Study Protocol

Official Title: THE USE OF FOOT REFLEXOLOGY IN ALLEVIATING ANXIETY SYMPTOMS: A RANDOMIZED CLINICAL TRIAL

NCT Number:

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1. Background and Rationale

Anxiety disorders are among the most prevalent psychiatric conditions worldwide, impairing quality of life and daily functioning. Despite effective treatments such as pharmacotherapy and cognitive-behavioral therapy, many patients remain partially symptomatic or experience side effects. Complementary and Integrative Practices (CIP) have gained attention as supportive strategies, and reflexology is one of these practices recognized by the Brazilian Unified Health System (SUS).

Foot reflexology is a non-invasive manual technique that applies pressure to specific reflex points on the feet, believed to correspond to organs and systems in the body. Preliminary studies suggest potential benefits in reducing anxiety and promoting relaxation, but further randomized controlled trials with rigorous methodology are needed.

2. Objectives

Primary Objective:

- To evaluate the effect of foot reflexology on anxiety symptoms, measured by the Beck Anxiety Inventory (BAI).

Secondary Objectives:

- To assess changes in psychological well-being and relaxation using the Tension-Anxiety subscale of the Profile of Mood States (POMS, reduced version).
- To record and analyze adverse effects related to the interventions.

3. Study Design

This is a randomized, parallel, controlled, double-blind clinical trial with two arms:

1. Foot reflexology intervention.
2. Sham reflexology (control group).

The study will last approximately 5 weeks, with 10 intervention sessions per participant.

4. Eligibility Criteria

Inclusion Criteria:

- Adults aged 18–80 years.
- Clinical diagnosis of anxiety disorder (confirmed by physician or psychologist).
- BAI score ≥ 11 (mild anxiety or higher).
- Ability to attend all intervention sessions and assessments.

Exclusion Criteria:

- Current psychiatric or psychological treatment with medication adjustments in the last 30 days.
- Use of other complementary therapies for anxiety during the study period.
- History of severe psychiatric disorders (psychosis, bipolar disorder).
- Foot injuries, ulcers, or contraindications to manual therapy.
- Pregnancy.

5. Interventions

Foot Reflexology Group:

- Protocol based on classical reflexology charts, applying pressure to reflex points related to stress and anxiety regulation. Each session lasts approximately 15 minutes per foot, totaling 30 minutes.

Sham Reflexology Group:

- Protocol involving superficial sliding movements and joint mobilization of the foot (hindfoot, midfoot, forefoot), without stimulation of reflex points. Movements include flexion, extension, circumduction, and gentle traction of metatarsophalangeal, tarsometatarsal, and ankle joints. Each session lasts 30 minutes.

6. Outcome Measures

Primary Outcome:

- Reduction in anxiety symptoms assessed by Beck Anxiety Inventory (BAI).
- Score range: 0 to 63.
- Higher scores indicate worse anxiety.

- Time points: baseline, after session 5, after session 10.

Secondary Outcomes:

- Tension-Anxiety Subscale of the Profile of Mood States (POMS – reduced version).
- Score range: 0 to 36.
- Higher scores indicate worse tension-anxiety.
- Time points: after each of the 10 sessions.
- Adverse effects.
- Recorded during and after each session.
- Frequency and intensity analyzed descriptively.

7. Randomization and Blinding

Participants will be randomized into intervention or sham groups using a computer-generated randomization list (randomization.com). Allocation will be concealed in sealed opaque envelopes.

Blinding:

- Participants will not be informed of the intervention type (reflexology or sham).
- Therapists will be trained but informed only that they are applying a “foot massage technique,” with no access to study allocation. They will not communicate with each other.
- Outcome assessors and data analysts will remain blinded to group allocation.

8. Data Collection and Management

Data will be collected at baseline and throughout the intervention sessions. Each participant will be assigned an anonymous code. Data will be stored in password-protected electronic files accessible only to the research team.

9. Statistical Analysis Plan

Descriptive statistics (mean ± SD) will be used for quantitative variables.

- Primary outcome (BAI): Repeated measures ANOVA (Group × Time) with post-hoc Bonferroni.

- Secondary outcomes (POMS): Repeated measures ANOVA (Group × Time).
- Adverse effects: Frequency distribution and Chi-square tests.
Significance level: $p < 0.05$. SPSS (IBM, v.29) will be used.

10. Risks and Benefits

Risks: Mild local reactions in the feet, such as redness, sensitivity, discomfort, or muscle soreness, which typically resolve within 48–72 hours. Transient tingling may occur. Serious adverse effects are not expected.
Benefits: Possible reduction in anxiety symptoms, improved relaxation and well-being, and contribution to scientific knowledge about reflexology.

11. Ethical Considerations

The study will be conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Committee. All participants will provide written informed consent before enrollment.

12. References

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