STUDY PROTOCOL

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Healthy Habits During and After Gestational Diabetes: A Cluster Randomised Family Intervention Controlled Trial in Northern Vietnam (VALID III)

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Administrative Information, Open Science, and Dissemination Policy

Administrative Information

Title

Healthy Habits During and After Gestational Diabetes: A Cluster Randomised Family Intervention Controlled Trial in Northern Vietnam (VALID III)

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Structured Summary

Background: Childhood obesity is a major global health burden, with increasing prevalence in many Asian countries, including Vietnam. However, health policies and programs in LMICs often rely on evidence derived from contexts that are not fully comparable, thereby limiting the effectiveness of interventions. Evidence shows that exposure to maternal gestational diabetes mellitus (GDM) is associated with an increased risk of childhood obesity. Early-life nutrition, particularly exclusive breastfeeding, plays a critical role in preventing this risk among children exposed to GDM. In a Vietnamese context, family members (husbands, grandparents and parents-in-law) significantly influence infant feeding and childcare practices.

Objective: To evaluate the effect of the “Healthy Habits” family-based health intervention on improving infant feeding practices and improving body composition in childhood.

Trial design: This study is a two-arm, parallel-group, superiority cluster randomised controlled trial with 1:1 allocation of clusters to the intervention (standard care + “Healthy Habits” – complex intervention [expanded package]) or control group (standard care + website access [basic package]). The unit of randomisation is communes (n=29), with stratified randomisation by rural/urban and population size to ensure balance between study arms. Outcomes will be assessed in mother–child dyads (individual level). Primary analyses will be conducted according to the intention-to-treat principle, accounting for clustering. The trial is designed according to the SPIRIT guidelines.

Participants: Pregnant women with GDM and their families (including infant, husband, grandparents, parents-in-law).

Intervention: A co-created intervention delivered during pregnancy and up to two years after birth that includes counselling, peer support, digital health elements, educational materials, and follow-up support on nutrition, infant feeding practices, physical activity, and

GDM management provided according to routine clinical practice in the Hung Yen province, Vietnam.

Control: Access to a website with GDM management + standard care.

Primary objective: To evaluate the effect of the “Healthy Habits” family health intervention on the duration of exclusive breastfeeding up to 180 days (6 months) after birth.

Secondary and other outcomes: To evaluate the effect of the “Healthy Habits” family health intervention on the proportion of (1) infants exclusively breastfed at 6 months after birth, and (2) child fat mass index (FMI) at 24 months after birth. Further, the trial aims to assess process outcomes and broader effects of the “Healthy Habits” intervention on maternal and child health and wellbeing.

Follow-up period: Participants will be followed until 24 months after birth.

Trial registration: Registered with ClinicalTrials.gov (Identifier: NCT07717515).

Key words: Gestational diabetes mellitus; pregnancy hyperglycaemia; exclusive breastfeeding; infant feeding; early-life nutrition; child adiposity; fat mass index; childhood obesity; lifestyle intervention; behavioural intervention; family-based intervention; caregiver involvement; maternal nutrition; physical activity; postpartum health; complementary feeding; Vietnam; low- and middle-income countries, intergenerational health.

Protocol Version

Version 10.1 date 08/07/2026

Roles and Responsibilities

Protocol contributors

Principal Investigators

1. Assoc. Prof. Nguyen Duc Thanh, Department of Management & Organizational Health, Thai Binh University of Medicine and Pharmacy, Hung Yen, Vietnam. Role: Study conceptualization, study design, protocol development, supervision of study implementation, reviewing and approving the final protocol.

Co-Investigators

1. Mrs. Dang Thi Ngoc Anh, Dept. of Environmental Health, Faculty of Public Health, Thai Binh University of Medicine and Pharmacy, Hung Yen, Vietnam. Role: Study design, protocol development, data collection and analysis, reviewing and approving the final protocol.
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3. Dr Nguyen Dang Kien, Department of Gynaecology & Obstetrics, Thai Binh University of Medicine and Pharmacy, Hung Yen, Vietnam. Role: Study design, protocol development, data collection and analysis, reviewing and approving the final protocol.
4. Mrs. Nguyen Thi Ai, Dept. of Management & Organizational Health, Thai Binh University of Medicine and Pharmacy, Hung Yen, Vietnam. Role: RCT manager, study design, protocol development, data monitoring, data collection and analysis, and contributed to reviewing and approving the final protocol.
5. Prof. Jens Søndergaard, Research Unit of General Practice, Department of Public Health, University of Southern Denmark, Odense, Denmark. Role: Study conceptualization, study design, protocol development, supervision of study implementation, data analysis, contributed to reviewing and approving the final protocol.
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8. Prof. Tine Mette Gammeltoft, Department of Anthropology, University of Copenhagen, Denmark. Role: Overall study design, study design, protocol development, and final approval of the protocol.

Trial sponsor

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Trial sponsor and funders

The trial is funded by The Danish Ministry of Foreign Affairs (DANIDA) (see 7a). The funder has no role in the design of the study; collection, management, analysis, or interpretation of data; or the decision to submit the manuscript for publication. The sponsor of the trial is Thai Binh University of Medicine and Pharmacy (TBUMP), which has overall institutional responsibility for the conduct of the study. Members of the research team are employed by TBUMP; however, the investigators retain full scientific independence and academic freedom in all aspects of the trial. The sponsor has no authority over the study design, data analysis, interpretation of results, or publication decisions. All trial-related decisions are made by the investigators in accordance with the study protocol and principles of Good Clinical Practice.

Trial oversight

The trial is coordinated by Thai Binh University of Medicine and Pharmacy (TBUMP), which is responsible for overall trial management, regulatory and ethics approvals, coordination between study sites, and ensuring compliance with the protocol and Good Clinical Practice (GCP). Danish researchers support TBUMP with capacity building for trial management. The study is conducted across multiple communes, with participant recruitment facilitated through two primary antenatal care sites: Thai Binh Maternity Hospital (public hospital) and Kim Ngân Clinic (private clinic). Communes serve as the unit of randomisation, and all participants within a given commune receive the same intervention allocation. At each recruitment site, trained study nurses are responsible for participant recruitment, provision of study information, obtaining informed consent, and supporting data collection. All study nurses receive standardised training from the VALID research group prior to study initiation. Training covers participant recruitment procedures, informed consent processes, and protocol-specific procedures to ensure consistency across sites and communes. Implementation of the intervention at the commune level is coordinated with local healthcare providers and relevant community-level stakeholders. Study staff are responsible for ensuring that intervention delivery aligns with the allocation of each commune. Data management and statistical analyses are conducted centrally by qualified personnel independent of intervention delivery. The randomisation sequence is generated externally by an independent statistician, and allocation is implemented at the commune level by the designated trial coordinator. Fidelity monitoring is performed through spot checks to ensure adherence to the protocol at both the individual and cluster (commune) level. Given the low-risk nature of the intervention, no independent steering committee or data monitoring committee will be established. Oversight of data governance and participant confidentiality is ensured through the involvement of a designated Data Protection Officer, who is responsible for compliance with applicable data protection regulations.

Open Science

Trial registration: ClinicalTrials.gov Identifier: NCT07717515

Protocol and statistical analysis plan

The full protocol and statistical analysis plan will be made available upon request from the corresponding author and may also be published in an open-access, peer-reviewed journal.

Data sharing

To the extent possible, aggregated data that cannot identify individual persons and data dictionary, and statistical code will be made available upon reasonable request after publication of the project results. Access will be granted to researchers with a methodologically sound research proposal, subject to approval by the study investigators and in accordance with applicable ethical and data protection regulations.

Funding and Conflicts of Interest

Funding

This study is funded by the Ministry of Foreign Affairs of Denmark (DANIDA) (project no. 26-12-KU).

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Conflicts of interest

All investigators declare no competing financial or non-financial interests.

Dissemination Policy

The project aims to generate and disseminate high-quality scientific evidence, thereby providing a robust foundation for research and policy dialogue in Vietnam and globally on addressing interactions between non-communicable diseases, with a particular focus on post–GDM–related behaviours and childhood obesity. The dissemination strategy targets three primary audiences: (1) the academic community; (2) policymakers and healthcare providers; and (3) the general public, including women and children of mothers with GDM. The project aims to engage with the audiences through these strategies:

1. To engage the academic community, research findings will be published in high-impact peer-reviewed international and national (Vietnamese) journals. The project will also be presented via posters and/or oral presentations at international/national conferences. Additionally, the research findings will be incorporated into teaching materials at Thai Binh University of Medicine and Pharmacy, particularly within postgraduate programs for specialists in obstetrics, paediatrics, and nutrition, providing physicians with the opportunity to access and apply the results in community healthcare.

2. To engage policymakers and healthcare providers, the project will organise workshops, seminars, and roundtable discussions with policymakers, healthcare experts, and community representatives in Hung Yen and Ha Noi. In addition, policy briefs will be developed and disseminated to stakeholders.

