


BMJ Open Development of a family-community interaction programme in the treatment of women with postpartum depression: protocol for a randomised controlled trial

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ABSTRACT

Introduction Postpartum depression has great harm and becomes a serious public health problem. Most women stay at home after childbirth, so the support from community and family is particularly important in the treatment of postpartum depression. The cooperation between family and community can effectively improve treatment effect of patients with postpartum depression. It is imperative to conduct a study on the collaboration and interaction among patients, family and community in the treatment of postpartum depression.

Methods and analysis The aim of this study is to determine the experience and demands of patients with postpartum depression, family caregivers and community providers for the interaction, construct an interaction intervention programme between family and community and promote the rehabilitation of patients with postpartum depression. From September 2022 to October 2022, this study will select postpartum depression patient families from seven communities in Zhengzhou City, Henan Province in China. The researchers, after training, will conduct semi-structured interview to collect research data. According to the integration results of qualitative research and literature review, the interaction intervention programme will be constructed and revised using the Delphi expert consultation method. Then the participants will be selected to accept the intervention of the interaction programme and evaluated through questionnaires.

Ethics and dissemination The study is approved by the Ethics Review Committee of Zhengzhou University (ZZUIRB2021-21). The results of this study will contribute to clarify the responsibilities of family subjects and community subjects in the treatment of postpartum depression, more effectively promote the rehabilitation of patients with postpartum depression and reduce the burden of family and society. Moreover, this research will be a profitable exploration at home and abroad. And the findings will be disseminated through conference presentations and peer-reviewed publications.

Trial registration number ChiCTR2100045900.

INTRODUCTION

Depression is a common emotional disorder, characterised by a high incidence, recurrence

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Women with postpartum depression, their family caregivers and community workers will be involved in the development of the intervention programme to overcome from depression (family-community interaction programme).
- ⇒ It only includes women who have depression after childbirth, and those who have suffered from depression and other mental diseases before childbirth will not be included.
- ⇒ The qualitative data will be used to construct family-community interaction programme, which favours a better understanding of this problem and provide new intervention programme for patients.
- ⇒ Research tools containing many subjective items may lead to some deviations in the results.

rate, disability rate and suicide rate. Perinatal period is the peak incidence of depression for women. In addition to those with a history of depression, many women have their first episode of depression during the perinatal period. Postpartum depression (PPD) is a serious psychiatric disorder in the first year after giving birth, with the prevalence of 10%–15% and the incidence rate increasing year by year.^{1–3} It has long-lasting serious effects on the mother, infant and family and has become a serious public health problem.^{4–7}

Most reports indicate that^{8–10} social support plays an important role in the treatment and rehabilitation of PPD. Low social support is believed to be one of the risk factors of PPD.¹¹ The social support system is composed of government, community, family and other subjects.¹² After childbirth and discharge, most parturients mainly return and stay at home. Therefore, the support from community and family is particularly important in the treatment of PPD.¹³ As the micro-environment for residents' living, community

has more significant advantages in the treatment of PPD compared with the traditional medical centres, which can realise whole process intervention, save resources, patients and families are willing to accept and so on.¹⁴ Therefore, community psychological service for PPD has become a community psychological service group that can not be ignored.

Family is the most basic and important environment of life. A harmonious family environment and stable family function can help pregnant women adapt to role changes and reduce negative emotions. Family support has been found to be of great significance in the treatment of PPD.^{15–18} When family members participate in the process of nursing education and nursing intervention, they can create a warm atmosphere conducive to the physical and mental recovery of pregnant woman. In addition to taking care of their daily life, they can also pay attention to the changes of their emotions in time, give more warmth, encouragement and support to parturient, and eliminate the occurrence of adverse emotions of parturient.¹² Letourneau *et al* found that postpartum mothers are most likely to rely on the support of their spouses.¹⁹ Moreover, the emotional and material support of their spouses and family members enable them to have better recovery environment, help alleviate the psychological pressure of puerperal women and buffer their emotional changes.²⁰ At present, due to the limited knowledge of postpartum psychological nursing and the lack of ability and methods to effectively identify maternal psychological problems, most of the family members tend to devote more energy to maternal physical and life care. However, the abnormal emotions of pregnant women sometimes will be regarded as the normal reaction of postpartum women, without attention and intervention.²¹ Therefore, family members and women expect the community to provide professional treatment and intervention to make up for the lack of family care in this process.²²

