

Monitoring of Pregnant Women Using Mobile Application REST (Risk identification, Evaluation counseling, Systematic monitoring, Troubleshooting): Protocol for Cluster Randomized Controlled Trial

Restu Pangestuti, Prima Dhewi Ratrikaningtyas, Adi Heru Sutomo

Submitted to: JMIR Research Protocols on: October 12, 2024

Disclaimer: © **The authors. All rights reserved.** This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on it's website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressively prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript	5
Supplementary Files	
Figures	
Figure 1	
Figure 2	
Figure 3	25

Monitoring of Pregnant Women Using Mobile Application REST (Risk identification, Evaluation counseling, Systematic monitoring, Troubleshooting): Protocol for Cluster Randomized Controlled Trial

Restu Pangestuti^{1, 2} MKM; Prima Dhewi Ratrikaningtyas¹ DR; Adi Heru Sutomo³ Prof Dr

Corresponding Author:

Prima Dhewi Ratrikaningtyas DR
Department of Biostatistics, Epidemiology and Population Health, Faculty of Medicine, Public Health, and Nursing Universitas Gadjah Mada
Depok, Sleman, Yogyakarta
Yogyakarta
ID

Abstract

Background: The Maternal Mortality Rate (MMR) in Indonesia is still quite high and has not reached the national target. In 2021, maternal mortality in Central Java province reached 199 per 100,000 live births (1,011 cases), an increase compared to 2020 of 98.6 per 100,000 live births (530 cases). The success of maternal health programs can be assessed through the main indicator of the Maternal Mortality Rate. Pregnancy monitoring is one of the efforts to reduce the increase in maternal mortality rates.

Objective: Improving maternal and child safety and health during pregnancy and childbirth through pregnancy monitoring using mobile applications.

Methods: The research design uses the Cluster Randomized Controlled Trial design, involving pregnant women in 11 sub-districts in Purworejo which are divided into 11 clusters in the intervention group and 11 clusters in the control group. The intervention group received monitoring using a mobile app while the control group received standard pregnancy monitoring in the Pregnant Women Class. The mentoring program includes the use of a REST mobile application (Risk identification, Evaluation counseling, Systematic monitoring, Troubleshooting) which consists of 10T pregnancy checks. The application is used by midwives and pregnant women starting from the second trimester of pregnancy to childbirth. The data analysis to be used is the T-test bivariate analysis to determine the relationship between two variables, and the multivariate analysis using logistic regression.

Results: The expected results of this study are that the use of REST mobile applications for pregnancy monitoring will increase the number of ANC visits, reduce the incidence of complications in pregnant women, normal delivery methods, and the birth weight of the baby more than equal to 2500 grams.

Conclusions: Pregnancy monitoring using the REST mobile application will have a significant influence on the number of ANC visits, the reduction of pregnancy complications, the improvement of normal delivery methods, and the birth weight of the baby within normal limits. Clinical Trial: Clinical Trials.gov NCT05741931.

(JMIR Preprints 12/10/2024:66774)

DOI: https://doi.org/10.2196/preprints.66774

Preprint Settings

- 1) Would you like to publish your submitted manuscript as preprint?
- ✓ Please make my preprint PDF available to anyone at any time (recommended).

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

¹Department of Biostatistics, Epidemiology and Population Health, Faculty of Medicine, Public Health, and Nursing Universitas Gadjah Mada Yogyakarta ID

²Department of Midwifery, Faculty of Health Sciences Alma Ata University Yogyakarta ID

³Faculty of Medicine, Public Health, and Nursing Universitas Gadjah Mada Yogyakarta ID

Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

- 2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?
- ✓ Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain verse, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <a href="https://example.com/above/example.com/abo

Original Manuscript

Restu Pangestuti, MKM^{1,4}, Dr. Prima Dhewi Ratrikaningtyas^{2*}, Prof. Adi Heru Sutomo³

¹Doctoral Program Faculty of Medicine, Public Health, and Nursing Universitas Gadjah Mada, Yogyakarta, Indonesia; restupangestuti@mail.ugm.ac.id

²Department of Biostatistics, Epidemiology and Population Health, Faculty of Medicine, Public Health, and Nursing Universitas Gadjah Mada, Yogyakarta, Indonesia; primadhewi@ugm.ac.id;

³Faculty of Medicine, Public Health, and Nursing Universitas Gadjah Mada, Yogyakarta, Indonesia; adi.heru.sutomo@ugm.ac.id

Monitoring of Pregnant Women Using Mobile Application REST (Risk identification, Evaluation counseling, Systematic monitoring, Troubleshooting): Protocol for Cluster Randomized Controlled Trial

Abstract

Background: The Maternal Mortality Rate (MMR) in Indonesia is still quite high and has not reached the national target. In 2021, maternal mortality in Central Java province reached 199 per 100,000 live births (1,011 cases), an increase compared to 2020 of 98.6 per 100,000 live births (530 cases). The success of maternal health programs can be assessed through the main indicator of the Maternal Mortality Rate. Pregnancy monitoring is one of the efforts to reduce the increase in maternal mortality rates.

Objectives: Improving maternal and child safety and health during pregnancy and childbirth through pregnancy monitoring using mobile applications.

