

Study Protocol and Statistical Analysis Plan

Study Protocol

Title:

Short-Term Effects of Acupuncture on Balance and Quality of Life in Women with Migraine: A Pilot Study

ClinicalTrials.gov Identifier (NCT Number):

Responsible Party:

Klaipėda University, Holistic Medicine and Rehabilitation Department

Principal Investigator:

PhD Laura Zaliene, Klaipėda University

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2. Background and Rationale

Migraine is a common neurological condition frequently accompanied by dizziness and impaired balance, which negatively affects quality of life. Pharmacological treatments often provide insufficient relief or are associated with side effects. Acupuncture has shown promise as a complementary therapy, but evidence regarding its short-term effects on balance and quality of life remains limited.

3. Objectives

Primary Objective: To evaluate the short-term effects of acupuncture on balance and quality of life in women with migraine.

4. Study Design

This is a single-arm, prospective pilot study without a control group. All participants received acupuncture treatment over a defined intervention period.

5. Participants

Inclusion Criteria: Female, ≥ 18 years, clinical diagnosis of migraine with dizziness, willingness to participate and comply with the protocol.

Exclusion Criteria: Severe comorbidities, contraindications to acupuncture, pregnancy, or refusal to provide informed consent.

6. Intervention

Participants underwent a short-cycle acupuncture intervention targeting standardized acupoints associated with migraine management (e.g., GB7, GB14, GB20, GV20, LI4, LR3, Yintang). Treatment was administered twice weekly for 3 weeks, resulting in a total of 6 sessions. Each session lasted approximately 30 minutes.

7. Outcomes

Primary Outcomes: Migraine intensity (VAS), postural stability (stabilometric parameters), and quality of life (SF-36).

Secondary Outcomes: Dizziness symptoms, participant-reported well-being.

8. Data Collection and Timeline

Baseline data were collected prior to the intervention. Post-intervention data were collected immediately after the last acupuncture session. All outcome measures were assessed at both time points.

9. Statistical Analysis

Descriptive statistics (mean \pm SD, frequencies) will be used to summarize participant characteristics and outcomes. Paired-sample t-tests or non-parametric equivalents will be applied to assess pre–post intervention changes. Effect sizes (Cohen's d) will be calculated. Missing data will be handled using available case analysis.

10. Ethics

The study protocol was approved by the Klaipėda University Bioethics Committee. All participants provided written informed consent before participation. The study adhered to the principles of the Declaration of Helsinki.

11. Dissemination

Findings will be disseminated through peer-reviewed publications and conference presentations. Results are intended to inform future randomized controlled trials.