Statistical Analysis Plan (SAP)

Official Title:

Clinical Evaluation of Kinesio Taping Outcomes in Stage II Cellulite: A Pilot Randomised Controlled Trial

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1. Introduction

This Statistical Analysis Plan (SAP) describes the planned analyses for the pilot randomised controlled trial evaluating the effects of kinesio taping on women with stage II cellulite. The SAP defines analysis populations, statistical methods, and reporting conventions in accordance with best practice guidelines.

2. Study Objectives

Primary Objectives:
- To evaluate the effect of kinesio taping on dermis density.
- To evaluate the effect of kinesio taping on low echogenic band (LEB) thickness.

Secondary Objectives:
- To assess changes in thigh circumference, body composition, cellulite stage, and skin moisture.
- To explore persistence of effects at 4 weeks post-intervention.

3. Study Design

This is a two-arm, open-label, parallel-assignment randomised controlled trial with an experimental group (kinesio taping) and a control group (no intervention).

4. Analysis Populations

The primary analysis will be conducted on the intention-to-treat (ITT) population, including all randomised participants who completed at least baseline and one follow-up measurement. Per-protocol analyses may be conducted excluding participants with major protocol deviations.

5. Endpoints

Primary Endpoints:
- Change in dermis density (baseline to 4 weeks).
- Change in LEB thickness (baseline to 4 weeks).

Secondary Endpoints:
- Change in thigh circumference, body composition, cellulite stage, and skin moisture (baseline to 4 weeks and 8 weeks).
- Persistence of dermal changes at 8 weeks.
- Exploratory regression of baseline fat percentage on changes in adiposity and cellulite measures.

6. Statistical Methods

Descriptive statistics (mean, standard deviation, median, interquartile range) will be provided for all continuous variables. Frequencies and percentages will be presented for categorical variables.

Comparisons between groups will be performed using independent samples t-tests (or Mann-Whitney U test if data are non-normal). Within-group changes will be assessed using paired t-tests (or Wilcoxon signed-rank test). Effect sizes (Cohen's d, Hedges' g) will be reported to quantify magnitude of differences.

For secondary analyses, linear regression will be used to explore associations between baseline body fat percentage and changes in adiposity outcomes. Significance will be set at $p < 0.05$.

7. Handling of Missing Data

Missing data will be evaluated for randomness. If <5% missing, analyses will be conducted using complete cases. If >5%, multiple imputation methods will be considered. Sensitivity analyses will be performed to assess robustness.

8. Interim Analysis

No interim analyses are planned due to the small sample size and short study duration.

9. Statistical Software

All analyses will be conducted using SPSS version 25.0. Supplementary analyses may be performed using R version 4.3 or later.

10. Reporting

Results will be reported in accordance with CONSORT guidelines. Tables and figures will be used to illustrate changes in primary and secondary outcomes. Effect sizes, confidence intervals, and p-values will be reported.

11. Ethical Considerations

All analyses will be performed on de-identified data. Analyses will adhere to ethical standards and respect participant privacy.