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STUDY PROTOCOL

THE EFFECTIVENESS OF LOCAL WISDOM-BASED COUNSELING TO PREVENT IRON DEFICIENCY ANEMIA AMONG PREGNANT WOMEN: A PROTOCOL OF A RANDOMIZED CONTROLLED TRIAL

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Abstract

Background: Anemia during pregnancy is a health problem that often occurs in developing countries. Local wisdom-based counseling is considered a new approach in preventing iron deficiency anemia among pregnant women by integrating cultural beliefs into antenatal counseling.

Objective: The study aims to measure the effectiveness of local wisdom-based counseling model among pregnant women to prevent iron deficiency anemia.

Methods: This paper outlines the protocol of a randomized controlled trial method. Two intervention programs will be developed, the local wisdom-based program and health-based counseling intervention program, and will be tested among 150 pregnant women from nine public health centers in one district of Aceh Province. Sample selection will be completed through a simple random selection process. The effectiveness of the interventions will be assessed using a self-report questionnaire and a hemoglobin test. Data will be analyzed using descriptive and inferential statistics.

Discussion: The expected outcome in this study is a significant difference in hemoglobin levels between both intervention groups. It is also expected that there will be an increase in knowledge, attitude, and behavior in the group who will receive local wisdom-based counseling intervention than the other group who will receive health-based counseling intervention. A local wisdom-based counseling approach is expected to give an effective model to reduce the prevalence of iron deficiency anemia among pregnant women. The effectiveness of this model may suggest the further application in the other regions.

Registration trial number: ACTRN12620000299909

KEYWORDS
anemia; iron-deficiency; hemoglobin; counseling; local wisdom; pregnancy

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BACKGROUND

Pregnancy with anemia is a health problem that often occurs in developing countries, causing many negative effects (Stephen et al., 2018). Anemia in pregnant women is indicated by hemoglobin (Hb) level less than 11 gr/dl (Silverberg, 2012; World Health Organization, 2001) and frequently caused by nutritional deficiencies, especially iron (Achebe & Gafter-Gvili, 2017). It is estimated that 42 percent of pregnant women worldwide suffer from anemia, where 50% of them are caused by iron deficiency (Ayano & Amentie, 2018; Srour, Aqel, Srour, Younis, & Samarah, 2018). In 2018, about 48.9% of pregnant women in Indonesia were classified as anemia and more than 50% of them are caused by a deficiency in iron, folic acid, and vitamin B12 (Ministry of Health, 2018; Zahrulianingdyah, 2016). The data published by Department of Health of Aceh Besar (2017) showed that the prevalence of anemia was 37.1% in Aceh Besar Regency.

The nutritional status of a pregnant woman is indirectly affected by the number of Antenatal Care (ANC) attendances, counseling from health workers, and the support from the husband (Vir, 2011; Wiradnyani, Khusun, Achadi, Ocviyanti, & Shankar, 2016). Health workers have a very important role to provide a proper antenatal care for pregnant women (Septiani, 2017). The observed cultural narrative has also been acknowledged significant for the pregnant woman's nutritional health (Vir, 2011; Wiradnyani et al., 2016).

In Indonesia, antenatal care service consists of communication, information and education, which are used as the counseling steps to

monitor and ensure nutritional adequacy of pregnant women, including the iron intake (Ministry of Health, 2010). The counseling is expected to encourage pregnant women to consume iron tablets to tackle the iron deficiency. Unfortunately, the availability of antenatal care in Indonesia only provides a pregnancy-related counseling. Further, the counseling relies on the mere limited information from the book published by the Indonesian Ministry of Health (Heru, Hasanbasri, & Hakimi, 2012; Septiani, 2017). To overcome the limitation of Indonesian antenatal care service, the locally observed cultural narratives can be integrated into antenatal counseling. Local culture is found to be a tool of social control, where it can be used to combat deeply-rooted bad behavior of insufficient iron intake during pregnancy (Kasnodihardjo & Kristiana, 2013).

Cultural value plays an important role in regulating life in various phases, especially during pregnancy where people consider pregnancy as a special event, where many rituals must be performed (Juariah, 2018). It is very important to integrate counseling with the local culture especially for people in Aceh because the majority of Acehnese pregnant women get information about pregnancy from cultural or religious sources (Iradukunda, 2020).

Acehnese is one of the ethnic groups in Indonesia that still adheres to cultural beliefs, located in the Sumatera. This region is known as the Porch of Mecca (the Holy City of Islam) and has the Islamic values that deeply attached to its people's daily lives, reflected on the people's mentality, behavior, and social order (Setyantoro, 2012; Usman, 2009). One of the Islamic values that is very influential on the continuity of pregnancy and trusted by the Acehnese people is the prayers and Qur'an recitation every night so that God will look after their womb. They also must listen and obey their husband following the words of **Rasulullah SAW** and that became one of the husband's support for his wife. Further, Acehnese people believe that all symptoms related to anemia are common during pregnancy so they should not worry about it. They have certain dietary restrictions that should not be consumed during pregnancy because it will affect the continuity of the pregnancy, such as the prohibition to consume crabs, shrimp and other seafoods, and to eat rambutan, pineapple, durian and papaya. There is also a belief to not consume crabs during pregnancy because the born baby will become naughty, and they may not consume satay (Batubara, 2015). These beliefs will cause pregnant women to be deficient in nutrients needed, causing anemia.