Both family and community play the important roles in the treatment of PPD. Studies have shown that community and family combined psychological intervention can improve the mastery of mental health knowledge of family members and contribute to the rehabilitation of patients with mental disorders,^{23 24} which has obvious effect on patients with poststroke depression.^{25 26} Granö *et al* also found greater improvement in functioning and self-reported depression and hopelessness among adolescents who received a need-adapted family orientated and community-orientated integrative treatment.²⁷ Moreover, Mundorf *et al*²⁸ believe that strengthening the relationship between community health workers and family members during perinatal period can affect PPD outcomes. Some studies have shown that in the community comprehensive home intervention for postpartum depressed pregnant women, family members are guided to actively participate,²⁹ which can effectively relieve the symptoms of PPD, improve the bad psychology of pregnant women, improve the quality of life and restore their physical and mental health.³⁰ However, community providers have focused primarily on maternal health issues and the cooperative interaction relationship between community service providers and family members needs further research. Two types of social interactions, collaboration and social support have been identified as particularly important in a caregiving context.

Given that social relationships with community service providers may serve as coping resources for families, proactive strategies to facilitate positive collaborative relationships to optimise family-community interactions may be beneficial.³¹ A recent review of Ris *et al*³² identified five important factors for community-based family caregivers: 'relationship building with professionals', 'negotiating with professional care', 'being professionally supported', 'managing role expectation and knowledge sharing' and 'collaborative practice' with home care nurses. And,

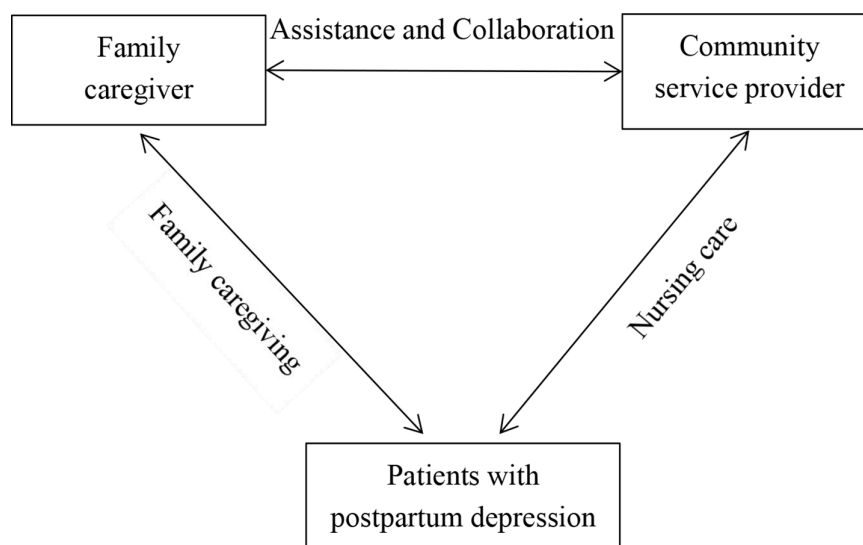


Figure 1 Interaction mechanism among the patient, family and community.

according to conceptual model by Ris *et al*, the interaction mechanism is adapted (see figure 1). To our knowledge, studies have not characterised the family-community interaction relationship during the treatment process of PPD. It is very necessary to realise the positive interaction among patients, family and community to integrate the advantages of family care and community professional services, which can improve the intervention and treatment effect of patients with PPD. While the interaction among patients, families and communities is a key factor in treatment of PPD, how to form a positive interaction is more of an open question.

