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Lipid-focused dietary education intervention in pregnant women: study protocol for an open-label, parallel, randomised, intervention study addressing adverse pregnancy outcomes in China

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ABSTRACT

Introduction The incidence of infants who are large-for-gestational-age (LGA) is on the rise in China, and its detrimental effects on health have received increasing attention. Diet-based interventions have the potential to reduce adverse birth outcomes, particularly in decreasing the occurrence of LGA infants. We aim to evaluate the effect of lipid-focused diet education based on the theories of behaviour change in pregnant women on maternal and offspring outcomes through a randomised controlled trial.

Methods and analysis We have designed an open-label, parallel, multicentre randomised controlled trial in collaboration with three hospitals in Beijing, China. Pregnant women will be recruited before reaching 12 weeks of gestation and will be randomised in a 1:1:1 ratio into three arms: (1) online education arm, (2) pregnancy nutrition checklist and 'one-page flyer' arm and (3) routine antenatal education. The primary outcome LGA will be recorded at birth. Demographic information, physical activity, sleep and medical history will be collected through questionnaires and case cards prior to enrolment. Questionnaires will also be used to collect dietary behaviours and psychosocial factors of pregnant women at enrolment, at 24–28 weeks and 34–36 weeks of gestation. Additionally, information on breastfeeding and complementary food supplementation for infants and young children will be obtained through questionnaires. Physical development indicators of children and taste tests will be assessed 3 years after delivery.

Ethics and dissemination The study has received ethical approval from the Capital Medical University Ethics Committee and other collaborating study centres. Informed consent will be introduced to pregnant women, and their consent will be obtained. The findings will be reported in relevant national and international academic conferences and peer-reviewed publications.

Trial registration number ChiCTR2300071126.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study is a rigorous cause-and-effect randomised controlled study.
⇒ This study includes a large sample size that will be able to detect small differences.
⇒ The pilot study has already proven that prenatal nutrition education activities based on behavioural change theory have beneficial effects on participants.
⇒ Due to the characteristics of the study design, participants are aware of the intervention they receive.
⇒ People to be included in the study are being recruited from different research centres and will receive different levels of routine maternal education.

INTRODUCTION

A large-for-gestational-age (LGA) baby is defined as a newborn weighing above the 90th percentile of newborns for the same gestational age (SGA). In China, approximately 10.1% of infants are classified as LGA,[1] and the incidence is higher among pregnant women with high gestational weight gain.[2] Studies have shown that LGA can have adverse effects on both pregnant women and infants. Maternal outcomes for those giving birth to an LGA infant are more likely to have a higher risk of caesarean delivery, birth canal injury and postpartum haemorrhage.[3] Infants who are LGA have an increased risk of shoulder dystocia, clavicle fractures, brachial plexus injury and increased admissions to the neonatal intensive care unit.[3] Follow-up studies have also shown that LGA infants face an increased risk of early obesity, metabolic disease and giving birth to LGA offspring.[4–6] Individuals giving birth to LGA infants or

experiencing excessive weight gain during pregnancy are associated with several risk factors in adulthood, including overweight and obesity, gestational diabetes mellitus (GDM), lack of physical activity during pregnancy and a high consumption of sugar and fat.[2 7]

The role of diet in gestational weight gain and the incidence of LGA

Several countries have established specific dietary guidelines for pregnant women, including China.[8] However, a dietary survey conducted in 2015 among pregnant women in eight major cities in China showed that the average energy intake during pregnancy was 2098 Kcal, with fat accounting for 36.4% (median 37.7%) of the total energy, exceeding the recommended amount of 25%–30%.[9] A 2016 study in Shaanxi, China, categorised foods into five major groups and analysed the energy sources for pregnant women from these different food groups. The main sources of energy for pregnant women were snacks (19%), meats (16%) and edible oil (11%), while the main sources of fat were cooking oil (25%), meats (24%) and nuts (16%).[10] In a recent 2021 dietary survey of pregnant women in Shanghai, China, the authors found that 66.6% of the participants exceeded the recommended intake levels for poultry and meat, and 46.3% exceeded the recommended oil intake.[11] The rapid industrialisation of the food system in developing countries such as China has led to increased availability of high-energy density and low-nutritional quality foods,[12 13] contributing to excessive dietary fat in pregnant women. Previous studies have suggested that a diet high in fat, particularly saturated fatty acids and low in polyunsaturated fatty acids in diet may be risk factors for GDM, excessive weight gain and LGA infants.[14–16] In cases of maternal overnutrition and insulin resistance, high levels of triglyceride are hydrolysed by placental lipase into free fatty acids and can enter the fetus.[17] Fetal exposure to excess freefatty acids may result in lipid storage due to limited fatty acid oxidation capacity, leading to a higher risk for adverse pregnancy outcomes, including LGA.[15 18] Observational study shows that maternal free fatty acid levels in early pregnancy are significantly associated with childhood overweight or obesity.[19]