Methods: The research design uses the Cluster Randomized Controlled Trial design, involving pregnant women in 11 sub-districts in Purworejo which are divided into 11 clusters in the intervention group and 11 clusters in the control group. The intervention group received monitoring using a mobile app while the control group received standard pregnancy monitoring in the Pregnant Women Class. The mentoring program includes the use of a REST mobile application (Risk identification, Evaluation counseling, Systematic monitoring, Troubleshooting) which consists of 10T pregnancy checks. The application is used by midwives and pregnant women starting from the second trimester of pregnancy to childbirth. The data analysis to be used is the T-test bivariate analysis to determine the relationship between two variables, and the multivariate analysis using logistic regression. Trial Registration: ClinicalTrials.gov NCT05741931.

Results: The expected results of this study are that the use of REST mobile applications for pregnancy monitoring will increase the number of ANC visits, reduce the incidence of complications in pregnant women, normal delivery methods, and the birth weight of the baby ≥ 2500 grams.

Conclusions: Pregnancy monitoring using the REST mobile application will have a significant influence on the number of ANC visits, the reduction of pregnancy complications, the improvement of normal delivery methods, and the birth weight of the baby within normal limits.

Keywords: pregnant women; midwife; antenatal screening; mobile health; application; randomized controlled trial.

I. Introduction:

The success of maternal health programs can be assessed through the main indicator of the Maternal Mortality Rate (MMR). Maternal mortality is defined as all deaths during the period of pregnancy, childbirth, and postpartum caused by its management but not due to other causes such as accidents or incidentals [1]. The gestation period is the focus of the main problem in preventing high maternal mortality rates. The World Health Organization (WHO) recommends that health workers improve consultation and care for pregnant women [2].

⁴Department of Midwifery, Faculty of Health Sciences, The University of Alma Ata

Antenatal Care (ANC) services in normal pregnancy are at least 6 times, 2 times in the first trimester, 1 time in the second trimester, and 3 times in the third trimester. Antenatal Care (ANC) examinations in normal pregnant women are carried out by a doctor at least 2 times, which are carried out in the first trimester and the third trimester [3]. Failure in pregnancy care or Antenatal Care (ANC) usually occurs due to social and economic factors such as low education and family income, too young or too old, living far from health facilities, unwanted pregnancy, and the consumption of illegal drugs [2].

The Maternal Mortality Rate (MMR) in Central Java Province in 2021 was 199 per 100,000 live births (1,011 cases), an increase compared to the MMR in 2020 of 98.6 per 100,000 live births (530 cases) and in 2019 of 76.93 per 100,000 live births (416 cases). Cases of maternal mortality increased from 2019 and resulted in increased maternal mortality. The cause of disruption in Maternal and Child Health services during the pandemic is due to major changes in health facility services and public health [4].

The condition of the still high mortality rate shows that the quality of maternal and neonatal services is not optimal. The issue of "three late" is still the main problem of maternal health services, namely late decision-making, late arrival at the referral point, and late getting the services needed at health facilities. The low quality of pregnancy examination services is also reflected in the low compliance with antenatal care standards which include 10 pregnancy examinations [5].

There are several studies on pregnancy using mobile applications such as the m4Change Application [6] which contains health promotion around Maternal and Child Health with the results of improving the quality of ANC. Research on the application used to monitor during ANC, namely PANDA (Pregnancy and Newborn Diagnosis Assessment) with the results of knowing the cause of pregnancy complications [7]. ImTeCHO (Innovative Mobile-phone Technology for Community Health Operations) application for scheduling home visits, screening for complications and counseling with effective results in areas that are difficult to reach by health facilities [8]. This mobile information technology can be used as a medium to monitor pregnancy by pregnant women and monitoring by midwives who conduct pregnancy checks. The use of mobile applications can be applied by considering the effectiveness and quality of use of the application.

Pregnancy monitoring is a decision-making action for pregnant women and their fetuses to overcome previous events in patients such as observation of fetal development. Pregnancy monitoring facilitates the discovery of abnormal developments so that early treatment can be given and reduces disorders and risks for pregnant women. If pregnancy disorders are found in the mother and fetus, efforts will be made to reduce the high risk of pregnancy [9].

Pregnancy monitoring is one of the efforts made by both health workers and health cadres in monitoring the condition of the mother and fetus during pregnancy. Monitoring by healthcare providers during the gestation period such as to provide accurate real-time data on how many pregnant women are enrolled in antenatal care (ANC), pregnant women's characteristics, interventions, and outcome approaches will improve ANC information systems that can reduce maternal mortality cases [10].

An assessment of the implementation of health services for pregnant women can be

carried out by looking at the coverage of K1, K4, and K6. K1 coverage is the number of pregnant women who have received antenatal services for the first time by health workers, compared to the target number of pregnant women in one work area within a period of one year. K4 coverage is the number of pregnant women who have received antenatal services according to the standard at least four times according to the recommended schedule in each trimester, compared to the target number of pregnant women in one work area within one year. Meanwhile, K6 coverage is the number of pregnant women who have received antenatal services in accordance with the standard of at least six examinations and at least two doctor's examinations according to the recommended schedule in each semester, compared to the target number of pregnant women in one work area within a period of one year. This indicator shows access to health services for pregnant women and the level of compliance of pregnant women in checking their pregnancy with health workers [3]

The pregnant women class is an effort to promote the health of the Government of Indonesia to prevent maternal and infant mortality rates. The Government of Indonesia began implementing the Pregnant Women Class Program in 2009. The program aims to increase pregnant women's understanding of pregnancy, the use of antenatal care (ANC) and postpartum family planning services, and increase awareness of infectious diseases. The target population of the pregnant women class is mothers with a gestational age of 22–36 weeks. Each class consists of a maximum of 10 pregnant women and is facilitated by midwives or health workers who have received training in pregnant women classes [11].

Mobile applications have been widely used by various groups. The use of mobile applications is often used to facilitate activities in the health sector. Mobile applications in the health sector are used by many parties, both from health cadres, health service users, and health service providers [12].

Mobile applications in health are often used to improve the quality of health services. The use of mobile applications can continue to evolve through the correction of errors adjusted to the needs [13]. There are many variations of mobile applications used for health purposes. Applications can contain patient medical records, health consultations, health training, as well as health promotion [14] [15]

Pregnant women make up a significant proportion of the world's population. With an average age of 30 years, pregnant women are a generation that wants to get to know new technologies and expand medical care in the digital sector. There are many types of mobile applications used in monitoring the health of pregnant women. Mobile applications are often used in the field of midwifery because they are considered appropriate and easy to implement. The use of this application is not only for pregnant women but also for several groups involved, including couples and families. Pregnancy applications are also developed to postnatal care and parenting. The success in modifying the pregnancy app and complying with the use of the app makes it a new lifestyle intervention for users [16].

Based on the description above, it is important to conduct the latest research related to the use of applications for pregnancy monitoring. The title of the research to be carried out is Monitoring Pregnant Women Using Mobile REST Applications (Risk identification, Evaluation counseling, Systematic monitoring, Troubleshooting): Cluster Randomized Controlled Trial. The objectives of the study to be carried out are to compare the presence of pregnancy complications,

compare the intervention group and the control group in the context of the number of pregnant women who give birth normally, compare the birth weight of babies who reach \geq 2500 grams, and compare the number of antenatal care (ANC) visits that reach \geq 6 visits

The benefits that can be received from the results of the study for pregnant women are expected to make it easier to monitor their pregnancy conditions, for village midwives to be able to assist in monitoring maternal health during pregnancy, recognizing maternal problems, and helping to make timely referrals. The benefits of research for related agencies are input for the Public Health Center, the independent practice of midwives and doctors, the Health Office, and the Regional General Hospital in monitoring pregnant women to prevent maternal and infant mortality. The benefits for researchers can motivate and facilitate community leaders, cadres and communities, as well as increase cross-sector cooperation in monitoring the health of pregnant women. For science, it can be a novelty in conducting pregnancy monitoring.

II. Methods

Study Design

This study is an experimental study with a cluster-RCT (Randomized Controlled Trial) design. Cluster-RCT is a research design that has multilevel characteristics. Generally, cluster-RCT research uses two levels, namely at the cluster or group level and at the individual level. In this study, it will refer to the class cluster of pregnant women and participants of the pregnant women class. The research design is described in the following table 1:

Table 1. Research Design.

Group	Activity sequence						
	1		2		3		4
Intervention	O_0	\mathbf{X}_1	O_1	X_2	O_2	X_3	O_3
Control	O_0	X_0	O_1	X_0	O_2	X_0	O_3
Information							
O_0	Early identification in pregnant women in the first class of pregnant women						
O_1	Observations in the second class of pregnant women (Trimester 2)						
O_2	Observations in the third class of pregnant women (Trimester 3)						
O_3	Observation of childbirth and newborn						
X_0	Standard intervention for routine pregnant women classes without						
	applicati	on					
X_1			REST mob	ile applic	ation for p	regnancy	monitoring for
				7 -		0 ,	O
X_2	mothers and midwives using 10T Monitoring in pregnant women after using the mobile application						
X_3	Monitoring pregnant women using mobile applications and preparing for						
3	childbirth during the third trimester						
	CIIIIUUIIU	n during t	iic uiiiu ui	IIICSTEI			

The research will be carried out after ethical approval is issued. The research locations are in 11 sub-districts in Purworejo Regency, namely Loano, Purwodadi, Bruno, Butuh, Purworejo, Bagelen, Kaligesing, Kemiri, Kutoarjo, Ngombol, and Pituruh. The eleven sub-districts were chosen because they have health centers with inpatient services that make it easier for pregnant women to give birth in their areas.

Population

The target population in this study is all pregnant women in Purworejo Regency. The affordable population is all pregnant women in 11 sub-districts. From this population, 14 inpatient health centers were obtained which included 22 clusters of pregnant women classes. In each cluster or class

group, pregnant women consist of 10 pregnant women who meet the criteria.

Inclusion criteria

Pregnant women with a gestational age of 20-22 weeks (Trimester 2), pregnant women who have a pregnancy examination at a health facility, mothers who plan to stay in the research area for at least the next 2 years, mothers are willing to participate in the research by signing an informed consent form.

Exclusion criteria

Suffering from chronic diseases that require special pregnancy care, it has been confirmed that they cannot give birth normally, unable to operate an android cellphone. The applicant will be dropped out if she moves outside the research area, cannot be contacted after agreeing to informed consent, decides to stop participating in the research.

Sample Size

The sample size in this study was determined based on the hypothesis test formula for the two population averages. Here is the formula of Lemeshow *et al.*, (1997):

$$n = \frac{2\sigma^2 (Z_{1-\alpha} + Z_{1-\beta})^2}{(\mu_1 - \mu_2)^2}$$

Where $Z_{1-\alpha} = 1$, 645 (at the level of trust 95%, one-way test), $Z_{1-\beta} = 0$, 842 (at power 80%), $\mu_{1-\mu_{2}} =$ average difference *outcome* (number of ANC visits, method of delivery, weight of newborn) between treatment and control groups that are considered clinically meaningful $\sigma =$ standard deviation of the combined group being compared.

