

Official Title

The Effectiveness of Psychological Empowerment Program in Preventing Postpartum Depression Among Pregnant Women in Indonesia: A Randomized Controlled Trial

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Study Protocol

Background and Rationale

Postpartum depression is a common maternal mental health problem that may affect women during pregnancy and after childbirth. It can interfere with maternal emotional well-being, infant care, mother–infant bonding, family functioning, and quality of life. In Indonesia, postpartum depression remains an important public health concern, while routine maternal health services still focus mainly on physical health monitoring. Preventive psychological interventions during pregnancy are limited, especially culturally appropriate programs that strengthen women’s internal psychological resources before childbirth.

Psychological empowerment is a relevant theoretical approach for preventing postpartum depression because it emphasizes women’s perceived control, self-efficacy, coping capacity, and active participation in managing life challenges. Pregnant women who have good perceived control and feel more confident and have a good way to cope with the challenges will be better prepared to manage emotional changes, stress, and parenting demands during the postpartum period. Therefore, this study will evaluate whether a structured Psychological Empowerment Program can prevent postpartum depressive symptoms and improve psychological empowerment indicators among pregnant women in Indonesia.

Study Objectives

The primary objective is to evaluate the effectiveness of the Psychological Empowerment Program in reducing postpartum depressive symptoms among pregnant women in Indonesia compared with routine antenatal care.

The secondary objectives are to determine whether the program improves self-efficacy, perceived control, and coping strategies from baseline to two weeks postpartum and six weeks postpartum.

Hypotheses

Pregnant women who receive the Psychological Empowerment Program will have lower postpartum depression scores than those receiving usual care.

Pregnant women who receive the intervention will improve or show higher self-efficacy, higher perceived control, and more adaptive coping strategies than those in the control group.

Study Design

This study will use a two-arm, parallel-group randomized controlled trial design. Eligible participants will be randomly allocated to either the intervention group or the control group using a 1:1 allocation ratio.

Study Setting

The study will be conducted in selected maternal and child health clinics or primary healthcare centres in Padang, West Sumatra, Indonesia.

Study Population

The target population is pregnant women in the third trimester of pregnancy. Participants will be recruited during antenatal care visits.

Eligibility Criteria**Inclusion Criteria**

Participants will be eligible if they are pregnant women between 30 and 33 weeks of gestation, aged 18 years or older, able to read and communicate in Indonesian or the local language, willing to participate in the study, and able to provide informed consent.

Exclusion Criteria

Participants will be excluded if they have a diagnosed severe psychiatric disorder, such as bipolar disorder or schizophrenia; have a high-risk pregnancy requiring specialized medical management; are unable to participate in the intervention schedule; or decline to provide informed consent.

Sample Size

The estimated sample size is 92 participants, with 46 participants allocated to the intervention group and 46 participants allocated to the control group. This sample size includes an allowance for potential attrition or loss to follow-up as much 20%.

Randomization and Allocation Concealment

Participants who meet the eligibility criteria and provide informed consent will be randomly assigned to either the intervention or control group. Randomization will be conducted using a computer-generated random allocation sequence with a 1:1 allocation ratio. Block randomization may be used to maintain balance between groups during recruitment. Allocation concealment will be maintained until participants are assigned to their study arm.

Blinding

Due to the nature of the behavioural intervention, participants and facilitators cannot be blinded to group allocation. However, data entry and/or data analysis may be conducted by a researcher who is not involved in intervention delivery where feasible.

Intervention Group

Participants assigned to the intervention group will receive the Psychological Empowerment Program in addition to routine antenatal and postnatal care. A total of 46 pregnant women will be divided into four groups based on their time convenience, with each group consisting of 10-12 women, that it would be beneficial to increase intervention fidelity and make it easier for the researcher to follow up at the time, as well as provide opportunities for more interactions within the peer group. Each group will receive the intervention at a different time. The program consists of structured 5 sessions in 3 weekly sessions (2 sessions in one week) designed to enhance lower depression scores, improve perceived control, self-efficacy, and coping behaviour during pregnancy and the postpartum transition. Sessions include psychoeducation, guided discussions, emotional coping exercises, communication and conflict resolution training, problem-solving activities, and practical parenting preparation. The intervention is delivered by trained healthcare professionals, including midwives, psychologists, and mental health nurses, through interactive workshops and supportive group activities.

