STUDY PROTOCOL

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A physical activity counseling intervention to promote health among pregnant women: a study protocol of randomized clinical trial



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Abstract

Background Pregnancy may result in gestational diabetes mellitus (GDM), discomfort, pregnancy-related musculoskeletal pain, sleep disturbances, and decreased quality of life in pregnant women. Physical activity during pregnancy can lower the odds ratio of developing GDM and offer numerous health benefits for mothers and infants. However, the prevalence of physical inactivity among pregnant women worldwide is high. The Behavior Change Wheel (BCW) can be used to develop interventions to enhance physical activity. However, no research has been conducted to evaluate the effectiveness of physical activity interventions among Chinese pregnant women using the BCW framework.

Methods/design We will conduct a single-center, parallel, randomized controlled trial at a maternal–child health care center. A total of 244 pregnant women at high risk for GDM will be randomly allocated to either a study group receiving a physical activity counseling intervention or a control group receiving standard care. The intervention will comprise one face-to-face individual counseling session combined with three weekly online group counseling sessions based on Motivational Interviewing, supplemented by four biweekly counseling before 24 gestation weeks, and WeChat group support (Tencent, Shenzhen, China). Educational materials will also be available on the WeChat Official Account. The program will begin before 12⁺⁶ gestational weeks, the counseling sessions will end before 24 gestation activity, the incidence of GDM and glucose level. The secondary outcomes will include gestational weight gain, sleep quality, quality of life, low back pain, pelvic girdle pain, physical activity-related variables, and maternal and newborns health outcomes.

Discussion This research will contribute to understanding the effects of a physical activity counseling intervention, including physical activity, incidence of GDM, glucose levels, gestational weight gain, sleep quality, quality of life, low back and pelvic girdle pain, and maternal and newborn health outcomes.

Trial registration Chinese Clinical Trial Registry (CHiCTR) ChiCTR2400081364, on February 29, 2024.

Keywords Physical activity, Behaviour change wheel, Gestational diabetes mellitus, Randomized controlled trial, Protocol

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Introduction

Gestation is a natural process characterized by a period of intense changes. Due to the substantial hormonal, physiological, psychological, physical, and lifestyle changes, pregnant women may have pregnancy-related discomfort [1], musculoskeletal pain [2], and poor sleep quality [3]. Studies also suggested that health-related quality of life among pregnant women is worse compared with the pre-pregnancy period [4, 5]. Furthermore, some pregnant women may develop gestational diabetes mellitus (GDM) [6].

GDM is one of the most common complications which is increasingly prevalent and is estimated to affect approximately 21.1 million live births worldwide with an incidence of 16.7% [7], and 22.9% in China [8]. GDM is associated with increased both short-term and long-term adverse health outcomes for both women and the off-spring, such as hypertensive disorders, preterm delivery, macrosomia, large-for-gestational-age, type 2 diabetes post-gestational diabetes, childhood obesity, metabolic syndrome and disordered glucose regulation in adolescents [9, 10]. Early prevention for pregnant women with high-risk is crucial for personal health and for reducing the social and healthcare burden associated with the treatment of diabetes and its complications.

Physical activity is promoted to the entire population including pregnant women for its overall health benefits [11]. Evidence indicates that physical activity beginning from the first trimester can prevent the development of GDM in pregnant women [12]. Moreover, Physical activity can also reduce pregnancy-related musculoskeletal pain [13], improve sleep quality [14], and self-perception of quality of life [15]. It is recommended that all pregnant women without exercise contraindications should engage in at least 150 min moderate intensity physical activity to gain health benefits [16].

Physical inactivity refers to not reaching public health guidelines recommendations for physical activity [17]. Physical inactivity is related to maternal obesity [18] and a risk factor for GDM [19]. Physical inactivity is the primary target for disease prevention and health promotion in public health policy [20]. Physical inactivity in pregnant women is a public health concern worldwide. Globally, the prevalence of physical inactivity in pregnant women is high, ranging from 38.3% to 74.3% [21, 22], in mainland China it reached 66.2% [23].

Unfortunately, routine antenatal care in mainland China does not provide physical activity-enhancing intervention. The Medical Research Council's (MRC) framework on developing and evaluating complex interventions suggests that complex intervention research should give sufficient and appropriate consideration to a theory-based perspective [24]. The Behaviour Change wheel (BCW) is a comprehensive theory guiding behaviour change intervention development. According to the BCW, the Capability, Opportunity, Motivation, and Behavior (COM-B) model and the Theoretical Domains Framework (TDF) [25] are used to identify the determinants of the target health behavior [26]. The TDF has 14 theoretical domains, including knowledge, skills (cognitive), behavioural regulation, physical skills, environmental context and resources, social influences, professional social role and identity, beliefs about capabilities, optimism, beliefs about consequences, intentions, goals, emotion, and reinforcement. It encompasses the individual, social and physical environmental constructs of the ecological model for behaviour change of physical activity among pregnant women [27]. The BCW also identifies intervention functions such as education, persuasion, incentivisation, training, modeling, and enablement, likely to be effective in bringing about behaviour change [28, 29]. The BCW provides theory-based linkages between COM-B components, TDF, intervention functions, Behavior Change Techniques (BCTs), and policy categories [26]. The BCW is useful in developing interventions targeted at physical activity improvement [30].