3. To disseminate research findings and healthcare interventions to the community, including postpartum women with a history of GDM, the project will develop various materials (e.g., leaflets, community guides, and short videos) highlighting maternal and childcare practices for women with prior GDM. These materials will be distributed at healthcare centers and shared via social media platforms such as Zalo.

Introduction and Objectives

Background and Rationale

Background

Childhood obesity is an increasing global health concern. Until recently, childhood obesity was considered a phenomenon exclusive to high-income countries; however, it is now rising rapidly in low- and middle-income countries (LMICs), entailing severe consequences for the children's health and quality of life, as well as national healthcare systems and economies [1–5]. Obesity affects children across their life course and increases the risk of developing non-communicable diseases (NCDs) later in life, including type 2 diabetes (T2D), cardiovascular disease, chronic respiratory disease, and cancer [6,7]. Therefore, the prevention of childhood obesity is a critical strategy for addressing the global NCD epidemic. Globally, NCDs are the leading cause of premature mortality, poverty, and disability, imposing formidable challenges on health systems [4,8]. Despite the crucial role of childhood obesity prevention in controlling NCDs, the majority of research and interventions have been conducted in high-income countries, leaving children in LMICs underserved [9,10].

In Vietnam, childhood obesity is becoming an increasingly urgent public health issue. In the context of rapid economic growth, urbanization, and globalization, the prevalence of overweight and obesity in children is rising: the most recent national survey revealed that 7.4% of children under 5 and 19% of those aged 5–19 are overweight [11]. At the same time, undernutrition remains a concern in Vietnam – the prevalence of stunting among children aged 6 months to 11 years is 8.7%, with the highest prevalence observed in those aged 1 to 3.9 years (12.1%), while the prevalence of wasting among children under 5 years of age is 3.8 % [12]. Vietnamese families today live in a food environment where infant formula and children’s food products are heavily marketed, while regulations governing processed foods and unhealthy beverages remain insufficiently enforced [13,14]. Vietnam’s National Nutrition Strategy emphasizes controlling childhood obesity, aiming to keep the prevalence of overweight and obesity below 10% among children under five by 2030, with particular focus on the period from pregnancy to the child's second birthday [15]. The Draft Law on Disease Prevention 2025 includes a dedicated section on nutrition, reflecting a formal recognition of the nutritional challenges facing Vietnamese children [16]. Furthermore, recognizing the importance of GDM for maternal and child health, the Vietnamese Ministry of Health issued updated national guidelines for GDM management in 2024, recommending universal screening for GDM among pregnant women [17].

Building upon previous research on T2D and GDM in Vietnam, the VALID III project focuses on childhood obesity following GDM, particularly in children aged 0–24 months. Research from the VALID II project conducted in Vietnam indicates an alarming prevalence of GDM, with over 25% of pregnant women diagnosed with the condition [18]. Similar prevalence rates have been reported in other Southeast Asian countries [19].

Although GDM typically resolves after delivery, it is associated with significant long-term health implications: offspring of GDM mothers face a higher risk of obesity, and both mother and child exhibit increased susceptibility to NCDs later in life [20,21]. Since early-life adiposity tends to persist into adulthood, the first few years of life represent a critical window for obesity prevention [22,23]. Notably, there is still a limited understanding of adiposity development in early childhood following GDM [24–26]. Given the significant role of GDM in the rising prevalence of childhood obesity and NCDs, appropriate antenatal and postnatal GDM management holds substantial potential for improving the lifelong health of women and children. However, in Vietnam and many other countries, this health promotion potential remains largely underutilised, and evidence to inform policies and interventions is still limited [27,28]. Further, in Vietnam, grandparents play a central role in child care during early childhood and strongly influence feeding practices and health behaviours [29,30], yet they are rarely included in obesity prevention efforts. There is therefore a clear need for interventions that move beyond individual-level lifestyle factors to engage family and community networks in the prevention of childhood obesity.

Rationale

While childhood obesity is rapidly increasing in LMICs, most existing research and interventions have been developed in high-income countries with nuclear family structures, while children in LMICs remain inadequately served. This represents a major paradox in global health – the burden of disease is concentrated in LMICs, yet the scientific evidence guiding interventions is predominantly generated in high-income settings where cultural contexts, economic conditions, and family structures differ substantially. As a result, health policies and programs in LMICs often rely on evidence derived from contexts that are not fully applicable, thereby limiting the effectiveness of interventions.

Previous studies conducted by the VALID group have provided essential insights into the prevalence and risk factors of GDM in Northern Vietnam, women's lived experiences with GDM, social support, mental health, and the feasibility of co-created self-care interventions [31–35]. Collectively, these findings highlight that the consequences of GDM are shaped by family dynamics, caregiving roles, and the broader social environment. Children born to mothers with GDM are at increased risk of adverse metabolic and growth outcomes, yet postnatal prevention efforts in this population have largely focused on maternal behaviours alone. Building on this evidence, the research team has established strong collaborations with local health facilities and developed substantial contextual knowledge and expertise in co-creation and intervention development. These foundations support the design of a family-based health intervention that is culturally appropriate, feasible, and responsive to local needs. Despite the recognised intergenerational risk associated with GDM, to the best of the research team’s knowledge, no previous randomised controlled trial has evaluated the efficacy of a family-based health intervention targeting children born following GDM. A rigorously designed RCT is therefore warranted to assess whether engaging the family unit can improve maternal and child health outcomes in this high-risk population.

Large evidence syntheses demonstrate that structured breastfeeding support interventions produce moderate but clinically meaningful improvements in breastfeeding duration and exclusivity, particularly around the postpartum transition period. Individual and group-based interventions across diverse settings, including low- and middle-income countries, have consistently shown extensions of exclusive breastfeeding of a magnitude comparable to or exceeding four weeks. Moreover, return to work is a well-documented inflection point for breastfeeding cessation, and interventions targeting support around this transition have been shown to prolong exclusive breastfeeding duration. These findings support the plausibility and clinical relevance of a four-week difference as a conservative and evidence-based effect size for a trial [36–38].

Objectives

Primary objective

To evaluate the effect of the “Healthy Habits” family health intervention on the duration (days) of exclusive breastfeeding up to 180 days after birth.

Hypothesis: The intervention group is expected to have a 4-week longer duration of exclusive breastfeeding compared with the control group.

Secondary objectives:

1. To evaluate the effect of the “Healthy Habits” family health intervention on the proportion of children exclusively breastfed at 180 days after birth.

2. To evaluate the effect of the “Healthy Habits” family health intervention on child fat mass index (FMI) and fat-free mass index (FFMI) at 24 months after birth.

   Hypotheses: The intervention group is expected to have a higher proportion of exclusive breastfeeding at 180 days after birth and a lower FMI and higher FFMI at 24 months after birth compared with the control group.

Other objectives

Other objectives of the trial aim to assess the broader effects of the “Healthy Habits” intervention on maternal and child health and wellbeing (see specific outcome under item 16).

Process-evaluation objective

Guided by the UK Medical Research Committee framework for complex interventions [39], the trial also aims to investigate participant experiences and mechanisms of effect of the intervention through a qualitative sub-study (ethnographic interviews and focus groups with parents and grandparents) in a purposefully sampled subgroup of intervention participants (n=20) to capture diverse perspectives.

Patient and Public Involvement (PPI)

PPI in Trial Design and Intervention Development

Patient and public involvement (PPI) is embedded throughout the formative phase of this trial to ensure that the intervention is culturally relevant, feasible, and responsive to the lived experiences of women with previous gestational diabetes mellitus (GDM) and their families. PPI activities include an ethnographic exploration phase followed by a series of co-creation workshops. In this study, "patients" are defined as women with a history of GDM, and the "public" includes key family caregivers (husbands, mothers, and parents-in-law) who significantly influence infant feeding and care practices. To maintain trial integrity, PPI contributors are purposively sampled from the previous VALID II project (clinicaltrials.gov NCT05744856) [34] and will not participate in the VALID III RCT.

Ethnographic Phase: We will conduct open-ended qualitative interviews with at least 20 family caregivers of children born after GDM. The interviews will be carried out in the family homes when the children are aged approximately 1–2 years, focusing on childcare and feeding decisions. The interviews will explore the following:

- Sociocultural norms and beliefs shaping exclusive breastfeeding and introduction of complementary foods
- Family dynamics and multi-generational influence on infant feeding decision-making
- Perceived challenges and facilitators to supporting healthy growth from pregnancy through 24 months after birth.

Findings from this phase will directly inform the initial design of intervention components, ensuring they reflect real family structures, cultural norms, and the practical needs and constraints of the target population.

Co-creation Workshops (Refining Strategy): Two sets of co-creation workshops will refine the intervention strategies and delivery modalities.

