STUDY PROTOCOL WITH STATISTICAL ANALYSIS PLAN

AND INFORMED CONSENT FORM

Title	:	**Feasibility Study of PcyCare (Pregnancy Care) : A Self-Learning Educational Platform for Pregnant Women**
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1. Study Overview

a.	Brief Title	:	Feasibility Study of PcyCare (Pregnancy Care) : A Self-Learning Educational Platform for Pregnant Women
b.	Acronym	:	PcyCare (Pregnancy Care)
c.	Study Type	:	Interventional
d.	Official Title	:	Feasibility Study of PcyCare (Pregnancy Care) : A Self-Learning Educational Platform for Pregnant Women
e.	Other Identifier	:	LUC20230708005
f.	Issuing Organization	:	Lincoln University College Malaysia

2. Study Descriptio

a. Brief Summary

1) Objective:

   This study aims to evaluate the feasibility and usefulness of the PcyCare self-directed education platform for pregnant women. This platform provides information on nutrition, pregnancy warning signs, mental health, and childbirth preparation.

2) Key questions:

   a) Is PcyCare easy to use for pregnant women?

   b) Do the platform's materials and features help improve participants' understanding of pregnancy and childbirth?

c) How do subject matter experts and information technology experts assess the quality of the platform's content and features?

3) Procedure:

Pregnant women will use PcyCare for one week, accessing educational materials, watching videos, and completing interactive quizzes. Their understanding and experience will be evaluated through feasibility and satisfaction questionnaires.

Content experts (midwifery lecturers/practicing midwives) and media/IT experts will assess the suitability of the platform's content and features through expert reviews and provide suggestions for improvement. Expected results: Information about ease of use, content quality, effectiveness of interactive features, and input from experts to refine the platform before wider trials.

b. Detailed Description

The PcyCare platform was developed as a self-directed educational medium for pregnant women, with the aim of improving understanding of nutrition, pregnancy warning signs, mental health, and childbirth preparation. This study aims to evaluate the feasibility, ease of use, and content quality of the platform prior to wider implementation, while also obtaining input from experts for platform refinement. This study involved 10 pregnant women as primary users. During the one-week study period, participants accessed the platform via smartphone or computer, read educational materials, watched interactive videos, and completed quizzes. Researchers collected data through feasibility and satisfaction questionnaires and assessed participants' understanding before and after using the platform. This activity aimed to determine whether the platform was easy to use and could improve pregnant women's understanding.

In addition, the study also involved 8 subject matter experts (midwifery lecturers/practicing midwives) and 5 information technology/media experts as evaluators of the platform's content and features. The experts assessed the scientific accuracy, completeness of the material, language, cultural appropriateness, visual quality, and interactivity of the platform using a special assessment instrument (expert review). Input from experts will be used to improve and refine the platform before it is tested more widely. The results of the study are expected to provide information on ease of use, content quality, effectiveness of interactive features, and recommendations for improvement from experts. This study will serve as a basis for

improving the feasibility and quality of PcyCare, so that the platform can be used as an effective and safe self-education medium for pregnant women at various educational and socio-cultural levels.

c. Conditions or Focus of Study

1) Feasibility study of digital health intervention in antenatal care
2) Self-learning educational platform for pregnant women

d. Keywords

1) Pregnancy care
2) Prenatal education
3) Self-learning platform
4) Feasibility study
5) Digital health intervention

3. Study Design

a.	Primary Purpose	:	Device Feasibility
b.	Study Phase	:	N/A
c.	Interventional Study Model	:	Single group
d.	Model Description	:	Participants will use the PcyCare self-learning educational platform for one week. There is no randomization, crossover, or control group. The study aims to evaluate the feasibility, usability, and content quality of the platform based on feedback from pregnant women as primary users and expert reviewers, including maternal health specialists and IT/media experts.
e.	Number Arm	:	1
f.	Masking :	:	None (Open Label)
g.	Masking Description :	:	Not applicable. This study does not involve masking or blinding as all participants and expert reviewers are aware of the intervention.
h.	Allocation	:	N/A
i.	Number of Participants	:	10

4. Arms and Interventions

a. Arm Experimental

1) Experimental : **PcyCare (Pregnancy Care) Users**

2) Arm Description : Participants in this arm, consisting of pregnant women, used the PcyCare self-directed education platform for one week. Participants accessed educational modules covering nutrition, pregnancy warning signs, mental health, and childbirth preparation. This intervention included interactive content, instructional videos, and quizzes. Data on ease of use, participant satisfaction, and increased understanding were collected through questionnaires. In addition, input from expert assessors in the fields of obstetrics and information technology will be used to assess the quality of the content and the suitability of the platform.