It is indicated that while many current interventions aimed at enhancing physical activity adherence show some efficacy, they often lack robust theoretical underpinnings [31]. Moreover, while supervised physical activity interventions in the first trimester could reduce the incidence of GDM during pregnancy [32], adherence was observed to be low in real-world settings [33-36], necessitating significant investments in time, professionals, resources, and finances. Another systematic review suggested that unsupervised home-based self-practice of tailored exercises for pregnant women could enhance symptom severity, maternal aerobic fitness, and sleep quality [37]. Physical activity counseling for unsupervised home-based self-practice of tailored physical activity may be suitable for women depending on their health status, work demands, and lifestyle patterns. Studies focusing on physical activity counseling have simpler designs, such as late in intervention beginning time [38, 39] and light intensity [40-42] to gain the efficacy of the intervention, yet their effectiveness of preventing GDM is still under investigation [43, 44].

Adequate evidence indicates that behavioral counseling interventions could limit excess gestational weight gain and improve health outcomes (i.e., gestational diabetes, emergency cesarean delivery) among pregnant persons and their infants (i.e., macrosomia, large for gestational age) [45]. It is recommended that clinicians offer pregnant women effective in-person behavioral counseling interventions [46]. Motivational interviewing (MI) can strengthen personal motivation and commitment to individualised goals by eliciting and exploring the person's own reasons for change, and addressing key barriers and enablers. It offers a method to deliver several effective BCTs [47]. In non-pregnant populations, motivational interviewing has been shown to improve physical activity levels [48]. Counseling based on Motivational Interviewing could provide individually tailored physical activity guidance, and it may provide the initial catalyst for behaviour change [47, 49]. The challenge remains how to maintain and support this change. Digital technologies provide an opportunity to support and promote PA remotely [50].

Social media has been used to improve communication between nurses and patients [51], promote Chinese urologists' practices [52], and provide online consultations for patients [53]. WeChat (Tencent, Shenzhen, China) has become the most prevalent social networking platform in China. WeChat users can set up WeChat groups, use WeChat mini programs and WeChat Official Account, upload Short Videos through WeChat Channels for free. The latest data from 2023 showed the number of WeChat users was up to 1.327 billion (Tencent, 2023) (https://www.tencent.com/zh-cn/investors/financialreports.html). Previous studies indicated that WeChat may be an effective tool to increase physical activity [54].

A physical activity counseling intervention based on BCW may have the potential to enhance physical activity during pregnancy. The physical activity counseling intervention will take into account the antenatal care schedule and be delivered both face-to-face and via WeChat. This paper presents the study design and methodology of a pragmatic parallel, randomized controlled trial (RCT). This RCT was designed to investigate the effectiveness of the physical activity counseling intervention on the pregnancy physical activity level, the incidence of GDM, glucose levels, physical activity, gestational weight gain, sleep quality, quality of life, low back pain, pelvic girdle pain, physical activity-related variables, and maternal and newborn health outcomes. It will contribute to early prevention of maternal and child diabetes, overweight, obesity, and other non-communicable diseases.

Methods/design

Study design and setting

This study is a parallel, randomized controlled clinical trial that will take place in Guangzhou, China. Guangzhou, a sub-provincial city with approximately 19 million residents, ranks as the fourth largest city in China in terms of GDP. This study will be conducted in a teaching hospital that has over 28,000 births annually. Ethical approval has been granted for Institutional Review Board of the School of Nursing at Sun Yat-sen University and the study hospital. This RCT was registered prospectively on the Chinese Clinical Trial Registry (CHiCTR), trial registration number ChiCTR2400081364, on February 29, 2024. This study is supported by the National Natural Science Foundation of China, grant no. 72174216.

This protocol follows the Standard Protocol Items: Recommended items to address in a clinical trial protocol and related documents (SPIRIT) guidelines. Table 1 presents the schedule of enrollment, interventions, and assessments. Figure 1 outlines the process of the study.

Eligibility criteria

Pregnant women with singleton pregnancies will be recruited before week 12^{+6} of gestation. Pregnant women with at least one of the following risk factors of GDM will be included: maternal aged \geq 35 years at delivery, prepregnant body mass index (BMI) \geq 24 kg/m², polycystic ovary syndrome, previous glucose intolerance, physical inactivity (moderate intensity physical activity less than 150 min per week), family history of type 2 diabetes, previous GDM, previous macrosomia, previous fetal anomaly, current pregnancy with fetus growing greater than the gestational age, hydramnion, or repeated colitis [19, 55].

The exclusions included preexisting diabetes, exercise contraindications (unexplained persistent vaginal bleeding, severe cardiovascular, respiratory, or systemic disease, incompetent cervix, multiple pregnancies, recurrent miscarriage, symptomatic anaemia, gestational hypertension, or uncontrolled hypertension or thyroid disease) [16].

Sample size

Suppose that the incidence rate of GDM is 22% in the study group and 40.6% in the control group [56]. A sample size of at least 98 women per arm is necessary to detect a between-group difference in GDM incidence (power of 80% and α =0.05). The ratio of participants between the study and control groups is 1:1. Assuming a dropout rate of 20%, the minimum target sample size required in each group is 122.

Recruitment and informed consent

Pregnant women intending to deliver at the hospital typically schedule their prenatal appointments between the 5th week of gestation and delivery. Eligible pregnant women will be approached by the researcher using an eligibility screening questionnaire. The study objectives and detailed explanations of the intervention will be provided to eligible pregnant women. Those who are willing to participate will be asked to sign informed consent and enrolled.

