# STATISTICAL ANALYSIS PLAN

**Official Title:**

# The Effectiveness of Conservative Treatment with Added Kinesio Taping in Decreasing Pain and Improving Hand Function and Grip Strength among Individuals with Lacertus Syndrome: A Pilot Randomized Controlled Trial

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Principal Investigator: Husam Taha

Program: PhD in Rehabilitation Sciences

Institution: Arab American University Palestine

# STATISTICAL ANALYSIS PLAN

**The Effectiveness of Conservative Treatment with Added Kinesio Taping in Decreasing Pain and Improving Hand Function and Grip Strength among Individuals with Lacertus Syndrome:**

**A Pilot Randomized Controlled Trial**

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| **Principal Investigator** | Husam Omar Taha |
| **Institution** | Arab American University Palestine |
| **IRB Approval** | R-2026/A/15/N |
| **Program** | PhD in Rehabilitation Sciences |

# 1. Introduction

This Statistical Analysis Plan (SAP) describes the pre-specified statistical methods for the pilot randomized controlled trial evaluating the effectiveness of conservative treatment with added Kinesio Taping in decreasing pain and improving hand function and grip strength among individuals with lacertus syndrome. This SAP was finalized before the database lock and unblinding of treatment allocation.

This document should be read in conjunction with the study protocol (Version 1.0, February 2026). In the event of any discrepancy between this SAP and the protocol, the SAP takes precedence for all matters relating to statistical analysis.

## 1.1 Study Objectives

**Primary Objective:** To evaluate the feasibility of conducting a Kinesio Taping intervention trial among adults with lacertus syndrome in the West Bank, Palestine, as assessed by recruitment rate, retention rate, and intervention adherence rate.

**Secondary Objective:** To obtain preliminary estimates of the treatment effect of Kinesio Taping (added to standardized conservative treatment) on pain intensity, upper extremity function, grip strength, and pinch strength.

## 1.2 Study Design Summary

| Parameter | Description |
|---|---|
| **Design** | Pilot, single-blind, parallel-group randomized controlled trial |
| **Allocation** | 1:1 ratio using covariate-adaptive minimization (Pocock and Simon method) |
| **Blinding** | Single-blind (outcomes assessor) |
| **Sample Size** | 30 participants (15 per group) |
| **Intervention Duration** | 4 weeks |
| **Assessment Timepoints** | Baseline (Week 0) and Post-intervention (Week 4) |

# 2. Analysis Populations

Three analysis populations will be defined for this study:

## 2.1 Intention-to-Treat (ITT) Population

The ITT population includes all participants who were randomized, regardless of whether they received the allocated intervention, adhered to the protocol, or completed the study. This is the primary analysis population for all effectiveness outcomes. Participants will be analyzed in the group to which they were originally randomized.

## 2.2 Per-Protocol (PP) Population

The PP population includes all randomized participants who completed the study without any major protocol deviations. Major protocol deviations are defined as: (a) failure to meet all inclusion criteria or meeting any exclusion criteria identified after randomization, (b) receiving the incorrect treatment allocation, (c) completing fewer than 50% of prescribed Kinesio Tape applications in the experimental group, (d) completing fewer than 50% of prescribed exercise sessions in either group, or (e) missing the Week 4 outcome assessment. This population will be used for sensitivity analysis only.

### 2.3 Safety Population

The safety population includes all participants who received at least one application of the study intervention (Kinesio Tape or conservative treatment). This population will be used for the analysis of adverse events.

## 3. Descriptive Analyses

### 3.1 Participant Flow

A CONSORT flow diagram will be presented showing the number of participants at each stage: screened for eligibility, excluded (with reasons), randomized, allocated to each group, received allocated intervention, lost to follow-up (with reasons), and included in each analysis population.

### 3.2 Baseline Characteristics

Baseline demographic and clinical characteristics will be summarized by treatment group using descriptive statistics. No formal statistical testing of baseline differences will be performed, as any observed differences are due to chance in a randomized trial. The following variables will be summarized:

| Variable | Type | Summary Statistic |
|---|---|---|
| Age (years) | Continuous | Mean (SD), Median (IQR) |
| Sex | Categorical | n (%) |
| Affected side (right/left) | Categorical | n (%) |
| Dominant hand | Categorical | n (%) |
| Symptom duration (weeks) | Continuous | Mean (SD), Median (IQR) |
| Occupation type | Categorical | n (%) |
| Baseline NRS score | Continuous | Mean (SD), Median (IQR) |
| Baseline QuickDASH score | Continuous | Mean (SD), Median (IQR) |
| Baseline grip strength (kg) | Continuous | Mean (SD), Median (IQR) |
| Baseline pinch strength (kg) | Continuous | Mean (SD), Median (IQR) |
| Recruitment site | Categorical | n (%) |
| Concurrent analgesic use | Categorical | n (%) |

Continuous variables will be assessed for normality using the Shapiro-Wilk test and visual inspection of histograms and Q-Q plots. Variables following a normal distribution will be summarized as mean and standard deviation (SD). Variables not following a normal distribution will be summarized as median and interquartile range (IQR). Both will be reported for all continuous variables.

# 4. Primary Analysis: Feasibility Outcomes

The primary outcomes of this pilot study are feasibility parameters. These will be analyzed descriptively and compared against pre-specified feasibility thresholds to determine whether progression to a definitive trial is warranted.

| Outcome | Definition | Target Threshold | Analysis |
|---|---|---|---|
| Recruitment rate | Number of participants enrolled per month over the 6-month recruitment period | ≥5 per month | Descriptive (total/months) with 95% CI |
| Retention rate | Proportion of randomized participants completing the 4-week assessment | ≥80% | Proportion with exact binomial 95% CI |
| Adherence rate | Proportion of prescribed tape applications completed (experimental group only) | ≥70% | Mean proportion with 95% CI |

Feasibility outcomes will be reported with 95% confidence intervals. The retention rate confidence interval will be calculated using the exact (Clopper-Pearson) binomial method. A traffic-light system will be applied to guide progression decisions:

- **Green (proceed):** All three feasibility thresholds met
- **Amber (proceed with modifications):** One or two thresholds not met, with identifiable corrective actions
- **Red (do not proceed):** All three thresholds not met, or fundamental issues with study procedures identified

# 5. Secondary Analysis: Effectiveness Outcomes

## 5.1 Overview of Outcome Measures

| Outcome | Instrument | Range | MCID | Direction of Improvement |
|---|---|---|---|---|
| Pain intensity | NRS | 0–10 | 2 points | Decrease (negative change) |
| Upper extremity function | QuickDASH (Arabic) | 0–100 | 8–16 points | Decrease (negative change) |
| Grip strength | Hand dynamometer | kg | 5–6 kg | Increase (positive change) |
| Tip pinch strength | Pinch gauge | kg | — | Increase (positive change) |
| Key pinch strength | Pinch gauge | kg | — | Increase (positive change) |
| Palmar pinch strength | Pinch gauge | kg | — | Increase (positive change) |

### 5.2 Primary Analytical Approach

The primary analysis for all secondary effectiveness outcomes will be conducted on the ITT population. For each outcome, a change score will be calculated as the Week 4 value minus the Baseline value. The between-group difference in change scores will be compared using the following approach:

- **Step 1 — Normality Assessment:** The Shapiro-Wilk test will be applied to change scores within each group. Visual inspection of histograms and Q-Q plots will supplement the formal test. A p-value > 0.05 on the Shapiro-Wilk test will be taken as evidence of approximate normality.
- **Step 2 — Between-Group Comparison:** If change scores are approximately normally distributed in both groups, an independent samples t-test will be used. If the assumption of normality is violated, the Mann-Whitney U test will be used as a non-parametric alternative.
- **Step 3 — Effect Size Estimation:** Cohen's d will be calculated for each outcome as the difference in mean change scores divided by the pooled standard deviation. Effect sizes will be reported with 95% confidence intervals. Cohen's d values will be interpreted as: small (0.2), medium (0.5), and large (0.8).

### 5.3 Significance Level

A two-sided significance level of $\alpha = 0.05$ will be used for all statistical tests. No adjustment for multiple comparisons will be applied, given the pilot nature of this study and the exploratory intent of the secondary effectiveness analyses. P-values will be reported as exact values and interpreted with caution, recognizing that this study is not powered for definitive hypothesis testing.

### 5.4 Clinical Significance

In addition to statistical significance, clinical significance will be assessed by comparing observed changes to the established minimal clinically important difference (MCID) for each outcome. The proportion of participants in each group achieving the MCID will be reported descriptively.

## 6. Missing Data Handling

### 6.1 Missing Data Prevention

Primary strategies to minimize missing data include flexible scheduling for outcome assessments, multiple contact methods for follow-up reminders, compensation for time and travel expenses, and clear explanation of study importance at enrollment.

