

FULL STUDY PROTOCOL,
STATISTICAL ANALYSIS PLAN (SAP)

Effectiveness of Deep Breathing and Three Typical Yoga Poses for
Kinesiophobia Among Knee Osteoarthritis Patients

Ethical Approval: 30/32/2024/ISRB/SR/SCPT

8th December 2025

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1. Personnel

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2. Introduction

2.1 Background & Aims

Osteoarthritis is a degenerative joint disease-causing joint pain, stiffness, and functional limitations due to progressive cartilage damage, structural changes, and synovial proliferation. OA prevalence is higher in women, with knee being the most affected joint, with 344 million people suffering from mild to severe osteoarthritis potentially benefiting from rehabilitation. A study in India found a significant difference in knee joint arthritis prevalence between rural (56.6%) and urban (32.6%) areas, with Asians having a higher risk. Kinesio phobia, or the fear of movement, has been linked to a number of illnesses, including shoulder pain, chronic low back pain, and chronic fatigue syndrome. Direct experiences or social learning have been found to have an impact on learning.

Deep breathing promotes calmness, emotional control, deeper thinking, and better metabolism, while shallow thinking can lead to impulsive behaviour, rapid breathing, and mistakes. Yoga is a mind-body therapy that combines physical and mental practice through postures and breathing, enhancing balance, strength, flexibility, and endurance through both upper and lower extremities. Exercise and physiotherapy treat knee osteoarthritis for nearly a century, second most prescribed treatment after oral medicine. Patients should exercise alone, at home, or in class.

By combining conventional physiotherapy with relaxation techniques like deep breathing technique and three typical yoga postures, our method not only helps people with Kinesio phobia but also improves their knee range of motion, balance, and coordination so they can actively resume their daily lives.

2.2 Background Literature Review

- **Subha Pragathi Kanniappan et al (2021)** concluded that people with OA knee experience increased levels of Kinesio phobia when their pain intensity increases in tandem with the evolution of their OA stage or degree. Disability, a lower quality of life, a decrease in exercise tolerance, and dependence are all possible outcomes of this. A crucial component of evaluation for improved rehabilitation results is determining the degree of Kinesio phobia.
- **Volker Busch, MD et al (2012)** The findings imply that breathing patterns have a significant impact on autonomic and pain processing. They could expand on recent research that found DSB and relaxation to be crucial components in the regulation of sympathetic arousal and pain perception, based on an experimental study methodology.
- **Elizabeth Whissell et al (2021)** proposed suggested that the motion patterns of the lunge and warrior II poses were comparable in terms of angular impulse, joint angles, and joint moments. Compared to the other two maneuvers, the triangle position may be better since it increases hip joint range of motion, strength, and dynamic stability.
- **Michael Langworthy et al (2024)** concluded that OAK is a common illness that causes a significant economic and humanistic burden due to its varied disease presentation and course. Although there are currently no known disease modifying treatments, a number of nonsurgical alternatives have been described. However, treatments that can significantly reduce pain and enhance functional outcomes are still needed. There is potential to better control pain and improve mobility thanks to recently developed therapy methods.
- **Tampa scale:**
In (2023) **Frederique Det al**, the Clinical Journal of Pain published a thorough systematic study that looked into the TSK's psychometric qualities in people with musculoskeletal pain. The purpose of the study was to determine the validity and reliability of various TSK

versions. The results demonstrated the TSK's reliability as a Kinesio phobia test in this demographic.

- **Visual Analog scale:**

VAS design, widely used in health condition appraisals, has been subject to variations in scale length and endpoint descriptors, making cross-study comparisons challenging. To improve comparability and reliability, standardization in VAS application is essential, as revealed by **Mimmi Astrom et al (2023)** scoping assessment.

- **Short-form McGill Pain Questionnaire (SF-MPQ-2):**

Jumbo et al. (2020) study examined the SF-MPQ-2's repeatability in individuals with musculoskeletal shoulder discomfort. Internal consistency and test-retest reliability of the questionnaire were evaluated. According to the results, the SF-MPQ-2 is a valid tool for assessing pain in this patient group, hence facilitating its application in both clinical and research contexts.

3. Study Protocol

3.1 Research Design Outline

The study aims to perform a comparative study on Knee Osteoarthritis with Kinesio phobia in Saveetha Medical Hospital.

Formerly titled “Effectiveness of Deep Breathing and Three Typical Yoga Poses for Kinesiophobia among Knee Osteoarthritis patients: A Comparative Study” involves documented diagnosis of knee osteoarthritis patients with Kinesio phobia. The three main outcomes that will be measured were Tampa scale, Visual analogue scale and short form McGill Pain Questionnaire (SF-MPQ 2).

3.2 Participants

Older aged patients from Saveetha Medical Hospital with Knee Osteoarthritis along with kinesiophobia will be eligible to participate in this study.

3.3 Recruitment

All Elderly patients with Knee Osteoarthritis along with Kinesio phobia will be enrolled in the comparative study. The patient's information and consent sheet will be distributed to patients which details including inclusion and exclusion criteria. Patients who agree to the investigation will be invited to undergo baseline assessments Tampa scale, Visual Analog scale, Short-form McGill Pain Questionnaire (SF-MPQ-2). All the patients will have to return a signed consent form to the site principal investigator.

3.4 Administration

For Deep Breathing:

The patients will be seated on chairs and will be given a 3-minute, 6 deep breaths per minute session along with the CP protocol 5 times a week for 3 weeks.

For yoga:

The steps with yoga mat include;

Due to the considerable knee extensor and adductor moments, attention should be paid throughout performance.