	Study period	1			
	Enrollment	Allocation	Post allocat	tion	Closeout
Time point	5-12+	5-12+	24-28	35-37	With in 3
Time point	Week's	Week's	Week's	Week's	days after
	gestation	gestation	gestation	gestation	delivery
	(T0	geotation	(T1)	(T2)	(T3)
	baseline)		()	()	(10)
ENROLLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS					
Physical activity					
promotion		•			
intervention					
Usual antenatal care		•			
ASSESSMENT					
Sociodemographic	Х				
data form					
Primary outcome					
Physical activity level	Х		Х	X	
Incidence of GDM			X		
Glucose on 75-g			X		
OGTT					
Secondary outcome					
Gestational weight	Х		Х	Х	
gain					
Fetus growth and	Х		Х	X	
development					
Low back pain and	Х		Х	X	
pelvic girdle pain					
Sleep quality	Х		Х	X	
Quality of life	Х		Х	X	
Physical activity-	Х		Х	X	
related variables					
Maternal outcomes			Х	X	Х
Childbirth outcomes					Х

Table 1 The schedule of enrollment, interventions, and assessments



Fig. 1 The outlines the process of the study

Randomization and blinding

Participants will be randomized to the intervention or control group at enrollment in the study. The randomization will be generated by a research assistant with no clinical involvement in the trial, utilizing a computergenerated random sequence. To ensure a 1:1 recruitment balance throughout the study, the randomization process will be conducted in blocks of four women. Consequently, each block will allocate two women to the intervention group and two women to the control group.

The research assistant will prepare sealed opaque envelopes containing the intervention arm to which each participant is allocated. Neither the study participants nor the researcher administering the intervention will be blinded, given the nature of the intervention. Each participant will be issued a unique three-digit study code. During data entry and analysis, the research assistant will be blinded to participants' responses using the study code.

Control

Participants in control group will receive routine antenatal care throughout pregnancy at $6-13^{+6}$, $14-19^{+6}$, 20-24, 24-28, 29-32, and 33-36 gestational weeks. Weekly examinations are conducted from 37 to 41 gestational weeks. An online pregnancy education program and offline classes are available to pregnant women focusing on nutrition, prenatal examination, childbirth preparation, and postpartum recovery.

Intervention

The physical activity counseling intervention was developed following a step-by-step application of the BCW framework [26]. The COM-B model combined with the TDF was used to diagnose the necessary changes in the sources of the target behavior, drawing from previous literature [27, 57–59]. Intervention functions were identified by synthesizing evidence from previous literature reviews on physical activity promotion or maintenance among pregnant women [16, 31, 45]. A quantitative study was also conducted to understand the physical activity pattern and characteristics among pregnant women and identify the intervention function pregnant women needed in physical activity behavior change (In Press).

Delivery modes of the intervention were chosen based on their affordability, practicality, effectiveness, acceptability, safety, and equity, all of which are crucial for enhancing the intervention's transferability into practice [26]. The intervention utilizes a combination of face-toface and remote delivery modes. Table 2 presents the identified changes needed and intervention functions aimed at improving physical activity among pregnant women, as identified by the COM-B model and TDF.

Apart from the routine antenatal care, the pregnant women will receive the intervention. The intervention includes eight physical activity counseling sessions, WeChat group support, and educational materials. Table 3 presents the intervention content details.

Firstly, the pregnant women in the intervention group will undergo an initial 60-minute individual face-to-face physical activity counseling session. The individual consultation, based on the MI principle, comprises four components (1) introduction of the etiology, risks and prevention of GDM; (2) a personalized session on physical activity, including sharing benefits, addressing safety concerns, discussing beliefs about consequences, building confidence, collaboratively planning with the researcher, addressing personalized challenges, and arranging followup support. This conversation is guided and modified from the Moving Medicine Primary Prevention https:// movingmedicine.ac.uk/consultation-guides/condition/ adult/primary-prevention-2/ (3) Providing access to educational resources and online learning videos; (4) Training in the essentials of performing walking or aerobic exercises, assessing physical activity intensity and safety, and maintaining a physical activity diary along with managing gestational weight gain. It is the most important session to provide the initial catalyst for behavior change. Appendix 1 presents the details of the first consultation.

Then 10 to 15 pregnant women at similar gestational week will be organized into a WeChat group. Another three weekly 40-min physical activity counseling sessions will be conducted in groups online via WeChat mini program Tencent Meeting, and these sessions should be completed before 16 weeks' gestation. During the other three counseling sessions, participants will discuss the benefits, barriers, and solutions to enhance physical activity. Knowledge and strategies to promote physical activity will be provided. The researcher will share ways other pregnant women find helpful to solve problem. Each session will also contain the themes of physical activity educational content sent to participants weekly. Session 1 will include health consequences, safety, benefits, intensity and type, contraindication, and precautions of physical activity during pregnancy. Session 2 will include behaviour regulation methods, such as selfmonitoring of physical activity, gestational weight gain, goal setting, action planning and habit formation. Session 3 will include strategies to address barriers to improve physical activity: limited time, anxiety and stress coping and pregnancy-related symptom management, and physical activity social support.

