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REKOMENDASI PERSETUJUAN ETIK

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Dengan ini Menyatakan bahwa Protokol dan Dokumen yang Berhubungan dengan Protokol berikut ini telah mendapatkan Persetujuan Etik:

No.Protokol	8521093009	No. Sponsor Protokol	
Peneliti Utama	1. Ni M. Dewianti 2. Prof. Dr. Stang, M.Kes	Sponsor	Pribadi
Judul Peneliti	Development of Application-based Education Model and Prenatal Yoga in Reducing the Occurrence of Cesarean Section (CS) Delivery: Study Protocol		
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Judul Review	<input type="checkbox"/> Exempted <input type="checkbox"/> Expedited <input checked="" type="checkbox"/> Fullboard	Masa Berlaku 18 Mei 2021 Sampai 18 Mei 2022	Frekuensi review lanjutan
Ketua Komisi Etik Penelitian	Nama: Prof.dr.Veni Hadju,M.Sc,Ph.D	Tanda tangan 	Tanggal 18 Mei 2021
Sekretaris komisi Etik Penelitian	Nama: Dr. Wahiduddin, SKM.,M.Kes	Tanda tangan 	Tanggal 18 Mei 2021

Kewajiban Peneliti Utama :

1. Menyerahkan Amandemen Protokol untuk persetujuan sebelum di implementasikan
2. Menyerahkan Laporan SAE ke Komisi Etik dalam 24 Jam dan dilengkapi dalam 7 hari dan Laporan SUSAR dalam 72 Jam setelah Peneliti Utama menerima laporan
3. Menyerahkan Laporan Kemajuan (progress report) setiap 6 bulan untuk penelitian resiko tinggi dan setiap setahun untuk penelitian resiko rendah
4. Menyerahkan laporan akhir setelah Penelitian berakhir
5. Melaporkan penyimpangan dari protocol yang disetujui (protocol deviation/violation)
6. Mematuhi semua peraturan yang ditentukan

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Development of application-based education model and prenatal yoga in reducing the occurrence of cesarean section (CS) delivery: Study protocol

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Abstract:

BACKGROUND: In the last 20 years, the public health community has expressed concerns over the unprecedented increase of cesarean section (CS) delivery. Rising global concerns over this escalation that has gone out of control should not be overseen. The purpose of this study is to develop an application-based education model and prenatal yoga to reduce the occurrence of cesarean section (CS) delivery.

MATERIAL AND METHOD: This study was an exploratory mixed methods research that consisted of two stages: stage 1, which was a qualitative study on model formulation through in-depth interviews and forum group discussions (FGDs); and stage 2, which aimed to test whether the formulated model was effective in reducing the occurrence of cesarean section delivery.

CONCLUSION: The result of this study was used to develop an application-based education model, which was combined with prenatal yoga, to reduce the occurrence of cesarean section delivery.

Keywords:

Application-based education, cesarean section, prenatal yoga, pregnancy

Introduction

Maternal mortality is caused by factors such as late referral, maternal medical history, and pregnancy complications, among others.^[1] One of the efforts taken in this regard is cesarean section (CS) delivery. Nevertheless, the utilization of CS delivery has gone out of control.^[2-5] Based on the WHO report from 1998 until 2015, that mean is occurrence of CS delivery as increased by 49% from 1998 until 2015.^[6-10] The number reaches 7,88% in developing countries in Europe such as Azerbaijan, Georgia, Serbia, Uzbekistan dan Tajikistan, while the increase in developed countries like Finland and Canada is around 2,36%.^[11,12] In America, based on the National Vital

Statistics System reports by the Centers for Disease Control and Prevention (CDC), the proportion of cesarean section in the United States in 2013 was 32.7% of the total recorded deliveries.

In Indonesia, based on the results of the Basic Health Research (RISKESDAS) in 2013, the percentage of cesarean childbirth was 9.8% and later rose to 17.6% in 2018.^[13] Based on Riskesdas, the incidence of CS delivery in Bali had increased from 18.3% in 2013 to 30.2% in 2018.^[14,15] The rate of CS delivery in Denpasar city is the highest, reaching 42.3% out of the total childbirth in 2019.^[15] The lack of mother's knowledge on the selection of delivery method and prevention of pregnancy complication cause anxiety and fear in expecting mothers when

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facing normal childbirth. This condition leads to the ever-increasing number of CS deliveries.^[10,16]