Therefore, this study attempts to construct the interaction programme among parturient family and community to address this research gap, based on the theory of social interaction. It is of great significance to strengthen the core function of family, improve the level of community participation, cultivate the sense of cooperation between family and community and realise the positive interaction among patients, families and communities.

Study aims

The overall goal of this programme of research is to develop and evaluate an intervention programme for women with PPD based on interaction of families and

communities (family-community interaction programme) to promote positive interaction between patients’ families and communities, and provide collaborative intervention and management programme for patients with PPD at home to reduce their depression and increase their quality of life. Specific objectives for each phase of development/evaluation include the following: (1) develop the programme content to construct the interaction programme between family and community for the women with PPD (phase A) from October 2022 to January 2023, (2) assess feasibility in terms of implementation (accrual rates, acceptability and level of engagement) and determine an initial estimation of effectiveness outcomes in a pilot randomised controlled trial (RCT) (phase B) from March 2023 to June 2023.

METHODS AND ANALYSIS

The study will consist of two phases (A and B) (see figure 2).

And patients, family caregivers and community staff all will be involved in two phases (A and B) of this study as stakeholder groups.

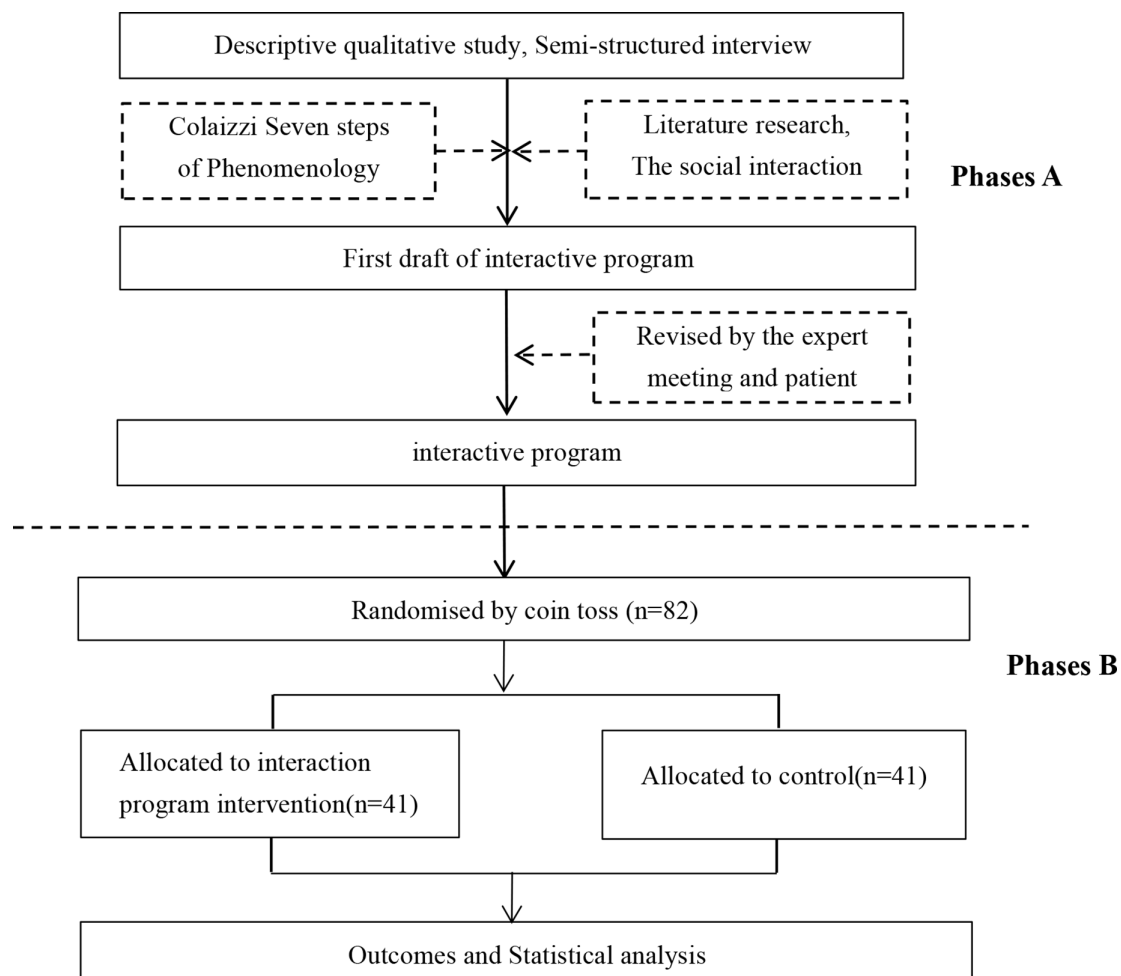


Figure 2 Study flow chart.

Phase A

We will construct the interaction programme among parturient, family and community to address the research gap based on the theory of social interaction.

Study design

Semi-structured interview in phase A will help to: (1) learn about the interaction experiences and care needs of women with PPD, family caregiver and the community staff; (2) design content, construct interaction programme and use the expert consultation to revise. This programme will help realise the positive interaction among patients' families and communities and reduce patients' depression symptom.

Participants

We will recruit participants through purposive samplings from the community health services centre in Henan. First we will contact the community staff and interview them after consent. After the interview, community staff will lead us to find family caregivers and women who meet the inclusion criteria within their jurisdiction. Thereafter, we will explain the purpose and significance of the study, and ask if they are willing to participate in the interview.

Eligibility criteria

After literature review, we will revise the inclusion/exclusion criteria after trial registration and update that as follows:

Inclusion criteria for parturient women: (1) aged 20–35 years; (2) able to communicate effectively; (3) Edinburgh Postpartum Depression Scale (EPDS) score ≥ 10 points; (4) consented after being informed and voluntarily participated in this study. Exclusion criteria: (1) have severe organ dysfunction; (2) presence of serious physical condition related to pregnancy including diabetes mellitus, severe high blood pressure or eclampsia; (3) miscarriage or stillbirth occurred during pregnancy and childbirth; (4) history or presence of other psychiatric disorders including mania and suicidal ideation and (5) refuse to provide written consent.

Inclusion criteria for family members: (1) no less than 18 years old; (2) people who are family members of the parturient and took care of them as a main caregiver; (3) with a good ability of communication. Exclusion criteria: (1) unwilling to participate in this study.

Inclusion criteria for community staff: (1) staff who is mainly responsible for taking care of parturient women in the community, and often came into contact with them; (2) worked in a community health service centre for >6 months; (3) consented after being informed and voluntarily participated in this study. Exclusion criteria: (1) unable to participate in the survey due to vacations.

Study setting

During phase A, the parturient women, their family caregivers and community staff will be invited to participate in the study by completing interview, who will be selected from seven communities in Zhengzhou, Henan Province.

Choose the time when the parturient women are in good mental state and have free time. The stakeholder groups will be investigated and interviewed separately to ensure that they did not interfere with each other. The interview place is chosen according to the interviewee's wishes, and is usually set in the patients' home or community meeting room.

Procedures

Semi-structured interview³³ is a research method in which the interviewer contacts the interviewee, carries out purposeful conversation and dialogue according to the interview outline, and then collects data. This study will interview patients with PPD, family caregivers and community workers according to the interview outline, explored the current situation their experience of interaction among patients, family and community, and provided reference suggestions for the formulation of interactive treatment plan.

The interaction items of interaction programme are formed based on the interactive experience and needs, literature research³⁴ and the social interaction theory.^{35 36} Then expert consultation³⁷ is used to modify interaction programme. Experts in psychological nursing and management, demography, sociology and other fields are invited to suggest modifications and provide theoretical and technical guidance. The expert consultation is divided into three rounds, including one round of online one-to-one open expert consultation and two rounds of Delphi expert consultation. According to Likert's 5-level scoring method, an opinion column is set up for experts to fill in their opinions. In addition, stakeholder groups will also be invited to provide suggestions for the revision of programme.

