STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Official Title:

Effects of a Wearable Device and Social Media-Based Intervention on Physical Activity and Sleep Quality in Adults: A Randomized Controlled Trial

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1. Introduction and Objectives

The objective of this randomized controlled trial (RCT) is to evaluate the efficacy of a wearable device-based intervention, supplemented with social media support, on enhancing physical activity (PA) levels and improving sleep quality among adults. The study specifically investigates whether motivational support via social media (LINE) provides incremental benefits compared to using a wearable device alone.

2. Study Design and Setting

This study employs a three-arm, parallel-group randomized controlled trial design conducted at National Chung Hsing University, Taiwan. A total of 75 participants are randomly assigned to one of three groups in a 1:1:1 ratio.

Arm 1 (Device + Support): Garmin wearable device + motivational support via LINE.

Arm 2 (Device Only): Garmin wearable device only.

Arm 3 (Control Group): No intervention (standard lifestyle).

3. Eligibility Criteria

Inclusion: Healthy adults aged 18-64 who own a smartphone and have not previously used wearable fitness trackers.

Exclusion: Individuals with medical conditions that contraindicate increased physical activity or those currently participating in other PA-related interventions.

4. Detailed Intervention Protocol

Wearable Technology: Participants in Arm 1 and Arm 2 are provided with a Garmin activity tracker. They are instructed to use the "Move Alert" feature, which vibrates to prompt movement after periods of prolonged sitting.

Social Media Support (Arm 1 only): A structured LINE group is

established for:

Weekly Education: Sharing health knowledge regarding the benefits of sleep and PA.

Interactive Support: Research assistants provide tailored feedback via digital stickers and respond to participant inquiries.

5. Outcome Measures

Primary Outcome: Change in Physical Activity (measured by steps/day and sedentary breaks).

Secondary Outcome: Change in Sleep Quality (assessed via standardized sleep quality questionnaires and device-derived sleep metrics).

Assessment Points: Data are collected at Baseline (T0), Post-intervention (T1, 1 month), and Follow-up (T2, 2 months).

6. Statistical Analysis Plan (SAP)

Data will be analyzed using SPSS software.

Descriptive Statistics: Baseline characteristics will be summarized as means (SD) or frequencies.

Main Analysis: A Two-way Mixed ANOVA (3 Groups × 3 Time points) will be performed to examine the main effects of "Group" and "Time," as well as the Group-by-Time interaction effect on total sedentary time.

Post-hoc Testing: If a significant interaction is found, Bonferroni-adjusted post-hoc tests will be conducted to identify specific differences between groups at each time point.

Significance Level: The alpha level is set at 0.05.