1. **Workshops with mothers and families:** Two sessions each with 15–20 women with prior GDM and their family members (early planning phase). Each session will include four homogeneous discussion groups of 5-10 participants. Groups will be separated by generational status (e.g., mothers/parents-in-law vs. younger women) to minimise power imbalances and the “seniority effect” commonly observed in Asian cultural contexts. This structure aims to facilitate open discussion among younger mothers regarding challenges in childcare and infant feeding without fear of contradicting elder family members. Further, a later follow-up workshop will be conducted with pregnant women/mothers only to assess feasibility and discuss how to conduct effective group counseling at the commune health station (CHS). Comments and suggestions to revise the new educational materials, which focus on the 1-2 year period.

2. **Workshops with healthcare professionals:** we will invite 6 directors and 6 staff who work in the maternal and neonatal healthcare. Two focus group discussions will be conducted to explore the advantages and disadvantages of health counseling in the CHS, also to gain insights and suggestions for an effective intervention group counseling in the CHS.

Across all workshops, the facilitator team will comprise staff trained and experienced in PPI methods to maintain equitable participation and ensure that all voices are heard. Further, the co-created content will be shared and discussed with a panel of experts.

PPI in Trial Conduct and Implementation

PPI contributors will play a vital role in improving participant materials and procedures (e.g., educational brochures, mobile app interfaces, private groups, etc.) to ensure the language is accessible and non-stigmatising.

Trial Design

Design, allocation, unit of randomisation and analysis framework

This study is a two-arm, parallel-group, superiority cluster randomised controlled trial with 1:1 allocation to the intervention (standard care + “Healthy Habits” – complex intervention [expanded package]) or control group (standard care + website access [basic package]). The unit of randomisation is the commune (cluster). All eligible mother–child pairs within a given commune will be assigned to the same study arm according to the cluster allocation.

Cluster randomisation is used due to the family-based and community-oriented nature of the intervention, which introduces a risk of contamination between participants within the same commune, healthcare setting, or social networks. Randomising at the cluster level reduces this risk and better reflects real-world implementation. The unit of analysis will be the individual participant (child-mother dyads), with statistical analyses accounting for clustering at the commune level using appropriate methods. The trial is designed as a superiority trial to evaluate whether the Healthy Habits intervention leads to improved outcomes compared with standard care + website access.

Population and follow-up window

Eligible participants will be enrolled at the time of GDM diagnosis (GA 24-28) and follow-up will continue until the child is 24 months after birth. Data collection will span pregnancy, delivery, and 24 months after birth.

Comparative aim

The trial is designed to determine whether the “Healthy Habits” intervention [extended package] differs to standard care + website access [basic package] on the prespecified clinical outcomes.

Primary comparative objective and hypotheses

- Null hypothesis (H_0): The length of exclusive breastfeeding is equal in the intervention and control groups.
- Alternative hypothesis (H_1): The length of exclusive breastfeeding differs in the intervention group and in the control group with 28 days - a difference considered clinically meaningful.

Methods – Participants, Interventions, and Outcomes

Trial Setting

The VALID III study will be conducted in northern Vietnam, primarily in the southeastern area of Hung Yen province. This area previously belonged to Thai Binh province before the administrative reform implemented in July 2025, when Thai Binh and Hung Yen were merged into a single administrative province. A total of 65 communes were identified as eligible for inclusion. Due to logistical and feasibility constraints, including prior engagement, accessibility, and capacity to support field activities, 29 communes in Hung Yen were selected for participation. The selection was conducted prior to randomisation and independent of study outcomes. Random allocation of the selected communes to intervention and control arms will ensure internal validity of comparisons. A list of participating communes is available from the study team upon reasonable request.

Participants will be recruited among pregnant women attending routine antenatal care at two collaborating healthcare facilities: (1) Thai Binh Obstetrics and Gynaecology Hospital and (2) Kim Ngan Clinic. Thai Binh Obstetrics and Gynaecology Hospital is a public hospital with approximately 11,000 deliveries per year, providing both antenatal and delivery care for pregnant women in the region. Kim Ngan Clinic is a private clinic that primarily provides antenatal care services for pregnant women. These two facilities were selected because they provide routine antenatal care and GDM screening for a large number of pregnant women in the study area. Based on findings from the VALID II study, approximately 25% of all pregnant women will be diagnosed with GDM according to the World Health Organization (WHO) recommendations [40].

The project will provide a free oral glucose tolerance test (OGTT) for GDM screening. The availability of the free OGTT provided by the project will be introduced by attending obstetricians during routine early antenatal visits, alongside posters and flyers at the participating hospital and clinic. As the OGTT is not covered under statutory health insurance, all procedural costs associated with the test will be fully covered by the project fund. Participants will incur no out-of-pocket expenses for study-related testing. This measure is intended to remove financial barriers to participation and adhere strictly to ethical guidelines without providing excessive financial incentives. When women attend the hospital or clinic for the OGTT, they will be approached by the research team and invited to participate in the study while waiting for their OGTT results. Participation in the

RCT is entirely voluntary, and declining participation will have no consequences for their clinical care, access to the free OGTT, or future treatment within the healthcare system.

GDM will be diagnosed using a 2-hour 75-g OGTT performed between 24 and 28 weeks of gestation. The diagnosis of GDM will be made when one or more of the following plasma glucose values are met or exceeded: fasting glucose ≥5.1 mmol/L, 1-hour ≥10.0 mmol/L, or 2-hour ≥8.5 mmol/L, according to recommendations from the WHO [40]. All women who are interested in participating in the RCT will undergo an includsion interview prior to knowing the results of the OGTT and their GDM status. Women diagnosed with GDM who accept to participate in the RCT will proceed with study participation and follow-up according to the study protocol, whereas women without GDM will not be followed further. For women who refuse to participate in RCT, the basic demographic data will be collected from women with their consent.

Participant recruitment and clinical data collection during pregnancy and around delivery will take place at Thai Binh Obstetrics and Gynaecology Hospital and Kim Ngan Clinic . Based on knowledge from the team's prior research project (VALID II), the majority of deliveries will take place at Thai Binh Obstetrics and Gynaecology Hospital, however, some women will delivery at another hospital. To minimise loss to follow-up among women who do not deliver at Thai Binh Obstetrics and Gynaecology Hospital, women who plan to deliver at another hospital will be monitored closely around the time of delivery. Follow-up assessments will primarily be conducted through home visits, allowing detailed assessment of maternal and child health in the family environment.

The intervention and follow-up period will run from the time of GDM diagnosis during pregnancy until the child reaches 24 months of age. The project is conducted through collaboration between Thai Binh University of Medicine and Pharmacy (TBUMP), the University of Copenhagen (UCPH), and the University of Southern Denmark (SDU), with collaboration from Hanoi Medical University (HMU) and Vietnamese health authorities.

Eligibility Criteria

Inclusion criteria

- Confirmed GDM diagnosis in the current pregnancy according to WHO criteria and enrolled no longer than seven days after diagnosis.
- Gestational age at enrolment ≤ 28+0 weeks of pregnancy.
- Maternal age ≥18 years at consent.
- Pregnancy with singleton gestation
- Residence within the study catchment area.
- Language proficiency sufficient to complete consent and study procedures in Vietnamese.

- Capacity to provide informed consent and willingness to participate in all trial procedures, including randomisation.

Exclusion criteria

- Pregestational diabetes (type 1 or type 2) diagnosed prior to this pregnancy.
- Severe chronic medical conditions and chronic severe mental health conditions likely to interfere with participation, safety, or outcome assessment (e.g., advanced cardiac, renal, hepatic disease; active malignancy; severe uncontrolled endocrine disease other than GDM, schizophrenia, active psychosis).
- Inability to provide informed consent[1].
- Pregnant women with multiple gestations.
- Pregnant women where it is biologically impossible for the woman to breastfeed, e.g., the woman has undergone bilateral mastectomy.
- Any other condition that, in the judgment of the investigators, makes participation inappropriate or infeasible, e.g., surrogate mother.

Interventions and Comparator

Intervention group: VALID III "Healthy Habits" Intervention (extended package)

Participants randomised to the intervention group will receive the VALID III "Healthy Habits" intervention – a culturally tailored gender-sensitive, intergenerational, complex health intervention designed to promote healthy habits during pregnancy and early childhood. The intervention targets women diagnosed with GDM and their families, particularly partners and grandparents, recognising the important role of extended family members in childcare, feeding practices, and household food environments in Vietnam. The intervention aims to support families in establishing practices that promote healthy infant feeding, maternal health and reduce the risk of childhood obesity. The intervention will start at time of GDM diagnosis during pregnancy and until 24 months after delivery.

The intervention will be co-created and is expected to include the following components:

1. *Nutrition and Infant Feeding Support (printed manuals + digital)*

Participants will receive practical guidance on:

- Optimal maternal diet during pregnancy and after birth
- Breastfeeding support starting in pregnancy and promotion of exclusive breastfeeding for 6 months
- Healthy complementary feeding practices
- Household food environments and family meal practices.

