounding factors, and optimize the internal validity of the study results.

RANDOMIZATION AND GROUP ALLOCATION:

- Participants meeting the inclusion criteria will be randomly assigned to one of the treatment groups using computer-generated randomization methods.
- Allocation concealment will be ensured to prevent selection bias, with treatment assignments concealed from both participants and investigators until after enrollment.

7.6 Intervention Groups:

Participants will receive physiotherapy interventions based on their assigned treatment group.

1. **Group-A:** Core stability exercises with electrotherapy group.
2. **Group-B:** Soft tissue release with manual therapy and stretching group.

3. **Group-C:** Postural correction exercises with contrast therapy group.
4. **Group-D:** (Control group) combination of electrotherapy with stretching and flexibility exercises group.

Each intervention will be administered by qualified healthcare professionals following standardized protocols. The frequency, duration, and intensity of interventions will be determined based on evidence-based guidelines and tailored to individual participant needs.

Intervention Duration: Interventions will be applied for four weeks.

Intervention Frequency: Frequency of interventions will be twice a week. Total 08 sessions will be applied to each participant at regular intervals as per standard clinical practice.

7.7 Intervention Procedures:

Core stability exercises:

These exercises, considering the exercise science principles (such as overload, volume, intensity and integrity), are based on the core stability exercises program. All exercises will start after a 5-minute warm-up session.

Warm-up exercises:

Dynamic stretching of hip flexors, pelvic tilts and cat-camel stretches. Each of these will be performed 5times with a minimum hold of 10-15seconds.

Core stability exercises:

Core stability exercises will be divided in two phases. One is basic phase which will continue for initial two weeks and will include some low intensity exercises. Second is advance phase which will continue for next two weeks and will include some additional high intensity exercises.

Basic phase:

Following exercises will be performed during this phase. Three sets of 8-10 repetitions of all exercises will be performed.

- Abdominal drawing-in and pull the lower back to the floor (Static contraction)
- Supine bridges

- Standard plank
- Lowering and lifting legs in supine position
- Rotational Knee Tuck

Advance phase:

Following exercises will be performed additionally during this phase along with continuation of exercises of basic phase. Three sets of 8-10 repetitions of all exercises will be performed.

- Crunches
- Plank with opposite arm and leg lift
- Reverse Crunch
- Crisscross Crunch
- Single leg glute bridge

After completion of the exercise session, there will be a cool down session of 5-10mins.

Cool down exercises:

Static stretching exercises will be performed in this phase. These will include knee to chest stretches, straight leg raises, and Russian twist stretches. General body stretches will also be included.

Manual Therapy:

Trigger point therapy:

The subject will be sitting positions. The expert physical therapist/healthcare provider in the will palpate trigger points. The trigger point will be marked by marker. The trigger point will then be pressed with thumb by increasing pressure gradually until patient reports that pressure has been converted into pain. The subject will be instructed to indicate this by saying "Yes" when pressure sensation converts to pain. The examiner will then hold for 5seconds and will release the pressure. This procedure will be repeated 5-6times for each trigger point.

Spinal mobilization:

Posterior-Anterior (PA) mobilization is a commonly used technique in spinal mobilization that targets the lumbar spine. This technique involves applying a controlled force to the spinous processes of the vertebrae to improve mobility and reduce pain.

Assessment: The therapist begins by assessing the patient's lumbar spine to identify areas of stiffness or pain. This may involve observing the patient's posture and conducting a range of motion assessments.

Patient Positioning: The patient will be typically positioned in a prone (face down) position on a treatment table. This position allows for optimal access to the lumbar spine while ensuring the patient is comfortable.

Hand Placement: The therapist will stand beside the treatment table and place their hands on the patient's lower back, specifically over the spinous processes of the lumbar vertebrae. The therapist's thumbs will be usually positioned on the spinous processes, while the fingers wrap around the sides of the lumbar region for support.

Application of Force: The therapist will apply a gentle, controlled posterior-anterior force by pushing downwards on the spinous processes. This force should be applied in a rhythmic manner, typically in sets of 30 seconds to 1 minute, allowing for a gradual increase in pressure as tolerated by the patient.

