BMJ Open

Behaviour model integrated by protection motivation theory and information–motivation–behavioural skills model applying in pregnancy weight management (PrInMAMa): a study protocol for a randomised controlled trial in China

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To cite: Ge J, Wang L, Peng X, *et al*. Behaviour model integrated by protection motivation theory and information–motivation–behavioural skills model applying in pregnancy weight management (PrInMAMa): a study protocol for a randomised controlled trial in China. *BMJ Open* 2022;**12**:e051275. doi:10.1136/bmjopen-2021-051275

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2021-051275).

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Received 14 March 2021
Accepted 22 December 2021

Check for updates

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ABSTRACT

Introduction Excessive gestational weight gain poses a significant threat to maternal and child health. The healthy behaviour theory has been increasingly applied to weight management during pregnancy, but research is still insufficient. The successful application of the protection motivation theory (PMT) and the information–motivation–behavioural skills (IMB) model in the field of healthy behaviour laid the foundation for this intervention study. The overall aim of this study is to test the effectiveness of interventions based on the behaviour model integrated with the PMT and IMB model (PMT–IMB model) on weight management and provide feasible methods for weight management during pregnancy.

Methods and analysis This prospective, single-centre, randomised controlled trial involves two steps. First, based on the PMT–IMB model, evaluation tools and intervention materials will be developed. Second, more than 800 women in the first trimester of pregnancy will be randomly assigned to two groups and will be followed until 1 week after delivery. The control group will receive standardised antenatal care (ANC), whereas the experimental group will receive both standardised ANC and interventions based on the PMT–IMB model. After three surveys (at enrolment, at 28 weeks of gestation, and on the day of hospitalisation for delivery), primary outcomes (scores of the subscales of the PMT–IMB model, scores of the pregnancy weight management strategy scale, and gestational weight gain) and secondary outcomes (pregnancy outcomes and pregnancy complications) will be obtained. Differences in outcomes between the two groups will be analysed to evaluate the effectiveness of the intervention.

Ethics and dissemination The study protocol has been approved by the ethics committee of Nanjing Medical University. All participants will sign an informed consent form prior to enrolment. The findings of the study will be published in peer-reviewed journals and presented at conferences.

Strengths and limitations of this study

- This is the first study to propose the protection motivation theory and the information–motivation–behavioural skills (PMT–IMB) model as a theoretical model for the interpretation, prediction and intervention of weight management behaviour during pregnancy.
- The PMT–IMB model covers all dimensions of the protection motivation theory and information–motivation–behavioural skills model so that the factors influencing weight management during pregnancy can be considered more comprehensively.
- Due to funding limitations, this study will be performed only in a specific range of populations, thus limiting the generalisability of these pregnancy weight management methods.
- Pregnant women who meet the inclusion and exclusion criteria but are not willing to participate in the programme may include those who are extremely resistant to weight management during pregnancy and may need more relevant health education.

Trial registration number ChiCTR2100043231

INTRODUCTION

Gestational weight gain (GWG) is considered a normal physiological change during pregnancy and is closely related to maternal and child health. Excessive GWG (EGWG), being overweight or obese, not only increases the incidence of pregnancy complications and adverse pregnancy outcomes[1–3] but also increases the risk of adverse health outcomes for offsprings throughout their life.[4 5] Based on the guidelines for weight gain during

pregnancy, revised by the American Institute of Medicine,[6] China has proposed an appropriate weight gain range during pregnancy for Chinese women.[7] The recommended GWG is as follows: underweight prepregnancy BMI (<18.5) gain of 12.5–18.0 kg, normal prepregnancy BMI (18.5–24.9) gain of 11.5–16.0 kg, overweight prepregnancy BMI (25.0–29.9) gain of 7.0–11.5 kg, and obese prepregnancy BMI (≥30.0) gain of 5.0–9.0 kg. Standardised antenatal care (ANC) in China provides measures and services for pregnancy weight management, such as diet and physical activity monitoring of pregnant women and measurement of their body weight at each ANC visit. However, the proportion of pregnant women with appropriate GWG is still low, and the problem of EGWG has become more prominent.[3 8 9] The rates of EGWG among pregnant Chinese women in the second and third trimesters are 53.6% and 46.5%, respectively; therefore, weight management during pregnancy needs to be improved urgently.[10]