Based on the results of calculations from previous research Souza *et al.* (2020), McNabb *et al.* (2015) Lund *et al.* (2014), then the minimum sample size for each intervention and control group was 90 respondents. In cluster randomized controlled trial research, it is necessary to take into account *design effect* (DE) in determining the size of the sample. The formula used is DE = 1+(m-1) ρ . [17] [2] [6] [18]

Based on the calculation results, an DE of 1,082 was obtained. Furthermore, the sample size that has been obtained is multiplied by the DE, resulting in a sample size of 97.38 which is rounded to 98 samples per group. Therefore, the total sample needed is 196 people, but taking into account the loss to follow-up of $\pm 10\%$ (based on a preliminary study of the attendance of pregnant women classes in 2019 in Purworejo Regency). Therefore, it is necessary to take a total of 216 (108 pregnant women in the intervention group and 108 pregnant women in the control group) at the beginning of the study, through cluster sampling.

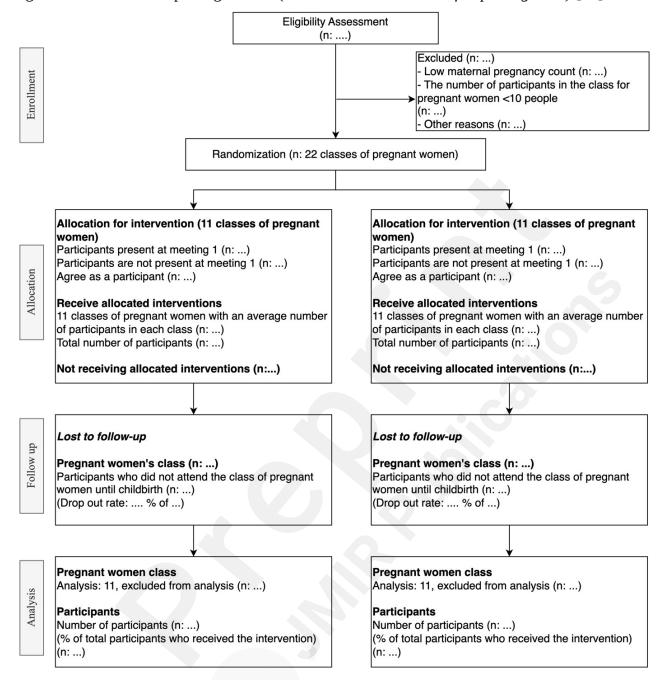
Randomization, Allocation, and Blinding

The determination of the cluster that is used as a research area begins by selecting 11 sub-districts in Purworejo Regency purposively based on the availability of inpatient public health center services in Purworejo Regency and in each sub-district 1 inpatient public health center will be taken. In each Puskesmas in Purworejo Regency, 2 groups of pregnant women classes are taken because in each class of pregnant women the maximum number of participants is 10 people.

The next step is to conduct random allocation to determine the clusters that are included in the intervention group and control group. First, create a list of cluster names in a Microsoft Excel file, with codes 1 to 22. Furthermore, the list of clusters is randomized with the help of a program/formula in Microsoft Excel to perform random allocation (*Compute Generated Random*

Allocation). Then the random numbers that appear for each cluster are sorted from the smallest number to the largest number (sorting), and the cluster names that appear in the order 1-11 are included in the intervention group while the clusters that appear in numbers 12-22 are included in the control group. The allocation of the group was kept secret until the sample received treatment for the intervention group. Blinding is not possible both for the treatment provider (researcher) and for the sample because the monitoring intervention allows for active interaction between the treatment provider and the sample. Figure 1 CONSORT Reporting Format (Consolidated Standards of Reporting Trial) [19].

Figure 1. CONSORT Reporting Format (Consolidated Standards of Reporting Trial) [19]



Intervention

The interventions that will be implemented are illustrated in the form of *Template for Intervention Description and Replication* (TIDieR) [20]

Table 2. Template for Intervention Description and Replication (TIDieR)

No	Activity Name	Pregnancy monitoring using REST apps
1.	Reasons for the	
	intervention	in government program activities that support
		pregnancy health such as pregnant women's classes.
		The pregnant women class is a monitoring effort to
		improve the welfare of mothers and babies.
		Monitoring using the REST application is expected
		to make it easier for pregnant women and midwives
		to monitor the health condition of mothers.
2.	Action	Providing assistance to mothers during pregnancy
		using mobile applications. Assistance is carried out to
		monitor the health condition of the mother and fetus.
		The mother will take part in a pregnant woman class
		and will be examined including 10 pregnancy
		examinations (height and weight, blood pressure,
		Mid-Upper Arm Circumference, Uterine Fundal
		Height, TT immunization, Fe Tablets, fetal
		presentation and fetal heart rate, counseling,
_		laboratory tests, and case management)
3.	Procedure	Conducting initial identification of mothers at the
		first meeting of the pregnant women's class. Mothers
		will be examined by midwives at every class meeting
		of pregnant women, the results of the pregnancy
		examination will be entered into the mobile
		application. Each mother will get a different
		evaluation from the midwife according to the results
		of the mother's pregnancy examination. Pregnant
		women's classes will be held 3 times, with a duration
		of approximately 90 minutes per meeting. In each
		implementation of the pregnant woman class, the
4.	Organizers	mother will be given pretest and posttest questions. Principal investigator: ensuring the readiness of
4.	Organizers	activities and the completeness of the equipment
		needed during the pregnant women's class.
		Midwife Facilitator: carry out examinations of
		pregnant women, provide counseling, and document
		examination results into mobile applications.
		Training: use of mobile apps.
		Cadres: assist midwives during the implementation
		of classes for progrant tromp. Training

of

classes

for

pregnant

women.

Training:

5. Intervention delivery model

measurement of height, weight, and blood pressure. Enumerator: assists the principal investigator in monitoring the progress of the pregnant women's class activities. Training: use of mobile apps.

The intervention was carried out face-to-face in each group of pregnant women.

6. Venue and Facilities

This pregnancy monitoring is carried out in the Purworejo Regency area. The infrastructure used is: stationery, mobile phones (smartphones), weight scales and height measuring instruments, tools to check haemoglobin levels, dopplers to check fetal heart rate, Mid-Upper Arm Circumference tape, and metline to measure uterine fundal height, digital sphygmomanometers, and research questionnaires.

Changes or modifications during the process

The time of the pregnant woman class adjusts the time of the mother and midwife according to the agreement.

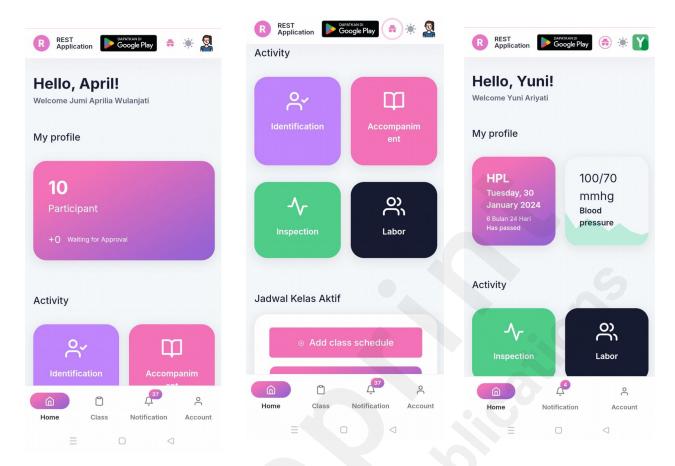
Pregnancy monitoring using the REST mobile application is adjusted to local conditions and the ownership of mobile phones by pregnant women. Furthermore, pregnancy monitoring using an application in the pregnant women's class can be carried out by midwives at the workplace or their respective practices.

8. Planning

On the mobile application, a reminder will be created to remind midwives and mothers of the date of the pregnant women's class. This reminder will appear in the form of a notification of the H-1 class of pregnant women.

The intervention given to the treatment group used a mobile REST application (Risk Identification, Evaluation counseling, Systematic monitoring, Troubleshooting). The application has been validated by three experts, namely an obstetrician and gynecologist, a health application expert, and a community midwifery expert. The application was piloted in a small group of pregnant women communities who were not involved in the intervention study. Evaluation includes format, substance, presentation and language. The results of the trial were measured by the distribution of simple questionnaires, interviews, and observations. After revision for refinement, the application is ready to use on research. REST applications that have been developed can be accessed through https://app.restsapp.com/site/login. Here is an image of the validated and tested app (see Figure 2)

Figure 2. Image of the Mobile REST Application on Midwife and Participant profiles.



Study Outcomes

All results will be measured at the end of the study when participants have undergone labor from both the control group and the treatment group.

Primary Outcomes

Pregnancy complications

Pregnancy monitoring using a mobile REST application can prevent complications during a mother's pregnancy compared to not using a mobile REST application. The use of an application can help prevent complications during pregnancy.

Methods of delivery

The use of REST mobile applications can identify conditions that lead to pathological conditions from the beginning of monitoring. Pathological conditions that are immediately resolved can facilitate the mother's delivery process for normal delivery.

Birth weight of the baby

The use of the REST mobile application in addition to monitoring the mother's condition as well as the health of the fetus. The group that uses the application will pay more attention to the development of the fetus and can anticipate that the baby's birth weight can reach a normal birth weight of ≥ 2500 grams.

Antenatal care (ANC) visits

The use of the REST mobile application records how many maternal examination visits to health

facilities, with the REST mobile application mothers who do not carry out examinations in accordance with the minimum ANC standard ≥ 6 times will receive a notification from the midwife to immediately carry out the examination.

Secondary Outcomes

Monitoring using the REST mobile application makes pregnant women play an active role in their pregnancy conditions, including recording examination results independently so that mothers' knowledge of examination results increases. The perception of pregnant women by monitoring using the REST mobile application will be better for the current pregnancy. Because mothers will easily monitor their condition, understand every health development experienced. Applications that have been used by midwives and pregnant women for pregnancy monitoring will be evaluated by assessing satisfaction from all aspects of use.

Ethical Considerations

The Medical and Health Research Ethics Committee (MHREC) of the Faculty of Medicine, Public Health and Nursing, Gadjah Mada University – Dr Sardjito General Hospital approved the study protocol, which was registered with the Forum for Ethical Review Committees in Asia and the Western Pacific (project number KE-FK-0653-EC-2023). The study was conducted according to Indonesia's 2021 National Health Research and Development Ethical Guidelines and Standards by the Health Research and Development Ethics Committee and the Declaration of Helsinki, as revised in 2013. ClinicalTrials.gov has reviewed this protocol (NCT05741931).

Participation in this research was voluntary, without any coercion. All participants received comprehensive information about the research, especially about the intervention that would be given and the possible benefits and risks. Participants were allowed to withdraw at any time without penalty.