b. Intervention Device

1) Device : PcyCare: Self-Directed Education Platform for Pregnant Women

2) Other Names
   a. PcyCare Self-Learning Educational Platform
   b. Digital Pregnancy Care Platform

3) Description : This intervention involves the use of the PcyCare self-directed education platform by pregnant women for one week. Participants will access educational modules on nutrition, pregnancy warning signs, mental health, and childbirth preparation. The platform includes interactive content, instructional videos, and quizzes to enhance participants' understanding. Data on ease of use, satisfaction, and increased understanding will be collected through questionnaires. In addition, midwives/practicing midwives and information technology/media experts will assess the quality of the platform's content and features through expert reviews to evaluate the platform's suitability and improvements before wider trials.

5. Outcome Measures

a. Primary outcome measures

1) Outcome : Usability of PcyCare Platform
2) Description : Assessment of the ease of use of the PcyCare platform by pregnant women, including module navigation, interactivity, and access to materials. Data was collected through a questionnaire on suitability and user experience.
3) Time Frame : 1 weeks after initial use of the PcyCare platform

b. Secondary outcome measures

1) Outcome : Expert Review Evaluation of PcyCare Platform
2) Description : Assessment of feasibility, content quality, and platform features by 8 subject matter experts (midwifery lecturers/practicing midwives) and 5 information technology/media experts using expert review instruments. These results were used to refine the platform prior to wider implementation
3) Time Frame : Performed immediately after the platform is tested by experts (1 week)

6. Eligibility

a. Accepts Healthy Volunteers : Yes
b. Sex : Female
c. Gender Eligibility Description : Pregnant women (Female)
d. Age Limits : 20 – 30 Years
e. Inclusion Criteria :
   1) Pregnant women aged 20–35 years
   2) Gestational age between 12 and 36 weeks
   3) Able to read and understand the language used in the PcyCare platform
   4) Owns a smartphone, tablet, or computer with internet access
   5) Provides informed consent to participate

f. Exclusion Criteria : 1) High-risk pregnancy requiring intensive medical care
2) Severe psychiatric or cognitive disorders that would prevent platform use
3) Participation in another conflicting educational or intervention study

7. Statistical Analysis Plan (SAP) and Data Analysis

1) Design & Data
   a. One-group pre–post feasibility study.
   b. Data: quantitative (questionnaire scores, usage logs) and qualitative (participant & expert comments).
2) Participant Characteristics
   a. Age, education, gestational age, parity.
   b. Analysis: mean ± SD or median (IQR) and frequency (%).
3) Feasibility
   a. Recruitment rate invited
   b. Completion rate: participants who completed all modules. Target ≥80%.
   c. Engagement: login duration & number of modules completed (mean ± SD).
4) Content Validity (Expert)/ Content Validity Index (CVI)
   a. I-CVI per item ≥0.78.
   b. S-CVI/Ave ≥0.9.
5) Qualitative Data

   Thematic analysis of participant/expert comments (point: ease of access, appearance, relevance of material).
6) Software
   a. SPSS for quantitative data.
   b. NVivo for qualitative data.

INFORMED CONSENT FORM

Research Title	:	Feasibility Study of PcyCare (Pregnancy Care): A Self-Learning Educational Platform for Pregnant Women
Research Objectives	:	You are invited to participate in a study evaluating PcyCare, a digital self-learning educational platform for pregnant women. The objective of this study is to assess the feasibility and ease of use of PcyCare in improving knowledge, self-care, and confidence during pregnancy.
Procedure	:	If you agree to participate, you will: 1. Complete an initial questionnaire about the ease of use of PcyCare as a self-care tool for mothers during pregnancy. 2. Use the PcyCare module on your device (smartphone/computer) for 1 week. 3. Complete a final questionnaire after use and provide feedback on your experience.
Risks	:	1. Minimal risk: possibility of mild fatigue when filling out the questionnaire. 2. No medical procedures or invasive procedures.
Benefits	:	1. You will gain increased knowledge and self-care skills during pregnancy. 2. The results of this study may help develop digital education services that are beneficial for pregnant women in the future.
Confidentiality	:	All data will be stored with an identity code, without including personal names. Data will only be used for research purposes and protected in accordance with applicable ethical and regulatory requirements.
Voluntary Participation		Your participation is entirely voluntary. You may refuse or withdraw from participation at any time without any consequences
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Consent

By signing below, I declare that I have read and understood the explanation of this research, had the opportunity to ask questions, and am willing to participate.

Participant Name	Signature	Date
_____	_____	_____