[1] The pregnant woman is the primary participant and will provide written informed consent. Other family members (e.g., husband, grandparents and/or parents-in-law) are involved during home visits, the study will be explained to them, and interviews will only be conducted if they agree and provide written informed consent.

2. *Physical Activity Guidance (printed manuals + digital)*

Participants will receive guidance on appropriate physical activity during pregnancy and the postpartum period. Instructional materials, including videos demonstrating suitable exercises and yoga for pregnant and postpartum women, will also be available through the project website. The intervention will also promote healthy family activities, encouraging parents and family members to engage in regular physical activity and active play with the child to support healthy family habits.

3. *Family Engagement*

Family members, including fathers/partners and grandparents, will be involved in the intervention to strengthen family support for healthy infant feeding practices and maternal health.

4. *Self-Care and GDM Management (printed manuals + digital)*

Participants will receive information and guidance related to GDM management, including dietary management and blood glucose monitoring, and free blood glucose testing at commune health station.

5. *Digital Support*

Digital tools will be used to support communication and participant engagement during the intervention. Communication with participants will be facilitated through the communication platform Zalo, which will be used to send reminders about study visits, health information, and motivational messages related to maternal and child health. Participants will also be introduced to the VALID project website (https://www.babaukhoemanh.com/en). The website was developed as an outcome of the previous VALID II project and provides guidance and instructional videos on GDM self-care. For VALID III, additional elements will be developed for the website, which only the intervention group will be able to access including educational materials and instructional videos on breastfeeding, infant feeding, and child health. The structure and content of the digital materials will be described in the VALID III intervention manual developed through a co-creation process with women with GDM, their families, and healthcare providers. The intervention group will also receive standard care in addition to the intervention.

6. *Group counseling at commune health stations*

To integrate digital health support with face-to-face primary care, structured group counseling sessions will be conducted at CHSs by trained primary healthcare workers. Women with GDM and key family members (husbands, grandparents) will receive practical

guidance, share experiences, and support one another in adopting healthy behaviors. The sessions will reinforce knowledge and self-care skills gained through the digital platform and support their application in daily life. This model links face-to-face primary care with continuous digital support, strengthening continuity of care and helping maintain healthy lifestyle behaviors throughout the postpartum period.

Control group: Standard Care + website access (basic package)

Participants randomised to the control group will receive standard care for GDM according to routine clinical practice in the Vietnamese healthcare system.

Standard care may include:

- routine antenatal care
- dietary counseling
- blood glucose monitoring
- referral to endocrinology counseling
- pharmacological treatment if clinically indicated.

In addition to standard care, participants in the control group will receive a link to the "VALID website" for guidance on managing GDM: https://www.babaukhoemanh.com/en.

Theoretical framework guiding intervention

This intervention is primarily guided by the 5-C model of accompaniment, a context-specific framework and theory of change developed in the previous VALID-II study. The model conceptualises accompaniment as a relational, process-oriented approach through which interventions support GDM self-care via presence, human connection, and sustained engagement. It identifies five key components – co-creation, combined knowledge, community spirit, continued presence, and commitment over time – that together describe how accompaniment operates and generates impact. The 5-C model specifies the mechanisms through which the intervention is expected to improve outcomes by enabling women to mobilise knowledge, leverage family support, and create space for self-care, thereby addressing practical, emotional, and social barriers. In this way, the intervention functions not only as a source of information but as a form of relational infrastructure that fosters engagement, empowerment, and behavior change [41].

Secondarily, the intervention is informed by Bronfenbrenner's social ecological model, which highlights how health behaviors are shaped by interacting influences across individual, interpersonal, community, and health system levels [42,43].

A key objective of this study is to further develop a theory of change for intergenerational obesity prevention after GDM. Building on the VALID-II approach, trial results will be used to deepen understanding of the mechanisms, pathways, and contextual factors through which accompaniment influences outcomes.

Adherence to Intervention

Adherence will be encouraged through regular communication with participants, culturally appropriate educational materials that match the lives of Vietnamese women and families, and ongoing engagement through the Zalo platform.

Participation in intervention activities will be documented by the research team.

Concomitant Care

All participants will continue to receive routine antenatal, delivery, and postpartum care throughout the study. Participation in the study will not affect access to healthcare services.

Outcomes

The effectiveness of the intervention will be evaluated using a combination of quantitative outcome measures and a process evaluation. The trial will assess a set of pre-specified primary and secondary quantitively outcomes, alongside additional exploratory outcomes to allow for broader hypothesis generation and secondary analyses. Analyses involving exploratory outcomes will be considered descriptive and interpreted with appropriate caution, given their non-confirmatory nature and the potential for multiple comparisons. The process evaluation will explore participants' experiences, implementation fidelity, and mechanisms of effect.

Quantitative outcomes

Primary Outcome

Primary outcome: Duration of exclusive breastfeeding	
Description of outcome	The primary outcome of the trial is exclusive breastfeeding, measured as a continuous variable representing the duration of exclusive breastfeeding during the first 180 days after birth. Infant feeding practices from birth to 180 days after birth will be prospectively recorded using a structured hard-copy Infant Feeding Diary, completed by mothers on a weekly basis. Participants will be provided with a booklet containing a table with 24 weekly rows (corresponding to the first 180 days). For each week, mothers will be instructed to indicate all types of feeding the infant received by ticking predefined categories, including Breast milk directly from the breast; Expressed breast milk; Infant formula; Water; Tea, juice, or other drinks; Infant cereal or porridge; Purees or solid foods. Mothers will be instructed to mark all applicable feeding types even if the item was given only once during that week, ensuring sensitive detection of any introduction of non-breastmilk foods or fluids. In addition, mothers will be asked to record the exact date of first introduction of any liquids other than breast milk or any foods by writing the date next to the corresponding checkmark as well as any relevant notes or contextual information in the comments field. The diary will be kept in the mother's home. During home visits at 3 months and 6 months after birth, research assistants will capture diary content in photographs which will be included in the project's database. Research assistants will receive standardised training and diaries will be used consistently throughout study arms.
Definition	As it is standard practice in Vietnam that children receive supplements while hospitalised and/or within the first week after birth, we define exclusive breastfeeding as breastfeeding with no other food or drink, not even water following the first week of birth. Breastfeeding by a wet nurse, feeding of expressed breast milk, and feeding of donor human milk all count as being fed breast milk. Prescribed medicines, oral rehydration solution, vitamins and minerals are not counted as fluids or foods. However, herbal fluids and similar traditional medicines are considered fluids, and infants who consume them are not exclusively breastfed.
Timepoint for assessment	Day 1-180 after birth.
Assessment methods	Weekly report in infant feeding diary.
Indicator definition	Length (in days) of exclusive breastfeeding during the first 180 days of life among infants.
Measurement of continuous outcome	Total number of days each infant was exclusively breastfed during the first 6 months of life, derived by integrating information from 24-hour recall data collected through monthly maternal feeding diaries and IYCF-based questionnaire at 6 months.

Secondary Outcomes

Secondary outcome: Proportion of exclusive breastfeeding at 180 days (6 months) after birth	
Definition	Proportion of exclusive breastfeeding (as defined above) at 180 days after birth.
Timepoint for assessment	180 days (6 months) after birth
Assessment method	*Prospectively:* Infant feeding diary.
Indicator definition	Percentage of infants at 180 days of age who were fed exclusively breastfed
Numerator	Infants 180 days of age who were fed only breastfed
Denominator	Infants 180 days of age included in study sample

Secondary outcome: Child fat mass index (FMI) at 24 months after birth	
Definition	Fat Mass Index (FMI)= Fat mass (kg)/height (m^2)

Timepoint for assessment	24 months after birth
Assessment method	Skinfold thickness measurements (SFM) and bioelectrical impedance analysis (BIA) with validated prediction equations
Indicator definition	Mean fat mass index (kg/m²) among children at 24 months of age, estimated using skinfold thickness measurements (SFM) and bioelectrical impedance analysis (BIA) with validated prediction equations
Numerator	Estimated fat mass (kg) for each child at 24 months, derived from SFM and/or BIA measurements using validated methods.
Denominator	Squared height (m²) of each child at 24 months, used to calculate FMI (fat mass ÷ height²).

Explorative outcomes

Explorative outcome*: Child anthropometry and body composition*	
Definition	Physical growth indices and body composition parameters including weight, recumbent length/height, mid-upper arm circumference (MUAC), skinfold thickness measurements (SFM), and bioelectrical impedance analysis (BIA)
Timepoint for assessment	At 6, 12, and 24months after birth
Assessment method	Skinfold thickness measurements (SFM) and bioelectrical impedance analysis (BIA) with validated prediction equations.
Indicator definition	Mean fat mass (kg) and fat-free mass (kg) among children at each assessment time point, estimated using skinfold thickness measurements (SFM), bioelectrical impedance analysis (BIA), and anthropometric measurements (weight and length/height) with validated prediction equations.
Numerator	Estimated fat mass (kg) and fat-free mass (kg) for each child at each time point, derived from SFM and/or BIA measurements using validated methods.
Denominator	Total number of children assessed at each respective time point.