The behavioural theory posits that internal factors such as awareness of information, psychological perception and behavioural skills are key to changes in health-related behaviours. Pregnant women who are more knowledgeable about weight management during pregnancy are more likely to control their GWG within the recommended range than those with less awareness of weight management during pregnancy.[11] Previous studies have found that pregnant women have insufficient psychological perception of weight gain, weak weight management awareness,[12] and a misunderstanding or are neglection of weight management during pregnancy.[13 14] Moreover, pregnant women still have extensive skill barriers in weight self-management.[15] Psychological perception deficiency hinders pregnant women from forming reasonable motivation for health protection behaviours, and information inadequacy and skill barriers are also important factors of unhealthy behaviours. Therefore, weight management strategies during pregnancy must consider psychological perception, awareness of information and behavioural skills related to weight control together.

At present, weight management for pregnant women mainly involves health education such as strengthening diet management, exercise guidance and individualised behavioural interventions based on the previous two methods.[16–19] Although studies have achieved good results from a holistic point of view, most intervention methods are simple combinations of various interventions and lack a systematic theoretical framework to support them. Studies have shown that interventions formed on a theoretical basis can be more effective than non-theoretical interventions on health-related behaviours.[20] From the perspective of health behaviour research, the analysis of relevant research performed in China shows that intervention studies with a theoretical basis[21 22] mostly focus on the respective effects of factors such as cognition[23] or skills on pregnancy weight management and ignore the more complicated path relationship between them. Therefore, the application of existing theories in the field of weight management during pregnancy is insufficient.

Protection motivation theory (PMT) states that protection motivation is a health decision made after the complete consideration of both threat and coping appraisal.[24] Threat appraisal refers to an individual's psychological perception of severity and vulnerability to unhealthy behaviours. Coping appraisal is a comprehensive result of response efficacy, self-efficacy and response costs for people, and evaluates a person's ability to cope with danger. The PMT plays an important role in explaining and predicting the protection willingness and behaviours of individuals.[25–29] In terms of behavioural interventions, PMT-based interventions can increase the occurrence of benign behaviours by improving individual cognitive levels.[30 31]

The information–motivation–behavioural skills (IMB) model, which was first proposed by Fisher *et al*[32] in their study of high-risk behaviours for HIV, has been applied to explain and predict the healthy lifestyle of adolescents[33 34] and the adherence to medication of patients with rare diseases.[35] Furthermore, behavioural interventions supported by the IMB model have proved to be applicable and effective in the health management of patients with chronic diseases.[36] The IMB model includes four core determinants: information, motivation, behavioural skills and behaviour. This model emphasises that explaining and predicting behaviour by using the motivation dimension alone is not enough and that the effect of information and behavioural skills on health behaviours should also be considered.

The wide application of the PMT and the IMB model in the interpretation, prediction and intervention of healthy behaviours provides a research basis for their application in the protective behaviours of pregnancy weight management. The PMT focuses on behavioural motivation and explains the formation of motivation for preventive behaviour from a psychological perspective. According to this theory, the IMB model can further associate motivation with information and behavioural skills, which cover the multiple dimensions needed to improve weight management during pregnancy. The combination of these two behavioural theories, namely, the PMT–IMB model, provides a more comprehensive behavioural theoretical model (figure 1). An intervention based on these two theories has proven to be effective in improving the psychological resilience and quality of life of patients with type 2 diabetes and reducing their blood glucose levels.[37]

The main purpose of this study is to demonstrate the effectiveness of health education interventions, that are designed based on the PMT–IMB model, on pregnancy weight management.

