Pilot and Feasibility Studies

STUDY PROTOCOL

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A co-created self-care and informal support intervention targeting women with gestational diabetes mellitus in northern Vietnam (VALID-II): a protocol for a two-arm non-randomised feasibility study

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Abstract

Background Gestational diabetes mellitus (GDM) is a transitory form of diabetes that presents during pregnancy with frequent adverse maternal and neonatal health consequences if left untreated. The prevalence of GDM is rapidly increasing in low- and middle-income countries such as Vietnam, and early sustainable interventions are important. The overall aim of this study—henceforth referred to as VALID-II—is to assess the feasibility of a co-created self-care and informal support intervention targeted at pregnant women with GDM. Further, the aim is to assess the potential efficacy of the intervention in reducing maternal and neonatal health complications compared with standard care.

Methods VALID-II is a two-site, two-arm, non-randomised feasibility intervention study in Thai Binh Province in northern Vietnam with a delayed start for the intervention group. The intervention study is nested in a larger cohort. In total, 2000 pregnant women will be screened for GDM, with an estimated 400 women screening positive according to the World Health Organisation—International Association of Diabetes and Pregnancy Study Group diagnostic criteria. First, 200 women who screen positive for GDM will be assigned to a control group that will receive standard care. Among the 200 women, 20 will take part in an in-depth ethnographic study along with their family members, and the intervention will be co-created with them. Second, once the intervention has been created, 200 women will be assigned to the intervention group, which will receive the intervention plus standard care. Twenty women and their families from the intervention group will also take part in an ethnographic study. The primary outcome is to evaluate how feasible the self-care intervention is (composite outcome: recruitment, retention, and acceptability). Other secondary outcomes include the number of new-borns born large for gestational age, prevalence and risk factors for GDM, self-care agency, self-care, and breastfeeding practices.

Discussion This study provides knowledge of the feasibility of informal/self-care and social support interventions and their preliminary impact on maternal and child health outcomes among women with GDM in northern Vietnam. Furthermore, it will inform parameters such as effect size and variance, which are essential for calculating the sample

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size needed to achieve the desired power in a future full-scale trial. This may guide decision makers in how to optimise the management of GDM in low- and middle-income contexts.

Trial registration NCT05744856. Trial status: Recruiting.

Keywords GDM, Self-care, Informal support, Vietnam, Co-creation, Feasibility, Trial

Background

Gestational diabetes mellitus (GDM) is a transitory form of diabetes that presents during pregnancy. It is the most common endocrinopathy complication among pregnant women [1], and it is defined as *any degree of glucose intolerance with onset or first recognition during pregnancy* [2]. A large body of evidence has revealed associations between GDM and adverse maternal and neonatal outcomes, including caesarean section (c-section) delivery, preeclampsia, preterm birth, macrosomia, birth injuries, neonatal respiratory distress, and neonatal hypoglycaemia [3, 4]. In addition, GDM can adversely affect the psychological well-being of affected women and the risk of developing type 2 diabetes in the future for both mothers and children [5–7].

The initial diagnostic criteria for GDM were established more than 50 years ago; however, diagnostic guidelines have changed over time and currently vary worldwide. In 2008, the International Association of Diabetes and Pregnancy Study Groups (IADPSG) Consensus Panel recommended the following threshold values for the diagnosis of GDM: ≥ 5.1 mmol/L fasting plasma glucose, a 1-h plasma glucose of ≥ 10.0 mmol/L or a 2-h plasma glucose of ≥ 8.5 mmol/L after a glucose challenge of 75 g. These criteria were later endorsed by the World Health Organisation (WHO) in 2013 [8]. Globally, the prevalence of GDM varies greatly depending on the country and the diagnostic criteria used, and the recent studies have shown that the prevalence of GDM may range from 4% to above 20% [9, 10]. In Vietnam, GDM affects up to 22.8% of pregnant women [10], and the Ministry of Health has defined the disease as a significant public health problem. However, systematic GDM screening is uncommon due to limited resources [11]. Consequently, Vietnam faces many GDM-related maternal and neonatal health issues that, to a large extent, could have been prevented if the disease had been diagnosed and treated during pregnancy.

Globally, there is growing awareness of the importance of locally grounded, informal self-care interventions for diabetes management [12]. According to the WHO, self-care is *the ability of individuals, families and communities to promote health, prevent disease, maintain health, and cope with illness and disability with or without the support of a health worker* [13]. Previous studies have shown that social support and self-care interventions have positive effects on quality of life among women with GDM [14] and self-efficacy [15, 16]; however, to date, there have been no GDM self-care interventions in Vietnam. Research on self-care and type 2 diabetes conducted in northern Vietnam shows that people living with type 2 diabetes mostly rely on their extended family for daily disease management and access to social and financial resources [17, 18]. However, the practice of informal support and self-care depends on the type of disease, social characteristics, and cultural practices; hence, it is crucial to develop a self-care intervention together with the target group and assess its feasibility before testing it in a full-scale trial.

