Study Protocol with Informed Consent Form

Official Title:

Effectiveness of a Pregnancy Care Digital Self-Care Intervention on Maternal Anxiety in the Third Trimester Within a Biopsychosocial Adaptation Framework: A Randomized Controlled Trial

ClinicalTrials.gov Identifier:

NCT07229989

Document Type:

Study Protocol with Informed Consent Form

Date:

August 26, 2025

Principal Investigator:

Nurul Jannah, M.Tr.Keb., M.Psi

Institution:

Lincoln University College Malaysia

Study Identification

1. Organization's Unique Protocol ID	:	LUC_02_Jannah
2. Brief Title	:	Pregnancy Care Digital Intervention for Maternal Anxiety in the Third Trimester (PCYCARE-RCT)
3. Acronym	:	PCYCARE-RCT
4. Study Type	:	Interventional
5. Official Title	:	Effectiveness of a Pregnancy Care Digital Self-Care Intervention on Maternal Anxiety in the Third Trimester Within a Biopsychosocial Adaptation Framework: A Randomized Controlled Trial
6. Secondary ID	:	LUC_02_Jannah
7. Issuing Organization	:	Lincoln University College Malaysia
8. Address	:	Jl. Tirto Agung, Pedalangan, Banyumanik, Semarang, Central Java, Indonesia

Data Monitoring

1. Data Monitoring Committee	:	No
2. Record Verification Date	:	March 2026
3. Overall Recruitment Status	:	Completed
4. Study Start Date	:	September 18, 2025 (Actual)
5. Primary Completion Date	:	September 20, 2025 (Actual)
6. Study Completion Date	:	December 30, 2025 (Actual)

Sponsors and Collaborators

1. Responsible Party	:	Principal Investigator
2. Investigator Name	:	Nurul Jannah, M.Tr.Keb
3. Investigator Username	:	njannah
4. Investigator Official Title	:	Principal Investigator
5. Investigator Affiliation	:	Lincoln University College Malaysia
6. Sponsor	:	Lincoln University College Malaysia

Oversight

1. FDA-Regulated Drug	:	No
2. FDA-Regulated Device	:	No
3. IND/IDE	:	No

Ethics Approval

1. Board Status	:	Approved
2. Approval Number	:	1111/EA/F.XXIII.38/2025
3. Board Name	:	Health Research Ethics Committee, Ministry of Health, Semarang Health Polytechnic
4. Board Affiliation	:	Ministry of Health, Semarang Health Polytechnic
5. Board Contact		Tel: 024–7460274; Email: kepk@poltekkes-smg.ac.id

Brief Summary

The goal of this clinical trial is to evaluate whether a digital self-care intervention (PCYCARE) can reduce pregnancy-related anxiety and improve biopsychosocial adaptation among third-trimester pregnant women.The main questions it aims to answer are:(1) Does the PCYCARE digital program reduce pregnancy-related anxiety in third-trimester pregnant women?(2) Does the intervention improve maternal knowledge, childbirth preparedness, and sleep quality?Researchers will compare participants who receive the PCYCARE digital program with those who receive routine antenatal care to determine the effectiveness of the intervention.Participants will:(1) Use the PCYCARE mobile-based program for 21 days, which includes educational modules and guided audio relaxation sessions(2) Complete two sessions per day (education and relaxation), each lasting approximately 10–15 minutes(3) Complete questionnaires at baseline and after the intervention to assess anxiety, sleep quality, maternal knowledge, and childbirth preparedness