Control Group

Participants in the control group will receive routine antenatal and postnatal care provided by the healthcare facility. Routine care may include pregnancy monitoring, general maternal health education, and standard services available in the clinical setting. The control group will not receive the structured Psychological Empowerment Program during the study period.

Intervention Content

Table 1. Overview of the Psychological Empowerment Intervention Program for This Study

Session	Topic	Objectives	Activities	Facilitators
Session 1 – Building Awareness & Sense of Control (90 mins)	<i>"Understanding myself and what I can control"</i>	<ol style="list-style-type: none"> 1. Introduce program and group norms. 2. Provide psychoeducation on postpartum depression (PPD). 3. Enhance awareness of controllable vs. uncontrollable factors. 	<ol style="list-style-type: none"> 1. Welcome & Group Building (10min) 2. PPD Introduction (15 min) 3. Control Mapping Activity (55 min) 4. Reflection (10min) 	Midwife
Session 2 – Strengthening Self-Efficacy (90 mins)	<i>"I believe I can"</i>	<ol style="list-style-type: none"> 1. Boost confidence and increasing self-efficacy 	<ol style="list-style-type: none"> 1. Check-In (10 min) 2. Psychoeducation: Self-efficacy for PPD (15 mins) 3. Efficacy exercise (20 mins) 4. Story Sharing (10 min) 5. Role-Play Scenarios (30 min) 6. Homework (5 min) 	Psychologist Midwife
Session 3 – Critical Awareness & Skill Development (90 mins)	<i>"Finding my support and building skills."</i>	<ol style="list-style-type: none"> 1. Increase awareness of available supports. 2. Strengthen structured problem-solving skills to face postpartum challenges. 	<ol style="list-style-type: none"> 1. Check-In (10 min) 2. Support Mapping (20 min) 3. Postpartum Problem-Solving Workshop (40 min) 4. Homework (10 min) 	Psychologist, Midwife
Session 4 – Coping Behavior (90 mins)	<i>"I know what to do and cope this mess"</i>	<ol style="list-style-type: none"> 1. Understand the role of coping strategies in preventing PPD. 2. Recognize unhelpful vs. helpful coping strategies. 3. Learn and practice specific coping techniques (relaxation, problem-solving, positive reframing). 4. Develop a personalized coping plan for pregnancy and postpartum. 	<ol style="list-style-type: none"> 1. Check in (10 min) 2. Psychoeducation: Understanding Coping behavior (25 min) 3. Skill Practice: Relaxation & Positive Reframing (30 min) 4. Individual Reflection: My Coping Plan (25 min) 	Psychologist, Midwife
Session 5 – Postpartum Empowerment Plan & Evaluation (90 mins)	<i>Less Depressed More Empowered</i>	<ol style="list-style-type: none"> 1. Develop individualized postpartum empowerment plan 2. Evaluation 	<ol style="list-style-type: none"> 1. Check-In (10 min) 2. Community Resources Brainstorm (20 min) 3. Postpartum Empowerment Plan (40 min) 4. Closing Ritual (20 min) 5. Course experience, comment & discussion 	Midwife

Intervention Program Content Validity

Prior to implementation in the randomized controlled trial, the intervention program underwent expert validation to establish content validity. This process aimed to ensure that the intervention components were theoretically grounded, relevant to the study objectives, and appropriate for the target population. A panel of experts was purposively selected based on their expertise in maternal mental health and psychological interventions. The expert panel consisted of 3–5 individuals with academic qualifications and professional experience relevant to perinatal mental health and the development of interventions.

Each expert will be provided with the intervention manual, including the program objectives, session structure, session content, delivery methods, and proposed duration. Experts will be asked to independently evaluate each session and activity using a structured content validation form. The evaluation focused on the relevance, clarity, coherence, and cultural appropriateness of the intervention components, as well as the alignment between program content and the underlying theoretical framework.

Item-level content validity will be assessed using the Content Validity Index (I-CVI), calculated as the proportion of experts rating each item as either relevant or highly relevant. A minimum I-CVI value of 0.78 was considered acceptable. The Scale-Level Content Validity Index (S-CVI) was also calculated to assess the overall content validity of the intervention program.

