Study Protocol and Statistical Analysis Plan

Document Title: Therapeutic Effects of Kinesiotape in the Management of Gonarthrosis: A Randomized Controlled Approach

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Study Protocol

Study Design

This study is a single-blinded, randomized controlled trial involving 38 individuals diagnosed with gonarthrosis according to ACR classification criteria. Participants are randomly assigned to two groups. Taping group (n=19) received kinesiotape application and a home exercise program, while participants in the control group (n=19) received only a home exercise program

Inclusion Criteria

- Having a diagnosis of primary gonarthrosis according to ACR classification criteria,
- Being between 45 and 65 years of age,
- Having a radiological diagnosis of gonarthrosis between Kellgren-Lawrence stage 1-3,
- Signing the informed consent

Exclusion Criteria

- Presence of a neurological disorder affecting muscle strength or balance,
- History of any surgical operation on the knee, hip, or spine,
- Physiotherapy or injections for the knee within the previous year,
- Presence of systemic conditions such as diabetes mellitus, vertigo, visual problems,
- History of severe trauma within the previous year

Interventions

In the taping group, the Mechanical correction technique and the Ligament/Tendon correction technique were applied using kinesiotape application. The taping procedure was repeated once a week, starting from the first week, for a total of 6 sessions. An individualized home exercise program was planned, considering EULAR and ACR recommendations. Each participant was given a structured home exercise program at least 3 days a week. The program included moderate-intensity aerobic exercises (e.g., walking) and muscle-strengthening exercises targeting the quadriceps and hamstring muscles, along with flexibility and balance exercises.

Outcome Measures

The demographic characteristics (age, gender, education, body mass index) were documented for both groups. The patients were evaluated two times with clinical assessment scales: Visual Analogue Scale (VAS) was used to assess pain, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire to assess pain, stiffness and functionality, Berg Balance Scale (BBS) to assess balance, Short Form (SF-36) to assess physical function,

physical role, emotional status, social function, general health, mental health, pain, quality of life.

Statistical Analysis Plan

Sample size was calculated using G-Power 3.1.3 software. The power and ">" levels were set to 0.80 and 0.05, respectively, and the effect size (ES) was set to 0.8. A priori analysis for the required sample size indicated that at least 21 subjects would be needed in each group. Thus, 23 subjects were used in each group to account for dropout cases (Cohen, 1992). The Kolmogorov-Smirnov and Shapiro-Wilk tests were used to determine whether the obtained measurements conformed to normal distribution, and the data were found to be normally distributed. Since the data were normally distributed, parametric tests were used in the comparisons. Whether there was a significant difference between the averages of these parameters measured before and after the treatment between the control and taping groups was analyzed by a t-test in independent groups, and whether there was a significant change between the parameters before and after the treatment in the taping and control groups separately was analyzed by a t-test in dependent groups. The change in parameters from pre-treatment to post-treatment was also analyzed for significant differences between groups using a t-test in independent groups. The data obtained in the research were analyzed using the SPSS (Statistical Package for Social Sciences) for Windows 20.0 program.