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Mom's Good Mood: screening and management of perinatal depression within primary healthcare system in China–protocol for an effectiveness–implementation design study

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ABSTRACT

Introduction The management of perinatal depression (PND) is challenging in China. The Thinking Healthy Programme (THP), developed under the core theory of cognitive–behavioural therapy, is an evidence-based approach that is recommended as a psychosocial intervention for managing PND in low/middle-income countries. Sparse evidence has been generated, however, to assess the effectiveness of THP and guide its implementation in China.

Methods and analysis A hybrid type II effectiveness–implementation study is ongoing in four cities in Anhui Province, China. A comprehensive online platform, Mom's Good Mood (MGM), has been developed. Perinatal women are screened using the WeChat screening tool (ie, Edinburgh Postnatal Depression Scale embedded as metrics) in clinics. Different intensities of the intervention are delivered through the mobile application for different degrees of depression, according to the stratified care model. The THP WHO treatment manual has been tailored to be the core component of intervention. Guided by the Reach, Effectiveness, Adoption, Implementation and Maintenance framework, process evaluations will be conducted to identify the facilitators and barriers to implementation and to modify the implementation strategy; summative evaluations will be carried out to examine the effectiveness of MGM in the management of PND within the primary healthcare system in China.

Ethics and dissemination Ethics approval and consent for this programme were obtained from Institutional Review Boards in China: Anhui Medical University, Hefei, People's Republic of China (20170358). Results will be submitted to relevant conferences and peer-reviewed journals.

Trial registration number ChiCTR1800016844.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study uses the plan–do–study–act cycle to guide the implementation process and structure an iterative process of change, which is a widely accepted model in healthcare quality improvement.
⇒ This study uses an effectiveness–implementation hybrid type II design, placing equal focus on effectiveness of intervention while also investigating the implementation in real world.
⇒ The design of using the comparison of cohorts A, B and C can test the effectiveness under real-world circumstances leading to enhanced generality of our project.
⇒ This study uses a mixed-methods approach guided by the Reach, Effectiveness, Adoption, Implementation and Maintenance evaluation model to undertake summative evaluation, which provides structure to systematically evaluate the impact of the whole project.
⇒ The uncontrolled nature of our study design may influence the rigorousness of the study.

INTRODUCTION

Perinatal depression (PND) refers to the onset of depressive symptoms, which persist for at least 2 weeks, during pregnancy and up until 1 year post partum.[1] The reported prevalence of PND ranges from 7% to 25% with a much higher prevalence in low/middle-income countries (LMICs) compared with higher-income countries.[2–4] One recent review indicated that the prevalence of depression was 19.7% antenatally and 14.8% postnatally in mainland China, and that an increasing trend in prevalence has been observed in the last decade.[5] Untreated PND can result in short-term and long-term adverse outcomes for both women and their children, including increased risk of pre-eclampsia, self-harm, suicide and infanticide,[6 7] and higher risk of adverse birth outcomes and offspring neurodevelopmental and behavioural outcomes.[4 8] Thus, identification and management of PND are crucial to improve the quality of life of women, children and their families.

PND is recognised as a non-psychotic and treatable depressive episode. Nevertheless, a low proportion (ie, 12%) of women with PND receive treatment.[9] There is a vast gap between the demand for—and provision of—mental healthcare services, due to inadequate and inequitable mental health resources. In China, mental health resources are mainly concentrated in urban areas, and many rural regions have no psychiatric hospital beds.[10 11] There are 1.7 psychiatrists and 1.9 psychiatric nurses for every 100 000 people, which was well below the global average of 4.15 psychiatrists and 13.0 psychiatric nurses per 100 000 people.[10 12] Symptoms of depression are being screened in some antenatal/postnatal clinics in China,[13] but screening has little benefit in the absence of subsequent interventions.[14]

What is more, the willingness of pregnant women and young mothers with depression to seek help is affected by their attitudes, possible stigma and personal treatment preferences, but their willingness is also affected by other factors such as childcare issues, lack of time and inconvenience.[15] High digitisation has become an important feature of society today, and people in China can easily access the internet with the rapid development of smart mobile phone technology.[16] Thus, this wide proliferation of mobile devices provides a new opportunity to reach and help women with PND.

The WHO's Mental Health Action Programme provided evidence-informed guidance and tools to create a screening and stepped-care management programme for PND that could be integrated within primary maternal and child healthcare services.[17] Screening programmes integrated within maternal and child healthcare services report better follow-up, management, therapy initiation and maternal outcomes than non-integrated programmes.[18] Since the release of the 'Deepening Healthcare and Pharmaceutical System Reform Plan' issued in 2009 by the Central Committee of the Communist Party of China and State Council, China has built a network of maternal and child health services that cover urban and rural regions.[19] Under this plan, all perinatal women and children aged 0–36 months have equal access to essential public health services in primary healthcare service centres, and there are enough primary healthcare providers (HCPs) to fully integrate mental healthcare into the maternal and child health system in China.