METHODS AND ANALYSIS

Study design

This is a prospective randomised controlled intervention trial that aims to test the effectiveness of health education

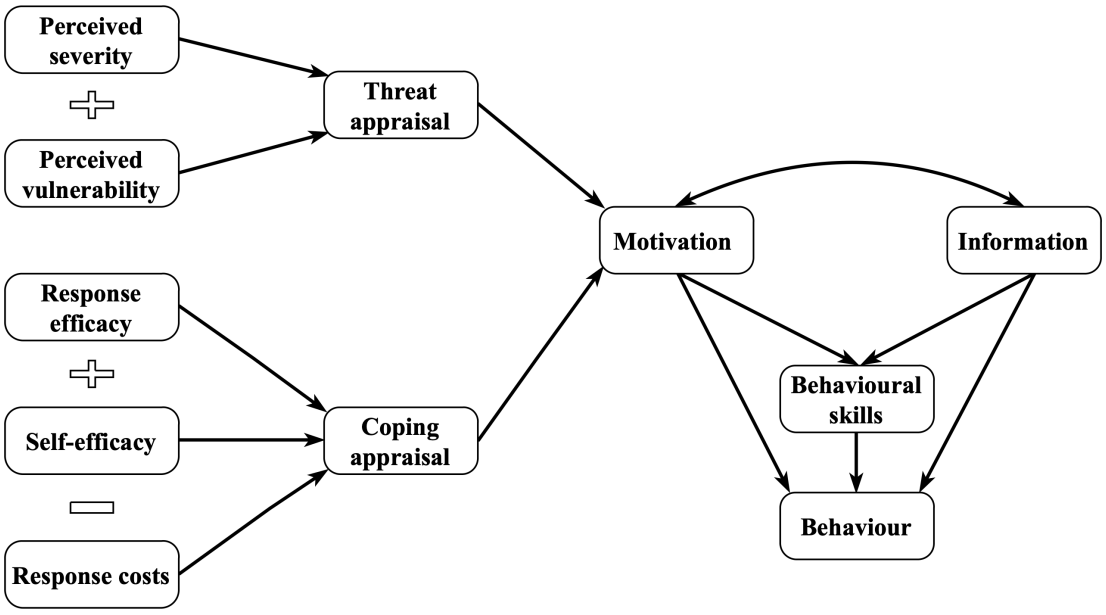

Figure 1 The PMT-IMB model. IMB, information–motivation–behavioural skills; PMT, protection motivation theory.

on weight management during pregnancy. This study will be conducted between June 2021 and December 2024. All pregnant women will be equally divided into an experimental and a control group by randomisation.

Preparation of evaluation tools and intervention plans

Instruments

Demographic questionnaire

A demographic questionnaire will be used to collect basic demographic information from participants and will include two sections. The first section will be a general information section and include questions on age, race, marital status, height, education level, career, income, health insurance, social support systems and medical history. The second section will be the main information section and focus on prepregnancy weight, weight during pregnancy (weight at the end of the second trimester and predelivery weight), pregnancy complications and biochemical indicators related to obesity.

Pregnancy Weight Management Strategy Scale

The Pregnancy Weight Management Strategy Scale (PWMSS), designed by Yan *et al*,[38] will be used to evaluate the effectiveness of pregnancy weight management strategies. This 27-item scale comprises six dimensions (management objectives, family support, dietary management, exercise management, stimulus policies and self-monitoring regulation) and uses a 5-point Likert scale ranging from 1 (never) to 5 (always). A higher PWMSS score indicates that more recommended strategies for weight management during pregnancy are used and that weight gain management during pregnancy is more effective. The content validity index (CVI) showed that the scale-level CVI/universal agreement (S-CVI/UA) is 0.83, scale-level CVI/average agreement (S-CVI/Ave) is 0.94 and item-level CVI (I-CVI) ranges from 0.85 to 1.00. Cronbach's α is 0.834. The Kaiser-Meyer-Olkin value is 0.819, and Bartlett's test of sphericity is significant (5298.004, p<0.001). The total variance of the six factors is 60.66%. The loading of each item is close to one in the corresponding factor, and the loading of the other factors is close to zero. The corresponding factor loading of each item is >0.5. This indicates that the scale has good structural validity.

