Statistical Analysis Plan (SAP)

Study Title: Efficacy of Photobiomodulation Therapy Using 980nm Versus 635nm Diode Lasers in the Management of Myofascial Pain Syndrome (LLLT-MPS_sEMG)

ClinicalTrials.gov Identifier (NCT Number): NCT07069764

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1. Introduction

This Statistical Analysis Plan (SAP) describes the pre-specified statistical methods and procedures that will be used to analyze data for the clinical trial entitled 'Efficacy of Photobiomodulation Therapy Using 980nm Versus 635nm Diode Lasers in the Management of Myofascial Pain Syndrome (LLLT-MPS_sEMG)'.

2. Study Objectives

Primary Objective: To evaluate the effectiveness of photobiomodulation therapy using diode lasers (980nm vs 635nm) in reducing myofascial pain.

Secondary Objectives: To assess improvements in mandibular function and muscle activity (measured using sEMG).

3. Outcome Measures

Primary Outcome: Change in pain intensity measured by the Visual Analog Scale (VAS) from baseline to post-treatment and follow-up.

Secondary Outcomes:

- Change in Maximum Mouth Opening (MMO) from baseline to post-treatment and follow-up.

- Change in Lateral and Protrusive Movements (LM, PM).

- Change in surface electromyography (sEMG) activity of masseter and temporalis muscles.

4. Statistical Methods

Normality of data distribution will be assessed using the Shapiro-Wilk test.

If data are not normally distributed, non-parametric tests will be applied.

Within-group comparisons across time points (baseline, post-treatment, follow-up) will be analyzed using the Friedman test, followed by post-hoc pairwise comparisons with Bonferroni correction if significant differences are detected.

Between-group comparisons will be conducted using the Mann-Whitney U test on change scores.

Significance will be set at $p < 0.05$.

5. Effect Size Calculations

Effect sizes will be calculated to quantify the magnitude of differences:

- Kendall's W for Friedman test results (within-group changes).

- Rank biserial correlation (r) for Mann-Whitney U test results (between-group comparisons).

6. Handling of Missing Data

If missing data occur, an intention-to-treat (ITT) approach will be applied. Sensitivity analyses may be conducted to evaluate the potential impact of missing data.

7. Interim Analyses

No interim analyses are planned for this study.

8. Software

All analyses will be performed using IBM SPSS Statistics (Version 25.0) or equivalent statistical software.

9. Approval

This SAP was finalized and approved prior to database lock and commencement of statistical analyses.