Decreasing the risk of LGA through diet intervention

Many previous studies have investigated the effect of dietary interventions on health outcomes. A prospective cohort study showed that pregnant women with better dietary fat quality (low saturated fatty acids, high polyunsaturated fatty acids) had a lower incidence of LGA.[20] An intervention aimed at preventing LGA and controlling birth weight provided guidance on a low-glycaemic, low-saturated fat diet and physical activity for pregnant women who were overweight or obese. The intervention reduced the incidence of GDM and LGA significantly.[21] In another trial, focusing solely on a low glycaemic index diet did not reduce the incidence of high birth weight, and fat intake was positively correlated with neonatal central adiposity.[22] This might be due to the fact that when recommending a low-carb diet, there also must be a focus on not exceeding the saturated fat recommendation, as low-carb foods are often replaced with foods high in saturated fat.[23] Moreover, meta-analyses have indicated that controlling saturated fatty acid intake for the general population might improve their metabolic status and reduce the risk of cardiovascular disease.[24 25] However, a low-fat diet alone did not achieve a better outcome in chronic disease prevention than a Mediterranean diet, which is characterised by a moderate amount of fat intake but mostly monounsaturated fat.[26] This might be due to the complexity of the dietary components of a dietary pattern. Increasing or decreasing a single nutrient without considering the overall macronutrient distribution of foods could have a negative impact on health outcomes, as the health effects of foods cannot be predicted by the content of any single nutrient group.[27] Research shows that from 1991 to 2011, the consumption of meat by Chinese residents continued to increase, but seafood remained relatively low.[28] This may be due to price and dietary habits.[28] Therefore, adopting direct Mediterranean dietary intervention for pregnancy dietary guidance in China may lead to poor compliance. In order to reduce pregnant women's high-fat diet behaviour, improve the quality of dietary fat (increase unsaturated fatty acids, decrease saturated fatty acids and eliminate trans fatty acids) and promote dietary balance, we develop a lipid-focused intervention based on the Dietary Guidelines for Chinese Residents. The main goal is to guide and encourage pregnant women to change unhealthy dietary behaviours characterised by a high-fat intake, which is supplemented by encouraging them to increase the consumption of vegetables and fruits, whole grains, deep-sea fish and shrimp, nuts, etc and adjusting the frequency of eating. The intervention starts in early pregnancy, as most women only visit the hospitals for dietary guidance when they realise they are already pregnant, and their motivation to change is strong when they become mother-to-be. Also, many pregnancies are unplanned in China, so it is more practical to start the intervention in early pregnancy.

Theoretical model for intervention

Pregnant women's dietary patterns are influenced by many factors, such as predetermined biological factors, early exposure and experience, psychosocial factors and environmental factors.[29] Previous studies have shown that lifestyle interventions and nutrition education addressing various determinants based on psychosocial theories could lead to positive changes in pregnant women's diet and physical activity levels.[30] A healthy lifestyle is beneficial for both pregnant women and their offspring.[31] Pregnant women are at a special life stage with a clear and urgent need for a healthy dietary pattern and a strong motivation to improve their offspring's health.[32] The theory of planned behaviour (TPB) shown in figure 1 was first proposed as a theory of reasoned action in 1975 to predict an individual's intention to engage in

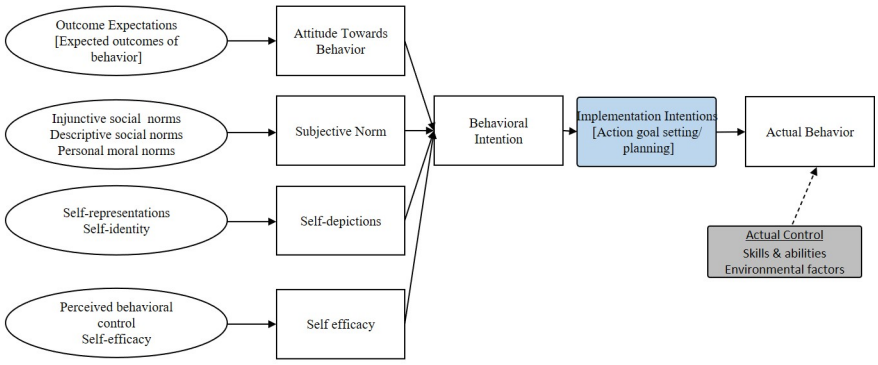

Figure 1 Extended theory of planned behaviour/reasoned action approach.

a behaviour at a specific place and time.[33] The TPB has been successful in predicting and explaining a wide range of intentions and behaviours, including diet, smoking, drinking, breast feeding and substance use.[34–37] It mainly focuses on enhancing the motivation of participants and takes into account the impact of attitudes, perceived norms and self-efficacy on the formation of behavioural intention. The application of the TPB theory has been on the rise since it was first introduced by Ajzen in 1985. As of 2010, more than 4000 publications cited the theory.[38] Many intervention studies based on the TPB model have also been effective in leading to positive changes in eating habits and nutrition status, such as increasing fruit and vegetable intake,[39] reducing unhealthy snack intake[40] and increasing calcium-rich foods intake.[41]

For this study, we have developed a multicomponent nutrition education intervention based on the extended TPB model,[29 42] as shown in figure 1, focusing on controlling total fat intake and improving the quality of diet lipids based on a balanced dietary pattern. Outcome expectations, self-efficacy and action goal setting are the centre of our focus. The primary aim is to assess whether the intervention will reduce the risk of the delivery of an LGA infant for pregnant women. Compared with group course education, prenatal dietary guidance provided by obstetricians may be more authoritative, convenient, and therefore, more useful for pregnant women. Therefore, while verifying the effectiveness of a lipid-focused dietary group education intervention based on TPB theory, this study established another intervention group that only distributed manuals that included intervention content. This low-cost and highly scalable intervention method provides a scientific basis for integrating intervention content into routine obstetric examinations in the future.

METHODS AND ANALYSIS

Study design

This is a multicentre, 1:1:1 ratio, parallel, open-blind randomised controlled trial (RCT). The study design strictly adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) quality standard criteria for RCTs. The participating centres in this study are Fuxing Hospital affiliated with Capital Medical University; Xuanwu Hospital Affiliated with Capital Medical University; and Beijing Haidian District Maternal and Child Healthcare Hospital, all located in Beijing, China. The detailed process is outlined in figure 2, and the timeline is shown in table 1. The study was initiated in May 2023 and is expected to conclude in August 2024. As of the revision date, the pilot study (2022), formal experimental course design and qualitative research (August 2023), and the cross-sectional survey of questionnaire reliability and validity (September 2023) have been successfully completed.

Eligibility criteria

Eligible participants will be pregnant women, inclusive of all gender identities.

Inclusion criteria

Singleton pregnancy, conceived through natural insemination, with a gestational age <12 weeks, and signed informed consent.

Exclusion criteria

Multifetal pregnancy, in vitro fertilization, pre-existing type 1 or type 2 diabetes, fetal malformations including chromosomal abnormalities or structural malformations detected by ultrasonography, fetal congenital infections or abnormalities, adherence to a restricted diet (including vegans), medical conditions that could potentially affect the intervention or follow-up (including severe cardiovascular and kidney diseases result in limited physical activity and require diet under professional guidance), and unwillingness or inability to provide informed consent.

Intervention

Eligible participants will be randomised into one of the three groups: (group 1) online nutrition education; (group 2) pregnancy nutrition checklist and 'one-page flyer' for self-learning and (group 3) routine antenatal education without any intervention.

Group 1: online nutrition education arm

The first intervention group will receive six sessions of 1-hour nutrition education by video conferencing (table 2). The course design was based on the TPB model and followed the DESIGN procedure[29] of Contento

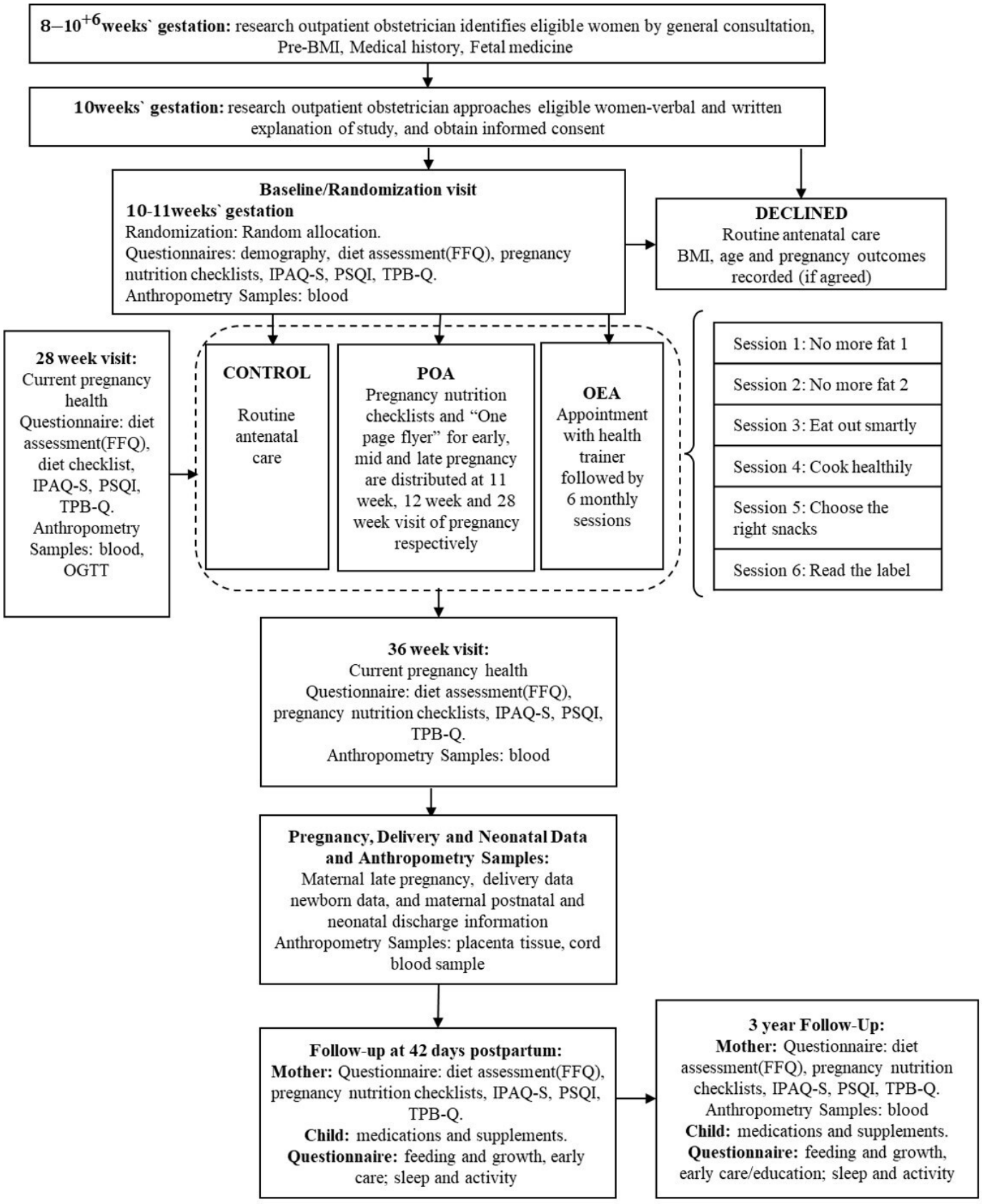

Figure 2 Study design including the screening, recruitment, randomisation process and the conduct flow. BMI, body mass index; FFQ, food frequency questionnaire; IPAQ-S, International Physical Activity Questionnaire-Short Form; OEA, online education arm; OGTT, oral glucose tolerance test; POA, pregnancy nutrition checklist and 'one-page flyer' arm; PSQI, The Pittsburgh Sleep Quality Index; TPB-Q, Theory of Planned Behaviour Questionnaire.

Table 1 Timeline of intervention and information collection

	Enrolment and allocation	Post-allocation				Postpartum	
Time point	**Before 11 weeks**	**11–12 weeks**	**24–26 weeks**	**34–36 weeks**	**Delivery**	**42 days postnatal**	**3 years postnatal**
Enrolment	√						
Eligibility screen	√						
Informed consent	√						
Allocation	√						
Interventions							
OEA		√	√	√			
POA		√	√	√			
RAC		√	√	√			
Assessments							
Baseline data							
Demographic		√					
Current pregnancy health			√				
Diet Assessment (FFQ), Questionnaire		√	√	√		√	√
Pregnancy nutrition checklist		√	√	√		√	√
TPB-Q		√	√	√		√	√
IPAQ, PSQI		√	√	√		√	√
Child Feeding and Development, early care, sleep and activity						√	√
Primary outcome							
LGA, GDM					√		
Second outcome							
Mantel pregnancy outcome (mode of delivery, pregnancy complications and GWG, etc)					√		
Fetal outcome (birth weight, placenta weight, SGA, preterm, Apgar score, etc)					√		
Infant length and weight						√	√

FFQ, food frequency questionnaire; GDM, gestational diabetes mellitus; GWG, gestational weight gain; IPAQ-S, International Physical Activity Questionnaire - Short Form; LGA, large-for-gestational age; OEA, online education arm; POA, pregnancy nutrition checklist and 'one-page flyer' arm; PSQI, The Pittsburgh Sleep Quality Index; RAC, routine antenatal care; SGA, same gestational age; TPB-Q, Theory of Planned Behaviour Questionnaire.

and Koch. The DESIGN procedure is a simple, systematic, six-step process that integrates food and nutrition science, psychological theories, education principles and communication skills. It provides a framework for planning theory-based, behaviour-focused nutrition education that translates theory and evidence into activities, materials, group discussions and social media. Two graduate students majoring in nutrition will lead the course. The overall goal of the course is to promote a balanced diet with a focus on controlling fat intake. The general goal can be further broken down into three specific behavioural change goals: choosing the right food to eat, cooking healthily and reading nutrition labels so they can identify healthy packaged food. According to the previous records of the participating hospitals, over 95% of the pregnant women have a high-school degree and all of them are literate, therefore, would be able to comprehend the course content.

Group 2: pregnancy nutrition checklist and 'one-page flyer' arm

A 17-item pregnancy nutrition checklist and 'one-page' flyer are distributed to the participants by physicians at

Table 2 Course topics and behavioural strategies

Them	Behavioural strategy	Diet topic
Session 1: No more fat 1	1. Outcome expectations 2. Factual knowledge and skill 3. Self-efficacy/perceive behaviour control 4. Analysis of pros and cons of change (behavioural intention)	Benefits of a balanced diet Recognising dietary gaps Identifying high-fat foods Using fists and hands to estimate servings, and overcoming Challenges associated with a high-fat diet
Session 2: No more fat 2	1. Negative outcomes of current behaviour 2. Perceived benefits 3. Self-depictions 4. Behavioural intention	The risks of trans fatty acids Knowing that a healthy cooked diet can be equally tasty Knowing that the mother's diet affects the child Learning to set dietary goals
Session 3: Eat out smartly	1. Negative outcomes of current behaviour 2. Knowledge and cognitive skills 3. Perceived norms 4. Self-efficacy	Understanding how to choose foods wisely when dining out or ordering delivery online
Session 4: Cook healthily	1. Perceived benefits 2. Skills and ability 3. Perceived barriers 4. Behavioural intention	Learning the recipes for healthy cooking
Session 5: Choose the right snacks	1. Perceived risk 2. Food and nutrition knowledge 3. Food preferences 4. Self-efficacy	Understanding the definition of ultra-processed foods Learning how to choose healthy snacks
Session 6: Read the label	1. Perceived benefits 2. Skills and ability 3. Perceived norms 4. Behavioural intention	Learning how to read nutrition labels and ingredient lists

their monthly pregnancy check-ups. Pregnant women can self-identify their nutrition problems through the checklist within 2 min and make behavioural changes by following the guidance in the 'one-page flyer'. The 17-item nutrition checklist was adapted from the FIGO checklist,[43] which is a very efficient way to assess the nutrition status of pregnant women.[44] This tool helps clinicians and pregnant women quickly identify imbalances in their dietary patterns. The checklist includes four parts: part 1: self-reported special dietary habits (eg, vegan, food allergy); part 2: self-reported height, weight and body mass index (BMI); part 3: 17 questions related to dietary habits with a focus on fat intake (most are yes or no questions) and part 4: grading criteria and interpretation of the checklist result. The 'one-page flyer' is an A4 paper-sized dietary instruction flyer. It is based on the TPB, including information on the adverse effects of a high-fat diet during pregnancy on mother and baby at the top of the page (outcome expectation), choosing healthy snacks, reading food labels, specific cooking tips using less oil (knowledge and skills), information on diet management aiming to increase confidence (perceived behaviour control and self-efficacy), guidance on establishing specific and feasible behaviour change goals (goal-setting using SMART theory).

Criteria for discontinuing or modifying allocated interventions

Not applicable due to the nature of the interventions.

Strategies to improving and measuring the adherence

Adherence to the online education sessions will be assessed by class attendance from sign-ins and visual scans of video conference attendees. We will set up an online group chat for participants to remind them to attend before the start of each class, and we will create a preclass check-in e-form, post-class Q&A and evaluation e-form to measure participation in the class. For the nutrition checklist and 'one-page flyer' arm (NOA), after the 17-item nutrition checklist and 'one-page flyer' were distributed, pregnant women underwent three dietary screenings in the early, middle and late stages of pregnancy, and provided one-on-one guidance on the main screening issues to improve maternal compliance.

The treatment will be considered complete if at least four out of the six sessions are attended for the online education arm. For the POA group, we will count the number of times pregnant women screen for nutritional issues (17-item pregnancy nutrition checklist) and use a questionnaire to investigate the reading status of 'one-page flyer'. Adherence to the nutrition behaviours will be assessed by an improvement of ≥3 points of their total scores of the 17-item pregnancy nutrition checklist compared with their total initial score.[45] The study population will be sorted according to adherence to the dietary guidelines, depending on the score: ≥12 high adherence, 6–11 moderate adherence and <6 low adherence.[45]

Relevant concomitant care permitted or prohibited during the trial

People who participate in this trial cannot participate in another trial.

Provisions for post-trial care

No post-trial care is needed since this is an educational intervention.

Outcomes

Adverse pregnancy outcomes

Primary outcome

The primary outcome will be the prevalence of LGA at birth, defined as the newborns with a measured birth weight above the 90th percentile (P_{90}) of the same sex were evaluated as LGA (growth standard for newborns by gestation in China, WS/T 800-2022).

Secondary outcomes

Neonatal: Birth weight, macrosomia (birth weight ≥4000 g), SGA (birth weight below the 10th percentile for gestational age) or low birth weight (birth weight ≤2500 g), preterm birth (<37 weeks' gestation), low Apgar score (Apgar<7), low birthweight infant (birth weight ≤2500 g), preterm birth (gestational age <37 weeks), Apgar score.

Maternal: GDM (GDM is diagnosed when the blood glucose value at any point in time meets or exceeds the above criteria: fasting, 1 hour after oral glucose and 2 hours after glucose thresholds of 5.1, 10.0 and 8.5 mmol/L, respectively), gestational hypertension (defined as >20 weeks' gestation, elevated blood pressure (BP) (systolic BP≥140 mm Hg or diastolic BP≥90 mm Hg) in the absence of proteinuria), caesarean section rate, birth canal injury rate, shoulder dystocia rate, maternal insulin treatment rate, maternal weight gain during pregnancy (maternal weight gain generally refers to maternal weight at delivery minus prepregnancy weight), preeclampsia (defined as >20 weeks' gestation, new-onset hypertension (systolic BP ≥140 mm Hg or diastolic BP≥90) mm Hg) and new-onset proteinuria (300 mg protein intake within 24 hours or urine protein/creatinine ratio 0.3 mg/dL), or in the absence of proteinuria, new-onset hypertension with new-onset thrombocytopaenia, renal insufficiency, impaired liver function, pulmonary oedema or cerebral or visual impairment), perinatal mortality (fetuses or neonates death at >28 weeks' gestation—within 7 days of postpartum).