Detailed Description

Background:Pregnancy-related anxiety is a common psychological condition during the third trimester and is associated with adverse maternal and neonatal outcomes, including preterm birth, shortened gestation, and impaired maternal–infant adaptation. Unlike generalized anxiety, pregnancy-related anxiety reflects condition-specific concerns related to fetal health, childbirth, and readiness for motherhood. Emerging evidence indicates that pregnancy-related anxiety is influenced by interconnected cognitive, psychosocial, and physiological mechanisms. Maternal knowledge contributes to cognitive appraisal and perceived control, childbirth preparedness reflects psychosocial readiness, and sleep quality represents a key physiological regulator of emotional stability. These domains interact dynamically, suggesting that pregnancy-related anxiety can be understood as a biopsychosocial adaptation process. Despite increasing use of digital health interventions in maternal care, many existing applications focus on single outcomes and lack theoretical integration across these domains. Therefore, there is a need for structured digital interventions that simultaneously address cognitive, psychosocial, and physiological pathways.Intervention Overview:This study evaluates PCYCARE, a digital self-care program designed to support integrated maternal adaptation during late pregnancy. The intervention consists of:(1) educational modules aimed at improving maternal knowledge and childbirth preparedness (cognitive and psychosocial domains), and(2) guided audio relaxation sessions aimed at supporting emotional regulation and improving sleep quality (physiological domain).Participants are instructed to complete two sessions per day (education and relaxation), each lasting approximately 10–15 minutes, over a 21-day intervention period.Study Objectives:The primary objective of this study is to evaluate the effectiveness of the PCYCARE digital intervention in reducing pregnancy-related anxiety among third-trimester pregnant women.Secondary objectives are to evaluate improvements in maternal knowledge, childbirth preparedness, and sleep quality, and to examine how these variables interact within a biopsychosocial adaptation model.Study Design:This study employs an individual randomized controlled trial (RCT) with a pretest–posttest design. Participants are randomly assigned in a 1:1 ratio to either the intervention group or the control group using stratified block randomization.Study Population:The study population consists of primigravida women in the third trimester of pregnancy (28–35 weeks of gestation) recruited from primary

health centers.Comparator:Participants in the control group receive routine antenatal care without access to the PCYCARE digital intervention.Outcomes and Biopsychosocial Model:The study includes four key measured variables:(1) Pregnancy-related anxiety (primary outcome)(2) Sleep quality (secondary outcome; physiological domain)(3) Maternal knowledge (secondary outcome; cognitive domain)(4) Childbirth preparedness (secondary outcome; psychosocial domain)All variables are measured at baseline and after the 21-day intervention using validated instruments.This study is guided by a digital biopsychosocial adaptation model in which:(1) Cognitive adaptation (maternal knowledge) enhances understanding and perceived control(2) Psychosocial adaptation (childbirth preparedness) supports readiness and coping(3) Physiological regulation (sleep quality) stabilizes emotional responsesWithin this model, sleep quality is hypothesized to function as a central pathway linking cognitive and psychosocial improvements to reductions in pregnancy-related anxiety.Significance:This study provides evidence for a theory-driven digital self-care intervention that integrates cognitive, psychosocial, and physiological mechanisms. The findings are expected to inform scalable strategies for improving maternal mental health and childbirth preparedness, particularly in resource-limited settings.

Condition and Keyword

Section	Item	Description
Conditions / Focus of Study	Primary Condition	Pregnancy-Related Anxiety (PrA)
	Additional Condition	Third Trimester Pregnancy
	Additional Condition	Maternal Anxiety
Keywords	Keyword 1	pregnancy-related anxiety
	Keyword 2	digital self-care intervention
	Keyword 3	maternal knowledge
	Keyword 4	childbirth preparedness
	Keyword 5	sleep quality
	Keyword 6	biopsychosocial model
	Keyword 7	third trimester pregnancy
	Keyword 8	mobile health (mHealth)

Study Design

Primary Purpose	:	Treatment
Study Phase	:	N/A
Interventional Model	:	Parallel Assignment
Model Description	:	This study is an individual randomized controlled trial (RCT) with a pretest–posttest design. Participants are randomly assigned in a 1:1 ratio using stratified block randomization into two parallel groups: an intervention group receiving the PCYCARE digital self-care program for 21 days, and a control group receiving routine antenatal care. The study evaluates the effectiveness of the intervention in improving maternal knowledge, childbirth preparedness, sleep quality, and reducing pregnancy-related anxiety.
Number of Arms	:	2
Masking	:	None (Open Label)

Masking Description	:	This is an open-label study. Due to the nature of the digital intervention, participants and investigators are aware of group assignments. Standardized outcome measures are used to minimize measurement bias.
Allocation	:	Randomized
Enrollment	:	120 (Actual)

