STUDY PROTOCOL, STATISTICAL ANALYSIS PLAN AND INFORMED CONSENT FORM

Official Title:

Foot Reflexology as an Adjunctive Therapy in Migraine Management: A Randomized Controlled Trial on Pain, Fatigue, and Quality of Life

NCT Number: NCT06828315

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1. Background and Rationale

Migraine is a chronic neurovascular disorder characterized by recurrent headache attacks and functional impairment. Complementary therapies such as foot reflexology have been proposed as adjunctive interventions to reduce symptom burden. High-quality randomized controlled trials evaluating its effects on pain, fatigue, and quality of life are limited.

2. Objectives

Primary Objective: To evaluate the effect of foot reflexology on pain intensity in individuals with migraine. Secondary Objectives: To assess the effect on fatigue severity and migraine-related quality of life.

3. Study Design

Single-blind, parallel-group randomized controlled trial conducted at a state hospital neurology clinic. Participants were randomized 1:1 to intervention (reflexology + standard care) or control (standard care). Assessments were conducted at baseline and after 5 weeks.

4. Study Population

Inclusion Criteria: Age 18–60 years; ICHD-3 migraine diagnosis; ≥2 attacks in past 6 months; VAS ≥4; written informed consent. Exclusion Criteria: Pregnancy; neurological disorders; prophylactic migraine therapy within 3 months; prior reflexology; recent alternative therapies; severe psychiatric disorders; contraindicating foot conditions.

5. Sample Size

Calculated using G*Power (α = 0.05; power = 90%). Minimum 38 participants per group required. Total enrolled: 78 (39 per group).

6. Randomization

Computer-generated allocation by independent researcher using sealed opaque envelopes.

7. Interventions

Intervention group received 10 reflexology sessions (twice weekly for 5 weeks; 30 minutes per session) in addition to standard care. Control group continued standard care.

8. Outcome Measures

Primary: Visual Analog Scale (0–10 cm). Secondary: Fatigue Severity Scale (9–63 total score); 24-Hour Migraine Quality of Life Questionnaire (15–105 total score).

9. Safety Monitoring

Adverse events were monitored at each study visit. Reflexology is low-risk; mild temporary discomfort may occur.

10. Statistical Analysis Plan

Analyses performed using SPSS v23.0. Descriptive statistics calculated. Normality assessed using Shapiro–Wilk test. Between-group comparisons: chi-square, independent t-test or Mann–Whitney U test. Within-group comparisons: paired t-test or Wilcoxon signed-rank test. Significance level set at $p < 0.05$. No interim analyses conducted.

11. Ethics

Approved by Scientific Research and Publication Ethics Committee (Approval No: 46; October 16, 2024). Conducted in accordance with the Declaration of Helsinki. Written informed consent obtained from all participants.

INFORMED CONSENT FORM

Invitation to Participate

You are invited to participate in a research study evaluating the effects of foot reflexology on migraine-related pain, fatigue, and quality of life.

Purpose of the Study

To examine whether foot reflexology has beneficial effects on migraine-related outcomes.

Study Procedures

Participants will be randomly assigned to intervention or control group. Intervention group receives 10 sessions over five weeks. Control group continues standard care. Questionnaires will be completed before and after the study.

Potential Benefits

Possible reduction in pain and fatigue and improved quality of life. No guarantee of benefit.

Potential Risks

Mild temporary discomfort may occur.

Confidentiality

All data will remain confidential and securely stored.

Voluntary Participation

Participation is voluntary and withdrawal is permitted at any time without penalty.

Statement of Consent

I have read and understood the information above and voluntarily agree to participate.

Participant's Name:

Signature:

Date:

Researcher's Name:

Signature:

Date: