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Camp-style lifestyle modification program (CAMP) for diabetes prevention among rural women with prior GDM: study protocol for a three-arm cluster hybrid type 2 randomized controlled trial

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Abstract

Background Intensive lifestyle interventions were effective to reduce the risk of type 2 diabetes mellitus (T2DM) for women with gestational diabetes mellitus (GDM) history. However, reaching these mothers and maintaining participation in lifestyle interventions is suboptimal in real-world settings. Effective, feasible and sustainable new lifestyle interventions are needed. The objectives of this three-arm trial are to (1) compare diabetes risk outcomes of an evidence-based intensive lifestyle modification (ILSM) intervention, a camp-style lifestyle modification program (CAMP) intervention, and usual care among women with GDM history; and (2) evaluate the comparative efficacy of the CAMP versus ILSM intervention on implementation outcomes.

Methods A three-arm cluster randomized clinical trial (RCT) using a hybrid type 2 implementation design will be conducted in two counties in Hunan province in China. Six towns from each county will be randomly selected and assigned to CAMP, ILSM, and the usual care group (25 women from each of 12 towns, 100 women in each arm). The ILSM includes six biweekly in-person sessions and 3-month telephone health consultations, while the CAMP consists of a 2-day camp-based session and 3-month health consultations via a popular social media platform. Both interventions share the same session content, including six lifestyle skills. Efficacy (T2DM risk score and behavioral, anthropometric, psychosocial, and glycemic variables) and implementation outcomes (recruitment, acceptability, feasibility, fidelity, and cost-effectiveness) will be collected at baseline, 6-month, and 12-month. Pre-planned ANOVA F-test and generalized estimating equations will be included to test time-by-arm interactions.

Discussion The CAMP intervention is expected to have better reach, better attendance, and comparable effectiveness in reducing the risk of T2DM, thus improving postpartum care for GDM in China. The delivery of a

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concentrated format supplemented with technology-based support may provide an efficient and effective delivery model for implementing maternal health promotion programs in primary care settings.

Trial registration Registered in the Chinese Clinical Trial Registry (ChiCTR2200058150) on 31st March 2022.

Keywords Woman, Gestational diabetes Mellitus, Prevention, Type 2 diabetes Mellitus, Implementation, Hybrid type 2 Randomized Control Design

Background

Gestational diabetes mellitus (GDM) is one of the most common complications in pregnancy, with a global prevalence of 10.6% [1, 2]. GDM affects 17.6% of pregnant women in mainland China, with a 3.5-fold increase over the past decade [3]. Women with GDM history had higher risks of developing type 2 diabetes mellitus (T2DM) later in life is 7-fold higher than those who had normal glycemia during pregnancy [4–6]. Lifestyle interventions are recommended as the first-line approach to prevent T2DM globally given the lower cost and scalability without side effects [7]. However, the effectiveness is tempered by variability in the design of the clinical trials and real-world conditions, which may limit wide-spread implementation to a broader audience [8, 9].

We have developed and confirmed the effectiveness of a group-based lifestyle intervention called Intensive LifeStyle Modification (ILSM), including six in-person sessions held every 2 weeks for 12 weeks and five monthly telephone-based sessions (provided by local nurses) [10]. Significant improvement in reducing T2DM risk among mothers (aged 31.9±4.9 years) with GDM history in rural China was demonstrated [11–13]. However, the implementation outcomes (recruitment rate 54.1%, attendance 65.0%) [13] fell below benchmark rates of 80% [14]. Such outcomes were comparable to the recent implementation studies of lifestyle interventions targeting women with GDM history, which showed 10–64% of young mothers (33.8±5.2 yrs) attended and completed all sessions, and 43% did not attend a single session [8, 15]. Reach and attendance among young mothers in health promotion interventions is a worldwide challenge [15].

Young mothers in our study reported barriers to attend the intervention sessions because of time constraints and difficulties in keeping appointments at frequent group-based sessions although in-person interpersonal interaction was attractive to them. In addition, the local nurse also proposed that frequent and decentralized sessions increased the workload of the organization and management. Taken together, stakeholders from providers and users positively endorsed a concentrated intervention held over weekends or long holidays combined with technology-assisted support to reduce the providers' workload and improve participation. These findings echo those in the literature, stating that frequent schedule adjustment and transportation are the main barriers women face in health promotion programs [16]. A concentrated format supplemented with technology-based support may be an effective delivery format of intervention alternatives in primary maternal healthcare settings, especially in rural areas when resources are limited.

