Study Protocol and Statistical Analysis Plan

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Study Title: A Co-created Self-care and Informal Support Intervention Study Among Women With GDM in Vietnam

1. Background and Rationale

Gestational diabetes mellitus (GDM) is a common metabolic disorder of pregnancy and is associated with significant short- and long-term risks for both mother and child. In Vietnam, the prevalence of GDM has increased substantially in recent years, while systematic screening, counselling uptake, and long-term self-management support remain limited. Although pharmacological treatment is available for severe cases, most women rely heavily on lifestyle modification, informal family support, and self-care practices for disease management.

Previous international studies indicate that self-care and social support interventions may improve quality of life, self-efficacy, and selected maternal and neonatal outcomes among women with GDM. However, such interventions are highly context-dependent, shaped by social norms, family structures, and health system capacity. To date, no structured self-care or informal support intervention for GDM has been developed or evaluated in the Vietnamese context.

The VALID-II study was therefore designed as a feasibility intervention study, with the primary purpose of determining whether a co-created self-care and informal support intervention can be implemented, accepted, and retained among women with GDM in northern Vietnam. The study is intentionally positioned as a preparatory step prior to a future randomized controlled trial and is embedded

within a larger observational cohort to allow simultaneous collection of maternal and neonatal outcome data .

2. Study Objectives

The primary objective of VALID-II is to evaluate the feasibility of a co-created self-care and informal support intervention for women diagnosed with GDM. Feasibility is defined as the extent to which the intervention can be successfully delivered and maintained under real-world conditions and is assessed through recruitment, retention, and acceptability.

Secondary objectives are exploratory and aim to assess the potential effects of the intervention on selected maternal and neonatal health outcomes, including self-care agency, perceived social support, breastfeeding practices, pregnancy outcomes, and neonatal morbidity. These analyses are intended to generate preliminary estimates of effect size and variance to inform the design of a future definitive trial.

3. Study Design

VALID-II is a two-arm, non-randomised feasibility intervention study with a delayed intervention design. The study is conducted in two sequential phases rather than in parallel.

In the first phase, women diagnosed with GDM are allocated to a control group and receive standard care. During this phase, a subgroup of women and their informal support persons participate in an embedded ethnographic study. Findings from this qualitative work inform the co-creation of the intervention.

In the second phase, after a delay of approximately three months, a new group of women diagnosed with GDM is allocated to the intervention arm and receives the co-created intervention in addition to standard care. This delayed design was chosen to allow meaningful intervention development grounded in participants' lived experiences and to ensure cultural relevance.

4. Study Setting

The study is conducted in Thai Binh Province, northern Vietnam. Participants are recruited from two health facilities: Thai Binh Maternity Hospital, a public hospital providing antenatal care and delivery services, and Kim Ngan Clinic, a private clinic providing antenatal care only. Both facilities serve urban and peri-urban populations and routinely perform oral glucose tolerance testing during pregnancy.

5. Study Population

Pregnant women attending antenatal care at the study sites are eligible for screening. Women are eligible for inclusion if they are ≤28 weeks' gestation at enrolment, reside in Thai Binh Province, are able to read and speak Vietnamese, and provide written informed consent. Both singleton and multiple pregnancies are eligible, and a history of GDM in a prior pregnancy does not preclude participation.

Women are excluded if they have known pregestational diabetes (type 1 or type 2) or severe chronic disease that would substantially interfere with pregnancy management or study participation.

6. Recruitment and Study Procedures

At the first antenatal care visit, eligible women are informed about the study by trained study nurses or midwives. After providing written informed consent, participants complete a baseline questionnaire and are scheduled for a standard 75-g oral glucose tolerance test (OGTT) at gestational age 24–28 weeks.

OGTT procedures follow WHO and IADPSG diagnostic criteria. Women diagnosed with GDM are invited to participate in follow-up data collection and allocated to either the control or intervention group depending on study phase. Women without GDM continue routine care but contribute delivery and neonatal outcome data via medical records.

Women diagnosed with GDM complete additional questionnaires during pregnancy (32–40 weeks gestation) and at 8–12 weeks postpartum. Delivery and neonatal outcomes are abstracted from medical records.

7. Intervention and Comparator

All women diagnosed with GDM receive standard care, which includes referral for counselling regarding diet, physical activity, and glucose monitoring. Because prior research indicated variable uptake of counselling, an ethical safeguard phone call is conducted by an endocrinologist to ensure that all women receive at least basic information about GDM self-care.