Explorative outcome: *Neonatal anthropometric measurements*	
Definition	Newborn physical growth parameters at birth, including birth weight, recumbent length, skinfold thickness (triceps, subscapular), and mid-upper arm circumference (MUAC)
Timepoint for assessment	At delivery
Assessment method	Calibrated electronic infant scales, infant length measuring board, skinfold calipers (SFM), and non-stretchable MUAC tape.
Indicator definition	Mean birth weight (g), mean length (cm), mean SFM (mm), mean MUAC (cm), and proportions of Large-for-Gestational-Age (LGA) or Small-for-Gestational-Age (SGA).
Numerator	Measured values of each index.
Denominator	Total live births assessed at delivery

Explorative outcome: *Child socio-emotional development*	
Definition	Child feeding patterns, behaviors, illness patterns, and environmental factors related to obesity risk, including dietary intake and diet quality, sedentary behavior and screen time, physical activity, sleep duration, parenting practices (feeding, activity, sleep), and household food environment.
Timepoint for assessment	At 6, 12 and 24 months after birth
Assessment method	Assessed using various validated including WHO Infant and Young Child Feeding (IYCF) questionnaire
Indicator definition	Mean levels or standardized scores of behavioural and environmental obesity risk factors (e.g., IYCF indicators, dietary quality scores, screen time (hours/day), physical activity levels, sleep duration, and parenting/environment scores) at each assessment time point.
Numerator	Measured values or scores for each behavioural or environmental factor for each child at each time point, derived from validated instruments (including WHO IYCF questionnaire).
Denominator	Total number of children assessed at each respective time point with available data.

Other outcome: *Maternal glycaemic control in pregnancy*	
Definition	HbA1c (glycated hemoglobin) reflects the average blood glucose concentration over the past ~8–12 weeks and is measured from a blood sample
Timepoint for assessment	Baseline (at diagnosis of gestational diabetes mellitus during 24-28 weeks of gestation) and at delivery
Assessment method	Venous blood samples using standardised laboratory method
Indicator definition	Mean change in HbA1c (%) from time of GDM diagnosis (GA24-28) to delivery among pregnant individuals, based on laboratory-measured HbA1c values.
Numerator	The individual change in HbA1c (%) from diagnosis to delivery for each participant, calculated as HbA1c at delivery minus HbA1c at baseline (GDM diagnosis).
Denominator	Total number of pregnant individuals with available HbA1c measurements at both diagnosis and delivery.

Explorative outcome: *Maternal long-term metabolic health*	
Definition	Maternal metabolic health biomarkers comprise measures of glycaemic control (HbA1c, fasting glucose), insulin metabolism (fasting insulin and C-peptide), and lipid metabolism (LDL cholesterol, HDL cholesterol, triglycerides, and total cholesterol).
Timepoint for assessment	24 months after birth.
Assessment method	Venous blood samples using standardised laboratory method
Indicator definition	Mean levels of maternal metabolic biomarkers, including HbA1c (%), fasting glucose (mmol/L), fasting insulin (pmol/L or µU/mL), C-peptide (nmol/L), and lipid profile components (LDL cholesterol, HDL cholesterol, triglycerides, and total cholesterol; mmol/L), at each assessment time point, measured using validated laboratory methods.
Numerator	Measured values of HbA1c, fasting glucose, fasting insulin, C-peptide, and lipid profile parameters for each participant at 24 months after birth.
Denominator	Total number of mothers assessed with available measurements for the relevant biomarker.

Explorative outcome: *Maternal Informal social support*	
Definition	Maternal perceived availability and adequacy of informal social support from family, friends, and significant others, reflecting the mother's access to emotional, informational, and practical support.
Timepoint for assessment	Baseline (24–28 weeks' gestation, at the time of the oral glucose tolerance test [OGTT]), 6, 12, and 24 months after birth
Assessment method	Assessed using a validated 12-item Multidimensional Scale of Perceived Social Support (MSPSS)
Indicator definition	Mean maternal perceived social support scores at each assessment time point, measured using the MSPSS, including: Total MSPSS score (overall perceived social support); Subscale scores for support from family, friends, and significant others; Scores are calculated according to standard MSPSS scoring procedures (mean of items, range 1–7), with higher scores indicating greater perceived social support.
Numerator	Individual MSPSS scores (total and subscale scores) for each participant at each time point, calculated as the mean of item responses.
Denominator	Total number of mothers assessed at each respective time point with available MSPSS data.

Explorative outcome: *Maternal quality of life*	
Definition	Maternal quality of life, including health-related quality of life, family health, and maternal mental health, reflecting physical, psychological, and social well-being after childbirth.
Timepoint for assessment	Baseline (at the time of the oral glucose tolerance test, performed between 24 and 28 weeks of gestation), 6, 12, and 24 months after birth
Assessment method	Assessed using validated instruments that measures health-related quality of life, including family health and functioning and maternal mental health, including EPDS, e.g., symptoms of depression, anxiety, or well-being)
Indicator definition	Mean scores of maternal quality of life domains at each assessment time point, derived from validated questionnaire instruments.
Numerator	Individual scores for each quality-of-life domain for each participant at each time point, obtained from validated instruments.

Denominator	Total number of mothers assessed at each respective time point with available questionnaire data.

Process evaluation of the intervention

Drawing on the UK Medical Research Council (MRC) framework for complex interventions [39], a process evaluation will be conducted to investigate participant experiences and the intervention's mechanisms of effect. This will include a qualitative sub-study to investigate family experiences with the intervention, drawing on ethnographic interviews and focus groups with parents and grandparents [34,39,44–46]. The qualitative study includes a subgroup of the intervention group (n=20), using purposeful sampling to ensure diverse perspectives. This qualitative approach moves beyond numerical data to understand the cultural mechanisms and social structures influencing intervention dynamics. Assessed through in-depth interviews and ethnographic observations with a purposive subsample of mother-grandparent dyads during home visits at:

- 6 months
- 12 months
- 24 months after birth

Key focus areas include:

- *Implementation and engagement*: how participants interact with the intervention activities, as well as the barriers and facilitators influencing access to and sustained participation.
- *Acceptability and perceptions:* participants' perceptions of the relevance, usability, and cultural appropriateness of the intervention content, as well as their trust in information provided by health professionals and peer networks.
- *Mechanisms of behaviour change:* how the intervention influences knowledge, self-efficacy, and self-care practices.
- *Social support pathways:* how peer support and family involvement are mobilised through the intervention, as well as the role of family members in facilitating or constraining behaviour change.
- *Contextual factors:* how family structures, gender norms, and sociocultural contexts shape engagement with and responses to the intervention, as well as the interaction between intervention recommendations and existing household practices. Qualitative findings will be integrated with quantitative results to provide a comprehensive understanding of intervention effectiveness and to explain variations in outcomes across participant groups and over time.

Harms

The intervention consists primarily of educational and behavioural components and is therefore considered low risk. Potential risks include:

- minor discomfort related to drawing blood, anthropometric or body composition measurements
- emotional discomfort when discussing infant feeding practices or family dynamics

- potential feelings of guilt, stigma, or perceived judgement related to infant feeding practices or challenges with breastfeeding
- potential privacy concerns related to digital communication through the Zalo platform.

Participants will be informed that participation is voluntary and that they may withdraw from the study at any time without consequences for their access to healthcare. Any adverse events reported by participants or observed by study staff will be documented and managed according to ethical guidelines.

Participant Timeline

A total of 2000 pregnant women at 24–28 weeks of gestation who attend Kim Ngan Clinic and Thai Binh Obstetrics and Gynecology Hospital for an OGTT will be recruited for the VALID III study. All enrolled participants will complete a baseline inclusion interview before receiving their OGTT results and knowing their GDM status. Women diagnosed with GDM based on national guidelines will be invited to participate in the VALID III RCT and be enrolled if they provide informed consent. Participants will be followed from pregnancy (GDM diagnosis at GA 24-28) with follow-up assessments at approximately 48 hours after birth and at 5-6 months, 12 months, and 24 months after birth. These follow-up assessments will primarily be conducted at hospital where they are admitted to deliver (please see more in the **Appendix 1 - Flowchart**).

Sample Size, Randomisation, and Blinding Procedures

Sample Size

<u>Primary outcome: Duration of exclusive breastfeeding up to 180 days after birth</u>

The primary outcome is duration of exclusive breastfeeding, treated as a continuous variable. The sample size calculation is based on data from the VALID II population, in which the duration of exclusive breastfeeding was 16.8 weeks (118 days) with a standard deviation (SD) of 9.4 weeks (66 days). The Healthy Habits intervention is designed to increase the duration of exclusive breastfeeding by 28 days (4 weeks), a difference considered clinically meaningful and supported by prior evidence. I.e., the trial is designed as a superiority trial, with the 4-week increase as the minimum detectable difference.