There are various reasons for the expectant mother to choose CS delivery or C-section, where many among those are debated.^[17] Many mothers who opt for CS are driven by non-clinical needs or maternal and/or fetal psychology. The factor that causes a high occurrence of CS deliveries in primigravida are as follows: (1) maternal fear of childbirth that leads to efforts to run away without tolerating the difficulties of mother and infant; (2) complication during pregnancy; (3) complications during labor and delivery; and (4) lack of education regarding CS delivery.^[18,19] Identifying the factors that drive the surge of CS is essential before making an intervention.^[17] If it is medically advised, CS delivery may prevent death of and other serious complications in the mother and infant. However, there are proven risks for some healthy mothers and infants who go through CS delivery.^[20]

Some other factors that affect the high occurrence of CS delivery are maternal factor, fetal factor, sociodemographic factor, health insurance factor and health facility factor, among others.^[3,18,21–23]

Intervention that may be taken to reduce the occurrence of CS delivery in accordance with the WHO recommendations is pregnant woman-targeted intervention, which involves education during pregnancy, training on the childbirth process, relaxation training programs, prenatal yoga, psychosocial-based prevention programs for the partner, and psycho-education for pregnant mothers who have a fear of pain during the childbirth process.^[12,24,25] An intervention model that can be executed to bring down the occurrence of CS delivery is an application-based education model and prenatal yoga. Some studies on prenatal yoga have been conducted including one conducted by, among others, Fereshteh Jahdiin 2016 who concluded that pregnant women who did prenatal yoga had a lower CS percentage compared to the control group ($P = 0.002$).^[26] Relevant research on education of pregnant women has been done by Fariba Shahhraki Sanavi in Iran by providing education for pregnant women in their third trimester to minimize the occurrence of CS delivery.^[10]

Education for pregnant women is provided through an application, which may be downloaded on any smartphone, that contains materials relating to danger signs of pregnancy, selection of childbirth method, indication of CS delivery, side effects of CS delivery, benefits and downsides of CS delivery as well as prenatal yoga videos. Education is provided twice a week through the application. It is delivered in the form of an audio-visual format. This is based on a research that

education which is delivered through audio visual media could increase knowledge and behavior on acetate acid visual examination.^[27] The current study was conducted to develop an application-based education model and prenatal yoga as an effort to reduce the occurrence of CS delivery.

Material and Method

Study design and setting

This study was an exploratory mixed methods research. The application-based education model and health prenatal yoga for reducing the occurrence of CS delivery was conducted in two stages [Figure 1]:

Stage 1: Stage of model formulation and creation

At this stage, a qualitative method was used to formulate the creation of an application-based education model and prenatal yoga.

Stage 2: Implementation and evaluation

The provision consisted of education for pregnant women regarding danger signs of pregnancy, selection of childbirth method, and childbirth process in Denpasar city, using a quantitative method. This was done to find out whether this application-based education model and prenatal yoga could reduce the occurrence of cesarean section. Quantitative study with quasi-experiment was used with pre-test and post-test following a control group design.

Study participant and sampling

In stage 1, which was a qualitative study, the subjects of this study were pregnant women, obstetrics and gynecology specialists, midwives and IT experts. Sample selection at this stage used purposive sampling. Pregnant women who were chosen to be the sample were those who had experience in childbirth either through C-section or vaginal delivery. The chosen obstetrics and gynecology specialists had given antenatal care (ANC) to pregnant women. Similarly, midwives were chosen in the same manner. IT experts were chosen based on their ability in making an application program.

Inclusion criteria

- Pregnant women who had prior experience in childbirth;
- Doctors who had given ANC;
- Midwives who had given ANC;
- IT experts who were capable of making an application program;
- Those willing to become a sample of this study.

Exclusion criteria

- Those unwilling and uncooperative during the study.

In Stage 2, the sample of this study were pregnant women who were on their second trimester with gestational age between 18 and 20 weeks who fulfil the inclusion criteria on intervention group and control group, where each group consisted of 30 participants. Selection of the sample was done through purposive sampling [Figure 1].

Inclusion criteria

- Primigravida on their second trimester with gestational age between 18 and 20 weeks who were willing to become respondents;
- Pregnant women who were cooperative throughout the duration of this study.

Exclusion criteria

- Pregnant women with history of abortion;
- Pregnant women with pregnancy complication(s); multigravida and grand multigravida on their second trimester.