Table 2 The identified changes needed and intervention functions aimed at improving physical activity among pregnant women, as identified by the COM-B model and TDF

COM-B component	TDF domain linking to COM-B component	Relevance of domain	Intervention function
Psychological capability	Knowledge	Know about prenatal physical activity and gesta- tional diabetes mellitus	Education
	Skills (cognitive)	Know how to do physical activity during pregnancy	Training
	Behavioural regulation	Develop skills of goal setting, self-monitoring of pre- natal physical activity	Training Education
Physical capability	Physical skills	Reduce the pregnancy-related discomfort symp- toms, and in a good state of health to be active.	Training
Physical opportunity	Environmental context and resources	Know how to do physical activity when time, resources and locations restricted.	Training Enablement
Social opportunity	Social influences	Get social support from families, partner and health care provider; Social comparisons with other pregnant women.	Modelling Enablement
Reflective motivation	Professional social role and identity	Identity with physical activity of pregnant women	Education Persuasion Modelling
	Beliefs about capabilities	Have confidence perform PA during pregnancy	Persuasion Modelling Enablement
	Optimism	Be confident that desired benefits will be attained of physical activity	Education Persuasion Modelling
	Beliefs about consequences	Recognize that physical activity during pregnancy is beneficial	Education Persuasion Modelling
	Intentions	Have the intention of physical activity during preg- nancy	Education Persuasion Modelling
	Goals	Set goal of physical activity during pregnancy	Education Persuasion Incentivisation Enablement
Automatic motivation	Emotion	Have positive emotions about physical activity dur- ing pregnancy	Persuasion Incentivisation Modelling Enablemen
	Reinforcement	Receive the incentives of prenatal physical activity	Incentivisation

Furthermore, participants will receive four biweekly ongoing supportive individual counseling from 16 to 24 gestation weeks (before OGTT). Two will be conducted face to face at 16, 20 gestation weeks when they come to antenatal care, and two will be conducted via WeChat call at 18, 22 gestation weeks. Participants will receive individual feedback on physical activity and gestational weight gain and also be praised for their achievements and encouraged to do more to maximize the benefits. Strategies are discussed to overcome barriers, facilitate change and reset realistic goals. The participants will be reminded to record their daily physical activity and share the benefits and feelings they've experienced on the WeChat Mini Program. All the counseling sessions will be based on MI principle.

The physical activity counseling follows the principle of exercise prescription [60], taking into account the individual's prior physical activity level and condition, gradually increasing the intensity and duration to align with the guidelines recommending at least 150 min of moderate-intensity physical activity per week [16]. Pregnant women are classified as apparently healthy adults, despite being recognized as a special population. Therefore, pregnant women adhere to the general guidelines of ACSM regarding the "FITT principle": F for frequency, I for intensity, T for type, and T for time [61]. Those who

Table 3 Intervention content

Physical activity counseling before 24 gestation week	
First individual counseling Face to face Before 12 ¹⁶ gestation weeks Duration: 60 min	 Introduction 5 min First, ask about the pregnant women's understanding of GDM, then introduce the harm of GDM, and explain the causes of GDM combined with the high-risk factors. Emphasize the importance of physical activity prevention. Conduct an individual consultation based on Motivational Interviewing 25–30 min This conversation, which is guided and modified from the Moving Medicine, it has four stages, engage, focus, evoke and plan, the details of the conversation are present in Appendix 1. Contents including: benefits share, respond to safety concerns, beliefs on consequence, build confidence, discuss with health provider and make a plan to solve personalized problems, arrange follow up and support. Provide access to the education resources and videos for online learning. Training of how to perform the walking or aerobic exercises, and how to assess intensity and safety, instruct how to record the daily physical activity and weight on WeChat. Pedometer/wrist-worn fitness tracker/smart phone is recommended to record the number of steps
Weekly group counseling sessions 3 times, online (Tencent meeting) After the initial counseling If not participating in a group session, the content will be given to the partici- pants by WeChat call individually. Duration: 40 min	For the project activity they do each day, so mining Each session will include the motivational interviewing as follows. Engage How about your health and physical activity levels last week? Focus What benefits have you gained since you began the moderate intensity physical activity? Evoke What are the top 2–3 reasons for you personally becoming more active? Plan
	What are the barriers in the way of your plan? Share ways other pregnant women find helpful to solve problems. Reset the physical activity goal and action plan personally. Each session will also contain the themes of the educational articles sent to participants weekly. Session 1 will include health consequences, safety, benefits, intensity and type, contraindication, and precautions of physical activity during pregnancy. Session 2 will include behaviour regulation methods, such as self-monitoring of physical activity, gesta- tional weight gain, goal setting, action planning and habit formation. Session 3 will include strategies to address barriers to improve physical activity: limited time, anxiety and stress coping and pregnancy-related symptom management, and physical activity social support.
Biweekly ongoing individual support counseling 4 times Two face-to-face physical activity ongoing support counseling during the ante- natal care at 16, 20 gestation weeks, two WeChat Call support at 18, 22 gesta- tion weeks Duration: 10 min	 Feedback on achievement of physical activity goals achieving and gestational weight gain Praise the achievement and encourage pregnant women to do more in their ability to gain more benefits. Find out the barriers to physical activity, and give advice to solve them. Remind participants to record the daily physical activity on WeChat Mini Program
Social support from the beginning of intervention until delivery	
WeChat groups Physical activity experience sharing on a public WeChat Mini Program	 Communication in WeChat groups between the researcher and pregnant women. The researcher sends reminders to pregnant women to be physically active and record their physical activity diaries, and answers their questions in the WeChat groups. Physical activity experience share and daily record on a public WeChat Mini Program. Pregnant women can not only keep a diary of their physical activity, but also see what other people are sharing. Summarize participants' achievement of physical activity goal weekly, and choose excellent cases for modeling in the WeChat group. Encourage pregnant women's partner and families to support and accompany them during physical activity.
Educational material	
Article combined with Short Videos for physical activity education recorded by medical staff via WeChat Official accounts 3 times/week	 The harm and prevention of gestational diabetes mellitus Physical activity during pregnancy according to the current guideline: safety, benefits, appropriate intensity and type, contraindication, precautions. The harm of physical inactivity for pregnant women. Gestational weight gain: guidelines, the importance of reasonable gestational weight gain, monitor and record. Behavioral regulation: Goal setting, self-monitoring and gradually building up activity levels. Overcome time limitation or kit requirements, and integrate moving into your daily routine. Address barriers to physical activity: strategies for managing pregnancy related symptoms Address barriers to physical activity: identify and appropriately respond to anxiety and other negative emotions during pregnancy. Address barriers to physical activity: strategies for preventing and relieve low back pain and edema of the lower limbs Peer experience sharing of pregnant women: Physical activity relieves discomfort during the first trimester Peer experience sharing of pregnant women: Obese pregnant women control their weight and glu- cose through physical activity Peer experience sharing of pregnant women: Say no to anxiety, keep fit and a good mood
Homebased Physical activity online resources	 Walking audio guidance for pregnant women at different level of physical activity. Aerobic exercises video