1.Crescent lunge pose:

- Begin by assuming the downward-facing dog pose.

- Take a breath, lift your right leg behind you, and then step your right foot forwards between your palms.
- Verify that the right ankle is in line with the right knee.

2. Warrior II pose:

- Start in mountain pose (Tadasana).
- Step your left foot back
- Extend your arms out.
- Position your hips
- Bend deeply into the right knee
- Gaze directly above your right middle finger
- Breathe, hold, and strengthen
- Step back into mountain pose

3. Triangle pose:

- Hold the position with your knees and elbows straight.
- Inhale. Raise your right hand straight above your head, parallel to your right ear.
- Take a breath. Bend your torso at the waist, to your left side.
- At the same time, slide your left arm down along your left leg until your fingers are at your ankle.
- Keep your head tilted to the left at this point.
- Inhale. Straighten yourself and stand erect. Repeat the pose on the other side.

For Conventional Physiotherapy:

- The exercises are intended to strengthen, stretch, and stabilise the knee's supporting tissues. Exercise protocol follows for 1 time a day, 5 days per week for 4 weeks.

1. Straight-leg raise (sitting):

- Maintain proper posture when sitting comfortably on the chair. One leg should be straightened, held for a slow count of ten, and then gently lowered.
- Repeat this at least 10 times with each leg.

2. Quadriceps stretch:

- While lying down, perform this at least once per day. Under the ankle of the leg that has to be worked, place a rolled-up towel.
- At the knee, bend the opposite leg. Firmly press the rear of your knee towards the floor or bed using the muscles in your straight leg.
- Hold for five slow counts. With each leg, repeat at least five times.

3. Hamstring stretch:

- Stretch your legs out in front of you while sitting on the floor.
- Bend one knee slowly while keeping your foot flat on the floor until it feels pleasantly stretched.
- Hold for five seconds. For five seconds, hold your leg as straight as possible. Do this ten times for per leg.
- Sitting on a sofa, move your foot along a board or tea tray if you are unable to reach the floor.

4. Knee squats:

- Grasp a chair or work surface for stability.
- Make sure your kneecap covers your big toe by squatting down.
- Go back to standing. Do this ten times or more.
- Aim for a little deeper squat as you get better.

- Keep your knees bent at a proper angle at all times.

3.5. Primary outcomes

Tampa scale:

The Tampa scale will initially be used to distinguish between non-excessive fear and phobia in patients with chronic musculoskeletal pain, i.e., the fear of movement. In its original form, the TSK will be a 17-item assessment checklist. It will use a 4-point Likert scale (Strongly Disagree-Disagree-Agree-Strongly Agree) with statements that will later be linked to the model of fear-avoidance, fear of work-related activities, fear of movement, and fear of re-injury.

Visual Analogue Scale (VAS):

The Visual Analogue Scale (VAS) is a widely used tool for measuring pain severity, with endpoints ranging from "no pain" to "worst pain imaginable." Patients mark points on the scale, and clinicians track changes over time. The VAS has been shown to have high internal consistency, with Cronbach's alpha coefficients ranging from 0.71 to 0.95. The VAS has been shown to have good construct validity, correlating with other measures of pain intensity, such as the Numerical Rating Scale (NRS) and the McGill Pain Questionnaire (MPQ).

Short-form McGill Pain Questionnaire (SF-MPQ-2):

The Short Form McGill Pain Questionnaire 2 (SF-MPQ-2) is a modified version of the original SF-MPQ, assessing pain in patients with various conditions. It comprises 22 descriptors rated on a 0-10 scale, providing a comprehensive evaluation of pain. The

SF-MPQ-2 has demonstrated strong internal validity. A 2020 systematic review published in the Annals of the Rheumatic Diseases found that the SF-MPQ-2 has good internal consistency, with Cronbach's alpha values ranging from 0.77 to 0.92.

4. Statistical Analysis Plan (SAP)

Descriptive and inferential statistics will be used. Normally distributed data will be presented by mean and standard deviation (SD), and non-normally distributed data will be presented by median and interquartile range. SPSS (version 22.0) will be used for all statistical analyses.

4.1 Primary Outcomes

The primary analyses will compare experimental vs control group guidelines on their mean and standard deviation: (i)Tampa scale, (ii) Visual Analogue Scale (VAS), (iii) Short-form McGill Pain Questionnaire (SF-MPQ-2) Comparison will be tested by using the Paired t test to find the significant difference within the intervention effects and between the two groups (Experimental control group and Experimental Group) using independent t-test. P values <0.05 has been considered statistically significant.

4.2 Missing Data

For patients who do not attend the assessment, the mean imputation of the assessment scores from their allocation group has been used.

5. Informed Consent Forms (ICF)

Written consent will be gained from the patients with Knee osteoarthritis along with Kinesio phobia using the consent forms attached to the application.

5.1 Rights and Risks to participants

Rights

The patients may decide to stop being a part of this research study at any time without explanation. The patients have the right to omit or refuse to answer or respond to any question that is asked about their condition. In addition, they have the right to ask any questions about the procedures practiced (unless answering these questions would interfere with the study outcome). If they having any questions on this information sheet/test/training, they may ask the investigator or research in-charge person before the study begins or during the course of assessment and interventions. Participation in this study is voluntary and it does not carry any remuneration or reimbursement.

Risks

Researcher does not anticipate any risk from this research study.

5.2 Privacy and Confidentiality

All patients will be de-identified and assigned a unique ID number at the time of enrolment, which will be recorded by the administration officer at the study site.

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