Qualitative feedback and suggestions from the experts were reviewed and used to refine the intervention's content, language, and session flow. Revisions were made accordingly prior to pilot testing and implementation in the main study. This expert validation process ensured that the intervention program possessed adequate content validity and was suitable for testing in the subsequent randomized controlled trial.

Intervention Fidelity

To ensure the effectiveness and lasting impact of the psychological empowerment program, we will use a strong plan to maintain its quality. This plan focuses on four key areas: participant involvement, facilitator skills, program quality, and participant understanding of the material. Keeping the program on track is essential for delivering it as we intended and allowing others to replicate it in different settings, we will monitor participant attendance by using sign-in sheets for each session and keeping track of how long each session lasts to stick to our planned 90-

minute format. If someone misses a session, we will offer make-up sessions or provide extra materials to keep them engaged and connected to the program. Facilitators will receive training before the program begins, covering the necessary theory and leading discussions, as well as including practice sessions. The training will be conducted in two parts: one focused on lecturing and the other on discussion related to the program. Ongoing self-assessments and peer evaluations will be implemented to help facilitators stay aligned with the program goals and encourage reflective teaching practices (Carroll et al., 2007).

To ensure quality through several methods. We will use checklists to monitor the effectiveness of our sessions. We will also evaluate sessions in real-time or through recorded reviews, and we will survey participants after each session to get their feedback on clarity, engagement, and relevance. Additionally, we will give brief quizzes that let participants explain ideas in their own words. These methods will help ensure the program is delivered correctly and that participants truly understand it. This approach will support their psychological empowerment and help us maintain reliable and valid research results (Bellg et al., 2004).

Outcome Measures

Primary Outcome

The primary outcome is postpartum depressive symptoms measured using the Edinburgh Postnatal Depression Scale. The EPDS consists of 10 items scored from 0 to 3, with total scores ranging from 0 to 30. Higher scores indicate more severe depressive symptoms. A score of 13 or higher indicates probable postpartum depression and need for further assessment.

Secondary Outcomes

- Self-efficacy will be measured using the General Self-Efficacy Scale. The scale includes 10 items scored from 1 to 4, with total scores ranging from 10 to 40. Higher scores indicate greater perceived self-efficacy.
- Perceived control will be measured using the Pearlin Mastery Scale. The scale includes 7 items scored on a 4-point Likert scale, with total scores ranging from 7 to 28. Higher scores indicate greater perceived mastery and control over life circumstances.
- Coping strategies will be measured using the Brief COPE Inventory. The Brief COPE includes 28 items assessing adaptive and maladaptive coping strategies. Higher scores on

adaptive coping domains indicate more effective coping, while higher scores on maladaptive coping domains indicate less effective coping patterns.

Assessment Time Points

Data will be collected at three time points. Baseline assessment will be conducted before the intervention during the third trimester of pregnancy. The follow-up 1 assessment will be conducted 2 weeks after delivery. Follow-up assessment 2 will be conducted at 6 weeks postpartum.

Data Collection Procedures

After eligibility screening and informed consent, participants will complete baseline questionnaires. Participants will then be randomized into the intervention or control group. The intervention group will attend the Psychological Empowerment Program, while the control group will continue routine antenatal care. Outcome measures will be collected at baseline, two weeks after delivery and six weeks postpartum.

Data Management

All participant data will be coded using unique study identification numbers. Personal identifying information will be stored separately from study data. Data will be kept securely in password-protected files and accessible only to authorized research team members. No participant names will be included in reports, publications, or uploaded study documents.

Statistical Analysis Plan

Data will be analyzed using software the SAS (Statistical Analysis System) version SAS 9.4 Maintenance 9 (9.4M9). All statistical tests will be two-tailed with a significance level set at $p < 0.05$.

1. Descriptive Statistics

Descriptive analyses will be conducted to summarize participants' demographic and baseline characteristics (e.g., age, parity, education, occupation, gestational age). Continuous variables will be presented as means and standard deviations or medians and interquartile ranges if not normally distributed. Categorical variables will be summarized using frequencies and percentages.

2. Baseline Comparison

To assess homogeneity between groups at baseline, the following tests will be applied: Independent samples t-test (for continuous variables), Chi-square test or Fisher's exact test (for categorical variables). This will ensure comparability between the intervention and control groups before the intervention begins.