Arms and Interventions

Arms	Interventions
Experimental : Intervention Group Arm Type: Experimental Arm Name: PCYCARE Intervention Group Description: Participants in this group receive the PCYCARE digital self-care program for 21 days. The program consists of two components: (1) educational modules aimed at improving maternal knowledge and childbirth preparedness, and (2) guided audio relaxation sessions designed to support emotional regulation and improve sleep quality. Participants are instructed to complete two sessions per day (education and relaxation), each lasting approximately 10–15 minutes.	**Behavioral: PCYCARE Digital Self-Care Program**PCYCARE is a mobile-based digital self-care intervention designed for third-trimester pregnant women. The program integrates two main components: (1) structured educational modules aimed at improving maternal knowledge and childbirth preparedness (cognitive and psychosocial domains), and (2) guided audio relaxation sessions designed to support emotional regulation and improve sleep quality (physiological domain). Participants are instructed to engage with the program twice daily for 21 days, completing both educational and relaxation sessions. Each session lasts approximately 10–15 minutes. The intervention is designed to support integrated biopsychosocial adaptation and reduce pregnancy-related anxiety.Other Name: 1. Pregnancy Care App 2. Digital Pregnancy Self-Care Intervention
Active Comparator : Routine Antenatal Care Group (control) Arm Type: Active Comparator Arm Name: Routine Antenatal Care Group Description: Participants in this group receive routine antenatal care without access to the PCYCARE digital intervention. Standard care includes regular antenatal check-ups, health education, and routine maternal monitoring according to local clinical guidelines.	**Other: Routine Antenatal Care**Participants receive routine antenatal care according to local clinical practice guidelines. Standard care includes regular antenatal check-ups, basic maternal health education, and routine monitoring of pregnancy. No additional digital self-care intervention or structured program is provided during the study period.Other Name:

OUTCOME MEASURES

PRIMARY OUTCOME MEASURE

Outcome	Description	Time Frame
Change in Pregnancy-Related Anxiety	Pregnancy-related anxiety is assessed using the Late Pregnancy Anxiety Scale–Indonesian Version (LPAS-ID), an 8-item Likert-type scale. Each item is rated on a 4-point scale, with higher total scores indicating greater levels of anxiety. The outcome is defined as the change in total score from baseline to post-intervention.	Baseline and 21 days (post-intervention)

SECONDARY OUTCOME MEASURES

Outcome	Description	Time Frame
Change in Sleep Quality	Sleep quality is assessed using the Maternal Sleep Quality Index for the Third Trimester – Indonesian Version (MSQI-T3-ID), an 8-item self-report instrument. Higher total scores indicate poorer sleep quality. The outcome is defined as the change in total score from baseline to post-intervention.	Baseline and 21 days (post-intervention)
Change in Maternal Knowledge	Maternal knowledge is assessed using the Third Trimester Pregnancy Knowledge Questionnaire (TPKQ), a 10-item multiple-choice instrument. Each correct response is scored as 1 and incorrect responses as 0, with higher scores indicating greater knowledge. The outcome is defined as the change in total score from baseline to post-intervention.	Baseline and 21 days (post-intervention)
Change in Childbirth Preparedness	Childbirth preparedness is assessed using the Childbirth Readiness Questionnaire (CRQ), a 9-item Likert-type scale. Higher total scores indicate greater preparedness for childbirth. The outcome is defined as the change in total score from baseline to post-intervention.	Baseline and 21 days (post-intervention)

Eligibility

1. Accepts Healthy Volunteers : No
2. Sex : Female
3. Gender Based : No
4. Minimum Age : 20 Years
5. Maximum Age : 35 Years
6. Eligibility Criteria **Inclusion Criteria:**
   (1) Pregnant women aged 20–35 years
   (2) Gestational age between 28 and 35 weeks (third trimester)
   (3) Primigravida
   (4) Able to read and understand the language used in the PCYCARE platform

(5) Owns a smartphone or digital device with internet access
(6) Willing to participate and provide informed consent.