Study objectives

The overall aim of the VALID-II intervention study is to co-create an informal support and self-care intervention with Vietnamese women with GDM and their informal support persons and evaluate the feasibility of the intervention.

Furthermore, this study aims to assess to the potential efficacy of the intervention on maternal and neonatal health outcomes. By "feasibility", we mean the degree to which the intervention can be carried out in practice. Feasibility is measured as a composite outcome through three indicators: recruitment, retention, and acceptability.

1. *Primary feasibility outcome*: To evaluate how feasible the self-care intervention is with respect to recruitment, retention, and acceptability.
2. *Secondary neonatal outcomes:* (1) large for gestational age (LGA), (2) Apgar score, (3) birth weight, (4) gestational age, (5) live birth, (6) macrosomia (birth weight above 4000 g), (7) macrosomia according to standard practice at the maternity hospital (birth weight above 3500 g), (8) neonatal hypoglycaemia, (9) preterm birth below gestational age (GA) 37 + 0, and (10) small for gestational age (SGA).
3. *Secondary maternal outcomes*: (1) prevalence of and risk factors for GDM, (2) perceived social support, (3) self-care agency, (4) self-care of GDM, (5) personal well-being, (6) gestational weight gain, (7) mode of delivery, (8) HbA1c level at the time of delivery, (9) breastfeeding practices, and (10) postpartum depression.

4. *Other outcomes*: (1) diet, (2) episiotomy, (3) physical activity, and (4) premature primary rupture of membranes.

An ethnographic study is embedded into this feasibility study. The outcomes of the ethnographic study are as follows: (1) co-creation of a self-care and informal support intervention, (2) in-depth knowledge of GDM self-care practices, and (3) an understanding of women's and family members' perceptions of GDM. Furthermore, this feasibility study is part of a larger cohort study that has objectives that go beyond this feasibility study (reported as secondary and other outcomes). This protocol is reported according to the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) statement and checklist [19, 20] (Supplementary material S1).

Methods

Design

VALID-II is a 2-arm non-randomised intervention study. Pregnant women will be assigned to either a control group or an intervention group with a delayed start (3 months).

Development of interventions on the basis of ethnographic research

The intervention will be co-created with a subgroup of women from the control group and their informal support persons. Initially, we developed a broad framework to serve as a foundation for the cocreation process informed by the literature and previous experiences from the field, e.g., suggestions for developing written educational materials, along with other communicative formats such as videos and networking among intervention participants via the Vietnamese messaging app Zalo. This preliminary scope is intended to be highly adaptable, allowing for substantial modifications on the basis of insights gained from our ethnographic studies and interactions with participants. Second, ethnographic research will be conducted among pregnant women diagnosed with GDM and their informal support persons, after which the intervention will be co-created with them and with local health care staff. This group will collaboratively participate in structured meetings with the research team to openly discuss and identify the specific self-care practices needed during pregnancy and for managing GDM. These discussions will be instrumental in understanding the preferences and requirements of women for self-care guidance, as well as the optimal delivery methods for intervention materials. During the co-creation process, we will engage deeply with women diagnosed with GDM and their families to ensure that the intervention is not only culturally sensitive but also aligns with their specific needs and preferences. This process is designed to be iterative, with the flexibility to introduce new elements into the framework or significantly alter the intervention on the basis of real-world feedback and cultural insights, ensuring that the final model resonates with the lived experiences of the target population.

The women were randomly recruited from among the full sample of women who were diagnosed with GDM. Recruitment ended when data saturation was achieved. The ethnographic interviews were conducted in the women's homes. All interviews were voice recorded and transcribed in full, and both ethnographic fieldnotes and interview transcriptions were systematically coded and analysed thematically. Before the co-creation workshop, the results from the ethnographic research of relevance for the intervention development were systematically compiled and shared with the research team.

Feasibility evaluation

The feasibility evaluation is in line with the recently published consolidated guidelines for behavioural intervention pilot and feasibility studies [21]. Feasibility is measured as a composite outcome comprising of the following outcomes:

Recruitment Recruitment will be estimated by calculating the proportion of eligible participants (pregnant women with GDM) who agree to participate in the intervention group. The progression criterion for recruitment is that >60% (95% CI, 53.2–66.6%) of the invited participants agree to be enrolled in the study.

Retention Retention will be estimated by calculating the proportion of included women in the intervention group who complete the study. The progression criterion is >60% (95% CI:, 53.2–66.6%) of all included participants provide delivery and postpartum data.

Acceptability Acceptability will be measured in a combined quantitative and qualitative study. It will be measured quantitatively via 5-point Likert scales among the intervention group (range, 1–5; minimum score: 1; maximum score: 5; higher score indicates high acceptability). It will be assessed qualitatively among a subgroup of the intervention group through an ethnographic study ($n=$ 20/10%) and their family members. The progression criterion for acceptability is a mean Likert score >3. There is no prespecified stop–go rule for qualitative data.