Monitoring Response: Throughout the mobilization, the therapist monitors the patient's response, adjusting the force and rhythm based on feedback. The goal is to achieve a comfortable level of pressure that promotes relaxation and mobility without causing discomfort.

Reassessment: After completing the PA mobilization, the therapist will reassess the lumbar spine to evaluate changes in pain levels and range of motion. This helps determine the effectiveness of the technique and guides further treatment.

Joint mobilization:

Maitland's mobilization technique is a manual therapy approach that focuses on the assessment and treatment of joint and soft tissue dysfunction. It is particularly effective for managing pain and improving mobility in the lumbar spine. It will be applied as follows:

Assessment: The therapist will begin with a thorough assessment of the lumbar spine, identifying areas of stiffness, pain, and restricted movement. This may involve observing the patient's posture and conducting a range of motion evaluations.

Patient Positioning: The patient will be typically positioned in a comfortable manner, often lying prone (face down) on a treatment table. This position allows the therapist easy access to the lumbar spine.

Hand Placement: The therapist will stand beside the treatment table and place their hands on the lumbar spine, specifically over the spinous processes of the vertebrae that require mobilization. The therapist's thumbs will be positioned on the spinous processes, while the fingers wrap around the sides of the lumbar region for support.

Application of Mobilization: Maitland's technique involves applying oscillatory movements to the lumbar spine. The therapist will use Grade-III joint mobilization:

Grade III: Large amplitude movement that reaches the end of the available range, aimed at increasing mobility.

Rhythmic Oscillation: The therapist will perform rhythmic oscillations, typically at a frequency of 1-2 times per second, for about 30 seconds to 1 minute. This will help to stimulate the joint mechanoreceptors and promote relaxation of the surrounding muscles.

Monitoring Response: Throughout the mobilization, the therapist will continuously monitor the patient's response, adjusting the force and rhythm based on feedback. The goal is to achieve a comfortable level of pressure that promotes relaxation and mobility.

Reassessment: After completing the mobilization, the therapist will reassess the lumbar spine to evaluate changes in pain levels and range of motion. This helps determine the effectiveness of the technique and guides further treatment.

Myofascial release:

Myofascial Release (MFR) is a manual therapy technique that focuses on relieving tension in the fascinating the connective tissue surrounding muscles. This technique is particularly beneficial for patients with non-specific low back pain.

Patient Positioning: The patient will be positioned comfortably, often lying down on a treatment table. The therapist may have the patient adopt a position that minimizes tension in the affected area, facilitating easier access to the fascia.

Gentle Palpation: The therapist will use his hands to gently palpate the soft tissue and identify areas of restriction. This involves applying light pressure to feel for resistance or tightness in the fascia.

Sustained Pressure: Once a restricted area is identified, the therapist will apply gentle, sustained pressure to the fascia for a prolonged period (typically 90 seconds). This pressure can be applied in various directions to encourage the fascia to elongate and release.

Stretching the Fascia: The therapist may also incorporate gentle stretching movements while maintaining pressure on the fascia. This helps to facilitate the release of tension and improve mobility in the affected area (Chaitow, L., & DeLany, J. 2015).

Postural Correction Exercises:

Hip Flexor Stretch:

- **How to Perform**: Kneel on one knee with the other foot in front, forming a 90-degree angle. Push subject's hips forward while keeping his back straight until he feels a stretch in the hip flexor of the kneeling leg. Hold for 20-30 seconds and switch sides.

Glute Bridges:

- **How to Perform**: Subject will lie on his back with your knees bent and feet flat on the floor. Lift his hips towards the ceiling by squeezing your glutes, creating a straight line from his shoulders to knees. Hold for a few seconds before lowering back down. Repeat for 10-15 repetitions.

Cat-Cow Stretch:

- **How to Perform**: Subject will Start on hands and knees. Inhale as his arch his back (cow position), and exhale as his round his back (cat position). Repeat for 10-15 cycles.

Dead Bug:

- **How to Perform**: Subject will Lie on his back with arms extended towards the ceiling and knees bent at 90 degrees. Slowly lower one arm and the opposite leg towards the floor while keeping back flat. Return to the starting position and switch sides. Repeat for 10-15 repetitions.

Wall Sits:

- **How to Perform**: Subject will Stand with back against a wall and slide down into a seated position with knees at a 90-degree angle. Hold this position for 20-60 seconds.