Data Analysis

Bivariate analysis

The bivariate analysis aimed to determine the effect of monitoring using mobile applications from 20-22 weeks gestation (Trimester 2) on the number of ANC visits, pregnancy complications, delivery methods, and birth weight. The data analysis test that will be used to test for significant differences between the two groups is the t-test. The chi-square test will also be carried out to determine the relationship between two variables whose measurement parameters have been categorized

Multivariate analysis

The multivariate analysis in this study will use multiple logistic regression. Regarding the research design that uses cluster randomized trials, adjustments are made by considering clusters (cluster adjusted) using multilevel logistic regression. In addition, as an effort to ensure the effect of modification or disruptive variables, a stratification analysis will be carried out.

Data Management

The data collected will be kept confidential for the duration of the study and disposed of after a period of 5 years. The data collection process from the beginning to the end of the study uses two different methods. In the control group, the data was collected using a form that would be transcribed into an electronic format and in the intervention group, the data was collected using an application and transcribed in electronic form that would be stored on a desktop computer. This stored data will be used for further analysis. The individual appointed as the chair of the student project committee at the institute will be responsible for overseeing data management.

Results

In July 2023, the preparation of the application was made and tested to small groups in the community, namely Midwives and Pregnant Women for a simulation using the REST application. In

September 2023, the REST application began to be developed and improved according to the results of the small group trial. The REST application, which will be used for pregnancy monitoring from pregnancy to delivery, has been copyrighted by the Ministry of Law and Human Rights of the Republic of Indonesia with ID 000655305.

In September 2023, REST mobile applications for pregnancy monitoring began to be introduced to respondents who will be involved in the study. The number of respondents who will be involved is 22 midwives at the Health Center and 220 pregnant women in Purworejo Regency. A total of 22 midwives will be divided into 2 groups, namely 11 REST application groups and 11 control groups. Each midwife will support 10 pregnant women so that there are 110 pregnant women in the REST application group and 110 pregnant women in the control group. The expected results after the intervention in the application group were an increase in normal birth rates, an increase in the number of ANC visits, an increase in the number of newborns with a birth weight of ≥2500 grams, and a decrease in the incidence of pregnancy complications compared to the control group.

Discussion

The advantages of using apps for pregnancy monitoring vary from app to app as each app provides different features. The results of previous research studies related to the use of applications for pregnancy are considered effective and are grouped into four categories, the first is applications that provide information (Health Gestation application and CHAT). This application provides the information that pregnant women need to monitor their pregnancy [2][21]. Second, the application is used to conduct counseling between midwives and pregnant women through text message and voucher component [18]. Third, an application that helps pregnant women to make decisions and provide mental support (QUiPP app and SP⁺) [14][22]. Fourth, applications that help pregnant women in managing during their pregnancy (Health assistant app and ImTeCHO). This application helps pregnant women do self-monitoring and understand the condition of pregnancy well [23][24] [8].

The REST mobile application is the first application designed to be used by midwives and pregnant women where the data input by midwives and pregnant women will be integrated with each other. The use of this application can also be used as a novelty of comprehensive maternal health monitoring. This study uses an RCT cluster design with the hope that there is a comparison group that will be used as a benchmark for the effectiveness of the use of REST applications.

The REST application is defined from Risk Identification, which is to identify risks by midwives from the results of the examination, Evaluation counceling, which is the existence of application-based counseling from pregnant women and midwives so that it makes it easier for pregnant women to make decisions, Systematic monitoring, which is systematic monitoring by midwives by focusing on 10T, which includes weight weighing and height measurement (T1), measuring blood pressure (T2), Determining Mid-Upper Arm Circumference (T3), Measuring Uterine Fundal Height (T4), Tetanus Immunization (T5), Giving Blood Supplement Tablets (T6), Determining Fetal Presentation and Fetal Heart Rate (T7), Counseling Including Childbirth and Postpartum Preparation (T8), Checking Haemoglobin Levels (T9), Providing Care as Needed (T10) [3]. Troubleshooting is determining the solution of problems by midwives to pregnant women in their group.

Limitations

The limitation of this study is that the research is only limited to monitoring from the beginning of pregnancy until the baby is born. The application is not equipped with monitoring features up to

postpartum and monitoring of children under five. The app installation process must be through a web address https://app.restsapp.com/ is not yet automatically available on the App Store or Google Play Store. The use of the application is still limited to the research area, namely in Purworejo Regency, Central Java, Indonesia. The output of the research is expected to have an effect on improving maternal and child health and will be developed more widely to the national and global levels.

Conclusions

The study with the design of a Randomized Controlled Trial on the use of REST mobile applications aims to compare the welfare of pregnant women in the intervention group and the control group. The REST application used by midwives and pregnant women in the intervention group will help monitor the activities of pregnant women classes that are routinely carried out by the Health Center. The control group that did not use the REST application carried out class activities for pregnant women in accordance with the implementation standards.

Acknoledgments

This research would not have been possible without the support of Gadjah Mada University and Alma Ata University Yogyakarta. The author of this protocol would like to thank all Village Midwives at the Purworejo Regency Health Center who have been willing to actively participate in monitoring participants (pregnant women) effectively. In addition to personal funds, this research was carried out with support from other parties through partial funding from the Doctoral Study Program in Medical and Health Sciences, Faculty of Medicine, Public Health and Nursing, Gadjah Mada University, through the 2024 Damas Grant Program (3030/UN1/FKKMK.1.3/PPKE/PT/2024). Data availability

The data sets generated during this study are available from the corresponding author on reasonable request.

Authors' Contributions

RP contributes to the design of REST mobile applications, data curation, publication drafting, and investigations. AHS contributes to conceptualization, supervision, review, methodology, and supervision of research implementation. PDR contributes to conceptualization, supervision, data curation, review, and editing.