The definitions of all other outcomes and how each outcome is measured are described in Table 1. The time points of measurement are described in the SPIRIT figure (Fig. 1).

Table 1 Overview of outcome measures

OBJECTIVE*	DEFINTION FOR OUTCOME MEASURE	TOOL
Primary feasibility outcome measures		
Recruitment	The ratio between the number of women eligible for the intervention study, i.e., invited to participate in the study, and number of women who accepts to participate in the study, i.e., completes the inclusion questionnaire. We have determined that recruitment completeness will be satisfied if > 60% of invited participants accepts to be recruited into the study	Inclusion questionnaire
Retention	The ratio between the number of women who accepts to participate in the intervention study, i.e., complete the inclusion questionnaire, and the number of women (1) with delivery data and (2) who completes the post-partum questionnaire. We have determined that retention completeness will be satisfied if > 60	Inclusion, medical record, and post-partum questionnaire
Acceptability	Acceptability will be measured using both quantitative and qualitative methods. Quantitatively, it will be assessed through 5-point Likert scales within the intervention group [Range: 1–5; Minimum score: 1; Maximum score: 5; Higher score indicates high acceptability]. We have determined that the acceptability is satisfied if there is a mean Likert score of > 3 Qualitatively, acceptability will be assessed group through an ethnographic study involving a sub-group of the intervention group (n = 20/10%) and their family members. There is no prespecified stop–go rule for the qualitative data	[Mixed method] Self-reported questionnaire and semi-structured individual interviews and family interviews
Large for Gestational Age[a]	The number of new-born with a birth weight above the 90 th percentile according to the gender and gestational age [Intergrowth]	Medical record
Secondary outcome measures		
Apgar score[a]	The Apgar score of new-borns measured 1 and 5 min after delivery (score: 0–10)	Medical record
Birth weight[a]	Birth weight of new-borns measured in grams	Medical record
Breast feeding practices[b]	Q1-11 in WHO's breastfeeding scale	Self-reported questionnaire
Gestational age[a]	The gestational age of new-borns at delivery	Medical record
GDM pharmacological therapy and counselling[b]	Nine categorical ad hoc developed items	Self-reported questionnaire
HbA1c[b]	Change in delta score gestational age 24 and 40	Blood sample
Live-born	New-borns that are live-born (yes/no)	Medical record
Macrosomia (Global)[a]	Number of new-borns with birth weight above 4000 g	Medical record
Macrosomia (Local context)[a]	Number of new-borns with birth weight above 3500 g. As the birth weight in most of Asia is lower than the global birth weight the local standard for macrosomia in the study setting is 3500 g rather than 4000 g	Medical record
Maternal gestational weight gain[b]	Change in delta weight (kilogram) among participants between gestational age 32–40 minus first measured/pre-gestational weight	Scale
Mode of delivery[a]	Number of participants with spontaneous vaginal delivery, assisted vaginal delivery, planned c-section or emergency c-section	Medical record
Neonatal hypoglycaemia[b]	Mmol/l of blood glucose (mmol/l) in newborns	Medical record
Perceived social support[b]	Change in delta score measured through the Multidimensional Scale of Perceived Social Support scale (MSPSS) [11 item 7-point scale ranging from 1–7]	Self-reported questionnaire

Table 1 (continued)

OBJECTIVE*	DEFINTION FOR OUTCOME MEASURE	TOOL
Preterm birth below GA 37 + 0[a]	Number of participants with spontaneous preterm birth or medical induced preterm birth below gestational age 37 + 0	Medical record
Post-partum depression[b]	Change in delta score at the Edinburgh postpartum depression scale (EPDS) [10 items on 4-point scale ranging from 0–3]. A cut-off of 10 will be used to determine as possible depression	Self-reported questionnaire
Self-care Agency[b]	Delta score between intervention and comparator group measured through the [15 items on 5-point scale ranging from 1–5]	Self-care Agency Scale-Revised (ASAS-R)
Self-care of GDM[b]	Delta score between intervention and comparator group [10 items on 8-point scale ranging 0–7]	Summary of Diabetes Self- Care Activities (SDSCA)
Small for gestational age (SGA)[a]	Number of new-borns below the 10 th percentile for birth weight according to gestational age	Medical record
Social support for breastfeeding[b]	Revised version of the social support for breastfeeding scale [3 items on 5-point scale range from 1–5, 11 binary items]	Self-reported questionnaire
Well-being[a]	Change in delta scores at the WHO 5 Wellbeing index [5 items on 6-point scale ranging from 0–5]	Self-reported questionnaire
Other outcome measures		
Diet[b]	Change in diet measured through ad hoc developed questions	Self-reported questionnaire
Episiotomy[a]	Number of participants where episiotomy is performed during delivery	Medical record
Physical activity[b]	Change in physical activity measured through ad hoc developed questions	Self-reported questionnaire
Premature Primary Rupture of Membranes (PPROM)[b]	Number of participants with Premature Primary Rupture of Membranes	Medical record
Prevalence of GDM[a]	Proportion of participants with GDM diagnosed according to WHO criteria	OGTT
Risk factors of GDM[b]	Number of pre-gestational and gestational risk factors for GDM prevalent among participants diagnosed with GDM (risk factor are defined as according to those known in the literature, e.g., age, BMI, family disposition, gestational weight gain)	Scale, self-reported questionnaire
Family health	The short form version of the Family Health Scale [10 items on a 5-point scale ranging from 1–5]. A total score of 0–5 indicates poor family health, 6–8 indicates moderate family health, and 9–10 indicates excellent family health	Self-reported questionnaire
Cost	Direct economic costs (in Vietnamese Dong/VND and USD) and indirect costs (human resources measured in hours) spent on developing the intervention	Direct and indirect economic deducted from the project
*Co-creation of intervention***		
Co-creation of self-care and informal support intervention	Participants from the pre-intervention control group and their informal support persons will identify the key elements for a sustainable informal support/self-care intervention	Semi-structured individual and family interviews
Ethnographic study***		
GDM self-care practices	Pregnant women with GDM and their informal support persons will provide in-depth information about their GDM self-care practices	Semi-structured individual interviews and family interviews