Knee to chest exercise: The knee-to-chest exercise is a simple stretch that targets the lower back and hip muscles, which can help alleviate low back pain. To perform it, subject will lie on his back on a flat surface with legs extended. Bend one knee and gently pull it towards chest using hands, keeping the other leg straight or bent with the foot flat on the ground while engaging core to stabilize his lower back against the floor. Hold the stretch for 20 to 30 seconds, breathing deeply, then slowly lower the leg back to the starting position and repeat with the other leg. For a variation, Subject will bring both knees to chest simultaneously, holding the position for the same duration. This exercise is effective in relieving tension in the lower back and improving flexibility (Fatemi R et al 2015).

Thoracic and lumbar extension: The thoracic and lumbar extension exercise is designed to improve spinal mobility and alleviate tension in the back. To perform this exercise, Subject will start by kneeling on all fours with hands directly under shoulders and knees under hips. Slowly arch back while lifting head and chest upwards, allowing lower back to extend naturally, and hold this position for a few seconds to feel a gentle stretch in the thoracic and lumbar regions. Then, return to the starting position and repeat 8 to 10 repetitions. This exercise helps counteract the effects of prolonged sitting and promotes better posture (Kim YW 2017)

Electrotherapy:

TENS: To apply Transcutaneous Electrical Nerve Stimulation (TENS) for non-specific low back pain, begin by cleaning the skin in the affected area with water or rubbing alcohol to ensure good electrode contact. Adhesive electrode pads will be placed on either side of the painful region, ensuring they are at least one inch apart to avoid overlapping stimulation. Connect the pads to the TENS unit and turn it on, adjusting the settings to a pulse frequency of 2Hz to 10Hz and a pulse width of 175µs to 200µs, which are commonly recommended parameters for pain relief. The TENS unit will be used for 20 minutes per session, up to four times a day, but it is advisable to avoid continuous use to maintain its effectiveness. This technique is designed to activate sensory nerves and may help reduce pain perception in the lower back (Johnson et al., 2022).

Infra-red Rays: To apply an infrared lamp for non-specific low back pain, position of the lamp will be approximately 12 to 18 inches away from the affected area, ensuring that the light is directed at the lower back. Before starting the treatment, it is advisable to remove any clothing or coverings that may obstruct the

light's penetration. Turn on the lamp and allow it to emit infrared light for about 15 to 30 minutes per session, ensuring that the skin does not become too hot; if discomfort occurs, adjust the distance or duration accordingly. This method utilizes the heat generated by the infrared light to promote blood circulation, reduce muscle tension, and alleviate pain in the lower back region. Studies have shown that infrared therapy can effectively reduce pain and improve function in patients with chronic low back pain (Tsagkaris C et al 2022)

7.8 Variables:

- Anterior Pelvic Tilt Angle (APT Angle)
- Pain
- Functional capacity
- Balance
- Quality of life

7.9 Outcome Measures:

Following outcome measures will be used to assess the effects of applied interventions:

Primary Outcome Measures:

1. **Anterior Pelvic Tilt Angle:** Anterior Pelvic Tilt Angle will be measured with digital photography and MicroDicom software.
2. **Pain:** Numeric Pain Rating Scale (NPRS) will be used for pain severity measurement.

Secondary Outcome Measures:

1. **Functional Capacity:** Evaluated through range of motion assessments, strength tests, and endurance tests.
    - **Muscle Strength:** Manual muscle testing (MMT) will be used for assessment of strength.
2. **Balance:** Balance of participants will be measured by Y balance test.
3. **Quality of life:** Quality of life will be measured by SF-36 Questionnaire.

7.10 Data Collection:

Data will be collected at three points of interventions as follows.

- **Pre-Intervention (Baseline):** Baseline assessments of all participants will be conducted before the interventions to establish initial measurements.
- Interventions will be implemented as per the assigned groups, ensuring consistency in treatment delivery and adherence to the defined protocols.
- **Mid-Intervention:** Assessment of all participants will be conducted at the end of 2nd week.
- **Post-Intervention:** Outcome data will be collected at the end of defined intervention duration i.e. four weeks to assess the effects of implemented interventions.

