

# **Statistical Analysis Plan**

**Official Title:** The Effect of Fermented Grape Juice Consumption on Fibromyalgia Patients

**NCT Number:** NCT ID not yet assigned

**Unique Protocol ID:** 1422809

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All analyses will be performed using IBM SPSS Statistics v25.0. Categorical variables will be summarized as frequency and percentage. Continuous variables will be assessed for normality using Kolmogorov–Smirnov test, skewness-kurtosis values, and graphical methods.

Normally distributed variables will be expressed as mean  $\pm$  SD; non-normal variables as median (min–max). Baseline comparisons will use Student t-test or ANOVA for normal variables, Mann–Whitney U or Kruskal–Wallis tests for non-normal variables.

Time (baseline, Week 4, Week 8), group, and group  $\times$  time interactions will be analyzed using repeated-measures ANOVA or linear mixed-effects models. Non-parametric equivalents (Friedman test) will be used when assumptions are violated.

Correlations will be assessed using Pearson or Spearman coefficients. Duloxetine use and dose will be included as covariates using ANCOVA or mixed models when appropriate.

Statistical significance will be set at  $p < 0.05$  with 95% confidence intervals.