Exclusion Criteria:

(1) High-risk pregnancy requiring intensive medical care
(2) Severe psychiatric or cognitive disorders that may interfere with participation
(3) Participation in another intervention or educational program that may affect study outcomes

CONTACT

1.	Central Contact Person	Nurul Jannah • +6289631376237 jannah14hoci@gmail.com
2.	Central Contact Backup	Gunavathy J Selvarajh +0 0 gunavathy@lincoln.edu.my
3.	Study Officials	Nurul Jannah Lincoln University College Malaysia Principal Investigator

LOCATION

Indonesia Primary Health Centers (Puskesmas) in Semarang Regency SEMARANG, JAWA TENGAH, Indonesia 50009 Principal Investigator: Nurul NJ Jannah

IPD SHARING STATEMENT

1.	Plan to Share IPD	: No
2.	Plan Description	: The individual participant data (IPD) collected during this study will not be shared with other researchers outside the study team. This decision is based on considerations of participant confidentiality, ethical approval limitations, and the scope of the current research. All data will be used solely for the purposes of this study and will remain under the control of the principal investigator and affiliated institution.

REFERENCE

Citation	Description
1. Jannah, N., Selvarajh, G., & Lestari, S. (2025). Feasibility and Acceptability of PcyCare: A Self-Directed Digital Platform for Maternal Health Literacy and Emotional Support. International Journal of Nursing Information, 4(2), 12–22. https://doi.org/10.58418/ijni.v4i2.168	This study evaluates the feasibility and acceptability of PCYCARE, a self-directed digital platform designed to improve maternal health literacy and provide emotional support during pregnancy.
2. Jannah, N., & Selvarajh, G. (2026). Late-pregnancy anxiety as a distinct multidimensional construct: Psychometric evidence from a community-based sample. Science Midwifery, 13(6), 1562–1570. https://doi.org/10.35335/midwifery.v13i6.2230	Pregnancy-related anxiety is assessed using the LPAS-ID, an 8-item Likert scale (1–4). Higher total scores indicate greater anxiety. The outcome is defined as the change in total score from baseline to post-intervention.

INFORMED CONSENT FORM

Study Title

Effectiveness of a Pregnancy Care Digital Self-Care Intervention on Maternal Anxiety in the Third Trimester Within a Biopsychosocial Adaptation Framework: A Randomized Controlled Trial

Clinical Trial Registration

ClinicalTrials.gov Identifier: **NCT07229989**

Principal Investigator

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Background of the Study

Pregnancy-related anxiety during the third trimester is a common condition associated with adverse maternal and neonatal outcomes, including preterm birth and impaired maternal–infant adaptation. This condition reflects specific concerns related to fetal health, childbirth, and readiness for motherhood. This study evaluates a digital self-care intervention (PCYCARE) designed to improve maternal adaptation through a biopsychosocial framework, integrating cognitive (maternal knowledge), psychosocial (childbirth preparedness), and physiological (sleep quality) components.

Purpose of the Study

The purpose of this study is to:

1. Evaluate whether the PCYCARE digital intervention reduces pregnancy-related anxiety
2. Assess improvements in sleep quality
3. Assess improvements in maternal knowledge
4. Assess improvements in childbirth preparedness

Risks and Discomforts

This study involves minimal risk. Possible discomforts include:

- Mild fatigue when completing questionnaires
- Minor discomfort during relaxation sessions

There are **no invasive procedures** or medical risks involved.

Potential Benefits

Participation may provide the following benefits:

- Reduction in pregnancy-related anxiety
- Improved sleep quality
- Increased knowledge about pregnancy
- Better preparedness for childbirth

Confidentiality

All collected data will be treated confidentially:

- Personal identifiers will be removed or coded
- Data will be securely stored
- Results will be reported in aggregate form without identifying participants

Data Use and Privacy

Your data will be used only for research purposes related to this study. Data will not be shared outside the research team and will remain under the control of the principal investigator.

Voluntary Participation

Your participation is entirely voluntary. You have the right to:

- Refuse to participate
- Withdraw at any time without any consequences or impact on your healthcare services

Contact for Questions

If you have questions or concerns about this study, please contact:

Nurul Jannah

Phone: +6289631376237

Email: jannah14hoci@gmail.com

PARTICIPANT CONSENT

I have read and understood the information provided above. I have had the opportunity to ask questions, and all my questions have been answered satisfactorily.

I voluntarily agree to participate in this study.

Participant Name : _____

Signature : _____

Date : _____

INVESTIGATOR STATEMENT

I confirm that I have explained the purpose, procedures, risks, and benefits of this study to the participant and answered all questions.

Investigator Name : _____

Signature : _____

Date : _____