The required sample size calculation through several steps A two-sample t-test for independent means was used, assuming a two-sided significance level of $\alpha = 0.05$, 80% power, and equal allocation between the intervention and control groups (1:1). A power level of 80% was selected as it is widely used in clinical research and represents an appropriate balance between statistical rigor and feasibility. Using an observed standard deviation of 9.4 weeks, the study is designed to detect a clinically meaningful difference of at least four weeks (28 days) in breastfeeding duration from a control mean of 16.8 weeks (118 days). This corresponds to a standardised effect size of approximately 0.43. Based on these assumptions, the required sample size is *176 women in total (88 per group).*

However, as the trial uses a cluster randomised design, with communes as the unit of randomisation, the sample size has been further adjusted to account for within-cluster correlation. The design effect (DE) is calculated as:

$$DE = 1 + (m - 1) \times ICC$$

where *m* is the average cluster size and ICC is the intra-cluster correlation coefficient. Based on local data from the communes where we will enroll, the mean is 24 pregnant women/month (urban communes) and 20 women/month (rural communes). Assuming an average cluster size of 22 participants per commune and an ICC of 0.01, the design effect is:

$$DE = 1 + (22 - 1) \times 0.01 = 1.21$$

Hence, the total required sample size is:

$$N_{total} = 176 \times 1.21 = 213 \text{ participants (214 since equal group size required)}$$

Because a substantial proportion of women in the study population return to work around 6 months, and because return to work is known to limit availability for follow-up assessments, an attrition rate of approximately 30% by the final assessment is anticipated.

The sample size was therefore adjusted as follows:

$$n_{\text{adjusted}} = \frac{214}{0.70} \approx 306 \text{ participants}$$

Thus, the final sample size required to ensure adequate power to detect a 4-week difference in breastfeeding duration is approximately 306 participants in total.

Recruitment

Participants will be recruited from Thai Binh Maternity Hospital and Kim Ngan Clinic in the study area. Trained research staff will approach eligible pregnant women at GA 24-28 who attend these facilities for OGTT. Eligible women will receive both written and verbal information about the study. Those who agree to participate will provide written informed consent prior to enrolment. Following the OGTT screening, only women diagnosed with GDM according to national guidelines will be invited to participate in the RCT. Recruitment will continue until the required sample size for the randomised controlled trial has been reached. Participant retention will be supported through close collaboration with local healthcare providers, flexible scheduling of follow-up visits, and home-based follow-up assessments.

To ensure that the required sample size for the trial is achieved, a multistage recruitment model was developed based on expected participation behaviour within the study population and observed patterns from the VALID II cohort.

Recruitment begins by inviting pregnant women at the time they are scheduled for routine GDM screening. However, not all invited women proceed through each step of the recruitment pathway. Based on clinical experience with this population and operational data from comparable screening programs, we anticipate the following sequential participation rates:

1. *Completion of GDM screening:* A small proportion (~5%) are expected to be unable to complete the GDM screening procedure (e.g., due to intolerance of oral glucose load), resulting in a 95% completion rate among attendees.
2. *GDM positivity rate:* Based on recent data in the target population, approximately 25% of screened women are expected to meet diagnostic criteria for GDM and therefore be eligible for the *trial.*
3. *Consent to randomisation:* Among women who screen positive for GDM, we expect 20% to decline randomisation, reflecting preferences around family involvement, lifestyle interventions, and postpartum follow-up demands. Thus, an estimated 80% of screen-positive women will consent to participate in the RCT.

When combined multiplicatively, these sequential proportions yield an estimated overall enrolment rate of 0.95 × 0.25 × 0.80 = 0.19, indicating that approximately 19% of invited women will ultimately be randomised into the trial. Thus, to achieve the planned sample size of 306 participants (after adjustment for clustering and attrition), the study will need to invite approximately:

$$\frac{306}{0.19} \approx 1{,}610 \text{ pregnant women}$$

However, to ensure adequate statistical power against real-world variations, such as a potentially lower GDM positivity rate or lower consent rates due to the intensive 24-month postpartum follow-up, the study aims to screen approximately 2,000 pregnant women. This recruitment target accounts for participation behaviour across all stages of the recruitment pathway and ensures adequate sample size for the primary outcome.

Randomisation

Randomisation will be conducted at the commune level, with communes serving as clusters. All eligible participants within a commune will be assigned to the same study arm. To ensure balance between study arms, a stratified randomisation will be used based on first commune type:

- Urban communes (n=5)
- Rural communes (n=24)

And secondarily population size within each commune to ensure an even distribution of population sizes. Within each stratum, communes will be randomly allocated in a 1:1 ratio to the intervention or control arm.

The list of communes, including commune type (urban/rural), population size, and corresponding old district names, is provided in **Appendix 2**

A map illustrating the geographic distribution of the communes included in the study area within Hung Yen province is provided in **Appendix 3**

Allocation Concealment Mechanism

Randomisation will be conducted at the commune level after identification and enrolment of all eligible communes and prior to participant recruitment. The communes will be informed about their intervention assignment prior to the start of implementation through formal written communication issued by the study team, followed by a briefing meeting to explain the intervention procedures, timelines, and expectations. The random allocation sequence will be generated externally by an independent statistician using computer-generated random numbers in Stata, with stratification according to predefined commune-level characteristics. The statistician responsible for generating the allocation sequence will not be involved in participant recruitment, intervention delivery, or outcome assessment. The allocation sequence will be securely stored and only shared with designated study personnel after all communes have been irrevocably assigned to the intervention or control arm. Investigators, clinicians, recruiters, and intervention staff will remain blinded to the allocation sequence throughout the randomisation process and will not be able to predict or influence assignment. Because the allocation sequence is generated independently and implemented without involvement of recruiting staff, allocation concealment is fully maintained.

Implementation

Following generation of the allocation sequence, each commune will be assigned to either the intervention or control arm. The allocation list will be securely transferred to the designated trial coordinator (RCT manager), who is responsible for implementing the assignments. Pregnant women who screen positive for GDM and provide informed consent will be enrolled into the study and receive the intervention corresponding to the allocation of their commune. The RCT manager will inform the intervention and control sites of new participants.

Blinding

Due to the behavioural and family-based nature of the intervention, participants as well as intervention facilitators – including outcome assessors (study nurses who conduct home-visits) – cannot be blinded to group assignment. This introduces potential risks of performance and detection bias. To mitigate these risks, several measures will be implemented. First, outcome assessments will follow standardised protocols, with detailed operational guidelines and structured data collection tools to minimize subjective

interpretation. Study nurses will receive rigorous training and regular supervision to ensure consistent application of measurement procedures across clusters. To limit differential behaviour between study arms, all communes will receive similar levels of contact with the study team, aside from the intervention itself. Clear guidance will be provided to intervention staff and participants to avoid introducing additional co-interventions. Finally, data analysts will remain blinded until the primary analysis is completed, with groups labelled as “Group A” and “Group B.”

Data Collection, Management, Statistical Analysis, Monitoring, and Ethics

Data Collection

Data collection methods

Data will be collected by trained study nurses and midwives. Information will be obtained through face-to-face structured interviews, clinical measurements, and the extraction of relevant information from hospital medical records.

At baseline during antenatal care visits, information on socio-demographic characteristics, health behaviours, dietary practices, and informal social support will be collected using structured questionnaires. Clinical information during pregnancy, including OGTT results, will be obtained from participants’ laboratory reports, as this test is performed as part of routine antenatal care at the hospital.

Anthropometric measurements of newborns and young children, including weight and length, will be obtained using calibrated electronic scales and length measuring boards following standardised measurement procedures. Fat mass and fat-free mass will be assessed using bioelectrical impedance analysis (BIA) and skinfold measurements (SFM). All measurements for the same mother-child pair will be performed by the same trained research staff member whenever possible to ensure measurement accuracy and comparability across time points.

During postnatal follow-up visits, the child’s caregiver will complete structured questionnaires on infant and young child feeding practices, child diet, physical activity, sleep habits, the household food environment, and household food security. Maternal outcomes, including mental health, quality of life, and informal social support, will also be assessed using pre-designed questionnaires.

All research staff involved in data collection will undergo standardised training prior to the start of the study. Measurement procedures will follow standardised guidelines, and all equipment will be calibrated regularly to ensure data quality.

Strategies to promote participant retention and complete follow-up

Several strategies will be implemented to maintain participant engagement and minimise loss to follow-up throughout the study period. Participants will receive reminders prior to scheduled visits through phone calls or messaging applications. Flexible appointment scheduling will be offered to accommodate participants' availability as well as follow-up in relation to planned vaccination visits.

If participants are unable to attend scheduled visits at the health facility, the research team will arrange alternative options such as rescheduling appointments or conducting home visits when feasible. For laboratory indicators other than the OGTT, which is performed at the health facility, biological sample collection may be combined with home interviews conducted by trained research staff. Biological samples collected as part of the study will be transported to the hospital laboratory and analysed according to standardised procedures to ensure sample quality and accuracy of laboratory results.