The Thinking Healthy Programme (THP), delivered by community health workers in Pakistan, has shown to be effective in reducing depression symptoms and could be used as part of a stratified care model for PND. THP is based on principles from cognitive–behavioural therapy (CBT), and was developed as a low-intensity psychosocial intervention for PND.[20–22] THP guides women to replace unhealthy thinking with helpful thinking through awareness of negative interpretations (eg, thoughts, beliefs, attitudes) and behaviours that perpetuate these negative interpretations.[23] The programme was shown to be effective when delivered by trained non-specialist providers in LMICs.[24 25] No study has been conducted to assess the effectiveness of THP or to guide its implementation in China. In response to this need, the Perinatal Depression Screening and Management (PDSM) Programme will adapt the THP manual for two types of interventions including animated videos for self-help treatment and one-to-one counselling through a video call, aim to tackle the PND issue within primary healthcare system in China.

Study goals and aims

We aimed to build a PDSM Programme to tackle the PND issue within primary healthcare system in China through establishing an online platform, namely Mom's Good Mood (MGM), and integrating into routine maternal healthcare in perinatal clinics. To achieve this goal, we have the following two specific aims:

Specific aim 1: to screen PND and deliver CBT among PND-positive women through the use of mobile devices and determine the effectiveness of internet-based CBT in reducing depressive symptoms among perinatal women in China.

Specific aim 2: to understand the barriers and facilitators of PDSM implementation, and formulate a practice guideline for scale-up. Our study is an effectiveness–implementation hybrid type II design, placing equal focus on investigating the effectiveness of internet-based screening and intervention while also investigating the implementation of PDSM in real-world settings. Hybrid type II design is used to combine elements of clinical effectiveness and implementation research to enhance public health impact, which are more direct blending of intervention effectiveness and implementation aims in support of more rapid translation.[26] We plan to apply a study design shaped, informed, and refined by both implementation science concepts and frameworks and by multilevel stakeholders. A mixed-methods approach will be used, incorporating a variety of qualitative and quantitative data collection techniques including surveys, structured interviews and psychometrically established measures.

METHODS AND ANALYSIS

Study sites

This study will be conducted in four cities in Anhui Province, China: Ma'anshan, Hefei, Bengbu and Fuyang (figure 1). Anhui Province, located in East China, belongs to the Central China Economic Zone, where mental health services have not yet been integrated into the primary healthcare system. Ma'anshan, located in southeastern Anhui, and which has undergone rapid economic development, has been selected as the pilot site. Hefei, the provincial capital of Anhui Province, has been selected as the site for validity determination. Bengbu, a mid-sized, urban city located in the northeast of Anhui Province, and Fuyang, a large agricultural city located in the northwest of Anhui Province, have been selected as scale-up sites to enhance our understanding of the transferability of our findings to different settings.