### 6.2 Missing Data Reporting

The amount and pattern of missing data will be reported by treatment group for each outcome variable. Reasons for missing data will be categorized as: participant withdrawal, loss to follow-up, missed assessment, or other (with specification). The pattern of missingness will be explored to assess whether data are missing completely at random (MCAR), missing at random (MAR), or missing not at random (MNAR) using Little's MCAR test and comparison of baseline characteristics between completers and non-completers.

### 6.3 Primary Missing Data Strategy

The primary method for handling missing outcome data will be multiple imputation (MI) using predictive mean matching. Twenty imputed datasets will be created. The imputation model will include treatment group, baseline value of the outcome variable, age, sex, and symptom duration as predictors. Rubin's rules will be applied to combine parameter estimates and standard errors across imputed datasets.

### 6.4 Sensitivity Analyses for Missing Data

The following sensitivity analyses will be conducted to assess the robustness of findings to different assumptions about missing data:

| Analysis | Description |
|---|---|
| Complete case analysis | Analysis restricted to participants with complete data at both timepoints |
| Per-protocol analysis | Analysis restricted to participants who completed the study without major protocol deviations |
| Worst-case imputation | Missing values in the experimental group imputed as no change; missing values in the control group imputed as maximum improvement |
| Best-case imputation | Missing values in the experimental group imputed as maximum improvement; missing values in the control group imputed as no change |
| Last observation carried forward | Baseline values carried forward for missing post-intervention data (equivalent to no change assumption) |

## 7. Safety Analysis

All adverse events will be summarized descriptively for the safety population, stratified by treatment group. Adverse events will be tabulated by type, severity grade (Grade 1–4), seriousness, and relationship to the study intervention. Skin reactions will be the primary safety outcome and will be reported as the incidence rate (number of events per participant) and the proportion of participants experiencing at least one adverse skin reaction. No formal statistical testing of safety outcomes will be performed due to the small sample size.

## 8. Additional Analyses

### 8.1 Minimization Balance Assessment

The success of the covariate-adaptive minimization procedure will be assessed by comparing the distribution of the five balancing variables (age category, sex, symptom duration category, baseline pain intensity category, and recruitment site) between treatment groups. Standardized mean differences will be calculated for continuous variables, and absolute differences in proportions for categorical variables. A standardized mean difference of less than 0.1 will be considered indicative of good balance.

### 8.2 Assessor Blinding Assessment

At the final assessment, the blinded outcome assessor will be asked to guess the treatment allocation for each participant and to rate their confidence in this guess on a 5-point Likert scale. The Bang Blinding Index will be calculated to assess the success of blinding, with values close to 0 indicating successful blinding and values close to 1 indicating complete unblinding.

### 8.3 Exploratory Descriptive Analyses

No formal subgroup analyses are planned due to the small sample size. However, exploratory descriptive summaries of outcomes may be presented stratified by age group (18–40 vs. >40 years) and symptom duration (4–12 weeks vs. >12 weeks). These exploratory analyses will be clearly labeled as hypothesis-generating and will not involve formal statistical testing.

## 9. Results Presentation

### 9.1 Tables

The following tables will be included in the results:

- Table 1: Baseline demographic and clinical characteristics by treatment group
- Table 2: Feasibility outcomes with 95% confidence intervals
- Table 3: Secondary effectiveness outcomes by treatment group (baseline, Week 4, change scores)
- Table 4: Between-group comparison of change scores with effect sizes and 95% CIs
- Table 5: Proportion of participants achieving MCID by treatment group
- Table 6: Adverse events summary
- Table 7: Sensitivity analysis results

### 9.2 Figures

- Figure 1: CONSORT flow diagram
- Figure 2: Forest plot of effect sizes (Cohen’s d) with 95% CIs for all secondary outcomes
- Figure 3: Individual participant change scores by treatment group for each outcome

## 10. Statistical Software

All statistical analyses will be performed using IBM SPSS Statistics version 28. Multiple imputation will be performed using the SPSS Multiple Imputation module. Effect size calculations and confidence intervals will be computed using SPSS syntax or supplementary calculation. All statistical code will be archived and made available upon reasonable request.

## 11. Reporting Guidelines

The results of this pilot study will be reported in accordance with the CONSORT 2010 statement extension for randomized pilot and feasibility trials (Eldridge et al., 2016). All primary feasibility outcomes will be reported with appropriate precision estimates. Secondary effectiveness outcomes will be reported with clear statements about the exploratory nature of the analyses and the limitations of interpreting effect sizes from small pilot studies.