

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Effectiveness of Tai Chi Compared With Standard Physiotherapy and
Virtual Reality Training on Balance and Functional Outcomes in Patients
With Knee Osteoarthritis

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Study Design: Randomized controlled parallel-group trial (3 arms)

Study Type: Interventional (Non-Drug)

Primary Purpose: Treatment

Masking: Single-blind (Outcome assessor blinded)

Estimated Enrollment: 96 participants

Study Duration: 4 weeks intervention

Ethics Approval: Approved by Ethics Committee of Jagiellonian University Medical College (No. 118.0043.1.208.2025)

Background and Rationale

Knee osteoarthritis (KOA) is a leading cause of disability in older adults. Exercise-based rehabilitation is recommended as first-line treatment. Tai Chi integrates balance control, closed kinetic chain movement, and neuromuscular coordination, which may provide superior functional improvements compared with standard physiotherapy or virtual reality-based training.

Objectives

Primary Objective:

To compare the effectiveness of Tai Chi versus standard physiotherapy and VR training on functional status (WOMAC total score) and balance (Berg Balance Scale).

Secondary Objectives:

- To evaluate changes in pain intensity (VAS).
- To assess dynamic balance (Timed Up and Go test).
- To assess knee joint range of motion (flexion and extension).

Study Design

Participants will be randomly assigned (1:1:1) to one of three groups: 1) Standard Physiotherapy, 2) Standard Physiotherapy + VR Training, 3) Standard Physiotherapy + Tai Chi. All interventions last 4 weeks. Assessments will be performed at baseline and at Week 4.

Participants

Inclusion criteria	Exclusion criteria
Diagnosed knee osteoarthritis	Patients with significant knee joint effusion and excessive valgus or varus deformity of the knee joint
Age between 60 and 80 years	Post-surgical status
	Patients with a body mass index (BMI) ≥ 34
	Patients after knee joint surgery
	Patients with severe clinically significant comorbidities that could interfere with study outcomes
	Lack of patient consent to participate in the study, as well as non-compliance or diagnosed psychiatric disorders
	History of stroke and other neurological disorders

Interventions

Arm 1: Standard Physiotherapy – manual therapy and physical modalities.

Arm 2: Standard Physiotherapy + 30 min/day VR training (Kinect).

Arm 3: Standard Physiotherapy + 30 min/day supervised Tai Chi

Outcome Measures

Primary Outcomes:

- Change in WOMAC total score (0–96).
- Change in Berg Balance Scale (0–56).
- Change in Timed Up and Go (seconds).

The interventions are low-risk behavioral therapies. Adverse events (e.g., musculoskeletal pain exacerbation, falls) will be recorded and monitored. No Data Monitoring Committee was established due to minimal risk.

Statistical Analysis Plan

Statistical analyses will be conducted using R Studio (v4.5.1). Two-sided significance level $\alpha = 0.05$. Primary analyses will follow the intention-to-treat (ITT) principle. Per-protocol analyses will be conducted as sensitivity analyses. Continuous variables will be summarized using mean \pm SD or median (IQR). Categorical variables will be summarized using frequencies and percentages.

Within-group comparisons: Wilcoxon signed-rank test. Between-group comparisons: Kruskal–Wallis test with Dunn post-hoc (BH correction). Effect size will be reported using epsilon-squared (ϵ^2).

Secondary Analysis

10.12.2025

Same analytical framework will be applied to secondary outcomes. Effect sizes will be reported.

Missing Data

Missing data will be assessed for pattern and mechanism. If $<5\%$, complete case analysis will be performed. If $>5\%$, multiple imputation methods will be considered.

Software

R Studio version 4.5.1.