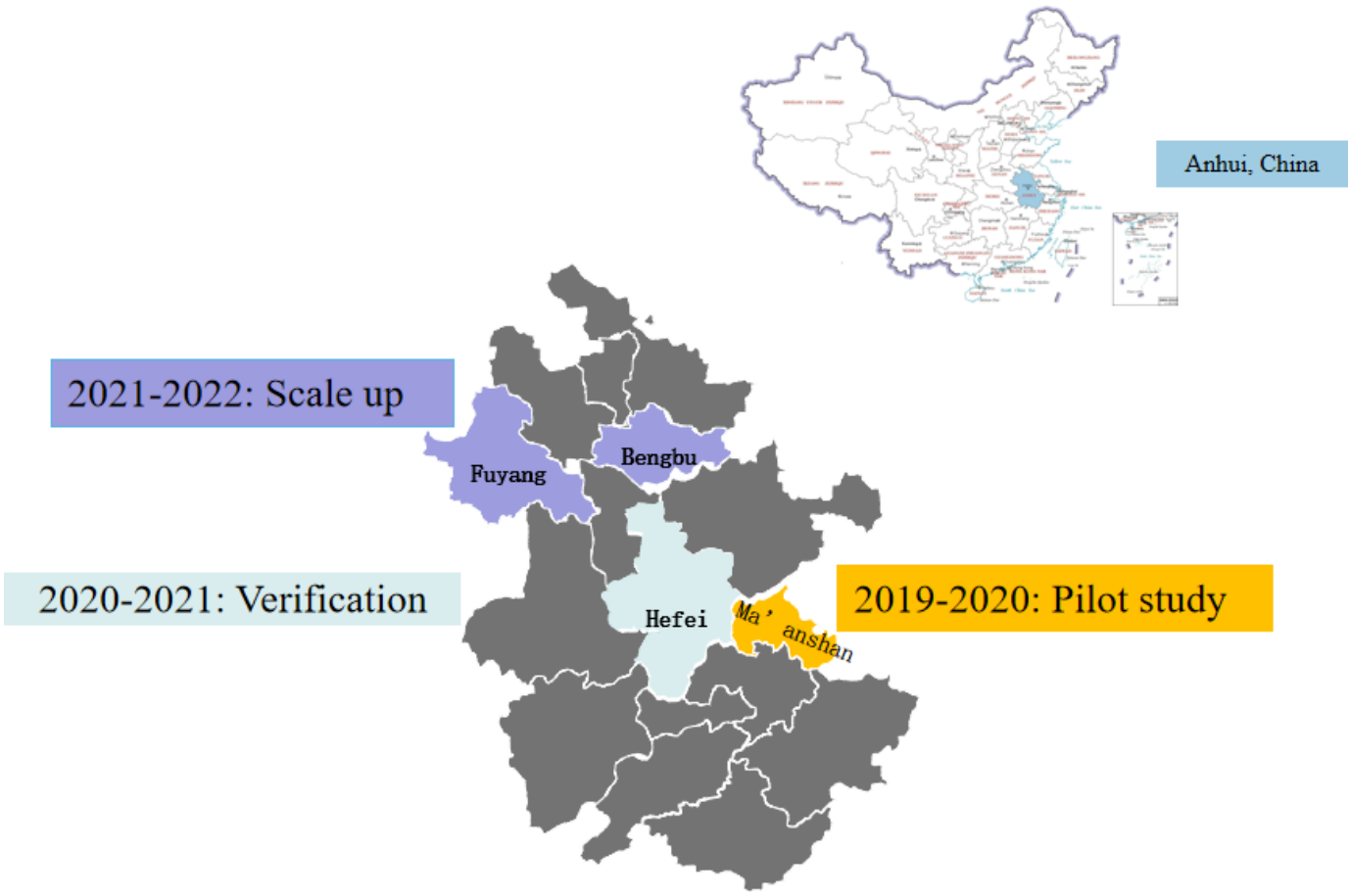

Figure 1 Map showing the distribution of study sites and the implementation plan at different sites.

The PDSM will be implemented in maternal and child healthcare centres (MCHCCs) in each of the four cities.

Study population

Our study will include a sequential model of recruitment. When perinatal women come to the maternal healthcare clinics for their prenatal or postnatal visit, HCPs will introduce the information of our study and invite them to participate. Recruited women for the study need to fulfil the inclusion criteria of during pregnancy or within 3 months after delivery. The exclusion criteria are having language barriers, or lacking a mobile phone or being unable to provide consent.

Specific aim 1: to screen and deliver CBT through the use of mobile devices and determine the effectiveness of internet-based CBT in reducing depressive symptoms among perinatal women in China

Design

Our study involves three stages: (1) pilot study; (2) determination of validity and (3) scale-up. During the pilot study, we aim to establish the PDSM online platform, develop a logical workflow in the field, and evaluate how internet-based CBT is used in the real world for perinatal women and identify opportunities for improving implementation in other cities. At the determination of validity stage, at the second site, we will then test the effectiveness of PDSM (ie, screening plus intervention) as a whole, as well as the effectiveness of the intervention alone, at different time points. At the scale-up stage, we will further validate the effectiveness of PDSM as a whole, in two different scale-up settings (figure 1).

In the pilot study, we will simultaneously implement the screening and management of depression during pregnancy and post partum in Ma'anshan City, Anhui Province. We will recruit women in their first trimester, and these women will be followed into their second trimester, third trimester, 42 days post partum, 3 months post partum and 6 months post partum. We will also recruit women at 42 days post partum and follow up with them at 3 months post partum and 6 months post partum. At each time point, depressive symptoms for each woman will be assessed using the Edinburgh Postnatal Depression Scale (EPDS) (see online supplemental figure 1). For women who are screened positive, different intensities of depression management (ie, hierarchical management) will be delivered according to the PDSM protocol (figure 2).

