Study Protocol with Statistical Analysis Plan

Study Title

The Effectiveness of Wearable Devices on Health Promotion in Individuals with Diabetes Mellitus

Principal Investigator

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Proposal to Conduct Research

Institutional Review Board
FWA: 00007392 | IRB: 0004173

2032697-1
IRB Number

09/14/2023
Approved

12/01/2023
Post-Approval Request(s)

09/14/2024
Approval Expires

1. Study Objectives

This randomized controlled pilot study aims to evaluate the effectiveness of wrist-worn activity trackers (Fitbit Inspire 2) on improving physical activity levels, cardiovascular risk factors, and quality of life in adults diagnosed with type 2 diabetes over a 4-week period.

2. Study Design

- Type: Interventional (Clinical Trial), two-arm parallel design
- Randomization: Yes (1:1 allocation)
- Blinding: None
- Duration: 4 weeks
- Sample Size: 20 participants (10 per group)

3. Eligibility Criteria

Inclusion Criteria:

- Age ≥ 18 years
- Diagnosed with type 2 diabetes (HbA1c ≥ 6.5% or fasting glucose ≥ 126 mg/dL)
- Willing and able to link a fitness tracker app to a smartphone

Exclusion Criteria:

- Use of assistive devices for walking
- Current smokers
- Pregnant or breastfeeding
- Already achieving ≥150 min/week of moderate-to-vigorous activity
- Comorbidities preventing participation in physical activity
- Current insulin therapy

4. Intervention and Control Groups

Intervention Group: Participants receive a Fitbit Inspire 2.

Control Group: Participants do not receive a wearable device.

5. Outcome Measures

Primary Outcomes:

- Physical activity: Measured using Global Physical Activity Questionnaire (GPAQ) and pedometer/mobile app data
- Cardiovascular risk: Measured using arterial stiffness (SphygmoCor), blood pressure, heart rate, fasting glucose, BMI, waist-to-hip ratio

Secondary Outcomes:

- Health-related quality of life: Measured using the RAND SF-36 Health Survey

6. Statistical Analysis

Descriptive statistics will summarize baseline characteristics. Non-parametric tests will be used:

- Friedman's test and Wilcoxon signed-rank tests (within-group change)
- Mann–Whitney U test (between-group comparison)
- Spearman's rho for correlations

Effect sizes (r) will be calculated. All analyses will be conducted using IBM SPSS v29. Significance set at $p < 0.05$.

7. Data Management and Confidentiality

Data will be stored in a secure BOX folder regulated by the PI. No identifiable data will be stored on local or personal devices. Data will be retained for five years post-study.

8. Risks and Benefits

Risks: Minimal; primarily related to fasting and physical exertion.
Benefits: Participants may gain insight into their physical activity levels and cardiovascular health.
Compensation: None, though participants in the intervention group may retain their Fitbit upon study completion.

9. Ethical Considerations

IRB Approval: Pacific University IRB #2032697-1
Informed consent is obtained electronically via Qualtrics in English or Spanish. No deception is used. Adverse events will be monitored and reported per IRB policy.

10. Timeline

- Recruitment: Upon IRB approval
- Data Collection: Week 0 (T0) and Week 4 (T1)
- Analysis & Dissemination: Expected completion within 3 months post-data collection