Interview outline

Patients with PPD

(1) What help have you received from family caregivers and community service providers? (2) What other help do you expect from them? (3) How do you view the relationship between family caregivers and community service providers? (4) How do you feel about the interaction between family caregivers and community service providers? What aspects are involved? (5) Have there been any conflicts between family caregivers and community service providers? How did this happen?

Family caregivers

(1) Has the community service providers ever assisted you? What is it? (2) What assistance would you like from providers? (3) How do you view your relationship with community service providers? (4) How do you feel about your interaction with community service providers? What aspects are involved? (5) Have you ever had a conflict with a community service providers? How did this happen?

Community service providers

(1) Have you ever provided assistance to family caregivers of patients with PPD? What is it? (2) How do you

feel about your relationship with your family caregiver? (3) How do you feel about your interaction with family caregivers in PPD patient care? (4) What do you think are involved in the interaction with family caregivers? (5) Have you had any conflicts with your family caregivers? How did this happen?

Outcomes

For qualitative data, the audio-taped interview will be listened repeatedly and transcribed verbatim. Two investigators will use Colaizzi phenomenological analysis method to work on the data analysis.³⁸ The qualitative data analysis focuses on willingness and needs of the parturient women, family and community to the interaction, interprets the reasons for the poor interaction and analyses the interaction relationship.

Phase B

In B phase, interaction programme will be introduced on pregnant women, their family caregivers and community staff to evaluate its operability and effect. Control group will be given routine home care and intervention group will accept the care of interaction programme. Outcomes of depression level, quality of life, family and community support will be measured through questionnaires.

Study design

A two-group parallel single-blind pilot RCT.

Eligibility criteria

Inclusion/Exclusion criteria have been previously described (phase A). Additional exclusion criteria will include participants who participated in phase A study.

Study setting

Participants will attend one in-person session to learn about the trial, obtain informed written consent and complete demographic and baseline measures (T1). Participants allocated to the intervention group will accept interactive programme intervention. The intervention place is chosen according to the interviewee's wishes, and is usually set in women's home or community.

Procedures

Following ethics approval, the study will recruit women using the methods described previously (phase A). Eligibility criteria will be confirmed, verbal consent obtained and an appointment for an initial study visit will be made. We will use a variety of methods to promote recruitment and retention, such as giving small gifts during the study and regular follow-up monitoring. The interaction programme will be burdensome for participants of intervention group, which we will assess in our process evaluation.

Randomisation

In this study, two communities with similar scale, environment, culture and configuration were selected conveniently. We will simultaneously recruit patients with PPD

and family caregivers in these two communities in Zhengzhou. Following completion of baseline measures, the participants in two communities will be randomised to the control or intervention group as two whole groups by coin toss.

Allocation

Patients and the family caregivers allocated to the control group will receive the usual care and support provided to women with PPD, including usual clinic appointments and follow-up. Participants randomised to the intervention group will use the family-community interaction programme intervention based on usual community care.

Blinding

It is not possible to blind the participants to group allocation due to the specific nature of the interaction programme intervention; however, a data analyst who is blinded to treatment allocation will conduct the analysis ensuring neutrality of the outcome assessment.

Outcomes

Timely intervention of PPD can solve physical and psychological problems of the parturient, improve quality of life and benefit the development of physical and mental health.^{39 40} Strengthening the interaction among patients, families and communities is conducive to the treatment of PPD.⁴¹ In B phase, questionnaire survey is used on patients, their family caregivers and community staff to evaluate the interaction programme. After literature review, we have revised the outcome measures after trial registration and updated that as follows. The primary outcome measures (EPDS) did not change. But we increased the secondary outcomes: Family Participation in Professional Care Scale and caregiving social support from community staff (*for family caregivers*) and the WHO Quality of Life-Bref (WHOQOL-BREF), Family Support Questionnaire (FSQ) and Social Support Rate Scale (SSRS) (*for patients*).

1. General information questionnaire: the general information questionnaire is designed in combination with literature research, which mainly is used to collect the social demographic data of the all participants.

2. Questionnaires for family caregivers: specifically, we assessed two characteristics of social interactions (ie, collaboration, support) between family caregivers and community-based service provider.