In the second phase, a cohort-controlled trial design in a real-world setting, in the second city in Anhui Province (ie, Hefei), will be used to evaluate the effectiveness of different components of PDSM. Women will be assigned to one of three different groups based on their recruitment time period. In group A, women in

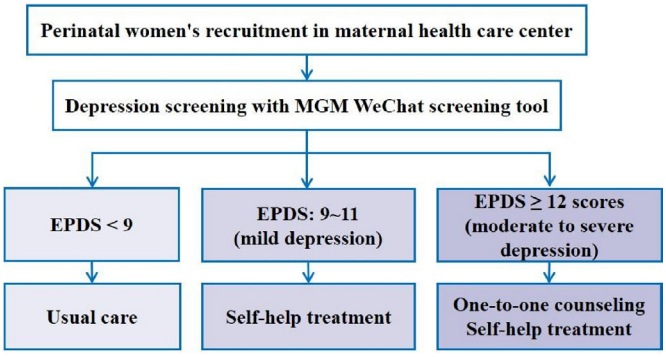

Figure 2 Flow chart of enrolment and hierarchical management in the PDSM Programme. EPDS, Edinburgh Postnatal Depression Scale; MGM, Mom's Good Mood; PDSM, Perinatal Depression Screening and Management.

their first, second and third trimesters will be recruited and screened simultaneously and will be re-evaluated at 42 days post partum. Group B women will be recruited and screened in their first, second and third trimesters simultaneously, and women positive for depression based on the EPDS will receive the intervention as detailed in the PDSM protocol. All women recruited in group B will be re-evaluated at 42 days post partum. Finally, group C women will be recruited and screened at 42 days post partum. Women with depression in each of these three groups will be followed up at 6 months post partum and 1 year post partum, to determine the long-term effects of the intervention (see online supplemental figure 2).

In the scale-up period, after we determine the effectiveness of PDSM for perinatal depression, we will optimise the implementation process to expand PDSM to two other cities in Anhui Province (ie, Bengbu and Fuyang). Screening and management of depression during pregnancy and post partum will be implemented at these sites, adopting the same design as that used for group B and group C in the second, cohort-controlled trial stage. Regardless of the stage (ie, pilot, validity determination, scale-up), women who are screened positive at 42 days post partum will be provided with the THP intervention (see online supplemental figure 3).

Quality improvement method

We will use the plan–do–study–act (PDSA) cycle to guide the implementation process and structure an iterative process of change, which is a widely accepted model in healthcare quality improvement.[27] The four-step PDSA cycle includes a 'plan' step that aims to develop the plan for improvement, the 'do' step to implement the plan, the 'study' step to collect and analyse the data, and the 'act' step to identify adaptations and guide the next cycle.

Establishment of the online platform

The online platform for the screening and management of perinatal depression, namely MGM, has already been developed. MGM consists of a WeChat screening tool, mobile application (ie, app) that delivers the intervention and website-based backstage management system. WeChat is a free social messaging app developed by Tencent, and is widely used across China. As of 2020, there were over 1.2 billion active users of WeChat.[28] The intervention app provides 11 self-administrated CBT-based video clips that can be accessed by women with various severities of depressive symptoms, and also provides one-to-one video counselling for women with moderate to severe depression symptoms. The backstage management system has been developed to supervise and manage the programme, and also to monitor and download data collected by the WeChat screening tool and intervention app.

Procedure for screening and management

After providing written informed consent, participants will be offered a QR code to scan to access demographics and screening questionnaires, including the EPDS. After participants submit the questionnaires, HCPs can review these questionnaires on the backstage management system. Then, feedback and suggestions will be provided to women both orally and through the WeChat forum before the woman leaves the clinic on the same day. HCPs will guide women for further action following the flow chart of hierarchical interventions in figure 2.

Training with HCPs

Prior to participant recruitment, all HCPs responsible for the programme will receive training about how to introduce our programme and attain informed consent, how to guide women through screening on the WeChat platform, how to operate the MGM intervention app, how to manage the participants under the HCP's account in the backstage management system and how to manage emergency situation.

Therapists are HCPs selected from maternal and child healthcare agencies with rich knowledge and experience in perinatal care. A master trainer and a local trainer will conduct training related to CBT for depression. The master trainer is a professor of clinical psychology and a leading expert in CBT, and has trained mental health professionals in many countries, including China. The local trainer is a registered supervisor of CBT and is proficient and experienced in CBT training. The whole training process teaches basic counselling skills, the MGM manual, and the theory and application of CBT. Therapists will receive six consecutive offline training sessions each lasting for 2–3 days, and will be assessed for competence at the end of the training using the Cognitive Therapy Rating Scale by the master trainer.[29]

Furthermore, audio recordings will be obtained from women who provide consent, for quality control purposes and to reassess the HCPs' CBT competencies. Only those trainees who achieve an overall satisfactory level of competence will be eligible to provide one-to-one counselling for perinatal women.