Camp-based programs offer a novel implementation strategy, that may improve participation by providing a concentrated intervention for those who face transportation barriers or schedule conflicts [17]. This format has been used in health education for patients with chronic health conditions (e.g., diabetes, cancer) [17], but little is known about the benefits of preventing chronic illness among high-risk groups who are not aware of the disease burden [18, 19]. However, more than a single camp session is needed to change and maintain lifestyle behaviors to prevent T2DM [18]. Maintenance sessions are needed after camp sessions to provide assessment, education, and ongoing behavioral support [18, 20]. Other implementation strategies for intervention providers such as external facilitation, peer comparison, and feedback during the camp and ongoing consultation sessions, could increase their passion and capability to engage in implementation; and these performances were also found to influence participants' engagement in interventions [21]. Thus, an adapted ILSM intervention via cooperating with these implementation strategies for intervention providers may reach a wider audience, facilitate participation, and maintain efficacy among women with prior GDM.

This study aims to: (1) compare the efficacy outcomes (T2DM risk score, behavioral, anthropometric, psychosocial, and glycemic variables) among an evidence-based intensive lifestyle modification (ILSM) intervention, a camp-style lifestyle modification program (CAMP) intervention, and usual care among women with prior GDM; (2) evaluate the comparative efficacy of CAMP versus ILSM intervention on implementation outcomes (recruitment rate, acceptability, feasibility, fidelity, cost-effectiveness).

Methods

In this study, we will use a three-arm, clustered RCT with a hybrid type 2 implementation design [22] to compare efficacy and implementation outcomes among the CAMP program, ILSM program, and usual care. The trial was registered in the Chinese Clinical Trial Registry (ChiCTR2200058150) and will be conducted in

accordance with the rules of Good Clinical Practice outlined in the Declaration of Helsinki. Ethics approval has been obtained from the Ethics Review Committee (E2021162). The study flowchart is displayed in Fig. 1.

Setting and randomization

This study will be conducted in Hunan province, which is representative of Central South China in geography (mixed plains and mountainous areas), climate (humid subtropical), demographics (Han and multi-minorities), developing economy, and health policy. To enhance generalizability, Yongding County which comprises 17 towns with a large ethnic minority population in Western Hunan, and You County, which comprises 14 towns with a large ethnically Han population in Eastern Hunan, were selected. These two counties represent different cultures, lifestyles, and ethnic groups in Hunan province, but have similar population sizes and birth rates. Six towns from each county (a total of 12 towns) will be randomly selected as clusters and assigned at random to three different arms using a randomization protocol available on the internet (http://stattrek.com/statistics/random-number generator.aspx). No specific eligibility criteria are identified for towns.

Study participants

The target population includes women from the selected towns with a history of GDM. Inclusion criteria are a history of GDM, ≥ 18 years of age, at least 6 weeks but within 3 years postpartum, intending to live in the research county for at least 2 years, having smartphones access, and being able to speak Chinese. Exclusion criteria: plan to be pregnant in the next 2 years, currently pregnant, have been diagnosed with T2DM, take medications that influence glucose metabolism, physical or cognitive disability, current history of substance abuse, history of severe psychiatric disorder, or previous participation in a lifestyle intervention.