Subscales of the PMT–IMB model

The PMT–IMB model serves as the theoretical framework of those scales, and the initial scales, which include seven dimensions (information dimension; behavioural skills dimension; and cognitive mediational process dimensions such as perceived severity, perceived vulnerability, response efficiency, self-efficacy, and response costs), will be established using the literature search and Delphi methods. Thereafter, the reliability and validity of the questionnaire will be tested using a small sample pretest. The formal version will be formed after adjustments to make the questionnaire more scientific. Finally, based on a large sample of a formal test, the reliability, structural validity and content validity of these subscales will be evaluated again to determine whether further generalisation is possible.

1. Survey on knowledge and behavioural skills related to pregnancy weight management: information subscale and behavioural skills subscale.
2. Perception of pregnancy weight management and negative health outcomes: five psychological perception subscales, including perceived severity, perceived vulnerability, response efficacy, self-efficacy and response costs.

Intervention materials

The other function of the formal test of the subscales is to provide evidence for the development of interventions.

Using Amos 23.0, a structural equation model will be constructed to explore the fit of the data to the PMT–IMB model. Each dimension in the PMT–IMB model will be a latent variable, and there will be five or more observation variables (items of the subscale) to prove it. Measurement models composed of a latent variable and its observation variables will then be constructed. The seven subscales of the PMT–IMB model represent seven latent variables; the weight management behaviour of pregnant women, as reflected by the results of the PWMSS, is also a latent variable in this study. Therefore, there will be eight measurement models in this structural equation model. The structural equation model will be designed according to the theoretical framework of the PMT–IMB model, with behaviour measured by PWMSS as the final dependent variable and the latent variables measured by the subscales of the PMT–IMB model as the independent variables. Finally, the pathway relationships between the seven dimensions of the PMT–IMB model and the weight management behaviour of pregnant women will be investigated.

The strengths and weaknesses of pregnant women's weight management behaviours from each dimension will be determined by the results of the analysis. Educational materials for intervention will be developed based on the results to customise intervention content for pregnant women and better intervene in their weight gain. For example, regarding the information dimension, we will refer to authoritative guidelines on pregnancy weight management and clinical recommendations to produce promotional material that is suitable for pregnant women. We will specifically design popular science knowledge to intervene in all aspects of the psychological perception of pregnant women. At the same time, we will show hands-on demonstrations by medical staff and video courses to improve the behavioural skills of pregnant women in weight management during pregnancy.

Implementation and evaluation of the interventions

Figure 2 shows a flow chart of the RCT procedures.