Table 1 (continued)

OBJECTIVE*	DEFINTION FOR OUTCOME MEASURE	TOOL
Perceptions of GDM	Pregnant women with GDM and their informal support persons will provide in-depth information about their perception of GDM	Semi-structured individual interviews and family interviews

* The outcomes marked [a] are collected for the whole screening population, i.e., approximately 2000 women

The outcomes marked [b] are collected for the GDM population, i.e. approximately 400 women

** The sample size for the co-creation process will be 20 as it will only be developed with a sub-sample from the control group

*** The expected sample size for the ethnographic study will be 40 participants: 20 from the intervention and 20 from the control group

	STUDY PERIOD									
	Allocation control	Post-allocation control group				Allocation intervention	Post-allocation intervention group			
TIMEPOINT**	0_c [GA 5-28]	t_{1c} [GA 24-28]	t_{2c} [GA 32-40]	t_{3c} [Delivery]	t_{4c} [8-12w pp]	0_i [GA 5-28]	t_{1i} [GA 24-28]	t_{2i} [GA 32-40]	t_{3i} [Delivery]	t_{4i} [8-12w pp]
ENROLMENT:										
Eligibility screen	X					X				
Informed consent	X					X				
Allocation	X					X				
Inclusion interview	X					X				
OTHER PROCEDURES:										
Oral glucose tolerance test (OGTT)		X					X			
OGTT interview		X					X			
Gestational age (GA) 32-40 interview			X					X		
Delivery (medical records)				X					X	
8-12 post-partum interview					X					X
INTERVENTIONS:										
[Standard care]		♦	—	—	♦					
[Self-care and informal support]							♦	—	—	♦
ASSESSMENTS:										
Socio-demographic data	X					X				
Recruitment (feasibility)						X				
Retention (feasibility)						X			X	X
Acceptability (feasibility, quantitively)						X		X		X
WHO-5 Well-being index	X	X	X		X	X	X	X		X
Height		X					X			
Weight	X	X	X	X		X	X	X	X	
Blood pressure		X		X			X		X	
GDM status		X					X			
Multidimensional Scale of Perceived Social Support (MSPSS)		X	X		X		X	X		X
Self-care Agency Scale-Revised (ASAS-R)		X					X			
Edinburgh Post-partum Depression Scale (EPDS)		X	X		X		X			X
Physical activity'		X	X				X	X		
Diet'		X	X				X	X		
Summary of Diabetes Self-Care Activities (SDSCA)			X					X		
Family health			X					X		
*Co-creation of intervention**		♦	—	—	♦					
*Perception of GDM***		♦	—	—	♦		♦	—	—	♦
*GDM self-care practices***		♦	—	—	♦		♦	—	—	♦
*Acceptability of intervention (feasibility, qualitatively)****							♦	—	—	♦
*Neonatal health outcomes*****				X					X	
*Maternal health outcomes******				X					X	
Breastfeeding practices					X					X
Social support for breastfeeding					X					X
Costs	X	X			X	X	X			X

Fig. 1 Spirit figure of Valid II study

* Ethnographic study and workshop with approximately 20 pregnant women from control group, their informal support persons**Ethnographic study with approximately 40 pregnant women (20 from control group/20 from intervention group) and their informal support persons*** Ethnographic study with approximately 20 pregnant women from intervention group and their informal support persons****Large for gestational age (LGA), Pre-term birth GA37+0, GA, Birth weight, Macrosomia (birth weight above 4000g), Macrosomia Vietnam (birth weight above 3500g, Live-born, Small for gestational age (SGA), Apgar score, Neonatal hypoglycaemia,*****Mode of delivery, Maternal gestational weight gain, HbA1c, Episiotomy, Premature Primary Rupture of Membranes (PPROM)

Setting

The VALID-II study will be conducted in Thai Binh Province in northern Vietnam. Participants will be recruited from two health facilities: Thai Binh Maternity Hospital and the Kim Ngan Clinic. Thai Binh Maternity Hospital is a public hospital with approximately 11,000 deliveries/year where pregnant women can receive antenatal care and deliveries, whereas Kim Ngan Clinic is a private health clinic where pregnant women can receive antenatal care only.