The intervention arm receives, in addition to standard care, a co-created self-care and informal support intervention. The intervention includes written educational materials, digital communication, peer networking, and guidance for involving family members in daily self-care practices. The precise content and delivery format are determined through an iterative co-creation process involving women with GDM, their informal support persons, and local healthcare staff.

8. Outcome Measures

The primary outcomes relate to feasibility:

- Recruitment is defined as the proportion of eligible women who consent to participate.
- Retention is defined as the proportion of enrolled women who complete delivery and postpartum follow-up.
- Acceptability is assessed using both quantitative Likert-scale measures and qualitative ethnographic interviews.

Secondary outcomes include maternal outcomes (e.g., self-care agency, perceived social support, gestational weight gain, HbA1c, breastfeeding practices, postpartum depression) and neonatal outcomes (e.g., birth weight, gestational age, large for gestational age, macrosomia, neonatal hypoglycaemia).

All outcomes and measurement tools are predefined and aligned with the published protocol .

9. Statistical Analysis Plan (SAP)

9.1 General Analytical Principles

This Statistical Analysis Plan is finalised prior to completion of data collection for the intervention group. Analyses will be conducted according to the intention-to-treat principle, whereby all participants are analysed in the group to which they were allocated based on study phase, regardless of intervention adherence.

Given the feasibility nature of the study, analyses are primarily descriptive and exploratory. Formal hypothesis testing is not the primary objective. All statistical tests, where performed, will be two-sided with a nominal significance level of

0.05. Emphasis will be placed on estimation, confidence intervals, and clinical plausibility rather than statistical significance alone.

9.2 Analysis of Feasibility Outcomes

Recruitment will be calculated as the proportion of eligible women diagnosed with GDM who consent to participate in the study. Retention will be calculated as the proportion of enrolled women who provide delivery data and complete the postpartum questionnaire. Both outcomes will be presented as percentages with corresponding 95% confidence intervals.

Acceptability will be analysed using a mixed-methods approach. Quantitative acceptability scores will be summarised using means, standard deviations, medians, and ranges. The predefined progression criterion is a mean Likert score greater than 3. Qualitative data from ethnographic interviews will be analysed thematically to explore participants' experiences, perceived usefulness, and barriers to engagement with the intervention.

9.3 Analysis of Secondary Outcomes

Secondary maternal and neonatal outcomes will be analysed descriptively and exploratorily. Continuous variables (e.g., birth weight, gestational age, self-care agency scores) will be summarised using means and standard deviations or medians and interquartile ranges, depending on distribution. Binary outcomes (e.g., large for gestational age, preterm birth) will be summarised as proportions.

For exploratory comparisons between intervention and control groups, regression models will be used where appropriate. Logistic regression will be applied to binary outcomes, and linear regression to continuous outcomes. Effect estimates will be presented as odds ratios or mean differences with 95% confidence intervals. No adjustment for multiple comparisons will be performed.

9.4 Adjustment for Confounding

Because the study uses a non-randomised design, baseline characteristics will be examined for imbalance between groups. If clinically relevant imbalances are observed, adjusted analyses will be conducted including key covariates such as maternal age, body mass index, parity, and gestational age at diagnosis. Adjusted analyses are considered exploratory and intended to inform future trial design rather than establish causal inference.

9.5 Missing Data

The extent and patterns of missing data will be described for all outcomes. Given the feasibility focus of the study, no formal imputation of missing data is planned. Analyses will be based on available data, and the potential impact of missingness will be discussed qualitatively.

9.6 Qualitative Data Analysis

Qualitative data from ethnographic interviews and fieldnotes will be transcribed verbatim and analysed using a content analysis approach. Coding will be performed iteratively, and themes related to feasibility, acceptability, self-care practices, and informal support will be identified. Qualitative findings will be used to contextualise quantitative results rather than to generate statistically generalisable conclusions.

10. Data Management

All quantitative data are collected and stored using REDCap on secure servers at Thai Binh University of Medicine and Pharmacy. Data exports for analysis will be performed using Stata, SPSS, or R. Access to identifiable data is restricted to authorised study personnel.

11. Ethics and Trial Status

The study has received ethical approval from the Ethics Council in Biomedical Research in Thai Binh (IRB – VN01.009). All participants provide written informed consent prior to participation. The trial is registered at ClinicalTrials.gov (NCT05744856) and is currently ongoing.