have pre-pregnancy physical activity habits (engaging in at least 150 min of moderate-intensity physical activity per week) can continue, ensuring the chosen activities are safe during pregnancy, for at least 30 min each session, 5 times per week. Inactive or overweight/obese pregnant women should begin with low levels of physical activity, gradually increasing frequency, intensity, and duration over time, initially incorporating 15 min of walking within their capabilities, and integrating walking into their daily routines. Personal preferences of the participants will also be taken into account during counseling sessions, especially in selecting the type of physical activity. According to current guidelines, recommended activities include brisk walking, stationary cycling, aerobic exercises, dancing, and swimming [16].

WeChat groups will be used to remind participants to perform physical activity, provide social support and facilitate comparison. Participants will be reminded to be physically active, record their physical activity diary and how they feel after achieving physical activity goal on the WeChat Mini Program in WeChat groups every day. Participants share their physical activity experiences and feelings after achieving the physical activity goal and record their daily on a public WeChat Mini Program. This not only incentivizes pregnant women to keep physically active but also enables them and establishes model for others. Weekly summary of physical activity meeting guideline will be conducted in WeChat groups. Excellent recordings of the participants will be displayed to motivate others to improve the physical activity. This initiative could serve as a model and enhance confidence in achieving physical activity goals. We also encourage pregnant women to seek help, support, and companionship from their partners and families when engaging in physical activity.

Educational materials, including physical activity educational articles, Short Videos resources, and home-based physical activity practices resources, will be disseminated via WeChat Official Accounts. The educational materials aim to enhance the capability, motivation, and opportunity for engaging in physical activity during pregnancy. The educational materials cover various aspects of pregnancy physical activity, such as its benefits, contraindications, methods for assessing safety, intensity, and volume of physical activity, self-monitoring of activity and gestational weight gain, goal setting, action plans, overcoming barriers, integrating activity into daily routines, seeking social support, and receiving guidance on physical activity. Home-based physical activity practices resources include two 30-min walking audio guides for pregnant women at different levels of physical activity, 40-min aerobic exercises video, one 15-min equipment-free resistance training video. Participants can make a choice according to their preferences and integrate physical activity into daily life.

The intervention will be delivered by the first researcher, who had been trained in MI skills and received an international certification of physical activity for pregnant women.

The MRC guidelines for evaluation complex interventions will be used to explore the process by which the intervention may have led to its effect or not [24]. Data collected from both quantitative and qualitative methods will assess the implementation of the intervention, the mechanisms of impact, and context effects. Table 4 presents the overview of the process evaluation dimensions.

Adherence to the physical activity intervention will be strongly emphasized and recorded in the physical activity diaries of women. Participants who develop obstetric contraindications to exercise will discontinue the exercise intervention but be included in the intention-to-treat analysis.

Outcome measurement and data collection

The primary outcomes include physical activity level at 24–28 and 35–37 weeks' gestation, the incidence of GDM and the glucose level during the 75-g oral glucose tolerance test at 24–28 weeks' gestation. The secondary outcomes include gestational weight gain, fetus growth and development, low back pain, pelvic girdle pain, sleep quality and quality of life, physical activity related variables at 24–28 and 35–37 weeks' gestation, maternal outcomes and childbirth outcomes within 3 days after delivery.

Physical activity will be measured using the pregnancy physical activity questionnaire (PPAQ) at baseline, 24-28 and 35-37 weeks' gestation. The Pregnancy Physical Activity Questionnaire (PPAQ) was used to evaluate the duration, types, and intensity of physical activity during pregnancy [62]. Zhang et al. translated the PPAQ into Chinese and culturally adapted it for use in China. The modified Chinese version of the PPAQ includes 31 items encompassing household/caregiving activities (14 items), occupational activities (5 items), sports/exercise activities (8 items), and transportation activities (4 items). The Chinese version of the PPAQ has consistently shown good reliability and validity, with a content validity of 0.940 and a test-retest intraclass correlation coefficient (ICC) of 0.944 [63]. According to the WHO physical activity guidelines [11], meeting the current physical activity guidelines is defined as engaging in at least 150 min of moderate-intensity physical activity per week.