Study procedures

Recruitment of the study population

Upon a pregnant woman's first antenatal care visit to one of the study sites, she will be approached by a study nurse/midwife, who informs her about the study and invites her to participate. The timing of the first antenatal care visit may vary from gestational week 5 to 28; hence, women may be included in the study on various points in their pregnancies. The majority of women have their first antenatal care visit around GA 12 and will be included at this time. If a woman consents to participate in the study, she will participate in a short inclusion questionnaire interview (baseline questionnaire) with the study nurse/midwife and be scheduled for an OGTT at GA 24–28.

Oral glucose tolerance test and diagnosis of gestational diabetes mellitus

The pregnant woman will undergo a standard OGTT at GA 24–28 at either of the study sites. She will arrive fasting in the morning, and a venous blood sample will be taken, and her fasting plasma glucose level will be measured. After the first blood sample, the patient will consume a 75 g dose of glucose while sitting, and 1 and 2 h after the glucose challenge, additional blood samples will be taken. The blood samples will be analysed at local laboratories at the two study sites, which are located less than 20 m from the waiting rooms. At the Kim Ngan Clinic, plasma glucose will be measured via an enzymatic reference method with hexokinase (Cobas 4000; Model: c311; Roche, Mannheim, Germany). At the Maternity Hospital, plasma glucose will be measured via the enzymatic reference method with oxidase (Analyser; Model: BA400; Biosystems, Barcelona; Spain). The diagnosis will be made according to the IADPSG Consensus Panel recommendations and the WHO's Diagnostic Criteria (2013) [22, 23]. GDM will be diagnosed if the glucose concentration is above one of the following three thresholds:

- Fasting plasma glucose: ≥ 5.1 mmol/L
- 1-h plasma glucose: ≥ 10.0 mmol/L
- 2-h plasma glucose: ≥ 8.5 mmol/L

A study nurse/midwife will attend each woman's OGTT appointment and conduct a second questionnaire interview with the pregnant woman (OGTT interview) while she waits for her 1-h and 2-h blood samples. Furthermore, height and weight will be measured at the OGTT visit via medical scales (Model TZ-120, Shanghai Guangzheng Medical Equipment Co., Shanghai, China). Blood pressure will be measured at all antenatal care visits via the same machine (Model: JPN600, Omron Healthcare Europe B.V., Hoofddorp, the Netherlands). If the OGTT shows that the woman does not have GDM, she will not be interviewed further and will simply participate in the study as a passive control. However, delivery and neonatal outcomes will be deducted from the woman's medical records. If she is diagnosed with GDM, she will participate in an additional questionnaire interview at GA32-40 either in person at health facilities or via telephone and at 8–12 weeks postpartum via a home visit.

Inclusion and exclusion criteria

Women will be included in the VALID-II study on the basis of the following criteria: (1) pregnancy ≤ 28 weeks; (2) singleton and multiple pregnancies; (3) residence in Thai Binh Province; (4) speaks and reads Vietnamese; and (5) agrees to participate voluntarily after informed consent. If a woman has had GDM in a prior pregnancy, she is eligible for inclusion in the study. Women will be excluded from the study on the basis of the following criteria: (1) pregestational diabetes (type 1 or type 2) and (2) severe chronic disease.

Study conduct

In the first phase of the study, all women diagnosed with GDM will be invited into the control group and referred to standard care, which is an invitation for a counselling session with an endocrinologist at Thai Binh Provincial General Hospital regarding diet, exercise, and blood glucose measurements and monitoring. Standard care entails that women be invited for a follow-up check-up in the antenatal care clinic every 4 weeks until delivery. If women do not attend the counselling session, they are not advised about GDM self-care. Since preliminary research has shown that not all women diagnosed with GDM attend counselling sessions at Thai Binh Provincial General Hospital, the VALID-II project setup includes a phone call to the women by an endocrinologist at the hospital of Thai Binh University of Medicine and Pharmacy (TBUMP) 1 week after the diagnosis. This phone call is made for ethical reasons to ensure that all women diagnosed under the auspices of the VALID-II project receive basic counselling about GDM. If the women report that they have received no counselling after the diagnosis, the VALID-II endocrinologist will offer basic

counselling by phone and encourage the women to seek care at Thai Binh Provincial General Hospital.