Intervention

Online intervention: considering Chinese context, the THP manual was significantly enhanced with new content,

transformed into a series of animated videos. Animated videos offer self-help treatment for women who score 9 or higher on the EPDS in learning how to ease their emotions by using CBT skills. The series of videos comprises four modules: (1) introduction to PND and how thinking influences emotions; (2) a module related to preparing for the baby, with information about health during pregnancy and relationships with people around her; (3) a module on the baby's arrival, containing sessions on the mother's health, her relationship with her baby and her relationships with people around her; (4) the homework module introducing how to complete the daily health calendar. Beyond that, one-to-one counselling based on the THP manual is offered for women who score 12 or higher on the EPDS. Counselling is delivered remotely through a video call lasting for approximately 45 min, to a maximum of 12 counselling sessions. The counselling follows two core steps: (1) learn to identify unhealthy thoughts; and (2) learn to challenge and replace unhealthy thinking with positive or healthy thinking. An online health calendar invites women to document, on a daily basis, their practice of the skill of thought replacement, and monitors women's moods and activities.

The online interventions including animated videos and one-to-one online counselling both aim at modifying unhealthy thoughts to ease the mood and activate behaviour to facilitate change.

Referral to the mental health centre: as recognition that some women with major mental health disorders might require specialist psychiatric services, HCPs in clinic are able to refer severely depressed patients to a mental health centre for clinical treatment and complete the referral before the women leave the clinic. Beyond that, any participant who develops severe depression over the course will get referral by the staff of the project for clinical treatment.

Emergency treatment: women are informed about the way we deal with emergencies when recruited. During screening, if a woman is found to have suicidal or self-harm ideation/attempt/action, HCPs in the clinics will confirm if she does have that suicidal or self-harm ideation/attempt/action, then issue a referral letter to the mental health centre with the consent of the women. We require that the referral must be completed before the women leave the clinic on the same day. For the woman who refuses a referral, HCPs in clinic will guide her to make an online appointment with a psychiatrist on MGM application before she leaves the clinic. Finally, for all women with suicidal or self-harm ideation/attempt/action, the staff of our project will call her emergency contact in 24 hours, which they have filled in when recruited, and are informed that we would make contact with them in certain conditions we are concerned about.

Intervene to enhance uptake and adherence

A supervision group will be established, including researchers in China and Canada, director of maternal and child healthcare agencies and a psychiatrist. During a weekly 60-minute implementation review session, research assistants will present updates regarding project progress and problems to researchers, directors, the psychiatrist and the project coordinator.

Specific aim 2: to understand the barriers and facilitators of PDSM implementation, and formulate a practice guideline for scale-up

Data collection

The research team members will visit each site before project implementation, to meet with key stakeholders. Each meeting will involve two in-depth interviews and three focus group interviews using a semistructured interview guide, to help adapt the programme to meet local needs. Key stakeholders include perinatal women and their family members, on-site policymakers and HCPs.

During implementation, we will also conduct stakeholder interviews as part of our process evaluation, to identify the facilitators and barriers to implementation at different sites and to optimise the process for better implementation. The PDSA cycle will be used to explore and identify facilitators and barriers at each study site, and to modify the implementation process and guide new adaptations at subsequent sites.

Data analysis

Mixed-methods combined qualitative and quantitative methods guided by RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) evaluation model will be used to undertake summative evaluation. In the following section, we outline the measures proposed for each dimension of RE-AIM that will be used to evaluate the PDSM Programme (table 1).

Analysis for specific aim 1

We strive to determine the reach and effectiveness of implementation through a three-stage design (pilot study, the determination of validity stage, scale-up stage) and examine the effectiveness of the different components of the PDSM.

Reach

Two measures will be the proportion and demographic characteristics of perinatal women (or women with depression) who participated in depression screening (or received the intervention), which indicate the extent to which the screening (or intervention) is reaching the intended general population (or target population).

Effectiveness

Effectiveness will be examined by comparing the prevalence of depression, defined as an EPDS score of at least 9, and the EPDS scores at 42 days post partum, through the following three parts:

Overall effectiveness of PDSM: in the second phase, women in group B will be recruited and screened in their first, second and third trimesters simultaneously, and women who are positive for depression based on the EPDS will receive the intervention. On the other hand, women in group C will be first recruited and screened at 42 days post partum. To determine treatment effectiveness of the PDSM, we will compare the prevalence of depression and EPDS scores between