Data Management

Data capture and entry

Data will be collected using hard-copy questionnaires and medical record extractions at the study sites. Trained interviewers will enter data into a secure electronic data capture platform hosted at Thai Binh University of Medicine and Pharmacy (TBUMP). The study will use REDCap (Research Electronic Data Capture), a widely used, validated, web-based data management tool designed for clinical and research data capture.

Data storage and security

All study data will be stored on a local, secure institutional server managed by TBUMP. Access to REDCap will be restricted to authorised project staff via individual, password-protected logins. Server access follows TBUMP's institutional data protection policies, and all connections are encrypted. In addition to electronic data storage, paper-based records are also maintained and securely stored in a dedicated project office at TBUMP, with access restricted and kept in a locked cabinet. Data will be retained for 10 years after trial completion in compliance with institutional and national research data retention standards.

Data pseudonymisation

All participant data will be pseudonymised at the point of entry. Identifying information will be stored separately from study data in a password-protected file accessible only to the Principal Investigator and designated data managers. A unique study ID will be used for all analytic datasets.

Signed informed consent forms will be stored separately from study data in a locked cabinet in a secure project office at TBUMP. Access will be restricted to authorised research staff only. Consent forms will not be entered into the study database.

Data quality procedures

Data quality will be maintained through a combination of automated data validation rules in REDCap and scheduled manual reviews. Automated validation rules will include:

- Range checks for numeric variables
- Allowable value restrictions for categorical fields
- Branching logic to prevent inconsistent entries
- Required field enforcement for critical variables
- Date format and chronological consistency checks

In addition to automated data validation, the study's data manager will conduct quarterly data quality audits to identify missing values, detect improbable entries, check cross-variable consistency, and verify a random sample of entries against original paper questionnaires and medical records.

Access to data

Access to the REDCap project will be limited to study project staff and data entry clerks, with role-based permissions to ensure that team members can only view or edit the data necessary for their responsibilities. A full audit trail will track all data creation, modification, and export events.

Statistical Methods

Statistical Methods for Primary and Secondary Outcomes

Primary outcome: Duration of Exclusive Breastfeeding (continuous outcome)

The primary analysis will compare the duration of exclusive breastfeeding between the intervention and control groups using a linear mixed-effects regression model, accounting for clustering at the commune level. A random intercept for commune will be included to account for within-cluster correlation. The primary effect estimate will be reported as the adjusted mean difference (MD) between groups with 95% confidence intervals and two-sided p-values ($\alpha = 0.05$). The model will include treatment group as the primary fixed effect and will adjust for stratification variables used in the randomisation (e.g., urban/rural and population size). Model assumptions will be assessed using residual diagnostics, including inspection of normality and homoscedasticity. If substantial deviations from normality are observed, a transformation of the outcome or a non-parametric sensitivity analysis will be considered. As a sensitivity analysis, a generalised estimating equation (GEE) with an identity link and exchangeable correlation structure will be used to estimate population-averaged effects.

Key Secondary Outcome: Exclusive Breastfeeding at 6 Months (binary)

The proportion of participants exclusively breastfeeding at 6 months will be analysed using a generalised estimating equation (GEE) model with a log link and binomial distribution to

estimate the risk ratio (RR), accounting for clustering at the commune level. An exchangeable working correlation structure will be specified. Robust standard errors will be used to ensure valid inference even if the correlation structure is mis-specified. Adjusted analyses will include stratification variables used in the randomisation. Additional exploratory analyses adjusting for baseline covariates will be reported separately.

Key Secondary Outcome: Child Fat Mass Index (FMI) and Fat-free Mass Index (FFMI) at 24 Months (continuous)

Mean FMI and FFMI at 24 months will be analysed using a linear mixed-effects regression model, including a random intercept for commune to account for clustering. Results will be reported as adjusted mean differences with 95% confidence intervals and two-sided p-values ($\alpha = 0.05$). Model assumptions will be assessed using residual diagnostics. If substantial deviations from normality are observed, appropriate transformations or non-parametric sensitivity analyses will be conducted. As a sensitivity analysis, a GEE model with identity link will be used to estimate population-averaged effects.

Definition of Analysis Populations and Group Assignment

For all outcomes, analyses will follow the intention-to-treat (ITT) principle, unless otherwise specified. The ITT population will include all participants enrolled in the trial and analysed according to the allocation of their commune (cluster) at randomisation, regardless of adherence to the intervention or protocol deviations. Because the unit of randomisation is the commune, participants will be analysed according to their cluster assignment. A per-protocol population will be defined for sensitivity analyses and will include participants with no major protocol deviations, as prespecified in the statistical analysis plan.

Handling of Missing Data and Post-enrolment Events

All enrolled participants will be included in the study and analysed according to their assigned cluster. However, some mother–infant dyads may be unable to contribute data to the primary outcome because post-enrollment events preclude exclusive breastfeeding, for example maternal death, pregnancies not resulting in live births, infants who die within the study period, or medical conditions that permanently prevent breastfeeding. In such cases, participants will be excluded onlyfrom analyses of specific outcomes for which valid measurement is not possible or clinically meaningful. Consequently, the analysis population may vary across outcomes depending on the availability and relevance of outcome data. All post-enrolment events affecting outcome ascertainment will be documented and reported in the trial flow diagram.

Another category of missing data includes outcomes that are theoretically measurable but not observed, for example due to non-attendance at follow-up visits or loss to follow-up. Patterns and reasons for missingness will be summarised by treatment group, taking clustering into account. We hypothesise that non-measurable outcomes will be rare and not systematically related to intervention assignment; however, differential occurrence by group will be formally assessed. For outcomes that are missing but theoretically measurable, multiple imputation under a missing at random (MAR) assumption will be

used, with imputation models including treatment group, cluster identifiers, and relevant baseline covariates to appropriately reflect the clustered structure of the data.

If evidence suggests differential missingness or implausibility of the MAR assumption, sensitivity analyses will include complete case analyses and worst-case/best-case imputation scenarios. For intercurrent events that preclude breastfeeding (e.g., infant death or maternal conditions preventing breastfeeding), additional sensitivity analyses will assess the robustness of findings, including analyses excluding these cases and analyses where such outcomes are assigned a value of zero duration of exclusive breastfeeding. Consistency of conclusions across analyses will guide interpretation.

Methods for Additional Analyses (Subgroup & Sensitivity Analyses)

Subgroup Analyses

Prespecified subgroups:

- Study site (Kim Ngan Clinic vs. Maternity Hospital)
- Age
- Education level
- First-time mothers
- Fertility treatment
- Infant sex
- Household form (Nuclear versus extended families/co-living with grandparents)
- Working conditions

These variables are clinically relevant predictors of breastfeeding behaviours and infant growth patterns and may plausibly modify the intervention effect. Subgroup analyses will be interpreted as exploratory, not confirmatory.

Sensitivity Analyses

Planned sensitivity analyses:

- Per-protocol analyses for all primary and key secondary outcomes.
- Time-to-event (stopping breastfeeding) for the primary outcome to estimate mean/median duration for censored observations
- Missing-not-at-random assumptions.
- Use of robust standard errors and, where appropriate, alternative correlation structures (for GEE models) to assess robustness of the findings to model specifications.
- Cluster-level analyses (e.g., comparing cluster means between groups) as a sensitivity analysis to confirm consistency of findings with individual-level analyses.
- Adjusted analyses adding covariates with baseline imbalance.

In Vietnamese culture, women may stay at their parental home for several months during the postpartum period. Therefore, it is possible that some participants who reside in the intervention commune may temporarily live in a control commune or vice versa. In addition to the abovementioned sensitivity analyses, the following sensitivity analysis will be conducted:

- Excluding participants with substantial cross-arm exposure, i.e., lived more than 60 days (2 months) in an opposite arm commune than the one they have been exposed to.

Further, preterm birth (<37+0 weeks of gestation) is associated with substantially different breastfeeding patterns and infant body composition. Major congenital anomalies of the child that are detected during pregnancy or after delivery may potentially affect the child's physical development and ability to breastfeed. Therefore, the following sensitivity analyses will also be conducted:

- Excluding mother-child dyads with preterm birth (<37+0 weeks of gestation)
- Excluding mother-child dyads with major child congenital anomalies.

Data Monitoring Committee & Trial Monitoring

Data Monitoring Committee

A Data Monitoring Committee (DMC) will not be established for this trial. The intervention is a minimal-risk behavioural programme and does not involve investigational drugs, medical devices, procedures, or other exposures with known or anticipated safety concerns. The likelihood of serious or unexpected harm is therefore considered low, and the trial does not warrant independent data safety oversight.

Oversight of study conduct, data integrity, and safety monitoring will instead be the responsibility of the Project Management Team, consisting of the Principal Investigator and designated co-investigators. This team will review recruitment progress, protocol adherence, data quality, and safety reports at regular intervals.