Changes in dietary behaviours

Changes in dietary behaviours will be assessed by a dietary behaviour questionnaire, which was adapted from previous food frequency questionnaires (FFQ).[46 47] The questionnaire includes questions on the intake and frequency of consumption of different categories of foods, particularly high-fat foods.

We will also assess knowledge and skills related to cooking habits that can reduce fat intake and reading nutrition labels to choose low-fat foods when shopping. Behaviours related to adherence to the dietary guidelines will be assessed by the 17-item pregnancy nutrition checklist.

Changes in psychosocial determinants based on the TPB model

A questionnaire was developed to assess the changes in the four components (attitude towards behaviour, subjective norm, perceived behavioural control and behavioural intention) related to diet behaviours (reducing fat intake, cooking healthily and reading nutrition labels) based on the TPB before and after the intervention. The questionnaire was based on previous studies,[39 48] and content validity has been confirmed by experts in nutrition. Attitudes, perceived norms, self-efficacy, self-depictions and behavioural intention will be assessed as the mean of the statements under each component measured on 5-point unipolar (+1 to +5) scales.

We conducted a questionnaire survey (a cross-sectional survey) on pregnant women at three study sites to test the reliability and validity of The 17-item pregnancy nutrition checklist, FFQ and TPB-Q. This helps us to make timely corrections to inappropriate issues before the research begins. This population was randomly distributed between the intervention group and the control group, reducing the bias caused by this confirmatory survey.

Postpartum follow-up

The feeding types and complementary foods added will be investigated 42 days after delivery through a questionnaire to be developed. Children will be followed again at 3 years of age for diet, taste preferences and physical development. Children's diets will be assessed by a food frequency questionnaire based on a previous study.[32] Children's physical development will be assessed by their weight, height, sitting height and body composition, measured by body weight metre, mechanical height/sitting height metre and body composition analyser, respectively.

Other measures

A baseline survey is used to collect information on participants' demography, lifestyle (eg, sleep, physical activity), and medical and family history. Pregnant women's age, educational background, parity, pre-BMI, height, pre-weight and other information are sourced from their pregnancy records. This file is established by community doctors after one-on-one questioning and measurement. The weight gain during pregnancy is measured on outpatient scales or home scales and reported to the investigator on their own.

Sample size

The RCT uses the incidence of LGA as the primary outcome. The incidence of LGA in the general population is about 11.0%,[49] while the incidence in the intervention group is expected to be 5.0%.[50] Assuming a type 1 error of 5% and a power of 80%, 318 participants will be recruited. Allowing for a 20% drop-out, 400 participants

will be needed for each of the three arms, with an overall sample size of 1200 participants for the study.[51]

$$n = \frac{(z_{1-\alpha/2}+z_{1-\beta})^2[p_1(1-p_1)/k+p_2(1-p_2)]}{(p_1-p_2)^2}$$

Recruitment

At the first prenatal check-up, all eligible pregnant women will be introduced to the purpose of the study, the intervention, and the potential benefits and risks. Participants who agree to participate, after obtaining written informed consent, will be randomised into three different groups. Randomisation will be performed by using a computer system that randomly assigns participants into one of the three groups: (1) online nutrition education+ pregnancy nutrition checklist and flyer (2) pregnancy nutrition checklist and flyer for self-learning and (3) usual care without any intervention.

Randomisation

Allocation

The computer system (http://www.jerrydallal.com/random/randomize.htm) generates randomisation sequences based on the need of the study. The name of the intervention group, the number of groups and the sample size for each group are entered into the system to generate the allocation plan. Participants in different groups will receive different invitation links for their intervention to have unified management.

Concealment mechanism

Allocation concealment is ensured as the randomisation code is not released until the participants have met the eligibility and signed informed consent. The allocation is performed automatically by the computer without human control. Participants will receive a new inclusion number after the groups are formed, and the number is also used as a participant ID for the intervention lessons.