Table 4 Overview of the process evaluation dimensions

Dimensions	Definition	Indicator	Measurement
Implementation			
Fidelity	Whether the intervention is faithfully implemented according to the protocol.	If the intervention is provided to partici- pants, beginning time; completion time; Whether they understand the educa- tion articles delivered to them or not; the response from the participants; if they request further question and what questions were raised.	Program records and documents; WeChat record; Interviews with participants in IG.
Dose	The quantity or amount of each interven- tion component delivered or provided.	Mean and range of length of counseling and telephone calls; The number of ses- sions received; The number of educa- tional articles completed reading.	Program records and documents; WeChat record
Adaptations	The adaptation refers to how well the intervention will be received.	Satisfactory rate	Satisfactory questionnaire
Reach	The extent to which the target audience comes into contact with the intervention.	Percentage of contacted eligible pregnant women who participate in this study; Adherence to each session; Percentage of the participants complet- ing the intervention.	Program records and documents
Mechanisms of impact	How did the effects of the specific intervention occurr?	Participant responses to and interactions with the intervention. Mediators, unexpected pathways and consequences.	Outcome data; Satisfactory ques- tionnaire; Interviews with participants in IG.
Context	Anything external to the intervention that may act as a barrier or facilitator. And the interaction with intervention and context.	Which factors have either facilitated or hindered working with physical activ- ity programs?	Interviews with participants in IG.

The 75-g oral glucose tolerance test will be administered between 24 and 28 weeks of gestation to diagnose gestational diabetes mellitus (GDM), following the criteria established by the International Association of Diabetes and Pregnancy Study Groups. Diagnosis will be based on fasting venous plasma glucose levels \geq 5.1 mmol/L and/or 1-hour glucose levels \geq 10 mmol/L and/or 2-hour glucose levels \geq 8.5 mmol/L [64].

Gestational weight gain will be measured at baseline, 24-28, and 35-37 weeks' gestation. Anthropometric measurements of maternal height (cm) and weight (kg) will be taken with participants wearing indoor clothing and no shoes at the study hospital using the same electronic scale. Pre-pregnancy BMI will be calculated using self-reported pre-pregnancy weight and height [weight $(kg) / (height (m))^2$]. According to the Working Group on Obesity in China, individuals may be classified as underweight if BMI < 18.5 kg/m^2 , normal weight if BMI is 18.5-23.9 kg/m², overweight if BMI is 24.0-27.9 kg/m², or obese if $BMI \ge 28 \text{ kg/m}^2$ [65]. According to the Institute of Medicine [66], a range for weight gain during the first trimester (0.5-2.0 kg, regardless of BMI) will be provided, along with BMI-specific ranges for weight gain per week during the second and third trimesters (0.45–0.59 kg for underweight, 0.36–0.45 kg for normal weight, 0.23–0.33 kg for overweight, and 0.17–0.33 kg for obesity). Gestational weight gain (GWG) will be calculated as the difference between weight measured at baseline, 24–28 weeks' gestation, and 35–37 weeks' gestation. Meeting the recommendations was defined as being within the Institute of Medicine cut points.

Fetal growth and development information will be assessed using measurements of biparietal diameter, abdominal circumference, and femur length, extracted from ultrasound reports at baseline, 24–28 weeks, and 35–37 weeks of gestation.

Sleep quality will be assessed using the Pittsburgh Sleep Quality Index (PSQI) at baseline, 24–28 weeks, and 35–37 weeks of gestation [67]. The PSQI is a self-report questionnaire that assesses sleep quality over a 1-month period. It is one of the most widely used sleep questionnaires and has been translated and validated into multiple languages, including Spanish, for use in antenatal and postpartum populations [68].

Quality of life will be measured by the 36-item Short Form Health Survey (SF-36) [69] at baseline, 24–28 weeks' gestation, and 35–37 weeks' gestation. The questionnaire comprises 36 questions that measure physical functioning, role limitations due to physical health, bodily pain, general health status, vitality, social functioning, role limitations due to emotional problems, and mental health over the past month [15].

Pregnancy-related musculoskeletal pain will also be measured at baseline, 24-28 weeks' gestation, and 35-37 weeks' gestation. Low back pain was defined as pain located between the 12th rib and the inferior gluteal folds. Pelvic girdle pain was defined as posterior pain arising from the region of the sacroiliac joints, anterior pain from the pubic symphysis [13]. In this study, these two terms are referred to as musculoskeletal pain. Along with an illustration of a woman marked with the definitions of low back and pelvic girdle pain, the history of pain will be assessed through questions regarding the frequency of musculoskeletal pain prior to the current pregnancy (habitual experience) and within the last 14 days, respectively. If musculoskeletal pain is experienced, women will be asked to rate the extent of pain experienced at its least, worst, and on average, using an 11-point numeric rating scale ranging from 0 (no pain) to 10 (worst possible pain) [70].