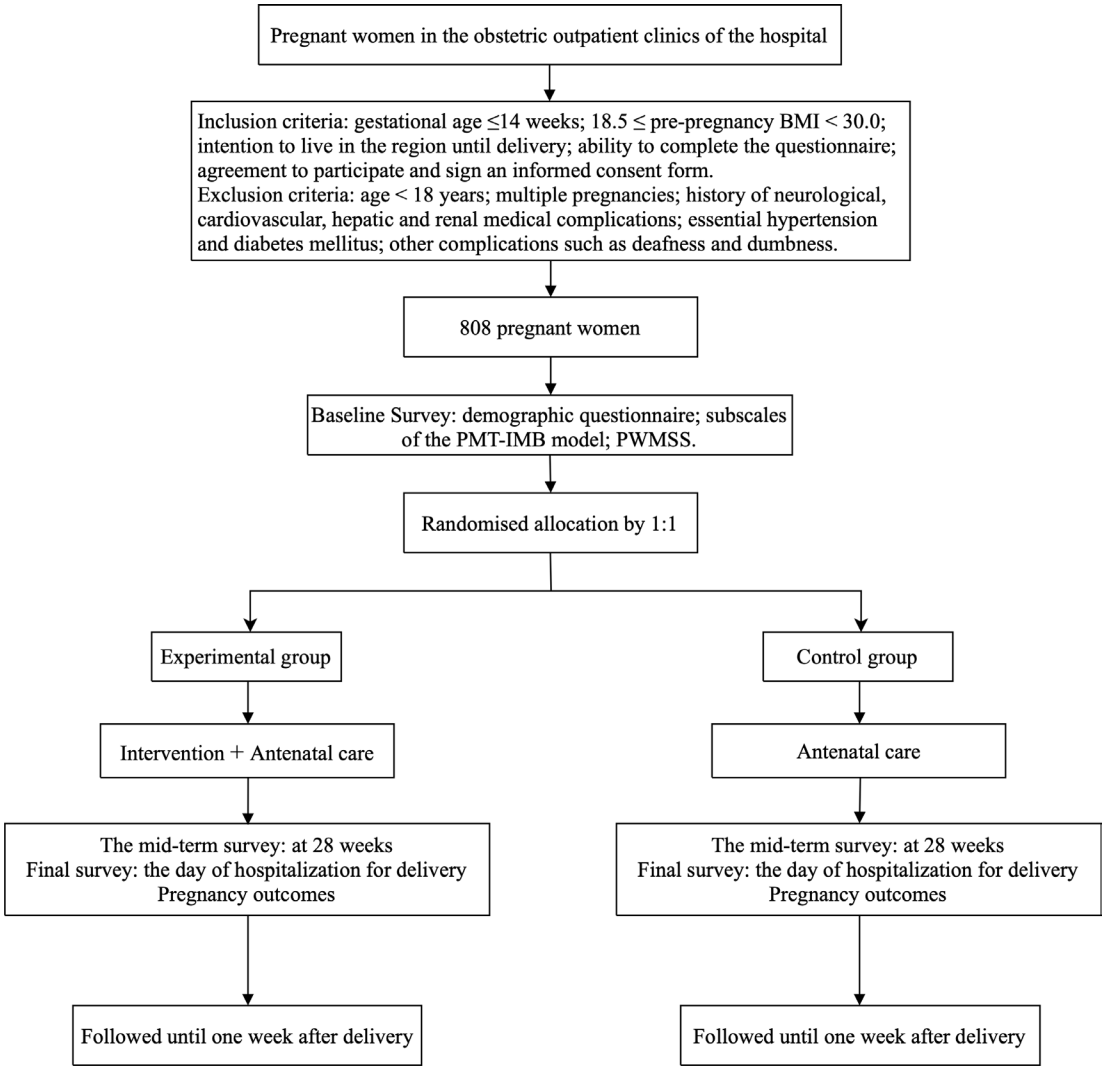

Figure 2 Flow chart of intervention implementation procedures. BMI, body mass index; IMB, information–motivation–behavioural skills; PMT, protection motivation theory; PWMSS, Pregnancy Weight Management Strategy Scale.

Study setting

This study will be conducted in Jiangsu Province, in one of the central cities of the Yangtze River Delta in China. The study site is a maternal and child healthcare hospital which accounts for approximately 40% of the city's annual births. This provides a sufficient and representative sample for this study. Given the trust relationship established between the hospital and pregnant women via long-term contact, selecting this hospital as the study site will be beneficial for improving the compliance of the participants.

Participants

Women in early pregnancy who visit the obstetrics and gynaecology clinic will be routinely asked about their medical history, specific information regarding their pregnancy, the institution where the pregnancy file will be registered, and where they expect to deliver. Investigators who are interns in the outpatient clinic will introduce the specific information of this study to pregnant women who meet the inclusion and exclusion criteria before they are recruited.

The inclusion criteria include: (1) gestational age ≤14 weeks, (2) 18.5≤prepregnancy BMI <30.0, (3) intention to live in the region until delivery, (4) ability to complete the questionnaire and (5) agreement to participate and sign an informed consent form.

The exclusion criteria include: (1) age <18 years, (2) multiple pregnancies, (3) history of neurological, cardiovascular, hepatic and renal medical complications, (4) essential hypertension and diabetes mellitus and (5) other complications such as deafness and dumbness.