The power calculations for sample size estimates are conducted based on the primary hypothesis of the superiority of CAMP and ILSM than control group for T2DM risk scores and insulin resistance. For women with a

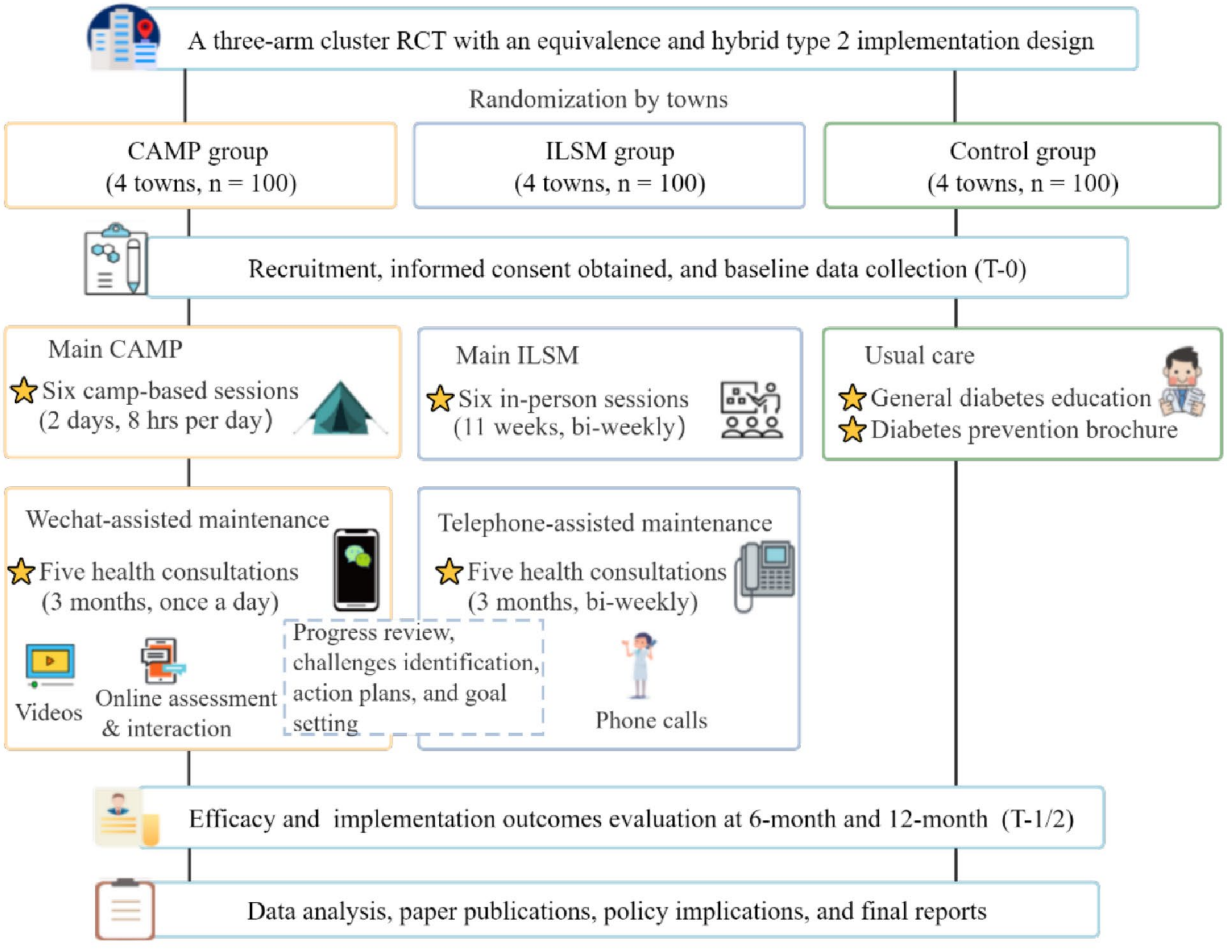

Fig. 1 Flowchart of the project

history of GDM who have relatively normoglycemic status, T2DM risk scores with a comprehensive assessment of potential risk factors are a more sensitive and stabling indicator. The risk score has also been widely used in tracking the effectiveness of intervention to prevent diabetes over time, such as in Finland, Germany and India [23–25]. At the same time, 75-g oral glucose tolerance test (OGTT-2 h) are also selected as co-primary outcomes because of its ability to identify isolated post-challenge hyperglycaemia. In this study, we assumed a decrease in the T2DM risk score and OGTT-2 h by 2 points and 0.87 mmol/L, respectively of ILSM (based on previous results) and CAMP groups and an inter-class correlation coefficient of 0.2 for cluster randomization. Recruitment of at least 20 participants per town will provide over 80% power at alpha=0.05. Allowing for attrition within 12 months, we will recruit a total of 300 participants, with 25 per town.