Maternal outcomes and childbirth outcomes will be extracted within 3 days after delivery from medical history. Maternal outcomes encompass gestational hypertension (defined as systolic blood pressure >140 mmHg or diastolic blood pressure > 90 mmHg at > 20 weeks' gestation without proteinuria), preeclampsia (both high blood pressure and proteinuria at 20 weeks' gestation), premature rupture of membranes (before 37 weeks' gestation or at delivery onset), postpartum hemorrhage (>500 mL blood loss within 24 h of delivery), and mode of delivery (vaginal, operative vaginal, or cesarean [elective or emergency]). Neonatal outcomes comprise gestational age at delivery, preterm birth (<37 weeks), Apgar score, birth weight, birth length, macrosomia (birth weight > 4000 g), low birth weight (birth weight < 2500 g), fetal distress (hypoxia during pregnancy or labor), amniotic fluid contamination (presence of meconium), number of LGA infants (birth weight>90th percentile), and number of SGA infants (birth weight < 10th percentile). LGA and SGA will be defined using international sex-specific newborn size standards for each gestational age, derived from the Newborn Cross-sectional Study subpopulation [71].

Additional factors related to physical activity will be assessed, including pregnancy physical activity knowledge [23], physical activity self-efficacy [72], pregnancy physical activity social support [73], and self-regulation [74]. According to the COM-B model and TDF, these factors are the main conceptual variables influencing pregnancy physical activity behavior, as they serve as behavioral mediators for achieving higher levels of physical activity and the physiological response to increased physical activity. Details about these measures can be found in Table 5.

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Physical activity related variables	Instruments
Pregnancy physical activity knowledge	Pregnancy physical activity knowledge questionnaire will be used to assess participants' knowledge about physical activity during pregnancy. The question- naire comprises seven-item question- naire developed according to the physi- cal activity guidelines in pregnancy and validated in Chinese pregnant women by Yao et al. [75]. The content validity was 0.92, and the Cronbach's a was 0.88 in a previous study [23].
Physical Activity Self-Efficacy	The Pregnancy Physical Activity Self- Efficacy Scale (P-PASES) will be used to measure pregnancy physical activity self-efficacy [76]. The scale comprises 10 items. Each item is scored on a 5- point Likert scale ranging from 5 points (strongly agree) to 1 point (strongly disagree). The total scores range from 10 to 50, with higher scores indicat- ing higher levels of physical activity self-efficacy. The PPASES has been demonstrated to have good psycho- metric properties, with a Cronbach's a value of 0.80 and test-retest reliability of 0.53 [76].
Physical Activity Social Support	The Pregnancy Physical Activity Social Support Scale (P-PASSS) will be used to measure social support for physical activity [77]. The scale comprises 24 items, each rated on a 5-point Likert scale ranging from 1 (strongly disagree) to 5(strongly agree). The total scores range from 24 to 120. Higher scores indicate higher levels of perceived social support for physical activities. The reported Cronbach's a coefficient of the P-PASSS was 0.92 [77].
Self-regulation	The Behavioural Regulation in Exercise Questionnaire (BREQ-2) will be used to measure the exercise motivation [74]. The C-BREQ-2 comprises 19 items with ratings on a 5-point Likert scale ranging from 0 (not true for me) to 4 (very true for me). It measures no- motivated, external, introjected, identi- fied, and intrinsic regulations of exercise behavior [78].

Baseline assessment will occur before 12^{+6} gestational weeks. Follow-up measurements will occur at 24–28 weeks, 35–37 weeks, and within 3 days after delivery. Table 1 provides a summary of the assessment.

Data management

After collection, each questionnaire is checked by the researcher to ensure data quality. If inconsistencies or missing data are found, the researcher will communicate with the participants to rectify them. Participant paper and electronic files will be maintained in secure storage and on a password-protected computer throughout the project. Non-numerical data will be coded according to predefined coding definitions. Data entry screening will be performed during input to ensure consistency between paper-based and electronic data. Participant files will be retained in storage for 5 years after the study's completion.

Statistical methods

All analyses will be done using the R Project (version 4.2.3). All statistical analyses will be done in the intention-to-treat population. Frequencies and percentages of categorical variables and mean, standard deviation, median, and range values of linear variables, will be used for descriptive statistics. Chi-squared and independent t tests will be used to examine group differences in the primary and secondary outcomes. Repeated analysis of variance will be used to assess within-patient correlations. By using a series of mixed-effects regression models with a likelihood-based approach, we will regress the score of PPAQ at follow-up to determine the effect on the baseline, group, time, group \times time, and confounders identified in the preliminary step. Effect sizes will be reported with 95% confidence intervals, and results will be considered significant if P < 0.05.

Discussion

Physical activity among pregnant women is associated with multi-level factors [27]. Physical activity promotion or maintenance interventions that include multiple layers of factors may be more effective. We develop the intervention based on BCW, and it combines the COM-B model and TDF to identify what need to change in physical activity among pregnant women, considering the personal factors, interpersonal factors, social and environmental factors. Physical activity counseling for pregnant women is not regulated during the usual antenatal care at present. This study aims to investigate of possible effects of the physical activity counseling interventions among pregnant women at high risk of GDM based on BCW.