(1) Family Participation in Professional Care Scale³¹

Family Participation in Professional Care Scale has 10 items and will be used to assess the extent to the collaboration between family members and community service providers, which were developed by Moorhead *et al* and were used by Ashida *et al* to measure provider-family social interactions in community settings. A 5-point Likert scale was used to assess collaboration in planning, providing care, information exchange, identifying resources, making decisions and evaluating the effectiveness of care strategies. Responses were never (1), rarely (2), sometimes



(3), often (4) and consistently (5). An average score was calculated for each participant to indicate overall levels of collaboration ($\alpha=0.92$ for family caregivers).

(2) Caregiving social support from community staff

Five questions assessed the extent to which family caregivers perceived receipt of social support from their provider. These questions were adopted from previous studies^{31 32 42} and was investigated in the population of family caregivers of patients with PPD, with good reliability. How often does this service provider: (1) help you maintain a positive relationship with the individual affected by PPD, (2) hinder your relationship with the individual (reverse coded), (3) help with your role transition as you hand off some caregiving responsibilities, (4) help you feel less angry about providing care and (5) help you feel less guilt when providing care? The responses were coded to indicate the frequency of support provision: never (1), rarely (2), sometimes (3), often (4) and all of the time (5). The average of five items was used to indicate overall levels of caregiving social support ($\alpha=0.76$).

3. Questionnaire for patients

(1) Edinburgh Postpartum Depression Scale (Chinese version)

The EPDS questionnaire has 10 questions,⁴³ and each can be scored from 0 to 3 points. The total score is 30 points. Symptoms are graded according to the reference standard: the total scores of EDPS <9 represent normal; 10–12 represent mild PPD; 13–15 represent moderate levels; scores >16 represent severe levels—the higher the score, the more severe the depressive symptoms. The scale performs well in reliability and validity (Cronbach's alpha nurses 0.79, the test-retest reliability is 0.85).⁴⁴ A large number of studies have shown that it can also be applied for screening and evaluating prenatal and PPD of pregnant women.^{45–47}

(2) The WHO Quality of Life-Bref

The WHOQOL-BREF is a widely used tool that has adequate reliability and validity to assess the quality of life. The WHOQOL-BREF questionnaire has 26 items including two general items and 24 items, and 24 items to evaluate 4 main domains of the quality of life, which referred to the physical status (7 items), psychological health (6 items), social relations (3 items) and environmental factors (8 items). Each item is scored using a 5-point scale ranging from 1 (very dissatisfied or very poor) to 5 (very satisfied or very good). Mean scores of items are multiplied by four to make domain scores ranging from 4 to 20. And scores of the two general items also range from 4 to 20, respectively. The higher the score, the better the quality of life. It has good reliability and validity. Its Cronbach's alpha values was 0.922.⁴⁸

(3) Family Support Questionnaire

The 15-item FSQ (Chinese version) will be used to measure the level of family support, which was developed by HaiYan Zhang revising Perceived Social Support Family Scale in 1999. A 0–1 rating scale is used for each item, with higher scores representing more family support. The

scale showed good reliability and validity when used in the Chinese population, and Cronbach's alpha was 0.95.^{49 50}

(4) Social Support Rate Scale

Shuiyuan Xiao developed this tool in 1986. The tool consists of 10 items in three dimensions including objective support, subjective support and utilisation of social support. The higher the total score of it, the higher the social support. Cronbach's alpha of the scale was 0.81 and the test-retest reliability was 0.92.⁵¹

Sample size

As for the qualitative study (phase A), participants are interviewed until the content of data obtained is no longer increased based on the methodological principle of data saturation.

The sample size (phase B) was calculated based on the PPD variable. We adopt the sample size estimation formula: $N1=N2=2[\bar{\sigma} (t_{\alpha} + t_{\beta}) / (u1-u2)]^2$, $\alpha=0.05$, $\beta=0.10$, $t_{\alpha}=1.96$ and $t_{\beta}=1.28$. Then, according to the literature,⁵² we know $u1-u2=2.81$ and $\bar{\sigma}=3.58$. Therefore, the sample size of patients of each group is about 34. However, considering the loss of follow-up rate of 20%, we will need a total sample size of 82 (41×2). Besides, at least one family caregiver per patient participated in the intervention together.