Sample size

The prevalence of EGWG in Jiangsu Province ranges from 37.2% to 41.5%.[39–42] To ensure that the sample size meets the needs of the study, the highest rate of EGWG in Jiangsu Province was used. Assuming that the rate of EGWG will decrease by 10% via experimental intervention with 80% power and 5% type I error rate, the sample size of the experimental group should be 363 according to PASS11.0. Considering a maximum loss to follow-up of 10%, the total sample size of the two groups has been set to 808 cases.

Training of investigators and intervention implementers

The investigators will be hospital staff who can accurately control the time of investigation and guarantee the quality of the collected data. They will be uniformly trained to conduct the survey using a structured interview approach when pregnant women are enrolled.

The intervention implementers will be selected from medical staff responsible for health education during pregnancy at the hospital. They will receive rigorous prejob training and assessment, which includes basic knowledge of the PMT–IMB model, intervention methods and communication skills.

Randomisation

To reduce the influence of confounding factors, the envelope method will be used for randomised grouping and allocation concealment. Random numbers generated by SPSS V.25.0 will be placed into envelopes with ID numbers in the order in which they are generated. The investigators will then open the envelopes sequentially by clinic order for pregnant women who meet the inclusion and exclusion criteria. Before grouping, the researchers will sort the random numbers from lowest to highest and set the first and last 50% as the intervention group and control group numbers, respectively. According to the random number in the envelope, the pregnant women will be randomly divided into two groups at a ratio of 1:1. To protect the personal privacy of the participants, the ID number on the envelopes will be used to replace all the identifiable information of the participants in the process of information collection and trial intervention. All participants will be included at the beginning of the study until the sample size required for the experiment is met.

Intervention

The intervention will start from the time of enrolment until the time of delivery, and all participants will be followed until 1 week after delivery. The experimental group will receive two types of interventions: one is weight management health education designed on the basis of the PMT–IMB model, which will be implemented from the information, behavioural skills, perceived severity, perceived vulnerability, response efficacy, self-efficacy and response costs dimensions. The other type is the standardised ANC from the "Guidelines for preconception care and prenatal care (2018)".[7] At the same time, the control group will only receive the standardised ANC.

The intervention implementation plan time will be the same as the recommended time for ANC visits, and the weight management and health education programme will be combined with routine ANC. This will reduce the differences caused by the different levels of attention of interventionists and prevent the negative emotions of pregnant women from affecting the study results due to the excessive number of interventions. Researchers will supervise the implementation of the intervention throughout the study to guarantee the quality of the intervention. Measures will also be taken during the study to avoid crossover between the control and experimental groups to reduce the influence on the evaluation of the actual effect of the intervention. To effectively improve the compliance of the participants, postpartum rehabilitation treatment will be provided free of charge to pregnant women who agree to participate in the study.

Data collection

Investigators will conduct one-to-one baseline surveys of participants when they are enrolled so that problems can be identified and corrected in time. The baseline survey will include the prepared questionnaires, including the

demographic questionnaire, subscales of the PMT–IMB model, and PWMSS. The mid-term and final surveys will be conducted at the first ANC visit in the third trimester (approximately 28 weeks) and on the day of hospitalisation for delivery, respectively. Except for the general information section of the demographic questionnaire, the same variable data will be measured again, similar to the baseline survey. Each survey should take approximately 25 min to complete. In addition to obtaining information from participants directly, pregnancy outcomes will be collected via medical records.

Outcomes

Primary outcomes

1. Scores on each subscale of the PMT–IMB model: the variation of scores represents changes in awareness of information, psychological perception and behavioural skills related to maternal weight management during pregnancy.
2. Score of the PWMSS: the scores represent the utilisation of existing weight management strategies in pregnant women and the effectiveness of their application.
3. Weight during pregnancy: weight change during pregnancy is the most direct indicator of the effectiveness of weight management during pregnancy. It is compared with the recommended value of weight gain during pregnancy to determine whether weight gain is reasonable.