This study has several strengths. We integrate physical activity counselling into the antenatal care, which would be helpful to promote clinical practice. We also considered personal preferences of the participants in counseling (e.g., when choosing the type of physical activity). When individual information is used to guide content, the intervention is inherently more complex than a onesize-fits-all treatment but may be more effective and attractive to participants [79]. Physical activity counseling will be conducted based on Motivational Interviewing, which may be more effective in physical activity promotion among pregnant women [80]. The intervention starts in the first gestation, allowing for an earlier time to decrease the insulin resistance [12]. We examine health outcomes, including low back and pelvic girdle pain, sleep quality, and quality of life. Moreover, we will conduct a process evaluation following the guidance of Medical Research Council guidelines.

The limitation of this study is that the physical activity level will be evaluated by subjective assessment questionnaires without objective equipment. We will ask our participants to keep a physical activity diary, including physical activity type, time, intensity, perceived exertion, walking steps and their feelings while exercising. We will not investigate the diet of pregnant women, so the results may be biased. In addition, this study is a single-center randomized controlled trial, and there may be limitations in external validity.

Conclusion

This paper describes the plan of implementing a physical activity intervention during pregnancy to reduce the incidence of GDM and improve the physical activity level, gestational weight gain, sleep quality, quality of life, low back pain and pelvic girdle pain, and maternal and newborn health outcomes. We will also conduct a process evaluation to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes. The effectiveness of the proposed program will be investigated in the future in a randomized controlled trial. The results could provide evidence for clinical practice for physical activity counselling during pregnancy, and inform the development and implementation of broadly reaching interventions in the community, academic, and clinical settings and could thus play an important role in the effort to improve the health of pregnant women and newborns.

Trial status

This study is approved by the Chinese Clinical Trial Registry (CHiCTR): (protocol ChiCTR2400081364). Recruitment commenced in July 2024. It is expected to be completed by May 2025. Data collection will be completed by February 2026.

Appendix 1

Table 6 Details of the individual consultation conversation based on motivational interview

Engage

1. Open the conversation

Would you be happy to spend a few minutes talking about physical activity before and during pregnancy

2. Assess impact of the condition

How has being pregnancy affected your physical activity levels and the things you enjoy? 3. Explore current activity

How much physical activity do you manage to get done in a regular day? On average

how many days each week do you do moderate or greater physical activity (like a brisk walk)? Focus

1. Find out what they already know

What do you know about the benefits of physical activity during pregnancy?

2. Share benefits

Can I share some other things people find beneficial to see what you make of them The benefits of physical activity during pregnancy: for pregnant women it could reduce the risk of excessive gestational weight gain, gestational diabetes, hypertensive disorders and symptoms of postpartum depression, improve the self-perception of quality of like Physical activity can also prevent preterm delivery, macrosomia, large-for-gestational-age infant. Prenatal physical activity may have potential preventative role on obesity, type 2 diabetes, and cardiovascular both mother and offspring in long term.

3. Encourage reflection

What do you make of what I have just said?

4. Explore how they think activity may help What do you understand about how physical activity might help you?

Example: Increased enjoyable physical activity and endorphin release, Improved self-esteem, self-efficacy and fitness, Better mood, Increased self-worth, energy and reduction in emotional and physical pain, Increased motivation to be active, interact with others and adopt challenge mindset, Increased enjoyable physical activity and endorphin release.

5. Respond to concerns What concerns might you have about becoming more active, if you decided to? Example: I already feel tired and you want me to do more.

Becoming more active is the most important treatment for persistent fatigue as it helps with body reconditioning and boosts energy levels. Many people find it a good way to take back some control over their health. Start slow and build up gradually in small bouts of activity (this just needs to be a few minutes). This can increase over time Increase the number of activity sessions first, then the duration of each activity, followed

by the intensity

Fvoke

1. Make it personal

What would be the top 2-3 reasons for you personally becoming more active, if you decided to?

2. Look forwards

Let's imagine that you did decide to live a more active lifestyle and were able to keep it up for six months or so, what benefits do you think you might gain?

3. Help them build confidence

On a scale of 0–10, how confident are you that, if you did decide to become more active, you would be able to keep up an active lifestyle for, say, 6 months, where 0 is not at all confident and 10 is extremely confident?" what makes you feel you could do this if you tried?""What

would help you become more confident?" 4. Summarise without adding anything

Can I summarise what I think you have said? Plan

1. Ask the key question

So, what do you think you will do?

2. Explore opportunities in daily routine How do you think you might get started?

3. Agree a plan

Can I share with you some things people find helpful when making a plan?

4. Troubleshoot What might get in the way of your plan?

5. Arrange follow up and support

Acknowledgements

We would like to thank the medical staff of Guangzhou Women and Children's Medical Center for their full support.

Authors' contributions

CX and GLL designed the randomized controlled trial and sought funding and ethical approval. CX, DYF and FCF are responsible for running all the aspects of the clinical trial, including screening, recruitment and intervention administration, follow-up, data collection, data analysis, and reporting, and communication of findings to participants. Data analysis will be conducted in consultation with the statistician. CX wrote the manuscript draft and GLL, DYF, FCF, and YX commented on and contributed writing to the original and edited drafts. The authors have read and approved the final manuscript.

Funding

This study is supported by National Natural Science Foundation of China, grant no. 72174216.

Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

Ethical approval has been granted for Institutional Review Board of the School of Nursing at Sun Yat-sen University and the study hospital. Written, informed consent to participate will be obtained from all participants.

Consent for publication

Consent will be collected from all the authors before submission of the paper for peer review.

Competing interests

The authors declare no competing interests.

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Received: 13 June 2024 Accepted: 31 January 2025 Published online: 08 March 2025

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