Conflicts of Interest

There is no conflict of interest

References

- 1. Kemenkes RI. Profil Kesehatan Indonesia Tahun 2021 [Internet]. Jakarta; 2022 [cited 2024 Aug 20]. 1–538 p. Available from: https://repository.kemkes.go.id/book/828
- 2. Souza FM de LC, Santos WN Dos, Santos RS da C, Silva VLM da, Abrantes RM de, Soares VFR, Silva RAR da. Effectiveness of mobile applications in pregnant women's adherence to prenatal consultations: randomized clinical trial. Rev Bras Enferm. 2021;74Suppl 5(74Suppl 5):e20190599.
- 3. Kemenkes RI. Pedoman pelayanan antenatal, persalinan, nifas, dan bayi baru lahir di Era Adaptasi

Baru [Internet]. 2020 [cited 2024 Aug 20]. 98 p. Available from: https://repository.kemkes.go.id/book/624

- 4. Dinkes Provinsi Jawa Tengah. Laporan Kinerja Instansi Pemerintah Tahun 2021. Dinas Kesehatan Provinsi Jawa Tengah [Internet]. 2021 [cited 2023 Jan 27]; Available from: https://dinkesjatengprov.go.id/v2018/storage/2022/05/LKjIP-Dinkes-Jateng-21-upload.pdf
- 5. Permenkes RI No 13. Tentang Perubahan atas Peraturan Menteri Kesehatan Nomor 21 Tahun 2020 Tentang Rencana Strategis Kementerian Kesehatan Tahun 2022 2024. Menteri Kesehatan Republik Indobesia. 2022;(3):1–592.
- 6. McNabb M, Chukwu E, Ojo O, Shekhar N, Gill CJ, Salami H, Jega F. Assessment of the quality of antenatal care services provided by health workers using a mobile phone decision support application in northern Nigeria: A pre/post-intervention study. PLoS One [Internet]. 2015;10(5):1–12. Available from: http://dx.doi.org/10.1371/journal.pone.0123940
- 7. Vilaplana EG, Petignat P, Benski AC, Soaroby A, Sormani J, Vassilakos P, Schmidt NC. Description of maternal morbidities amongst 1000 women during pregnancy in ambanja, madagascar opportunities and challenges of using an mhealth system. Int J Womens Health. 2020;12:823–33.
- 8. Modi D, Dholakia N, Gopalan R, Venkatraman S, Dave K, Shah S, Desai G, Qazi SA, Sinha A, Pandey RM, Anand A, Desai S, Shah P. MHealth intervention 'ImTeCHO' to improve delivery of maternal, neonatal, and child care services-A cluster-randomized trial in tribal areas of Gujarat, India. PLoS Med [Internet]. 2019;16(10):1–24. Available from: http://dx.doi.org/10.1371/journal.pmed.1002939
- 9. Wahyuni Mohamad R. Pemanfaatan System Informasi Mobile Bagi Kesehatan Ibu Hamil dan Anak [Internet]. Vol. 3, Jambura Nursing Journal. 2021. Available from: http://ejurnal.ung.ac.id/index.php/jnj|32
- 10. Hakiemafrizal S, Hakiem N, Oktarina D, Handayani D, Mardhatillah A. Health Workers Readiness for mHealth Implementation Jurnal Sistem Informasi. Journal of Information System). 2022;18(1):18.
- 11. Azhar K, Dharmayanti I, Tjandrarini DH, Hidayangsih PS. The influence of pregnancy classes on the use of maternal health services in Indonesia. BMC Public Health. 2020;20(1):1–9.
- 12. Bonnell S, Griggs A, Avila G, Mack J, Bush RA, Vignato J, Connelly CD. Community Health Workers and Use of mHealth: Improving Identification of Pregnancy Complications and Access to Care in the Dominican Republic. Health Promot Pract. 2018 May 1;19(3):331–40.
- 13. Karamolahi PF, Bostani Khalesi Z, Niknami M. Efficacy of mobile app-based training on health literacy among pregnant women: A randomized controlled trial study. Eur J Obstet Gynecol Reprod Biol X. 2021 Oct 1;12.
- 14. Carlisle N, Watson HA, Seed PT, Carter J, Kuhrt K, Tribe RM, Shennan AH. Impact of a medical mobile phone app (QUiPP) for predicting preterm birth on the anxiety and decisional conflicts faced by women in threatened preterm labour. Midwifery. 2021 Jan 1;92.
- 15. Watson HA, Carlisle N, Seed PT, Carter J, Kuhrt K, Tribe RM, Shennan AH. Evaluating the use of

