Cover Page

Official Study Title:
Effects of a Programmed Reflexology Therapy on Sleep Quality, Insomnia, and Fatigue Among Individuals with Poor Sleep Quality: Evidence for Autonomic Nervous System Modulation

ClinicalTrials.gov Identifier:
NCT Number: *Pending*

Document Type:
Statistical Analysis Plan

Date of Document:
[06/25, 2025]

Statistical Analysis Plan

All statistical analyses will be performed using validated statistical software (e.g., SPSS version 22). Descriptive statistics will summarize participant characteristics and baseline variables, with continuous data presented as mean ± standard deviation and categorical data as frequencies and percentages. Data normality will be assessed using the Shapiro–Wilk test and visual inspection of distribution plots.

This study uses a randomized crossover interventional design. Primary and secondary outcomes will be analyzed using within-participant comparisons accounting for intervention conditions (manual reflexology treatment [MRT] vs foot massage equipment [FEM]) and time (pre- and post-intervention). For normally distributed outcomes, repeated-measures analysis of variance (ANOVA) or linear mixed-effects models will be applied to assess main effects of intervention, time, and their interaction. When normality assumptions are not met, non-parametric equivalents (e.g., Wilcoxon signed-rank test or Friedman test) will be used.

The primary outcome (sleep quality assessed by the Pittsburgh Sleep Quality Index) will be analyzed by comparing changes from baseline to post-intervention between MRT and FEM conditions. Secondary outcomes include insomnia severity (Insomnia Severity Index), fatigue (Fatigue Assessment Scale), and autonomic nervous system function assessed by heart rate variability (HRV). HRV outcomes include time-domain indices (SDNN, RMSSD, pNN50) and frequency-domain indices (LF, HF, LF/HF ratio). Acute (week 1) and cumulative (week 6) intervention effects will be examined separately.

Potential carryover effects will be evaluated by comparing baseline values between intervention periods and by including period and sequence effects in analytical models. A predefined washout period was implemented to minimize residual effects.

Adjustments for multiple comparisons will be applied for HRV parameters and questionnaire subscales using Bonferroni correction or false discovery rate control, as appropriate. Effect sizes will be reported to support clinical interpretation. Statistical significance will be set at a two-sided p value < 0.05. Analyses will be conducted on a per-protocol basis, including participants who completed both intervention periods with adequate compliance.

Sample Size and Power Considerations: Sample size estimation was based on prior studies reporting moderate within-subject effects of reflexology interventions on sleep-related outcomes and heart rate variability parameters. Assuming a moderate effect size (Cohen's d = 0.5), a two-sided significance level of 0.05, and statistical power of 80%, a minimum of 28 participants was required to detect significant within-participant differences in a crossover design. To account for potential attrition and incomplete data, a total of 32 participants were recruited. This sample size is consistent with previous crossover trials investigating autonomic and sleep-related responses to complementary therapies.

Informed Consent Form

The Informed Consent Form (ICF) has been approved by the Institutional Review Board (IRB) and is provided in Chinese. The document is written in clear, lay language and describes the study purpose, procedures, potential risks and discomforts, anticipated benefits, and participant rights. The approved ICF is available as a non-editable PDF file. If required, the document can be uploaded upon request.

This document constitutes the approved English version. Certain titles of screening instruments and questionnaires remain in Chinese because the original source materials were provided as scanned image files and could not be directly modified. To ensure consistency and clarity, English annotations have been added to provide a complete English-language presentation.

FJU-IRB F-034 /20201110

Fu Jen Catholic University Institutional Review Board

510 Chung Cheng Rd, Hsinchuang District, New Taipei City 242062, Taiwan
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Certificate of Approval

I. FJU-IRB NO：C113172

II. Study Institution(s): Department of Exercise and Health Science/ National Taipei University of Nursing and Health Sciences

III. Investigator：Professor Wen Ching Huang

IV. Research team member(s)：Shih-Pei Chen/Department of Exercise and Health Science/National Taipei University of Nursing and Health Sciences

V. Title of protocol：Effects of manual foot reflexology and foot massage machine intervention on autonomic nervous system activity and sleep quality

VI. Protocol Version：第2版，2025/06/18 Version 2, 2025/06/18

VII. Informed Consent Form：第2版，2025/06/18 Version 2, 2025/06/18

VIII. Place of execution(s)：國立臺北護理健康大學

IX. Study Tools：

1. Recruitment Version:第2版，2025/06/18 Version 2, 2025/06/18
2. 腳底按摩實驗/第2版，2025/06/18 Reflexology Screen,Version 2, 2025/06/18
3. 腳底按摩實驗疲勞評估量表/第2版，2025/06/18 Questionnaires,Version 2, 2025/06/18

X. Frequency of Interim Report：one year

XI. Study Approval Period：2025/06/19~2026/06/18

The protocol has been approved by the Institutional Review Board of Fu Jen Catholic University. The committee is organized under, and operates in accordance with Regulations of Fu Jen Catholic University and governmental laws and regulations. Continuing Review Application should be submitted to Institutional Review Board no later than 4 weeks before current approval expired. The investigator is required to report protocol amendment and serious adverse events in accordance with the Fu Jen Catholic University and governmental laws and regulations.

Fu-li Chen

Chair's Signature
Institutional Review Board

06 / 25 / 2025

Date（mm / dd / yyyy）