In the second phase of the study, women will be invited into the intervention and offered the intervention in addition to standard care. The second phase of the study will occur approximately 3 months after the first phase. We opted for a 3-month delay between the control and intervention groups rather than a parallel two-arm randomised controlled trial (RCT) to allow for the co-creation process and ensure that the intervention will be deeply informed by participant insights and cultural contexts.

Sample size

This study aims to determine whether VALID-II intervention is feasible before the development of an RCT. Thus, the study is not powered to detect significant differences in clinical outcomes, and no formal power calculation has been conducted. However, we do have a large sample size in our study, as this feasibility study is nested in a larger cohort with objectives that go beyond the primary objectives of the feasibility study (reported as secondary neonatal, maternal, and other outcomes). Approximately 2000 women will be enrolled in the study, and the women will be invited in chronological order, starting from the start date of the study. An expected 400 women will be diagnosed with GDM, of whom 200 will be allocated to the control group and 200 to the intervention group. These 200 women in the intervention group are the primary target population of the feasibility study (Fig. 2). The progression criteria for the "recruitment rate" and "retention rate" are > 60% (95% CI, 53.2–66.6%). This means that more than 120 women (95% CI, 106–134 women) must be recruited and retrained in the intervention group to be deemed feasible according to these criteria. As stated above, an ethnographic study will be conducted among 20 women and their informal support persons out of the 200 women in the control arm, and these persons will be invited to co-create the intervention together with health personnel. Similarly, an ethnographic study will be conducted among 20 out of the 200 women in the intervention group—and their informal

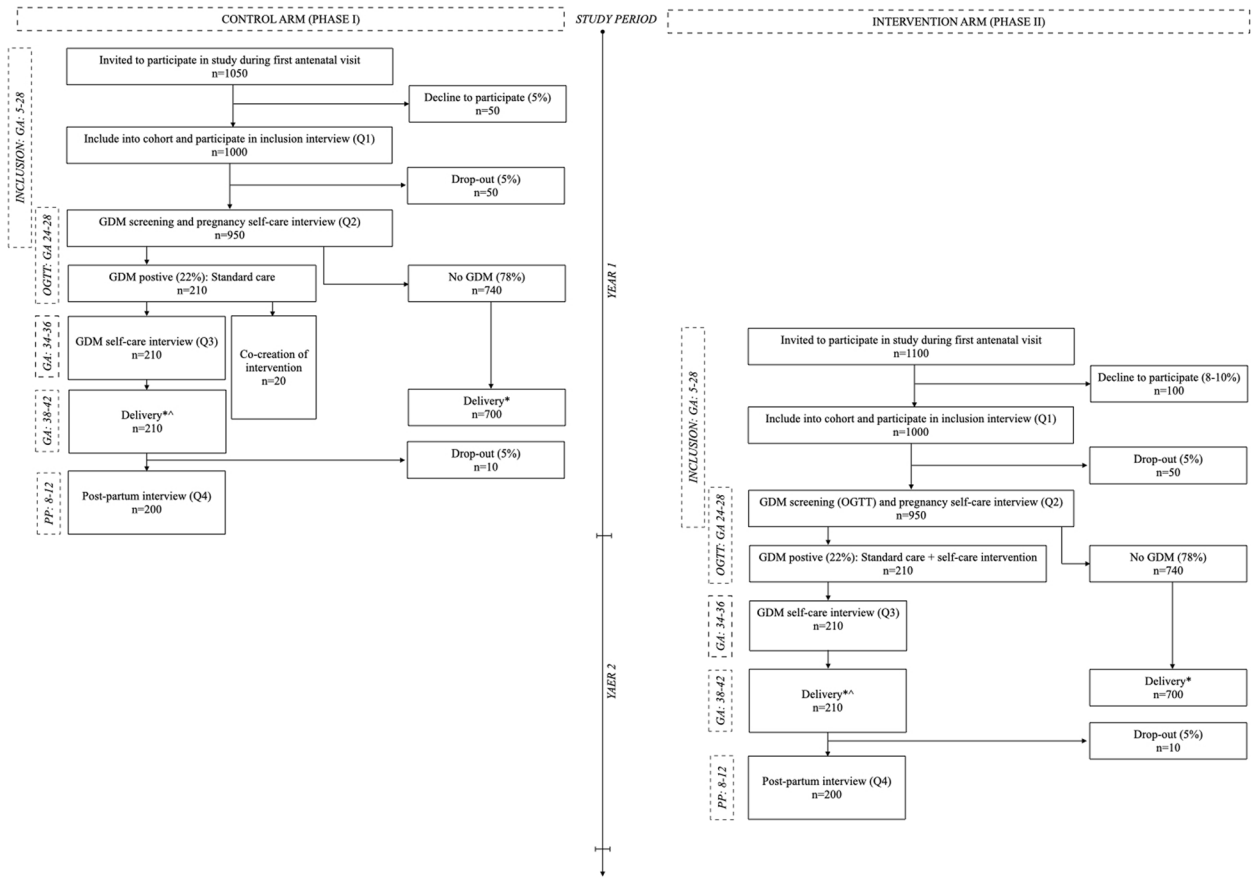

Fig. 2 Flow chart of Valid II study

support persons—to collect in-depth information about the acceptability of the intervention.