Recruitment

We will recruit the participants through recruitment flyers and telephone invitations. The two county-level hospitals which have the largest birth number in the respective counties were selected as the research sites. Recruitment flyers containing inclusion criteria and contact information will be posted there and the town level hospitals. Telephone invitations will also be conducted by trained local registered nurse from the two county-level hospitals. First, they will review the medical records of the women who delivered babies in either the maternal health care providers of each county will allow us to identify potential participants. These women who meet inclusion criteria will receive a phone call from nurses to explain the purpose of the study and determine interest in participation. Once potential participants express their interest, nurses will confirm their eligibility and invite them to participate. Signed informed consent will be obtained in-person. The recruitment rate and reasons why women decline to participate will also be documented.

Intervention

Intervention content All participants will receive usual care based on current clinical guidelines and recommendations for T2DM prevention, including general information about their diabetes risk, the importance of lifestyle behavior, and a recommendation for diabetes screening every 3 years. As part of usual care, a brochure on diabetes prevention of the six lifestyle skills (i.e., orientation and goal setting, healthy eating patterns, physical activity, stress management, family support on healthy lifestyle patterns, and relapse prevention) will be provided to each participant. The CAMP and ILSM interventions are guided by Social Cognitive Theory [26]. Both interventions share the same session content with the aforementioned six lifestyle skills with different delivery format, as described below.

Participants in the ILSM group will receive the intervention following the ILSM protocol [11]. The program comprises six biweekly, in-person group-based sessions and five biweekly telephone health consultations for three months. Each in-person session will last 90 min, and each telephone health consultation will last about 20 min (100 min in total). Telephone sessions will be conducted one week after each in-person session, to review of progress toward dietary, physical activity and goals, identify challenges faced in achieving goals, assist with setting new action plans, and encourage achievement of goals [11].

Participants in the CAMP group will receive the intervention following the CAMP protocol which was finalized based on a pilot study (n=25). The intervention includes a 2-day camp-based session and 3-month maintenance sessions via WeChat which is the most commonly used social media platform in China. Six lifestyle skills in six sessions with the same length and content as the ILSM program will be presented over 2 days. Maintenance health consultations will be provided once a day for 3 months via a WeChat mini-program (Software copyright owned by our team, No.2021SR1055662), which has been tested for usability and acceptability with the target population. Participants will be asked to watch a 1-minute video on the six lifestyle skills promotion which was developed and evaluated by the experts panel. And then, they need to answer five multi-choice questions based on the specific video content. The short video-based tool kit includes 90 videos. In addition, participants will be encouraged to comment or ask questions in a chat community or chat privately with the trained local nurses about their goal achievement and challenges with feedback provided within 24 h during working days. Privacy settings of the WeChat mini program will be used to safeguard personal information.

Intervention delivery Twelve local registered nurses (6 per county/hospital) will be trained to work as the local project field officers and each nurse will be responsible for organizing a group of 25 participants from each town. The research team will go to counties to train each nurse for one intervention arm they are responsible for (i.e., CAMP, ILSM, or usual care). The CAMP or ILSM training will include self-study, class sessions, and live practice, which is anticipated to take two days, with homework and practice required between training. Training will cover orientation of the project's goals; protection of human subjects; protocol and documentation; motivational interviewing techniques for behavioral change; team roles, responsibilities, and supervision. These nurses will be responsible for

making site arrangements, conducting the interventions, and scheduling onsite data collection with the participants for each group. Details of an intervention's content will be provided using a specified protocol and manual for each group. A research assistant will serve as a resource person at each research site and attend sessions to prompt the nurses if they overlooked any content or activity via a fidelity checklist.

Implementation strategies

Appropriate implementation strategies will be adopted to improve the participation of targeted women and intervention providers. The 2-day concentrated sessions of CAMP group will be held on weekends accompanied by themed meals or visiting activities (e.g., Hospital History Museum, Health Education Gallery) to increase the feasibility and attractiveness of interventions. Child care, air conditioning, transportation and/or accommodation allowance, healthful snacks, and drinks will also be provided at the CAMP and ILSM in-person sessions. The follow-up maintenance sessions will be delivered via WeChat to facilitate participation and outreach only for CAMP group.

