

Dated: 9th May, 2025

Official Title:

“Effectiveness of Mulligan Mobilization Technique and Proprioceptive Exercises among Patients with Knee Osteoarthritis in Karachi”

Study Protocol

Subjects and Data Sources:

The study population will include individuals diagnosed with knee OA, aged 40 years and above, clinically diagnosed mild to moderate primary OA in knee. Participants will be recruited from a physical therapy clinic, and will be screened for inclusion and exclusion criteria. **Inclusion criteria** will include diagnosed cases of knee OA with mild to moderate Grade of OA (According to Kellgren and Lawrence Scale) and the ability to walk without assistive devices for at least 50 feet. **Exclusion criteria** will include patients have Kellgren and Lawrence <grade 2 or above grade 3, history of knee surgery, knee joint replacement, patients have been administered corticosteroid injections in last six months, history of mental illness, autoimmune disorder, neurological or orthopedic conditions affecting the lower limbs and the presence of other conditions that may affect balance or gait.

Experimental Procedure:

Group A:

In group A after giving pulsed ultrasound a set of Proprioceptive Exercise for 30 sessions continuously, the details are as under:

Pulsed Ultrasound:

In this procedure, a pulsed ultrasonic wave with a frequency of 1 MHz and a power of 2 W/cm² will be utilized. The wave will be applied using a 5 cm diameter applicator for a duration of 5 minutes per session. The pulsed mode will have a duty cycle of 1:4. The patients will be placed in a supine (face-up) position, and a non-medicated acoustic gel will be applied to the targeted area. The ultrasound therapy will be administered to the superomedial and lateral regions of the knee using a circular motion. The ultrasound probe will be positioned at right angles to ensure the optimal absorption of energy by the tissues. Following the Pulsed Ultrasound, Proprioceptive Exercises will be given as detailed under:

- i. **One leg balance-** It requires flexing the opposite leg at the knee, hip, and ankle while standing on the affected foot. This position will be hold for one minute (60 seconds), followed by rest for 10 to 20 seconds, then continue this process twice more. Three repetitions of the same exercise will be performed with the unaffected leg after a brief break.
- ii. **Blind advanced one leg balance-** The task will resemble one-legged balance, but the participant will be required to close their eyes while executing the routine, and then repeat it two more times.
- iii. **Toe walking-** In this activity, the participant will be instructed to walk a 20-meter distance while balancing on their toes with their toes pointing straight ahead. They will then be asked to walk the same distance again, but this time with their toes pointing outward. After a brief rest, the entire procedure will be repeated once more.
- iv. **Heel Walking-** The participant will be guided to walk a distance of 20 meters while balancing on their heels with their toes pointed straight ahead. Next, they will be instructed to walk on their heels with their toes pointing outward, followed by walking on their heels with their toes pointing inward. After a brief rest, the entire procedure will be repeated once more.
- v. **Cross body leg swings-** To perform this exercise, the participant will lean slightly forward with their hands resting on a wall for support. They will shift their weight onto the affected leg while swinging the other leg in front of their body. This movement will be repeated 15 times. After a short rest, they will then perform 15 repetitions with the unaffected leg serving as the weight-bearing limb.

Group B:

The treatment plan for Group B involves administering pulsed ultrasound with same protocol followed by Mulligan mobilization techniques, including lateral, medial, and rotational glides. Each session will consist of 2 sets of 10 repetitions. The treatment will be conducted three times a week on alternate days for a total of 10 weeks.

i. Mulligan Mobilization for Medial Glide:

During the treatment, the patient will be positioned in a prone (face-down) posture. To execute a medial glide, the therapist will position themselves on the side opposite to the target knee. They will place a belt around the patient's waist and lower leg, aligning the upper edge of the belt with the margin of the tibial joint. Using one hand to stabilize the thigh above the knee and the other hand to support the lower leg, the therapist will apply a medial force to the knee using the belt. The therapist will then instruct the patient to flex their knee while maintaining the glide.

ii. Mulligan Mobilization for Lateral Glide:

To administer a lateral glide to the knee, the therapist will position themselves next to the affected knee. They will employ the belt to facilitate the glide by applying force from the opposite side. The therapist will position the belt appropriately and apply lateral pressure to the knee joint, creating the desired glide. This technique helps to mobilize the knee joint laterally and improve its range of motion.

iii. Mulligan Mobilization for Rotation Glide: -

While the patient is lying in a supine (face-up) position, the therapist will proceed by holding onto the lower leg and internally rotating the tibia on the femur. Ideally, it is advantageous if the fibula also moves downward (ventrally) at the same time. The therapist will sustain this glide while instructing the patient to flex their knee joint. Once in the flexed position, the therapist will apply overpressure with their hands, further enhancing the mobilization of the knee joint. This technique helps to improve joint mobility and can be effective in addressing specific limitations or restrictions in knee movement.

Group C:

In Group C after giving pulsed ultrasound with same protocol, traditional physical therapy will be given.

The stretching exercises consist of:

- **Stretching of the Gastrocnemius and Soleus Muscles**
 - **Frequency:** 3–5 times per week.
 - **Intensity:** Stretch to the point of mild discomfort, not pain.
 - **Time:** Hold each stretch for 30 seconds and repeat 3 times on each leg.
 - **Type:** Static stretching.
 - **Procedure:**
 - **Gastrocnemius Stretch:** Stand facing a wall with one foot forward (slightly bent) and the other foot back (straight). Press the back heel into the floor and lean forward to feel the stretch in the calf.
 - **Soleus Stretch:** From the same position, slightly bend the back knee while keeping the heel on the ground to target the lower calf (soleus muscle).

