Statistical Analysis Plan

Study Title: Synergetic effects of lowenergy laser and exercise on pain, kinesophobia, disability, and quality of life in adolescents with patellofemoral pain syndrome: A randomized clinical trial.

1. Analysis Principles

- Primary Analysis Set: All statistical analyses will adhere to the Intentionto-Treat (ITT) principle, including all randomized participants in the groups to which they were originally assigned.
- Handling of Missing Data: Missing data will be handled using multiple imputation via Stochastic Regression Imputation.

2. Software

- All statistical analyses will be performed using Stata software, version 15.1 (Stata Corp, College Station, TX).
- Figures and graphs will be generated using GraphPad Prism, version 10.3.0 (GraphPad Software Inc.; San Diego, CA, USA).

3. Primary Outcome Analysis

- The primary objective is to assess the group-by-time interaction effect for all dependent outcome measures.
- Primary Statistical Model: A 2x2
 mixed-model Analysis of Variance
 (ANOVA) will be used. This model
 will include one between-subjects
 factor (Group: Intervention vs.

- Control) and one within-subjects factor (Time: Pre- vs. Post-intervention).
- Exception for Pain Intensity: For the pain intensity outcome, the Aligned Ranks Transformation ANOVA (ART-ANOVA) will be utilized as a non-parametric alternative robust to violations of normality.

4. Assumption Checking

 The normality of the residuals for the mixed-model ANOVA will be formally assessed using the Shapiro-Wilk test.

5. Follow-up Analyses

 If a statistically significant group-bytime interaction is found in the primary ANOVA/ART-ANOVA, posthoc paired samples t-tests will be conducted to evaluate within-group (intra-group) changes from baseline to post-intervention.

6. Effect Sizes

- Effect sizes will be calculated and reported as follows:
 - Within-group effects: Hedge's g (to account for small sample bias).
 - Between-group interaction effects: Partial Eta-Squared (n²p).

7. Significance Level

 The statistical significance threshold (alpha level) for all tests is set at p < 0.05.