

# STUDY PROTOCOL

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

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

**Unique Protocol ID:** 1422809

**Document Date:** 22 September 2025

## **Outcome Measures**

### *Primary Outcome Measures*

#### 1. Fibromyalgia Impact (FIQR)

Change in Fibromyalgia Impact Questionnaire–Revised (FIQR) total score (0–100); lower scores indicate reduced symptom burden.

Time Frame: Baseline to Week 8

#### 2. Pain Severity (VAS)

Change in average pain intensity assessed by a 0–10 cm Visual Analog Scale; lower scores indicate less pain.

Time Frame: Baseline to Week 8

#### 3. Gastrointestinal Symptoms (GSRS)

Change in Gastrointestinal Symptom Rating Scale (GSRS) total score and subscale scores; higher scores indicate worse symptoms.

Time Frame: Baseline to Week 8

#### 4. Sleep Quality (PSQI)

Change in Pittsburgh Sleep Quality Index (PSQI) global score (0–21); lower scores indicate better sleep quality.

Time Frame: Baseline to Week 8

#### 5. Depressive Symptoms (BDI)

Change in Beck Depression Inventory (BDI) total score (0–63); lower scores indicate fewer depressive symptoms.

Time Frame: Baseline to Week 8

### *Secondary Outcome Measures*

#### 6. Total Antioxidant Status (TAS)

Change in circulating total antioxidant capacity; higher values indicate improved antioxidant defense.

Time Frame: Baseline to Week 8

#### 7. Total Oxidant Status (TOS)

Change in cumulative oxidant load; lower values indicate reduced oxidative burden.

Time Frame: Baseline to Week 8

#### 8. Oxidative Stress Index (OSI)

Change in OSI ( $\text{TOS} \times 100 / \text{TAS}$ ); lower values indicate improved redox balance.

Time Frame: Baseline to Week 8

#### 9. Oxidative Damage Markers

Change in plasma malondialdehyde (MDA) and serum 8-hydroxy-2'-deoxyguanosine (8-OHdG).

Time Frame: Baseline to Week 8

#### 10. Inflammatory Biomarkers

Change in TNF- $\alpha$ , IL-6, and hs-CRP concentrations.

Time Frame: Baseline to Week 8

#### 11. Serum Sirtuin-1 (SIRT1)

Change in circulating SIRT1 levels measured by ELISA.

Time Frame: Baseline to Week 8

#### *Other Pre-specified Outcome Measures*

#### 12. Anthropometric and Cardiometabolic Measures

Changes in body weight, BMI, waist circumference, waist-to-hip ratio, systolic and diastolic blood pressure, and lipid profile.

Time Frame: Baseline to Week 8

#### 13. Dietary Measures

Changes in dietary polyphenol intake (Phenol-Explorer–based) and Dietary Antioxidant Quality Score (DAQS).

Time Frame: Baseline to Week 8

*The research protocol is summarized in Figure 1.*

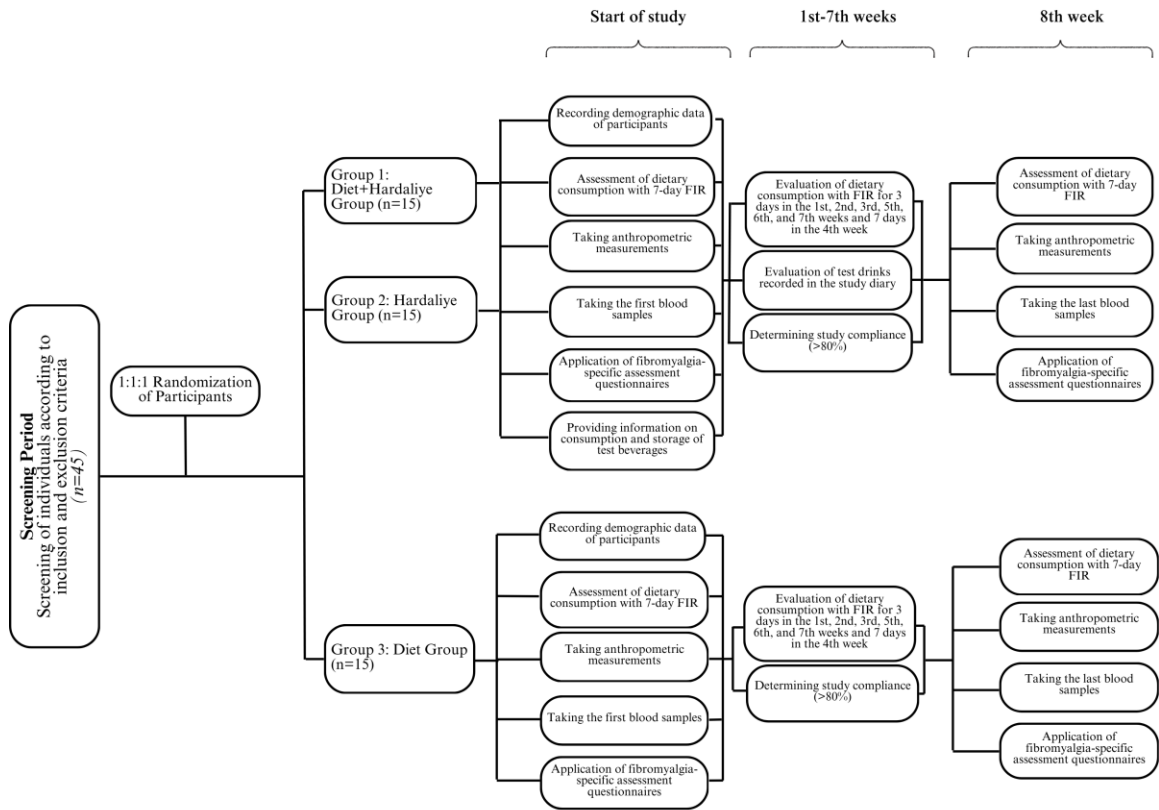


Figure 1. Study Flowchart