Data management

All data will be collected through questionnaires and interview by the researchers in the survey, which will be strictly and anonymously preserved by their assistants.

Statistical methods

Qualitative data. For qualitative data, the audio-taped interview will be listened repeatedly and transcribed verbatim. Two investigators will use Colaizzi phenomenological analysis method to work on the data analysis.³⁸ Before the formal analysis, the interviewees will be coded with letters A–H to process personal sensitive information such as their names. Then Colaizzi phenomenological analysis method is used to extract the effective content, code, classify and simplify the relevant content, extract the theme and return to the interviewees for confirmation and finally refine the interview theme.

Quantitative data. The quantitative data will be entered using Epi-Data V.3.1 by two persons and analysed using SPSS V.20.0. First, data are summarised using descriptive statistics. Then the mean±SD ($\bar{x}\pm s$) is used to describe the measurement data, and the rate and constituent ratio of count data are used to describe the statistics.

Patient and public involvement

The study was developed from the perspective of patients to construct interaction intervention that can be used in community settings. Two patients, their family members and community staff as representatives were members of research team to comment on study design including patient information sheets and topic guides for the qualitative interviews to ensure that all aspects of the study are patient focused and explore issues that patients value.

And they will continue to be actively involved in the development and revision of interaction programme. Finally, the results will be disseminated to the participants in the form of a lecture and fellowship at the end of the study. If the programme proves to be viable, it will be offered and guaranteed to the participants.

DISCUSSION

It is known that there are many problems in the interaction among patients, family and community in the treatment of PPD. To our knowledge, similar studies are relatively sparse in the international evidence. To solve these problems, this study takes a step further to elucidate the underlying programme about interaction between family caregivers and community employees.

The social interaction theory^{34 35} is added as the theoretical basis of this project. This study constructs the interaction programme to promote the formation of benign interaction among patients, family and community, which meets the care needs of the parturient at home, improves their quality of life and enriches the social interaction theory and solves some deficiencies in the current research (ie, the lack of benign interaction). It is of great significance that the project will, for the first time, describe the interaction programme between family and community in the context of the parturient with PPD.

The study will be conducted in seven communities. Even though this may be considered a small sample with a limited universality, this study will still build the interaction programme of family-community-women with PPD. The results will provide a basis, relevant suggestions and directions for the further development of this kind of research.

It is very valuable to study the interaction among family, community and the depressed parturient at home. Collecting qualitative data can help us analyse their interaction from a special perspective and enable us to accurately construct their interaction programme. The formulation of an interaction programme can strengthen the collaboration among patients, families and communities, and the timely feedback from family members and patients can help community staff provide more effective care.¹⁶ This in turn will contribute to the development and dissemination of interaction among patients, family and community.

The study will be completed in collaboration with the parturient women, family members and community staff. According to Storm and Edwards,⁵³ this method is the basis for promoting users' participation. Nevertheless, the non-standardisation of the interaction programme may be regarded as a research limitation. Nonetheless, it is still a key to introducing a feasible interaction programme. If the programme proves to be viable, then implementation will be just around corner. As mentioned above, the potential of the programme cannot be overshadowed, since it requires no additional labour or costs, and fulfils

the wishes of pregnant and parturient women and family members, as well as the ideals of community staff.

Ethics and dissemination

The study has been approved by the relevant ethical review committee (ZZUIRB2021-21). All participants will receive written and verbal information about the aim of the study. They will be informed that participation is voluntary, that they have the right to withdraw without specifying why and that confidentiality will be assured. Informed consent will be specified by all participants. The findings will be disseminated through conference presentations and peer-reviewed publications.

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Disclaimer The research is independent, however, and the views expressed in this article are solely those of the authors.

Competing interests None declared.

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