Table 1 Summative evaluation of the PDSM using the RE-AIM evaluation framework

RE-AIM domain	Outcome(s)/indicator(s)	Data source	Indicator definition/clarification
Reach	MGM coverage	Outpatient records; backstage management data	The proportion and demographic characteristics of perinatal women in primary care who participated in depression screening The proportion and demographic characteristics of depressed women in primary care settings who received the intervention
Effectiveness	The overall effectiveness of PDSM	Baseline survey; backstage management data	Comparison of depressive symptom distributions between baseline and implementation group
	The effectiveness of the intervention		Comparison of reductions in symptoms of depression between intervention and control group
	The effectiveness of implementation in different trimesters		Comparison of reductions in symptoms of depression between women recruited in different periods
Adoption	HCP adoption	Perinatal department-based healthcare provider survey	The percentage of HCPs in perinatal department referring at least one woman to PDSM Project
Implementation	Implementation fidelity	Stakeholder interviews; backstage management data	Degree to which intervention(s) were implemented by HCPs, as detailed in PDSM protocol Use of MGM in perinatal women with depression
Maintenance	Individual level	Backstage management data	Proportion of depressed women who watched three or more self-treatment videos Proportion of moderate to severe depressed women who accepted three or more counselling sessions
	Setting level	Stakeholder interviews after implementation	The extent to which PDSM becomes institutionalised or part of the routine organisational practices at each study site

HCPs, healthcare providers; MGM, Mom's Good Mood; PDSM, Perinatal Depression Screening and Management; RE-AIM, Reach, Effectiveness, Adoption, Implementation and Maintenance.

group B and group C at 42 days post partum. In the scale-up, we will further validate PDSM effectiveness at different sites by comparing the prevalence of depression and EPDS scores at 42 days post partum between participants' follow-up from pregnancy and participants first recruited and screened at 42 days post partum.

Effectiveness of intervention: in the second phase, women in groups A and B will be recruited and screened in their first, second and third trimesters simultaneously, while women in group B will receive the intervention and women in group A only receive usual care. We will make a comparison of the prevalence of depression and EPDS scores at 42 days post partum, among participants positive for depression during pregnancy between group A and group B, to evaluate the effectiveness of the intervention, during pregnancy, in improving the depression symptom at 42 days post partum.

Determine the best trimester to implement PDSM: in the second phase, both groups A and B will consist of individuals from different trimesters of pregnancy. Thus, we will conduct analyses stratified to different trimesters comparing EPDS scores at 42 days post partum among groups A, B and C, to determine in which trimester we should implement PDSM.

Statistical analysis plan

Analyses will use 'intent-to-treat' samples. Baseline demographic characteristics will be compared among the different groups using X^2 tests, t-tests or analysis of variance for independent samples. EPDS scores and the prevalence of depression at 42 days post partum among different groups will be compared using analysis of covariance. The effects of MGM components on EPDS scores will be analysed using generalised linear mixed-effects models adjusting for multiple covariates. Nominal significance will be set as $p<0.05$.

Outcomes of interest

We will focus on two domains of the RE-AIM model–reach and effectiveness and will set up multiple groups to mainly determine the effectiveness of different components of the PDSM (eg, screening, intervention and screening integrated into intervention).

Analysis for specific aim 2

The barriers and facilitators of PDSM implementation will be examined in part through the examination of adoption, implementation and maintenance aspects of the RE-AIM process (table 1).

Adoption

The representativeness and percentage of HCPs in the perinatal department who referred at least one woman to the PDSM Programme.

Implementation

Focus on the extent to which the PDSM Programme was delivered as intended. We will analyse specific implementation information from stakeholder interviews conducted during the implementation process.

Maintenance

Maintenance will be measured, in part, as the proportion of women with depression who watched at least three videos, as well as the proportion of moderate to severely depressed women who receive three or more one-to-one counselling sessions. At the level of the healthcare centre, maintenance refers to the extent to which PDSM becomes institutionalised or part of the centre's routine organisational practices and policies, 1 year after study completion.

In addition to those mentioned above, in-depth and focus group interviews will be transcribed verbatim, coded and analysed using NVivo software.

Outcomes of interest

We will examine the three domains of the RE-AIM model—adoption, implementation and maintenance to recognise barriers and facilitators of PDSM.

Patient and public involvement

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

The ultimate goal is to integrate maternal mental health into the primary healthcare system and to reduce the disease burden of PND across China. Within this overall goal, the project has three prominent characteristics. First, we will take full advantage of the maternal and child healthcare system in China, to make the PND screening and management services accessible to nearly every woman. Second, the integration of offline screening and online intervention is a key feature of this programme. Trained HCPs can increase the credibility of the programme and can provide health education to raise awareness of PND, while the online intervention can provide a convenient and flexible way for women with depression to obtain care. Third, the trained counsellors are HCPs with rich knowledge and experience of maternal healthcare, and may form a new cohort of service personnel to help perinatal women.

While the PDSM Programme aims to bridge the gap between the need for mental health services and the provision of treatment in the primary healthcare system, there are several barriers that need to be overcome. The first barriers are the inadequate state support system and the insufficient mental health practice in primary health system. Although the Chinese National Mental Healthcare System Guidelines (2008–2015) aimed to establish mental health clinics and community mental healthcare, the guidelines were not fully met.[12] Of the four MCHCCs in our current programme, only one centre in Ma'anshan was conducting PND screening, but provided no subsequent interventions for depression. Given the exorbitant demand for mental healthcare, coupled with an insufficient number of specialists especially in rural areas, the current programme will arm primary HCPs with a simple and brief tool.