Data Collection Tools and procedures:

- Digital Camera
- MicroDiCom Software
- Tripod stand
- Numerical Pain Rating Scale (NPRS)
- MMT
- Y Balance kit (safety belt use)

Pelvic Tilt Angle measurement:

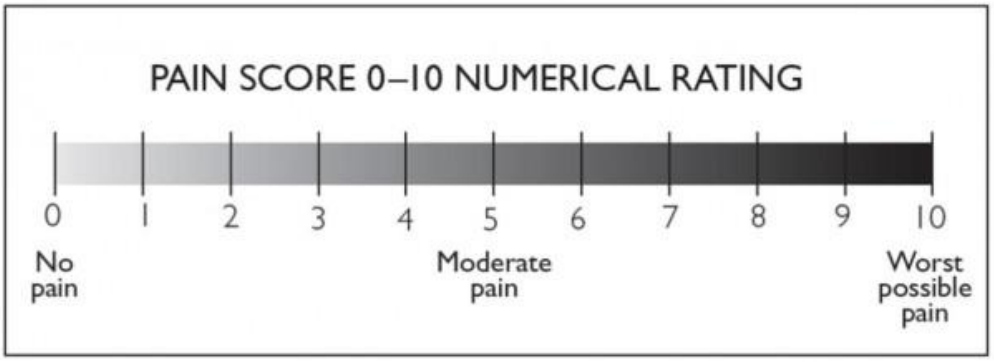
The angle that is formed between the horizontal plane and a line that is drawn from the anterior superior iliac spine (ASIS) to the posterior superior iliac spine (PSIS) while the individual is standing in a calm position is known as the pelvic tilt. According to (Alviso et al. 1988), it is determined by the muscular and ligamentous forces that play a role in the relationship between the pelvis and the neighboring segments. There is a forward rotation of the pelvis, which is known as an anterior pelvic tilt. This rotation is accompanied by an increase in lumbar lordosis, and it is believed to relate to several common musculoskeletal problems, including low back pain (Day et al., 1984). Physical therapists have been using the degree of pelvic tilt to evaluate routinely therapeutic procedures that either directly or indirectly affect the standing position of the pelvic tilt in the sagittal plane (Sanders and Stavrakas, 1981). This is because anterior pelvic tilt has been linked to a loss of core stability, and as a result, the degree of pelvic tilt has been used to evaluate these procedures.

The subject's left and right anterior superior iliac spines (ASIS) and posterior superior iliac spines (PSIS) will be noted before they are photographed. All procedures will be carried out in a room that has a background that does not reflect light. At a height of 0.90 meters and a distance of 2.90 meters from the volunteer, the camera will be mounted on a tripod and placed on the level and plumb. This will allow for the taking of these images. The participants will stand with their arms crossed over their chests. MicroDicom software will be utilized in order to perform analysis on the digital images that have been captured. To determine the pelvic tilt angles, the ASIS and PSIS markers will be used. These angles will be collected from the right and left side views, respectively. A line will be drawn horizontally between the ASIS and the PSIS in order to calculate the angle of the pelvis as viewed from the side. It is considered typical for the pelvis to have a horizontal tilt of up to 11 degrees in the anterior direction. Males have a normal pelvic tilt value of 9.5 degrees, whereas females have a normal value of 13 degrees. (mazhar et al. 2021)

Pelvic tilt in literature was measured in different ways by different scholars. The method we chosen is digital photography MicroDicom software was previously used by researchers (mazhar et al. 2021) to measure APT angle. The reliability testing of tools were calculated by same scholar and reported as reliable tool.

Pain Measurement:

(Rodriguez CS, 2001) The Numeric Pain Rating Scale (NPRS) is an outcome measure that is a uni-dimensional measure of the intensity of pain experienced by individuals. The eleven-point numeric scale spans from '0' indicating one pain extreme (for example, "no pain") to '10' representing the other pain extreme (for example, "pain as bad as you can imagine" or "worst pain imaginable"), with '0' being the least amount of pain possible (Jensen MP (1993) (Rodriguez CS (2001).



Functional capacity:

Balance Assessment:

Y balance is a reliable and valid instrument for balance measurement. It is a very useful tool to assess dynamic balance in different subjects.

