STUDY PROTOCOL

Version 1.0 – Date: September 9, 2025

Document Type: Study Protocol

Official Title: A Cross-Sectional Observational Study to Evaluate Psychological Well-Being, Depression, and Health-Related Quality of Life and Their Demographic and Clinical Correlates in Adults With Type 2 Diabetes Attending an Outpatient Metabolic Clinic

Sponsor: National Taiwan University Hospital

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NCT Number: Pending assignment

Protocol Version and Date: Version 1.0 – September 9, 2025

IRB Approval: National Taiwan University Hospital REC – Approval No. 202508155RIND

Study Site: Outpatient Metabolism Clinic, National Taiwan University Hospital, Taipei, Taiwan

Confidentiality Statement: This document contains confidential information that must not be disclosed to anyone other than the study sponsor, investigators, and authorized regulatory authorities without prior written permission.

Signatures

Principal Investigator: _____ Date: _____

Study Coordinator: _____ Date: _____

1. Study Summary

This study investigates the psychological well-being, depression severity, and health-related quality of life among adults with Type 2 Diabetes. It aims to identify demographic and clinical correlates that may influence these outcomes to inform integrated physical and psychological care strategies in diabetes management.

2. Study Design

This is a cross-sectional observational study conducted at a single site (National Taiwan University Hospital). Participants will complete standardized questionnaires during one outpatient visit. There is no follow-up period, and no intervention is administered.

3. Study Population

Eligible participants include adults (≥20 years old) diagnosed with Type 2 Diabetes attending the outpatient metabolism clinic. Exclusion criteria include inability to consent or complete questionnaires due to cognitive impairment or language barriers.

4. Sample Size

A total of approximately 500 participants are anticipated, based on feasibility and sufficient statistical power to detect medium effect sizes in multivariate analyses ($\alpha = 0.05$, power = 0.8).

5. Data Collection Instruments

Participants will complete the following validated instruments:
- EQ-5D-5L for health-related quality of life.
- PHQ-9 for depression severity.
- Shalom Scale for psychological well-being.

In addition, demographic and clinical data (e.g., age, sex, education, diabetes duration, HbA1c, BMI, and complications) will be collected from medical records or self-report.

6. Variables and Measures

Independent variables include demographic (age, sex, education, marital status, employment), and clinical variables (HbA1c, BMI, disease duration, complications).
Dependent variables include Shalom Scale total score (psychological well-being), PHQ-9 total score (depression severity), and EQ-5D-5L index and VAS (health-related quality of life).

7. Statistical Analysis Plan

Data will be analyzed using descriptive statistics, correlation analysis (Pearson's r), group comparisons (t-test or ANOVA), and multiple linear regression to identify predictors of psychological well-being.
All analyses will be performed using SPSS or R statistical software, with a significance level of 0.05.

8. Confidentiality and Data Protection

Participant information will be coded and de-identified. Only authorized research staff will have access to the key linking identifiers to data. Data will be stored securely in password-protected systems approved by the institution and retained for at least three years following study completion.

9. Ethical Considerations

This study was reviewed and approved by the National Taiwan University Hospital Research Ethics Committee (Approval No. 202508155RIND). Participation is voluntary, and all participants will provide written informed consent. The study poses minimal risk as it involves only questionnaire completion and data collection from existing medical records.

10. Contact Information

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This English version is prepared for public posting on ClinicalTrials.gov under 42 CFR Part 11.