There is insufficient public awareness of PND in many countries. Social and family support are, however, strongly implicated in the aetiology and treatment compliance of women suffering from PND.[30] Thus, psychological education should be strengthened in primary healthcare. Moreover, participant treatment compliance will no doubt be a key determinant of the success of our project. During the implementation process, we will continuously identify factors that affect programme use and find strategies to maximise usage.

Aside from the online platform, MGM, to make our project more replicable across China, we have developed a standard training manual for both HCPs responsible for screening and counselling, and a standard process for monitoring the implementation. In addition, by considering local culture and conditions, we are planning to do interviews among key stakeholders before implementing our project, and to develop a more personal manual in each place to further promote our project through multiple ways, such as social media.

Our study also has methodological limitations. To test the effectiveness under real-world circumstances, we use the cohorts A, B and C rather than a randomised controlled study, which may influence the rigorousness of the results. Indeed, a randomised controlled trial is the most powerful type of design in clinical studies, especially in studying the clinical effectiveness of the intervention. However, the purpose of our project was to explore the effectiveness of MGM under real-world circumstances, so we believe the design of using the comparison of cohorts A, B and C may lead to enhanced generality of our project as well.

In conclusion, the current study will generate evidence regarding the effectiveness and feasibility of a well-developed PDSM system, namely MGM, for PND in primary healthcare settings in China. Critical features of the programme include convenient screening, convenient and culturally appropriate mobile materials, extensively trained HCPs and integration into the healthcare system. If we achieve robust results informing PND management, it may be possible to consider the scale-up of the programme more broadly within China or to other countries.

ETHICS AND DISSEMINATION

Ethics approval and consent for this programme were obtained from Institutional Review Boards in China: Anhui Medical University, Hefei, People's Republic of China (20170358). Results will be submitted to relevant conferences and peer-reviewed journals.

Data statement

The datasets generated during the study are not currently publicly available because the study is still ongoing. Data will be available from the corresponding author on reasonable request once the study is completed.

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Contributors FT and BZ conceived and designed the study. ML, MJ, YG, HL, YH and XY did the data collection and contributed to the design of the programme. ML and MJ drafted the manuscript. BZ and YC critically revised the manuscript. All authors have read and approved the final version.

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Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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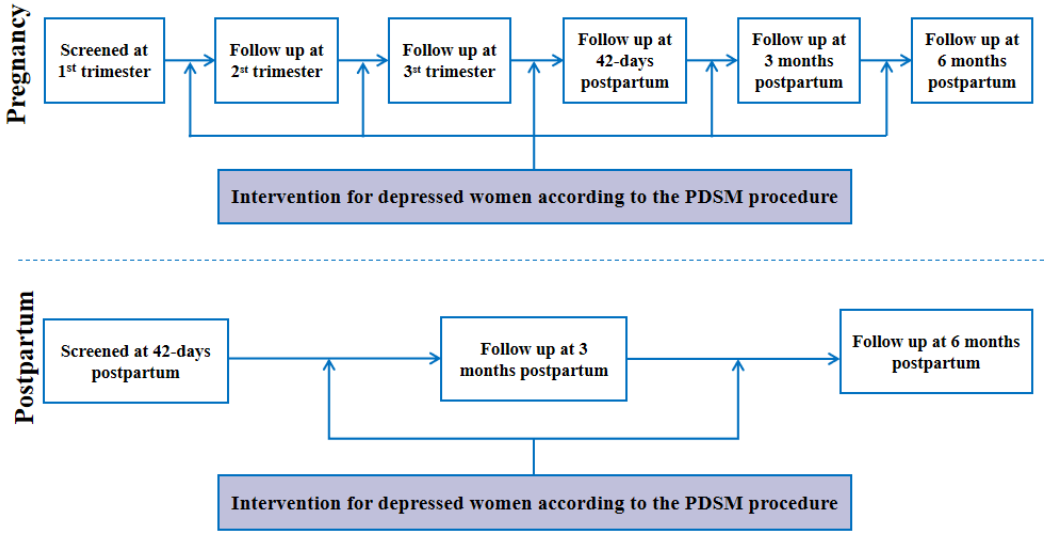

Figure S1 Recruitment and flow of participants in pilot study in Ma'anshan.