- **Stretching of the Hamstrings**

- **Frequency:** 3–5 times per week.
- **Intensity:** Stretch to a tolerable point of tension without causing pain.
- **Time:** Hold each stretch for 30 seconds and repeat 3 times on each leg.
- **Type:** Static stretching.
 - **Procedure:**
 - **Seated Hamstring Stretch:** Sit on the floor with one leg straight and the other bent. Reach forward toward the toes of the straight leg while keeping the back straight.
 - **Standing Hamstring Stretch:** Place one foot on a low step or surface. Keep the elevated leg straight and hinge forward from the hips to feel the stretch.

- The strengthening exercise for the Quadriceps muscles is also included.

- **Quadriceps Strengthening**

- **Frequency:** 2–3 times per week (allow 48 hours of rest between sessions).
- **Intensity:** Moderate resistance, starting at **50–60% of 1RM (Repetition Maximum)** and progressing gradually.
- **Time:** Perform **3 sets of 10–12 repetitions.**
- **Type:** Open kinetic chain exercises.
- **Procedure:**
 - **Straight Leg Raise:** Lie on your back with one leg bent and the other straight. Slowly lift the straight leg to a height of 30–45 degrees and lower it down under control.

- The closed-kinetic chain exercises comprise:

- **Seated Leg Press**

- **Frequency:** 2–3 times per week.
- **Intensity:** Moderate resistance, starting at **50–60% of 1RM** and progressing as tolerated.
- **Time:** Perform **3 sets of 10–12 repetitions.**
- **Type:** Strengthening exercise.
- **Procedure:** Sit on a leg press machine with knees at 90 degrees. Push the platform away until the legs are nearly straight (avoid locking the knees), then return to the starting position.

- **Partial Squat**

- **Frequency:** 2–3 times per week.
- **Intensity:** Body weight or light resistance (e.g., holding a small dumbbell).
- **Time:** Perform **3 sets of 10–15 repetitions.**
- **Type:** Closed kinetic chain exercise.

- **Procedure:** Stand with feet shoulder-width apart. Lower the body to about 45 degrees of knee flexion, keeping the back straight and knees aligned over toes. Return to the starting position.
- **Step-Up**
 - **Frequency:** 2–3 times per week.
 - **Intensity:** Body weight or light resistance (e.g., holding a small dumbbell).
 - **Time:** Perform **3 sets of 10–12 repetitions** on each leg.
 - **Type:** Closed kinetic chain exercise.
 - **Procedure:** Use a step or bench of appropriate height. Step up with one leg and bring the other leg up to the step. Step down with the same leg and repeat.

Data Analysis:

Data will be analyzed using descriptive statistics to summarize baseline characteristics of the three groups, and inferential statistics to compare outcomes between the groups. To evaluate changes within the groups over time and differences between the groups at each time point, a repeated measure analysis of variance (ANOVA) will be applied. This statistical analysis allows for the examination of within-group variations across multiple time points and the comparison of group differences at each specific time point.

INFORMED CONSENT FORM

Title of Study: Effectiveness of Mulligan Mobilization Technique and Proprioceptive Exercises among Patients with Knee Osteoarthritis in Karachi

Introduction: You are being invited to participate in a research study. Please read this form carefully and feel free to ask any questions you may have before agreeing to participate.

Purpose of the Study: The purpose of this study is to compare the effectiveness of Mulligan Mobilization Technique versus Proprioceptive Exercises on pain, range of motion, functional status, balance and quality of life among patients with knee OA.

Procedures: If you agree to participate in this study, you will be asked to complete a series of questionnaires to evaluate your pain, range of motion, functional status, balance and quality of life. You will also receive either Mulligan Mobilization Technique, Proprioceptive Exercises or Traditional Physical Therapy depending on the group you are randomly assigned to. Mulligan Mobilization Technique is a manual therapy technique that aims to improve joint mobility and reduce pain. Proprioceptive Exercises are exercises that focus on improving balance and joint position sense. The treatment will be performed by a licensed physical therapist who has been trained to perform both techniques. You will receive 30 sessions of treatment over a period of ten weeks. Each session will last approximately 45 minutes.

Risks and Benefits: There are no anticipated risks associated with participating in this study. However, some participants may experience temporary pain or discomfort during the treatment sessions. The benefits of participating in this study include the potential to improve pain, range of motion, functional status, balance and quality of life among patients with knee OA. Participants are requested not to perform other treatment or take any painkillers during the period of intervention and evaluation.

Confidentiality: Your participation in this study will be kept confidential. Your personal information will be kept in a secure location and will only be accessible to the researchers involved in the study.

Voluntary Participation: Your participation in this study is completely voluntary. You have the right to withdraw from the study at any time without any penalty.

Contact Information: If you have any questions or concerns about the study, please feel free to contact **Muhammad Atif Khan** (Principal Investigator) at 0092-332-2281028 or mak_physio@yahoo.com.

Consent: By signing below, you acknowledge that you have read and understood the information provided in this form, and you voluntarily agree to participate in the study.

Participant Signature: _____

Date: _____

Researcher Signature: _____

Date: _____