3. Effectiveness of the Intervention

The primary analysis will evaluate the effect of the Psychological Empowerment Program on postpartum depression and associated psychological variables (e.g., perceived control, self-efficacy, skill development and coping behavior). Independent t-tests will be used to compare the mean outcome scores between the intervention and control groups at post-test and follow-up. Paired t-tests will be conducted within groups to assess changes from baseline to follow-up.

4. Longitudinal Analysis Using Generalized Estimating Equations (Zhang et al.)

To examine the time \times group interaction effect and account for repeated measurements (baseline, post-intervention, and follow-up), GEE analysis will be employed. This model is suitable for analyzing longitudinal data where observations are correlated within subjects over time.

The outcome variable (e.g., EPDS score) will be modeled as a function of time, group, and time \times group interaction, adjusting for relevant covariates (e.g., baseline score, demographic factors). An exchangeable correlation structure will be specified, and the robust standard error estimation will be used to ensure accurate inference.

5. Handling Missing Data

Missing data will be handled using intention-to-treat (ITT) analysis. If more than 5% of the outcome data are missing, multiple imputation will be considered to minimize bias

Ethical Considerations

This study will be conducted in accordance with ethical principles for human participant research. Ethical approval will be obtained from the relevant institutional review board or ethics committee before recruitment begins. All participants will receive clear information about the study purpose, procedures, potential risks and benefits, confidentiality, and voluntary participation. Written informed consent will be obtained before enrollment.

Participants who show high depressive symptoms or indicate risk of self-harm will be referred to appropriate mental health or clinical services according to the study safety protocol.

Risks and Benefits

The intervention is considered low risk because it involves education, discussion, coping skills training, and supportive activities. Some participants may feel emotional discomfort when discussing pregnancy, childbirth, or psychological distress. Facilitators will be trained to respond sensitively and provide referral information if needed.

Potential benefits include improved understanding of postpartum depression, increased confidence, better coping skills, improved perceived control, and stronger preparation for the postpartum period.

Confidentiality

All information collected during the study will be kept confidential. Data will be stored securely and reported only in aggregate form. Participants will be identified using study codes, and no names or identifying information will appear in publications or uploaded documents.

Trial Registration

The trial will be registered in ClinicalTrials.gov before participant recruitment begins. The registration record will include the study design, eligibility criteria, intervention details, outcome measures, and data-sharing plan.

Dissemination Plan

The findings will be disseminated through dissertation reporting, peer-reviewed journal publication, academic conferences, and communication with relevant maternal health stakeholders. Results may inform future maternal mental health programs and preventive strategies for postpartum depression in Indonesia.

Individual Participant Data Sharing Plan

De-identified individual participant data underlying the results reported in publications may be made available upon reasonable request. Shared datasets may include demographic characteristics, baseline measures, intervention allocation, and outcome data for EPDS, GSES, Pearlin Mastery Scale, and Brief COPE Inventory. Data will be available beginning six months after publication of the primary study results and will remain available for five years. Access will be granted to qualified researchers with a methodologically sound proposal and an approved data use agreement.

Informed Consent Form

Psychological Empowerment Program to Prevent Postpartum Depression among Pregnant Women in Indonesia

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You are invited to participate in a research study evaluating a psychological empowerment program for pregnant women. Please read the information below before deciding. This study examines whether an empowerment program can improve coping, perceived control, self-efficacy, skill development and reduce postpartum depression risk. If you agree to participate, you will complete questionnaires and may join five empowerment sessions depending on group assignment. Sessions last 90 minutes. Participation is voluntary, and you may withdraw at any time without affecting your health services. Minimal risks include emotional discomfort from personal questions. You may skip any question. While direct benefits are not guaranteed, you may gain psychological skills, and your participation may advance maternal mental health programs.

All data will be kept confidential. Your name will not appear in reports. Data will be coded securely. Each participant will receive a snack box and money Rp.50.000 for transportation fee for every session

Contact the researcher for questions or the Ethics Committee for participant rights. By signing, you confirm understanding and voluntary agreement to participate. Thank you for your cooperation.

Participant Name: _____

Participant Signature: _____ Date: _____

Researcher Name: _____

Researcher Signature: _____ Date: _____