The Y Balance Test (YBT) is a dynamic balance assessment tool that evaluates an individual's balance and functional symmetry through reaching tasks. The participant stands on one leg (the stance leg) with the opposite leg positioned behind them, maintaining a slight bend in the knee and keeping their hands on their hips for balance. The test consists of three reach directions: anterior (forward), posteromedial (diagonal backward toward the stance leg), and posterolateral (diagonal backward away from the stance leg). For each direction, the participant leans while keeping the stance leg straight and touches the reach indicator with the toes of the opposite leg, performing three attempts per direction and recording the best distance reached. After completing the reaches on one leg, the participant switches to the opposite leg and repeats the procedure. The distances reached are measured and recorded, allowing for a composite score to be calculated by summing the best reach distances from each direction. This test helps identify balance capabilities and potential risks for injury by comparing scores between the two legs.

Quality of Life Assessment:

The SF-36 is an indicator of overall health status. It has eight scaled scores; the scores are weighted sums of the questions in each section. Scores range from 0 - 100 (McHorney CA,1994, Ware JE, 1993, Ware JE, 1992)

Sections:

- Vitality

- Physical functioning
- Bodily pain
- General health perceptions
- Physical role functioning
- Emotional role functioning
- Social role functioning
- Mental health

Lower scores = more disability, higher scores = less disability

7.12 ETHICAL CONSIDERATIONS:

- Intervention environment (lighting, cleanliness, comfortability, temperature control, waiting area) will be managed to be satisfactory, minimizing any distress to the participants during study.
- Any research study must justify the potential benefits of the study against the any possible harm/distress caused to the participant(s). This involves considering the scientific significance of the research, its potential impact on human health, and whether the benefits outweigh the ethical concerns raised.
- Self-designed informed consent form will be used for all participants prior to enrollment, and the study protocol will be reviewed and approved by the institutional ethics committee.
- Participants will be assured of confidentiality and their right to withdraw from the study at any time without consequences.
- Study will strictly take care of principal of beneficence by minimizing risks and not exposing to any serious risks to participants.
- Researcher is will duly follow the obligation of research to report the findings of study accurately, without any forgery, manipulation or selectivity.
- Helsinki guidelines will be duly followed during conduction of study.

7.13 Limitations:

- Finding target population with proper diagnosis and referral from concerned healthcare

professionals

- Finding equal samples from both genders
- Getting permission to take body images for calculating the required angle.
- Funding and resource limitations in the form of insufficient funds and limitation in staffing.
- Generalizability of study may be impaired by the fact that it is confined to a specific geographical area and referral problems can be faced by researcher as well.

6. Gantt Char

Gantt Chart for Research Progress of PhD in Health Sciences (Pysical Therapy)

Title: Comparative Analysis of Different Physiotherapy Interventions on Anterior Pelvic Tilt in Subjects with Non-Specific Low Back Pain: A Randomized Controlled Trial

Researcher Name: Mahtab Ahmad Mukhtar Patafi | University: Lincoln University | Student ID: 131221122228

Project Start Date: 1st March 2024

Project End Date: 31st June 2025

WBS	Task	Start	End	Duration	% Done
1	**Proposal**				
1.1	Literature search for Available Study Gap	1st Mar-24	31st May-24	90Days	100
1.2	Idea & Title Generation	1st Jun-24	30th Jun-24	30Days	100
1.3	Writing Proposal and Submitting	16th Jun-24	31st Jul-24	45Days	100
2	**Research Conduction**				
2.1	Research Work	1st Aug-24	15th Sep-24	45Days	0
2.2	1st Progress Report	16th Sep-24	30th Sep-24	15Days	0
2.3	Research Work	1st Oct-24	15th Nov-24	45Days	0
2.4	2nd Progress Report	16th Nov-24	31st Nov-24	15Days	0
2.5	Research Work	1st Dec-24	15th Jan-25	45Days	0
2.6	3rd Progress Report	16th Jan-25	31st Jan-25	15Days	0
2.7	Research Work	1st Feb-25	15th Mar-25	45Days	0
2.8	4th Progress Report	16th Mar-25	31st Mar-25	15Days	0
2.9	Writing Thesis	1st Apr-25	15th May-25	45Days	0
2.10	Submission of Thesis	16th May-25	15th Jun-25	30Days	0