Implementation

The enrolment of the participants will be done by doctors who do not have information on group allocation, as the randomisation happens after the recruitment. Participants are first divided into different categories according to the plan and then randomised into three groups by research assistants of the study using the computer program.

Doctors will distribute the pregnancy nutrition checklist and one-page flyer to participants. Research assistants will guide how to use these materials.

Online nutrition education sessions will be delivered by two research assistants who are Ph.D. students majoring in nutrition. The course content and study materials have been reviewed by experts in nutrition.

Blinding

Due to the nature of the study design, it is not possible to blind participants or researchers in the study regarding the intervention type. Therefore, the study is blinded only to the clinical nurses responsible for grouping. Nurses responsible for enrolment recruitment were unaware of the grouping.

Procedure for unblinding if needed

Not applicable and the trial will not be blinded.

Statistical analysis

For demographic variables and outcomes, continuous variables will be presented using either the mean or median depending on whether they conform to a normal distribution, and categorical variables will be summarised using frequencies (%). The differences in LGA and GMD incidence among the three groups will be compared using χ^2 tests. Analysis of variance will be used to assess differences in birth weight, and the generalised estimating equation will be used for comparing gestational weight gain.[52]

We will use three analytical methods to analyse our study population.[53–55]

The intention-to-treat population (ITT), which includes all participants based on their initial random grouping, regardless of whether they completed all interventions; modified ITT population (mITT), which defined by excluding participants when the primary outcome (eg, stillbirth or intrauterine death of the newborn, congenital malformations) is absent; population per protocol (PP), which includes only those individuals with good adherence to the intervention for the purpose of analysis. For prerandomisation, baseline analysis, and primary and secondary efficacy variable analysis, we will use mITT analysis. The primary outcome analysis will initially use ITT for preliminary analysis and then use PP for the comparison of robustness.

The missing value treatment programme follows the guidelines outlined in CPMP/EWP/1776/99. Missing values are filled in for the main variables only, applying the following principles[56]: primary missing value imputation strategy: we will use imputed case analysis for the primary outcome (ie, the occurrence of LGA, which was defined as a birth weight greater than the 90th percentile of the mean weight of children of the SGA and sex); secondary missing value imputation strategy: we will use multiple imputations using the control group observations to fill missing data. The primary analyses are based on worst-case imputation scenario, while sensitivity analyses are conducted using the results of multiple imputations.

To identify susceptible subpopulations, we will conduct subgroup analysis by defending subgroups by research centres, corresponding obstetricians or nutrition physicians. Demographic variables such as age, pre-BMI (According to standard of recommendation for weight gain during pregnancy period, the prepregnancy BMI of pregnant women is divided into four categories: <18.5 kg/m^2, 18.5 kg/m^2≤BMI<24.0 kg/m^2, 24.0 kg/m^2≤BMI<28.0 kg/ and BMI≥28.0 kg/m^2), parity, level of education and place of residence will be used for sensitivity analyses.

Patient and public involvement

Before the formal commencement of the study, we will conduct a pilot study which includes a process evaluation and interviews with obstetricians, dietitians and pregnant women. The comments and recommendations gathered from these participants regarding the intervention will guide the revision and improvement of the final intervention. Throughout the intervention phase, we will document the intensity and completeness of the intervention, along with the acceptability and satisfaction levels among pregnant women. In this process, pregnant women, obstetricians and nutritionists will contribute their opinions and feedback on the study design, implementation, frequency and other aspects of the course content.

ETHICS AND DISSEMINATION

The study received ethical approval from the Capital Medical University Ethics Committee(Z2022SY077, Z2023SY137). Additionally, ethical approval was also granted by all centres. The research design followed SPIRIT recommendations and was registered with the Chinese Clinical Trial Registry (ChiCTR2300071126). The findings will be reported in relevant national and international academic conferences and peer-reviewed publications.

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Contributors HY led the design of the research protocol, HZ, IRC, PAK and SS gave design comments and feedback on the scheme. YZ and XG drafted and wrote the protocol, and HY, IRC and PAK reviewed and edited it. All authors contributed to the research project.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

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