Secondary outcomes

1. Pregnancy outcomes (delivery gestational age, delivery mode, Apgar score, birth weight and adverse pregnancy outcomes).
2. Pregnancy complications (gestational diabetes mellitus, hypertensive disorder complicating pregnancy, hyperlipidaemia during pregnancy, etc).

Data management

After the questionnaire is collected and sorted, data will be entered into the EpiDataV.3.1 database by two specially trained personnel to guarantee data quality. The original material will be stored and archived safely after use, and the storage time will be in accordance with the study plan and scientific research management requirements of the research centre. Only the researchers of our team will have access to the data and materials, and nobody will be able to access it without authorisation. A person independent of the study team will be responsible for data management and monitoring and will have the right to supervise the implementation of interventions. During the recruitment of participants, their basic characteristics will be analysed at different periods (200 and 400 included) to determine the rationality of the recruited method. At the end of each survey, treatment compliance, outcomes and adverse events will be analysed to evaluate the feasibility of the current implementation plan and whether adjustments are needed.

Statistical analyses

Data will be analysed using the intention-to-treat (ITT) analysis and per-protocol (PP) analysis. The PP analysis will exclude patients who are lost to follow-up early because the efficacy of the programme in these patients will generally be poor. Given that subjects with poor compliance tend to have a higher risk of outcome events, the results of the ITT analysis are more conservative. For an experiment with rigorous design and high execution quality, the results of the ITT and PP analyses are not expected to differ significantly; therefore, simultaneous analysis can be mutually verified.

All data will be analysed using SPSS (V.25.0). A two-tailed p value<0.05 will be regarded as statistically significant. Continuous variables will be described as mean±SD or as median (IQR) and will be tested using a two-sample independent t-test, Wilcoxon rank sum test or variance analysis. Categorised variables will be expressed as frequencies and percentages and will be tested using the χ^2 test. First, the baseline survey data will be analysed to determine whether the differences in the basic characteristics of the two groups before the intervention are statistically significant. Second, to evaluate the effect of pregnancy weight management intervention on the basis of the PMT–IMB model, the continuous outcome variables (the score on each subscale of the PMT–IMB model and scores of PWMSS) and categorised outcome variables (appropriate weight gain during pregnancy, pregnancy complications and pregnancy outcomes) between the two groups will be compared. Unconditional logistic regression will be used to estimate the association between various factors and the outcome of weight gain by ORs and 95% CIs with potential confounders adjusted.

Patient and public involvement

Participants were not involved in the development of the research question, study design or implementation. The application of the Delphi method will involve experts in the design of subscale items during the preparation stage of the evaluation tools. The selected hospital staff will then be involved throughout the intervention. All participants will be informed of the study results after completion of the study.

ETHICS AND DISSEMINATION

The study protocol and informed consent have been approved by the ethical review committee of Nanjing Medical University (NMU 2020-63). The proposed interventions are generally considered safe for both maternal and foetal health; therefore, stop guidelines are not planned. Participants are allowed to withdraw from the trial at any time; however, the reasons for this should be explained and recorded. As much as possible, a final questionnaire should be administered before withdrawal. When necessary, the intervention methods of the subjects will be revealed while guaranteeing that it will have a minimal effect on the trial. All participants will be fully

informed of the contents of this study before they are recruited and will sign an informed consent form. Given that this study is registered at the Chinese Clinical Trial Registry, modifications to the protocol will be recorded on this platform. The results of this study will be presented at national and international conferences and published in peer-reviewed journals. Original data without personally identifiable information will be available after the article has been published.

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Contributors All authors contributed to the conception and design of this study. JG and LW drafted the manuscript and XP, CZ, SZ, MZ, HY and ST revised the manuscript. All authors approved the final version to be submitted to the journal.

Funding This study was supported by grants from the National Natural Science Foundation of China (72074122, 71603131) and Philosophy and Social Science Research of Jiangsu Higher Education Institutions of China (2020SJA0306).

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer-reviewed

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