A private social media group will be set up for nurses to share success and challenges in intervention implementation. The principal investigator and research assistants are available to answer questions or provide advice regarding the implementation and send daily verbal encouragement and compliments to each nurse. Peer learning activities will also be held through regular webinars (once a week for a total of 12 sessions) to discuss successes and challenges and share experiences for implementing the recruitment and intervention. They will receive stepped incentives/allowances (money and honors) according to their performance.

Blinding

Due to the nature of the interventions, it is not possible to mask participants or nurses in the group assignments. All data assessors will be blinded to group assignments, and allocation will be concealed from the study statistician in charge of developing and conducting the statistical analysis program. To avoid contamination, the nurses and participants will be asked to sign a non-disclosure agreement not to share the training materials or protocol with others before the completion of the study.

Data collection and measurement

To guide evaluation of the implementation outcomes of interventions, we will use the RE-AIM model which assesses an intervention's potential for sustainable implementation in real-world settings [27]. We will evaluate reach, efficacy, and implementation due to time constraints. The trained data assessors (i.e., research assistants who do not know the group assignment) will collect data at the research sites. Self-report questionnaire data will be collected by paper and pencil; anthropometric data will be measured at baseline (T-0), 6-month (T-1), and 12-month (T-2); and glycemic outcomes will only be measured at T-0 and T-2. The trained local nurses will call all participants to remind them of upcoming data collection sessions. All implementation outcomes during the study period will be documented by trained research assistants. On completing each data collection, participants will receive 50 RMB for their time and transportation.

Demographic and clinical characteristics

Sociodemographic factors (age, marital status, education, occupation, annual household income, and ethnicity), health characteristics (smoking status, alcohol consumption, pre-pregnancy BMI, gestational weight gain, parental history of diabetes, GDM), and clinical characteristics (diagnosis of GDM, number of pregnancies, pregnancy complications, birth weight of children, gestation week at delivery, treatment for GDM) will be collected by a self-report survey at baseline.

Efficacy outcomes (efficacy domain)

The primary outcomes The primary outcomes include a comprehensive T2DM risk score and the biomarkers of insulin resistance. T2DM risk score will be measured by the Chinese Diabetes Risk Scale (CHINARISK) [28], adapted from the Canadian Diabetes Risk Questionnaire and widely validated in the Chinese population. The questionnaire's sensitivity is 73%, with a positive predictive value of 57% and a negative predictive value of 78%. The biomarkers of insulin resistance will include glucose values on the oral 75 g glucose 2 h post-load glucose tolerance test (OGTT-2 h). Blood samples will be collected after 12 h of fasting, followed by blood samples taken 2 h after consuming 75 g of glucose.

The secondary outcomes The secondary outcomes include anthropometric (BMI, and waist circumference), behavioral (dietary intake, intention to eat Low Glycemic Index Foods, physical activity, daily steps), and psychological (self-efficacy and social support for diet and physical activity) outcomes.

Anthropometric outcomes BMI will be calculated by dividing each participant's body weight in kilograms by their height in meters squared (kg/m^2). Waist circumference will be measured on a horizontal plane, midway between the inferior margin of the ribs and the superior border of the iliac crest.

Behavioral outcomes Dietary intake will be assessed by the validated food frequency questionnaire [29] to collect information on staple foods, legumes, vegetables, fruits, and dairy consumed in the past 3 months. The Intention to Eat Low Glycemic Index Foods will be assessed with a 24-item questionnaire that uses a 7-point Likert scale, on which higher scores indicate a greater intention to eat low glycemic-index foods. The Cronbach's α ranged from 0.78 to 0.93 in previous studies. Physical activity will be assessed by the validated Chinese version of the International Physical Activity Questionnaire (Short Form) [30] to recall the intensity and duration of physical activities during the past 7 days. Daily steps will be measured on 7 consecutive days using the StepWatch Activity Monitor on their smartphone.