Data management and statistical analysis

The quantitative data will be entered and managed through the Research Electronic Data Capture (REDCap) [24] and exported to Stata v17 [25], SPSS, or R program [26] for statistical analysis. REDCap ensures that data are stored at a secured, web-based server at TBUMP in Thai Binh, Vietnam. The analysis of the quantitative feasibility outcomes will include the use of frequencies and percentages with 95% CIs to convey the precision of the estimates. The ethnographic data for feasibility—i.e., acceptability of the intervention—as well as other ethnographic data will consist of fieldnotes and transcriptions of voice recorded interviews. These will be systematically coded and synthesised via a content analysis strategy. The analysis for the secondary neonatal and maternal outcomes will be intention-to-treat, and logistic regression analyses will be performed to assess the potential associations between self-care activities and neonatal and maternal health outcomes. If an imbalance in baseline characteristics and potential confounders exists, adjustments will be made. The data will be analysed according to the intention-to-treat principle.

Patient, public, and private sector involvement

Patients and their informal support persons will be involved in designing the content of the intervention so that it meets their needs and is acceptable to them. Furthermore, to ensure that the intervention is aligned with national priorities, the Ministry of Health in Vietnam (General Department of Preventive Medicine) and the Western Pacific Hub of the WHO's Human Reproduction Programme serve as secondary partners in the project.

Discussion

This protocol outlines a feasibility intervention study that aims to generate new knowledge and provide new solutions to the public health problems posed by GDM in Vietnam. The project adopts a multidisciplinary approach and combines research methods from epidemiology, ethnography, and participatory design. Cumulatively, this research project will facilitate the incorporation of informal support and self-care into daily GDM management and provide knowledge of the feasibility of a future full-scale RCT.

Informal support—also known as social support—is becoming a fundamental part of noncommunicable disease management [27]. It has been evaluated in various pregnancy studies [28–30], and increased social support is associated with a reduced level of stress and better pregnancy outcomes [31]. However, the effect of social support on pregnancy is moderated by other social factors, such as low well-being [32] and unhealthy nutrient intake [33]. Furthermore, it is important to note that these social factors vary broadly among ethnic groups and countries and are therefore important to consider when assessing the effect of social support on disease management. The results of VALID-II will form a theoretical basis for understanding the role of social support among pregnant women in Vietnam and fill a crucial knowledge gap on the role of informal support in daily self-care among women living with GDM. In addition, the project will contribute to a far deeper understanding of the social barriers and supporters that influence the outcomes of a pregnancy complicated by GDM in Vietnam. In addition, VALID-II will assess the potential benefits of a nonpharmacological intervention focused on facilitating GDM self-care and women's social support for maternal and neonatal outcomes, which is likely a sustainable and feasible way of addressing the issue of GDM in a lower middle-income country, such as Vietnam, in addition to or as a supplement to pharmacological treatment. As a result, this will advance the current evidence for best-practice management of GDM in resource-limited settings. The data-driven conclusion of this project will assist policymakers and clinicians in the daily management of GDM, and if the intervention is effective, it may reduce the burden of GDM on individuals, families, and society as a whole. Finally, VALID-II is a multidisciplinary and multinational collaboration that will also enhance the research capacity and organisational skills of researchers in Vietnam.

A limitation of this study is that it is not powered to detect an effect of the intervention on our clinical secondary outcomes. Although the effects of self-care practices on the outcome of pregnancy have been reported elsewhere [28–31], research on whether there is any association between self-care and GDM has been scarce, and most studies have been performed in high-income countries. Thus, a proper sample size calculation was not performed, as it would likely not yield a robust and reliable estimate of the sample size required to document a potential effect of the intervention among women with GDM in the setting studied. Nevertheless, it is believed that this study will add to the very limited knowledge base on the effects of self-care interventions and social support among women with GDM in LMICs. It is widely recognised that most pilot and feasibility studies are underpowered to detect clinically significant effects on their outcomes [21], and we expect that our large sample size—although not informed by a power calculation—is sufficient to make informed decisions about both the feasibility of the intervention and the preliminary efficacy of the intervention, thereby informing parameters such as

effect size and variance, which are essential for calculating the sample size needed to achieve the desired power in a future large-scale RCT. Another limitation of our study is that for ethical reasons, we have had to ensure that all women enrolled in the study and diagnosed with GDM receive basic GDM counselling, although this may not always be the case in a nonstudy context. This standardisation may influence the potential effect of our intervention. However, as the intervention was not informed by a formal power calculation, interpreting the magnitude of its effect may be challenging and should be approached with caution. Furthermore, potential confounders may exist when comparing the intervention and control groups, as we used a non-randomised design; i.e., we may have had to adjust for confounders in our analyses, which may have limited the power to detect potential differences between standard care and the intervention. Furthermore, in-person community-based recruitment places restrictions on the geographical scope of our project, so the data and designed interventions may not be representative of other areas in the country.