Data collection tool and technique in stage 1

Stage of Model Formulation and Creation

In stage 1, the data collection tools were interview guidelines and focus group discussion guidelines

Procedure

Formulation and creation of the application program were carried out in three phases:

- **The First Phase**
The first phase of this research was done using a qualitative method through an in-depth interview with five pregnant women as informants relating to their experience in obtaining information on pregnancy, utilizing media in delivering education, as well as information on the conduct of prenatal yoga.
- **The Second Phase**
The second phase used focus group discussions (FGDs) on the formulation of an application-based education model and prenatal yoga to reduce the occurrence of CS delivery with two obstetricians, two midwives, and one IT expert with expertise on programming or software for the model that would be developed. Results of the in-depth interview were used as a reference for the FGD, which was subsequently utilized as a basis of the model creation.
- **The Third Phase**
This phase was a creation phase in which trials on pregnant women were conducted in the working region of the Public Health Center (Puskesmas) in north Denpasar with the total sample of 30 pregnant women, revision and model socialization.

On stage 2: Implementation and evaluation

In stage 2, the data collection tool is a questionnaire sheet.

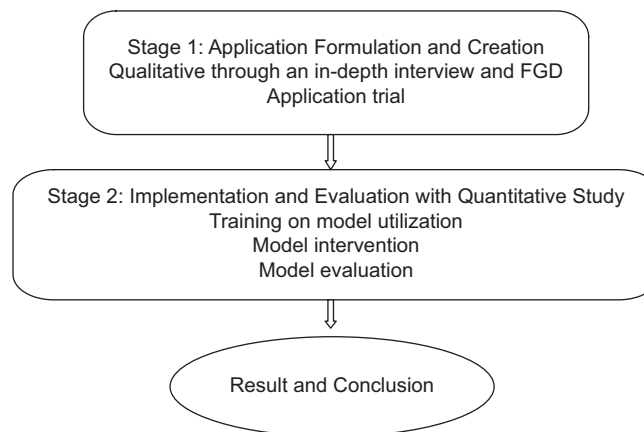


Figure 1: Stages of mixed method study

Procedure

Quantitative approach was following in three phases:

- **The First Phase**
During this phase, three enumerators were trained to use the application model to reduce the incidence of CS delivery. As for prenatal yoga, it was carried out by a midwife who was certified as a prenatal yoga instructor.
- **The Second Phase**
During this phase, model intervention was done on pregnant women. Participants who had been recruited for this study were pregnant women with gestational age between 18 and 20 weeks. Application-based education intervention was given to pregnant women along with prenatal yoga. Education was delivered to pregnant women through pregnant women-related materials in the form of video, which was available in the application. Pregnant women did prenatal yoga, using the existing video in the application, twice a week for 30 minutes and it might be done with prenatal yoga community through four meetings throughout the intervention, i.e., two meetings during the first trimester and two other meetings during the second trimester. Prenatal yoga in a prenatal yoga community was done at a gymnastic studio by a midwife who had certification as a prenatal yoga instructor.
- **The Third Phase**
During this phase, evaluation of the intervention results was conducted. Evaluation was conducted on pregnant women regarding their knowledge of and behavior toward selection of childbirth methods as well as the effectiveness of the intervention on CS delivery, which was carried out by knowing the number of CS deliveries that pregnant women had been through.

The process of qualitative data analysis used thematic data analysis with five stages, i.e., data reduction, data presentation, data analysis, conclusion and

verification, as well as a narration of the analysis result. Quantitative analysis was used to examine the significance of differences on mean of variables before and after the intervention using paired sample *t*-test. As for comparison between groups, analysis test with independent *t*-test was conducted.

Ethics consideration

This protocol received ethical approval from the ethics committee of the Faculty of Public Health, Hasanuddin University, Makassar with the code of ethics number 9880/UN4.14.1/TP. 01.02/2021.

Discussion

This research aimed at developing an application-based education model and prenatal yoga to bring down the occurrence of CS delivery. The education model was developed through creation of an application that would make it easier for pregnant women to obtain information regarding pregnancy and CS delivery, the impact of CS delivery, if it is performed on pregnant women without medical indication. This research combined the provision of education and prenatal yoga for pregnant women that could be performed at home. The results of this research might become a solution for reducing the number of CS deliveries, which had been increasing. In this study, it was carried out on primigravidae, and for further studies, it can be carried out on all pregnant women.

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Conflicts of interest

There are no conflicts of interest.

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