Psychological outcomes Self-efficacy and social support for diet and physical activity will be assessed by an 8-item Diet and Physical Activity Self-efficacy Scale - the Chinese version [31] and the validated Social Support for Diet and Physical Activity Scale of the Chinese version [32], respectively. These four scales are scored on a 4-point scale, with higher scores indicating higher levels of individual self-efficacy and social support for eating and exercise. The Cronbach's α for the Dietary Self-Efficacy Scale and the Physical Activity Self-Efficacy Scale ranged from 0.93 to 0.95 and 0.87–0.97, respectively, and ranged from 0.86 to 0.89 and 0.78–0.87 Dietary Social Support Scale and the Physical Activity Social Support Scale.

Implementation outcomes

Reach domain Recruitment rate, eligibility exclusions, and enrollment will be calculated. Reasons for declining participation or not completing the study will be documented.

Implementation domain *Individual level*: Acceptability of the ILSM and CAMP programs will be collected by a self-report 4-item satisfaction questionnaire which was finalized according to our intervention content; feasibility will be evaluated by attendance, attrition, and engagement of each intervention. *Organizational level*: Fidelity will be recorded by a trained research assistant using a fidelity checklist, which aligns with the content and sequence for each session. Cost will be measured by the costs accruing to the health and social care system and to individuals and families for the intervention and for health care, including inpatient and ambulatory care, medicines, personnel costs to deliver the ILSM, and other procedures and treatments. We will also assess the costs falling on individuals and families for non-medical costs (travel, child-minding, and time / lost income).

Data analysis

Data confidentiality will be ensured, both during the implementation phase of the study and in any resulting presentations or publications. All statistical analyses will be conducted using SPSS (version 26). Descriptive statistics such as frequency, percentage, and mean will be used to summaries all outcomes and variables. Intention-to-treat (ITT) analysis will be used in which participants who lose contact or drop out in the follow-ups will be treated as a failure to achieve any efficacy outcome. Multiple imputations will be used to compute missing data for efficacy outcome variables. Baseline group comparisons will be conducted by chi-square test, Fisher's exact test, or Kruskal-Wallis test depending on variable types and distribution. Bonferroni corrections were used for multiple comparisons, with $p<0.05/n$ (n is the number of subgroups) considered statistically significant.

For Aim 1, we expect both the CAMP and ILSM programs to be superior to usual care for all efficacy outcomes. If both intervention arms are shown to be effective, a secondary exploratory analysis will be planned to evaluate if CAMP is more effective than ILSM. Estimates and significance testing will be done using repeated measures analysis of variance. We will test the normality of residuals using standard tests and supplement the ANOVA F-test for interactions with robust GEE (generalized estimating equation) estimates of the group by time interactions using a Wald Chi-Square Test. We expect the time path of efficacy-related outcomes for the CAMP and ILSM programs to be similar enough to accept the null hypothesis (CAMP and ILSM) by time interactions. If we observe meaningful and significant differences between the CAMP and ILSM programs, we will characterize them with respect to time (baseline, 6 months, 12 months) and the nature of the outcome. The cluster, potential baseline covariates, such as age, months after delivery, ethnicity, education, marriage, occupation, and family income will be controlled to adjust estimates for cluster differences and control variance inflation.

Comparison of implementation outcomes in Aim 2 will focus on (a) measuring and testing differentials in rates of recruitment and retention and (b) data collected from participants on the acceptability and feasibility. We will also calculate the operation cost for each intervention; this consisted of expenses on manpower and materials needed for training, recruitment and intervention delivery.

Discussion

This is one of the first studies to examine the effectiveness and implementation of two delivery formats of interventions (standard in-person sessions versus hybrid camp-style sessions) aimed at reducing the risk for diabetes among women with a GDM history. The camp sessions

include the same intervention content as the ILSM standard sessions but via a more concentrated delivery format, the follow-up sessions on a social media platform versus telephone sessions for the ISLM group, which may allow for more support and motivation via communication with other participants. In the proposed study, it is hypothesized that the camp-style intervention will be as effective as the ISLM in-person format in reducing T2DM risk but the camp-style format will reach a wider audience and improve participation. If successful, the camp-style format may be applied to other lifestyle interventions and become a model for implementing diabetes prevention interventions in primary care settings.