A strength of this study is that in addition to the intervention, the study also assessed many other GDM-related health outcomes, which will help us better understand the issue of GDM and the consequences of the disease in Vietnam. Additionally, the intervention will be constructed on the basis of extensive qualitative research with women with GDM and their informal support persons. This will ensure that the intervention model is participant driven and tailored to the cultural and social dynamics of northern Vietnam. Moreover, although no new-born outcomes are measured at the postpartum interview, the data of this study may be used to establish a cohort of mother–offspring pairs with a history of GDM for future research projects.

Conclusions

This study provides information about the feasibility of co-created self-care and social support interventions targeting women with GDM in northern Vietnam and the maternal and neonatal may guide decision makers in how to address GDM in low- and middle-income contexts.

Study duration/trial status

The total duration of the study is anticipated to be 3 years. The inclusion of the control group started in January 2023 and is anticipated to finish 4 months later. The inclusion of the intervention group started in March 2024. The follow-up period is up to 47 weeks [range 24–47] depending on the GA at inclusion, which may vary from GA 5 to GA 28. The end of the study will be in December 2026. The study has been registered at ClinicalTrials.gov: NCT05744856. Trial status: Recruiting.

Abbreviations

C-section	Caesarean section
EPDS	Edinburgh Postpartum Depression Scale
GA	Gestational age
GDM	Gestational diabetes mellitus
LGA	Large for gestational age
MSPSS	Multidimensional Scale of Perceived Social Support Scale
OGTT	Oral glucose tolerance test
RCT	Randomised controlled trial
REDCap	Research Electronic Data Capture
PPROM	Premature primary rupture of membranes
SGA	Small for gestational age
SDSCA	Summary of diabetes self- care activities
SPIRIT	Standard Protocol Items: Reporting Interventional Trials
TBUMP	Thai Binh University for Medicine and Pharmacy
WHO	World Health Organisation

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40814-025-01657-x.

Additional file 1: S1 Spirit checklist.

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Authors' contributions

DSL drafted the manuscript in collaboration with DKN and contributed to conceptualising the study. VR, TG, ICB, CAV, JS, DWM, TDN, DCN HHL, and NTD participated in designing the study and drafting the protocol. HML, DTKV, TAN, TPHV, XBN, TG, and DKN contribute to the collection of data, whereas DSL, ICB, VR, CAV, JS, DWM, TDN, and DCN monitor the data collection. DSL, MHL, DTKV, NAD, TAN, TPC, XBN, DWM, JS, TG, and DKN contributed to the data analysis. All the authors contributed to refinement of the study protocol and approved the final manuscript.

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Data availability

No data monitoring committee oversees the conduct of this study. Individual participant data that underlie the results reported in the articles will be shared after deidentification (text, tables, figures, and appendices). The sharing of data must adhere to the General Data Protection Regulation (GDPR) in Denmark and the guidelines in Vietnam. The data will be available immediately following publication. No end dates. All requests for data should be addressed to Thanh Duc Nguyen (contact details stated in Clingov). Thanh Duc Nguyen will review the request and involve all applicable/relevant parties in the decision-making outcome (i.e., all Vietnamese and Danish collaborators). Data will be shared with researchers who provide a methodologically sound proposal. New projects that result in data sharing should meet the high standards (quality, ethical, and financial) maintained by this study.

Declarations

Ethics approval and consent to participate

The VALID-II study was approved by the Ethics Council in Biomedical Research in Thai Binh on 1 December 2022 (IRB – VN01.009). All participants provided written informed consent.

Consent for publication

All the authors consent to publish this study protocol.

Competing interests

The authors declare that they have no competing interests.

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Dissemination

VALID-II aims to produce and disseminate new knowledge reflecting scientific excellence, thereby contributing to a solid platform for policy debate in Vietnam and internationally on how to address NCD-reproductive health interactions, with a particular focus on GDM. The project's dissemination strategy includes three main audiences: (1) the scholarly community; (2) the policy/health service delivery community; and (3) the general public, including pregnant women as health service users/consumers. To reach the scholarly community, the project will produce articles for high-impact peer-reviewed scientific journals, both in Vietnam and internationally, while also engaging in debate at international conferences through paper presentations on the basis of research findings. Furthermore, research capacity building and research-based education in Thai Binh Province are key elements of this research project. To reach policy makers and health service providers, VALID-II will organise two stakeholder meetings in Thai Binh and one policy-maker round-table discussion in Hanoi, producing three policy briefs for dissemination to stakeholders. To communicate research and intervention results to the general public, including pregnant women, the project will produce at least three op-eds for Vietnamese newspapers and a short documentary film for circulation on social media, portraying pregnancies, and family lives with GDM.

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