STATISTICAL ANALYSIS PLAN (SAP)

Study Title: Dry Needling as an Adjunct to Rehabilitation of Temporomandibular Dysfunctions—Randomized Controlled Pilot Study

Project: IGA_FZV_2025_015
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1. Objective of the Statistical Analysis

The objective will be to evaluate the effectiveness of standard rehabilitation supplemented by a single dry needling intervention compared with standard rehabilitation alone in patients with myofascial temporomandibular disorders (TMD).

The analysis will focus on changes in pain intensity and quality of life, as well as the preliminary estimation of treatment effect sizes.

2. Study Design and Population

The study will be designed as a prospective, randomized, controlled pilot trial with two parallel groups.

A total of 40 patients will be enrolled and randomly allocated in a 1:1 ratio:

- **Experimental group (n = 20):** Standard rehabilitation supplemented by a single dry needling intervention.
- **Control group (n = 20):** Standard rehabilitation alone.

Both groups will undergo 10 rehabilitation sessions over a five-week period.

3. Outcome Measures

Two main clinical outcome measures will be assessed:

- **VAS (0–10):** Pain intensity elicited by standardized algometric pressure.
- **WHOQOL-BREF:** Quality of life assessed using a validated questionnaire.

Assessments will be performed at three time points:

- **T0:** Before initiation of treatment (baseline).
- **T1:** 24 hours after the first therapeutic intervention.
- **T2:** After completion of the rehabilitation program.

4. Statistical Methods

Statistical analyses will be performed using **IBM SPSS Statistics, version 30**.

The normality of data distribution will be assessed using the Shapiro–Wilk test.

Depending on the characteristics and distribution of the data, the following methods will be applied:

- **Paired t-test or Wilcoxon signed-rank test** to assess within-group changes.
- **Independent-samples t-test or Mann–Whitney U test** to compare changes between groups.
- **Descriptive statistics:** Mean, standard deviation, median, and interquartile range (IQR).

The primary analytical focus will be on direct between-group comparisons of changes from T0 to T1 and from T0 to T2.

The statistical significance level will be set at $\alpha = 0.05$, using two-sided tests. Where appropriate, results will be supplemented with effect size estimates and 95% confidence intervals.

5. Interpretation of Results

Given the pilot nature of the study and the limited sample size, the results will be interpreted as exploratory.

No formal adjustment for multiple comparisons will be applied; this limitation will be explicitly considered when interpreting statistical significance.

The findings will provide preliminary evidence regarding intervention effectiveness, estimates of variability in clinical outcome measures, and methodological information to support the design of a subsequent randomized controlled trial with a larger sample size.