We will incorporate principles of pragmatic trials and implementation science by using a type 2 hybrid effectiveness-implementation design instead of the traditional sequential scientific approach (moving from clinical efficacy to effectiveness and then implementation) which requires significant time and resources [22]. The hybrid design allows for the simultaneous evaluation of efficacy and implementation outcomes, thus addressing gaps in clinical efficacy and actual use of interventions in real-world practice. The evaluation of hybrid designs involves careful attention to assessing outcomes related to both clinical effectiveness and implementation success, and we will evaluate the implementation outcomes based on the RE-AIM framework. The framework has been used extensively to improve the development and evaluation of complex interventions that have a greater likelihood of wide-spread implementation and sustainability in clinical practice.

This study has four notable strengths: (1) we propose a novel implementation strategy: camp-style intervention delivery format with a social media-based maintenance tool kit in maternal health promotion, which may reach a wider audience of women with GDM history in a cost-effective way; (2) the intervention will be delivered by local registered nurses who will receive unified training, which may facilitate reach and sustainability under limited labor and material resources conditions; (3) optimized implementation strategies, such as standardized training material and video-facilitating technology to ensure intervention fidelity, peer learning/champion-experience sharing activities and stepped incentive/allowance to increase motivation and capability, will be adopted; (4) a robust RCT design methodology including cluster randomization, masking of data collection and analysis, and intervention fidelity evaluation, will be used. In addition, we also developed some refined strategies with local health workers to ensure successful implementation of the study. For example, recruitment will start in March as it is the end of the Chinese New Year Festival of a long holiday when people tend to create personal goals, including health-related goals, and our lifestyle programs address both physical and psychological needs [33].

The researchers acknowledge several weaknesses: (1) we are unable to assess change in the incidence of T2DM, which will be infrequent at 12 months; (2) the self-report measurements for physical activity may have recall bias, although the daily step will also be evaluated by the Step-Watch Activity Monitor on a smartphone; (3) clustered nature is prone to variance inflation, but we will minimize this risk by adjusting for clusters as a confounder; (4) we considered randomizing multiple local nurses from the same site to different conditions to ensure homogeneity, this would have presented a potential risk of contamination due to close contacts exist among these nurses, but confidentiality measures, such as signing non-disclosure agreement will be adopted.

This hybrid implementation-effectiveness study has the potential to illuminate the processes and complexities associated with supporting the adoption of an evidence-based program in resource-limited settings. If successful, a camp-style lifestyle program may contribute to wide-spread reach, better attendance, and intervention effectiveness in reducing the risk of T2DM, thus offering a novel, promising approach in implementing a maternal health promotion program in rural areas. This study will provide RCT-level evidence on camp-style lifestyle programs to the evidence-based clinical practice guidelines and is likely to provide valuable insight into T2DM prevention in low-resource areas.

Abbreviations

T2DM	Type 2 diabetes mellitus
GDM	Gestational diabetes mellitus

Supplementary Information

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Supplementary Material 1

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Author contributions

YC was responsible for conceptualizing and designing study, writing and revising manuscript, and preparing for publication. QZ contributed to literature review of related research and was a major contributor in writing the Introduction part of manuscript. WL and QL focused on methodology and were major contributors in designing and implementation of intervention. JC, RW and MP Wang participated in conceptualization, and revising and editing manuscript. JW focused on writing the part of sample size calculation, randomization and data analysis. JG was responsible for study design and conceptualization, methodology, project administration, resources and review. All authors read and approved the final manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
The study has been approved by the Ethical Review Board of Xiangya School of Nursing Central South University (NO. E2021162) and registered in Chinese Clinical Trial Registry (ChiCTR2200058150) on 31st March 2022. The trial will be conducted in accordance with the rules of Good Clinical Practice outlined in the Declaration of Helsinki. Potential participants will be all informed about the study in writing and orally. The information will describe the purpose and process of the study, the method used and publication plans. The information will also include confidentiality assurance, the principles for voluntary participation and included contact information to the researcher and organization behind the study. The written information will also include a form for obtaining a written informed consent. All the participants need sign and return the written informed consent prior to participation.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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