Study Protocol

Title: The Impact of Robot-assisted Digital Education on Prenatal Women's Health Literacy

NCT Number: NCT20230940

Document Date: 2025-05-04

1. Background and Rationale

The study addresses the increasing need for efficient, standardized prenatal health education, especially in light of nursing workforce shortages. Robot-assisted education presents a novel digital solution that may reduce anxiety and enhance health literacy among pregnant women, particularly those diagnosed with gestational diabetes mellitus (GDM).

2. Study Objectives

- Primary Objective: To evaluate whether robot-assisted digital education reduces anxiety among pregnant women with GDM.

- Secondary Objectives: To examine the impact on health literacy, satisfaction with health education, and acceptance of digital technologies.

3. Study Design

Type: Randomized Controlled Trial (RCT)
Setting: Obstetrics outpatient clinic of a regional hospital in Taiwan
Duration: November 2023 to January 2024
Groups:
  - Experimental group: Robot-assisted education
  - Control group: Tablet-based video education
Blinding: Single-blind (participant and assessor)

4. Participants

Inclusion Criteria:
- Pregnant women aged ≥21
- GDM diagnosis
- Taiwanese nationality
Exclusion Criteria:
- Chronic illness
- Cognitive impairment or language barrier

5. Intervention

A 30-minute robot-assisted session on GDM information using visual, audio, and interactive storytelling features.

6. Outcomes

Primary: Hamilton Anxiety Rating Scale (HAMA)
Secondary: Health Literacy Questionnaire (HLQ), Satisfaction (adapted Black et al.), Technology Acceptance

7. Ethics

Approved by the Institutional Review Board of Taipei Medical University. Informed consent obtained(ethical approval number N202309040).

8. Data Availability

Available upon reasonable request to the corresponding author.

Statistical Analysis Plan

Title: Statistical Analysis Plan for the RCT “The Impact of Robot-assisted Digital Education on Prenatal Women’s Health Literacy”

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1. Sample Size Calculation

Using G*Power with a medium effect size (d = 0.5), alpha = 0.05, power = 0.80. Minimum of 64 participants required. Target recruitment: 80 (to allow for dropouts).

2. Randomization

Block randomization via computer-generated sequence. Allocation concealed until participant assignment.

3. Analysis Methods

Baseline Characteristics: Independent t-tests or chi-square
Primary Outcome (Anxiety): Independent samples t-test
Secondary Outcomes:
- Health literacy, satisfaction, technology acceptance: t-tests
- Associations: One-way ANOVA and chi-square tests

Software Used: SPSS v25
Missing Data: Excluded from per-protocol; ITT analysis with multiple imputation recommended in future studies

4. Significance Level

Two-tailed tests with $\alpha = 0.05$.