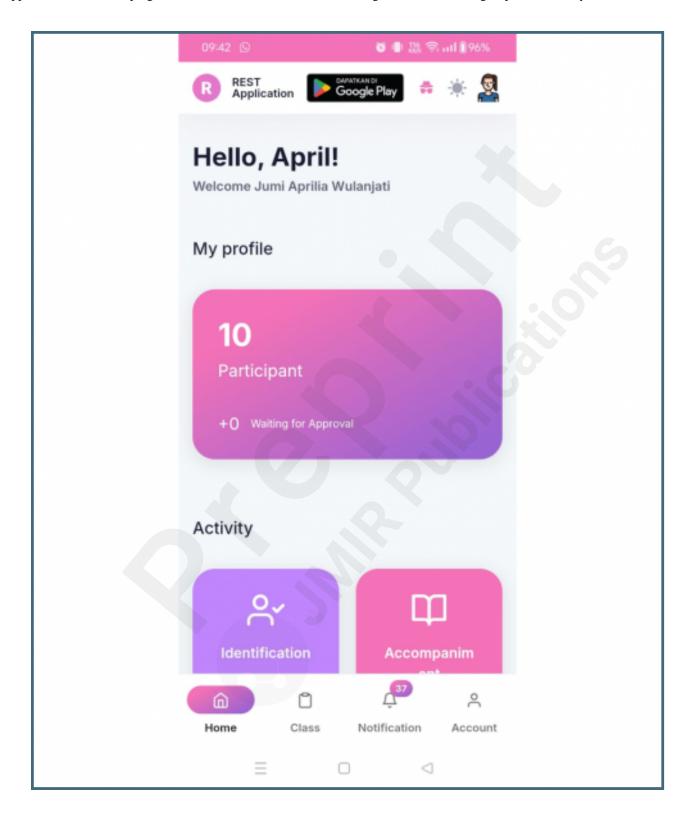
the QUiPP app and its impact on the management of threatened preterm labour: A cluster randomised trial. PLoS Med. 2021 Jul 1;18(7).

- 16. Brusniak K, Arndt HM, Feisst M, Haßdenteufel K, Matthies LM, Deutsch TM, Hudalla H, Abele H, Wallwiener M, Wallwiener S. Challenges in Acceptance and Compliance in Digital Health Assessments during Pregnancy: Prospective Cohort Study. JMIR Mhealth Uhealth. 2020 Oct 1;8(10).
- 17. Vierron E, Giraudeau B. Design effect in multicenter studies: Gain or loss of power? BMC Med Res Methodol. 2009;9(1).
- 18. Lund S., Nielsen Birgitte B., H. Maryam, Boas Ida M., Said Azzah, S. Khadija, Rasch Mkoko H.M. and V. Mobile phones improve antenatal care attendance in Zanzibar: a cluster randomized controlled trial. BMC Pregnancy Childbirth. 2014;14(29):1–10.
- 19. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: Extension to cluster randomised trials. BMJ (Online). 2012 Nov 3;345(7881).
- 20. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, Altman DG, Barbour V, Macdonald H, Johnston M, Kadoorie SEL, Dixon-Woods M, McCulloch P, Wyatt JC, Phelan AWC, Michie S. Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. BMJ (Online). 2014 Mar 7;348.
- 21. Buchanan L, Anderson E, MBiostat HX, Phongsavan P, Rissel C, Wen LM. Sources of information and the use of mobile applications for health and parenting information during pregnancy: Implications for health promotion. Health Informatics J. 2021;27(3).
- 22. Hackett K, Lafleur C, Nyella P, Ginsburg O, Lou W, Sellen D. Impact of smartphone-assisted prenatal home visits on women's use of facility delivery: Results from a cluster-randomized trial in rural Tanzania. PLoS One. 2018 Jun 1;13(6).
- 23. Liu Y, Wang X. Application of Smart Mobile Medical Services in Maternal Health Care Management. Contrast Media Mol Imaging. 2021;2021.
- 24. Ledford CJW, Canzona MR, Cafferty LA, Hodge JA. Mobile application as a prenatal education and engagement tool: A randomized controlled pilot. Patient Educ Couns. 2016 Apr 1;99(4):578–82.

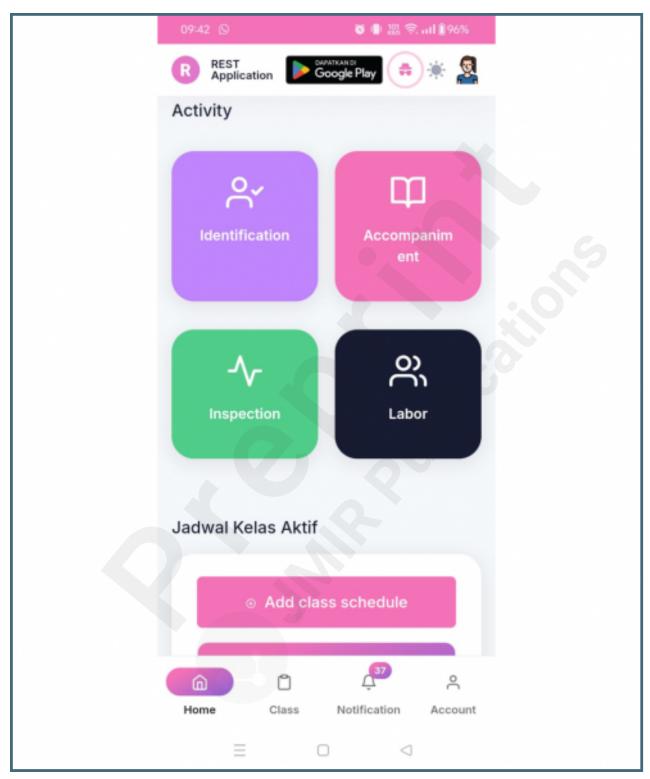
Supplementary Files

Figures

The application display on the Midwife User is different from the participant because in the Midwife application there will appear detailed data of pregnant women who are members of the Pregnant Women class group monitored by each midwife.



Midwives can fill in the data of the results of the mother's examination during the implementation of the pregnant women class and pregnant women can see it in the pregnant women user.



Pregnant women (participants) can monitor their pregnancy based on the results of the examination that have been input by the Facilitator Midwife and pregnant women can also fill in the results of the examination carried out outside the implementation of the pregnancy class.