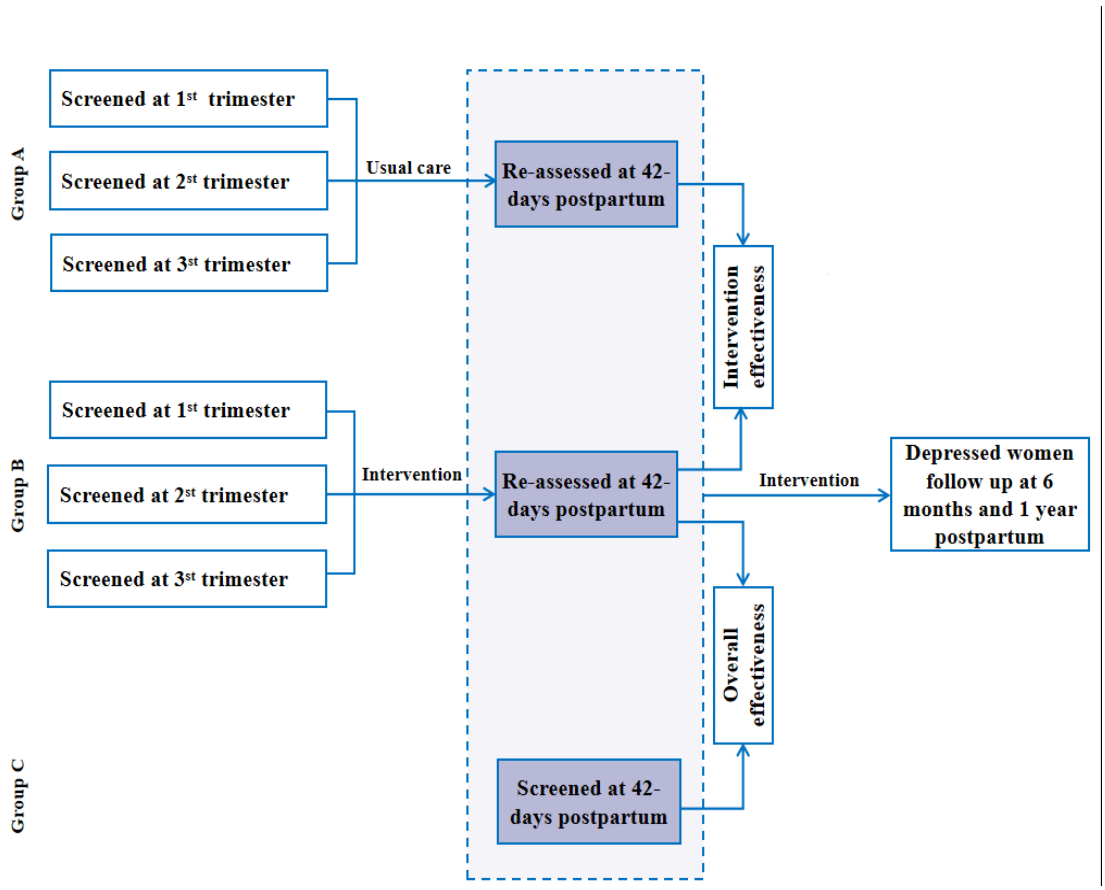

Figure S2 Study design at Hefei during the validity determination stage.

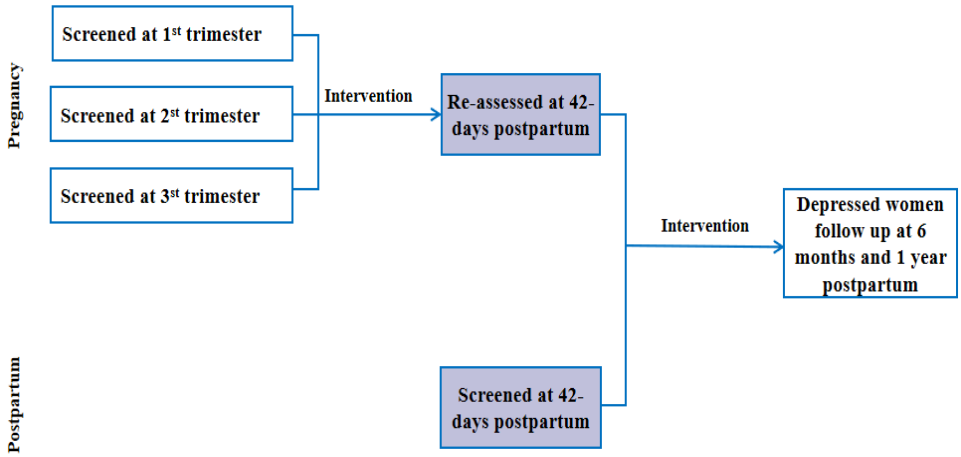

Figure S3 Study design in Bengbu and Fuyang in the scale up stage.