Item 28b: Interim analyses and Stopping Guidelines

No interim analyses are planned for this study. Given the minimal risk of the behavioural intervention and the absence of anticipated adverse effects, no formal statistical stopping guidelines have been defined.

The trial will continue as planned unless new information arises that suggests the intervention may pose unforeseen risks, in which case the Principal Investigator will consult with the ethics committee and sponsor regarding potential protocol modifications or pausing of recruitment.

Harms and safety monitoring

The intervention is classified as minimal risk. Nevertheless, procedures are in place to ensure that any adverse events (AEs) or concerns are appropriately captured and managed. AEs will be identified by data collectors during study visits or through reports from participants. The Project Team will assess the nature, severity, and relatedness of each event. All AEs determined to be relevant to the study will be reported to the study sponsor (DANIDA) and to the Ethics Committee at Thai Binh University of Medicine and Pharmacy (TBUMP) in accordance with their reporting requirements.

Serious adverse events (SAEs)

Although SAEs are not expected, any SAE that occurs during the study period—whether or not related to the intervention—will be reported to the ethics committee and sponsor within their mandated timelines.

Stopping rules

There are no predefined stopping thresholds, given the behavioural and low-risk nature of the intervention. Any decision to pause or terminate the study will be made collaboratively by the Principal Investigator, sponsor, and ethics committee based on emerging evidence or unanticipated concerns.

Data sharing plan

The investigators support the principles of transparency and responsible data sharing. However, this study involves sensitive clinical data related to reproductive and child health, and data sharing must comply with applicable ethical and legal requirements. In Vietnam, the Personal Data Protection Law (Law No. 91/2025/QH15) establishes strict provisions governing the processing and sharing of personal and sensitive data, including requirements related to informed consent and data security. The informed consent obtained from participants does not explicitly permit unrestricted public data sharing.

Therefore, the study data will not be made publicly available. Aggregated data that cannot identify individual persons may be shared under a controlled access model upon reasonable request to the corresponding author, subject to review of the proposed use, compliance with ethical approvals, and execution of an appropriate data use agreement. Requests will be evaluated to ensure that data are used for scientifically valid purposes and interpreted within an appropriate clinical context.

Ethics and Dissemination

Ethical approval

The study protocol was approved by the Ethics Committee of Thai Binh University of Medicine and Pharmacy (No.14/GCN-HĐĐĐ-YDTB) before the study was initiated. All participants will be provided with full information about the study, including their rights as research participants. Participation in the study will be entirely voluntary. Written informed

consent will be obtained from all participants before enrolment in the study, and participants will have the right to refuse participation or withdraw from the study at any time without affecting their access to routine healthcare services.

For postnatal follow-up activities involving infants and young children, consent for the child's participation will be obtained from the mother or legal guardian.

Any modifications to the study protocol that may affect the study objectives, design, eligibility criteria, data collection procedures, or participant safety will be submitted to the ethics committee for review and approval prior to implementation.

Confidentiality

All personal information collected during the study will be kept confidential. Each participant will be assigned a unique study identification number, and only authorised members of the research team will have access to identifiable data. Electronic data will be stored on OneDrive and protected by secure passwords, while paper-based documents will be kept in locked cabinets in offices with restricted access.

Remuneration

Participants will receive 100,000 VND per interview to compensate for travel costs and time spent in the study. This compensation is not intended to influence or coerce participation in the research. For co-creation workshops, participants will receive 250.000 VND as compensation for their time. In addition, they will be reimbursed for travel expenses, calculated based on the distance between their home and the workshop venue.

Declaration of interests

The research team declares that there are no financial or personal conflicts of interest related to this study.

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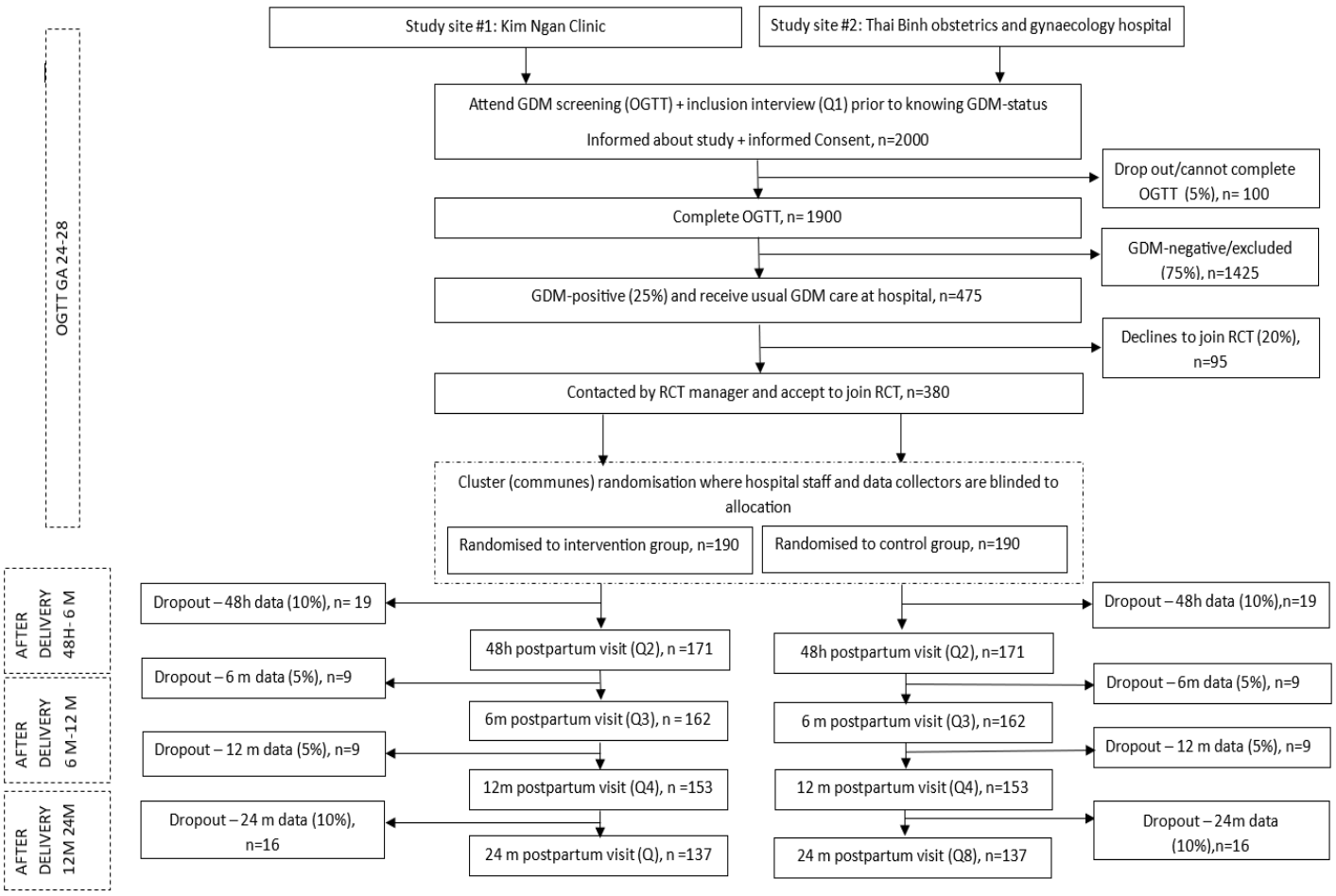
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Appendix 1 - Flowchart

Appendix 2. Characteristics of communes included in cluster randomization

Area	No.	New commune name	Population size	Old district/city name
Urban	1	Thái Bình	62930	Thai Binh city
	2	Trần Lãm	92332	
	3	Trần Hưng Đạo	44449	
	4	Trà Lý	42359	
	5	Vũ Phúc	41183	
Rural	6	Đông Hưng	47564	Dong Hung district
	7	Bắc Đông Hưng	22776	
	8	Nam Đông Hưng	23753	
	9	Bắc Tiên Hưng	40859	
	10	Đông Tiên Hưng	23017	
	11	Nam Tiên Hưng	30143	
	12	Tiên Hưng	25365	
	13	Bắc Đông Quan	22776	
	14	Đông Quan	23414	
	15	Kiến Xương	47725	Kien Xuong district
	16	Lê Lợi	26442	
	17	Quang Lịch	19479	
	18	Vũ Quý	27276	
	19	Bình Thanh	23169	
	20	Bình Định	22058	
	21	Hồng Vũ	23459	
	22	Bình Nguyên	19083	
	23	Trà Giang	19775	
	24	Vũ Thư	42998	Vu Thu district

	25	Thư Trì	26132	
	26	Tân Thuận	30460	
	27	Thư Vũ	35540	
	28	Vũ Tiên	38380	
	29	Vạn Xuân	36661	



Appendix 3. Map of Hung Yen province showing study communes