On the other hand, Acehnese culture also has a habit that supports pregnancy, where there is a custom of bringing nutritious food and fruits to pregnant women in the seventh month of pregnancy. They also believe that consuming *janeng* fruit (one of the tubers that are widely found in the Aceh Besar region) is beneficial for pregnancy because it contains iron. This attitude and behavior has a big effect on the pregnancy itself (Batubara, 2015). In Acehnese culture, the value of life is conveyed through poetry or called *narit/hadis maja* (Hoesin, 2018). There is a lot of *narit maja* in Acehnese culture that influences pregnant women's attitude and behavior, one of them is that Acehnese culture believe that headache is a sign of symptoms from lack of blood (anemia). It can happen because pregnant women do not consume foods rich in nutrients.

The aforementioned data above clearly indicated the importance to integrate the counseling with the Acehnese culture. Thus, this paper outlines a study protocol to develop an antenatal counseling model to tackle iron deficiency anemia during pregnancy by adopting the cultural approach. The intervention with the cultural reinforcement that is conducted in this research is expected to give a positive effect to the pregnant women. This study will assess the effectiveness of counseling interventions combined with local culture in preventing iron-deficiency anemia during the pregnancy, which the increase of hemoglobin will be taken as an indicator of the short-term success.

METHODS

Study Design

The study will employ a randomized controlled trial (RCT) with pre- and post-test control group design in order to identify the effectiveness of counseling intervention programs in preventing iron-deficiency anemia during pregnancy. The comparison will be conducted on an individual basis in both intervention and control groups' participants.

Participants

Study participants will be recruited from nine Public Health Centers (PHCs) in Aceh Besar Regency, Aceh Province, Indonesia. Initially, the nine PHCs will be randomly selected for the study and assigned into one of the two intervention programs (the Local Wisdom-based Counseling Intervention Group [LWCI Group] or the Health-based Counseling Intervention Group [HCI Group]) or as a control group. Then, a total of 150 participants (50 pregnant women for each group) will be recruited for the study from the selected PHCs. The PHCs recruitment process and assignment will be carried out using a simple random sampling technique (a lottery). Sample size was estimated using Cohen (2017) formula, with medium effect size and a power of 0.08, and confidence level at 95%. Sample criteria will include pregnant women with the following criteria: (1) in the second trimester of pregnancy; (2) having no complications; (3) willing to participate in this study; (4) Acehnese, and; (5) domiciled in the Aceh Besar Regency. Pregnant women with complications will be referred to public services or doctors and not included in this study.

Instruments

A self-developed questionnaire will be used to measure program effects on participants' knowledge, attitude, and behavior. The questions are specifically prepared for the use in this study based on the program intervention materials and in line with the seven factors proposed in the Leininger Concept. The content validity test of the questionnaire has been conducted involving three experts from relevant area. Comments from the experts had been used to improve the validity of the questionnaire. The reliability test with the critical value of .361 involving 30 pregnant women will be conducted before the intervention programs started. Overall, the questionnaire is divided into several sections as follows.

1) Participants' characteristics; this section will assess participants' characteristics (such as age, religion, job, parity, obstetric status, family income, last education) and data about their current pregnancy (gestational age, birth spacing, weight, upper arm circumference).

2) Knowledge about iron deficiency anemia during pregnancy; section 2 will measure the knowledge of pregnant women about iron-deficiency anemia during pregnancy. This section will consist of 20 multiple-choice questions related to knowledge about the causes, signs, symptoms, and effects of the iron deficiency anemia, as well as the food

sources and foods that support or inhibit the absorption of iron in the body. The total score for this variable ranges from 0 to 20 (1 point for the correct answer and 0 point for the wrong answer), with high scores reflect the individual has good knowledge in preventing iron-deficiency anemia in pregnancy.

3) Attitude toward iron deficiency anemia during pregnancy; section 3 will measure the pregnant women's attitude toward iron deficiency anemia during pregnancy. This section will comprise 20 statements and will be measured by a five-point of Likert scale, ranging from 5 (strongly agree) to 1 (strongly disagree). The total score for this variable ranges from 20 to 100, with high scores reflect the individual good attitudes in preventing iron-deficiency anemia.

4) Behavior about iron deficiency anemia during pregnancy; the last section comprises questions to measure the participants' behavior about iron-deficiency anemia during pregnancy. This section will consist of 17 statements related to the daily activities of pregnant women that induce iron-deficiency anemia, routine antenatal care attendance, and husband's support during pregnancy. The variable will be measured by multiple-choice questions with four possible answer choices (+4 point for the best choice and +1 point for the worst choice). The total score for this variable ranges from 17 to 68, with high scores reflect the individual good behavior in preventing iron-deficiency anemia during pregnancy.

The questionnaire formulation, development process, content, and program trials are presented in Figure 1 as follows.

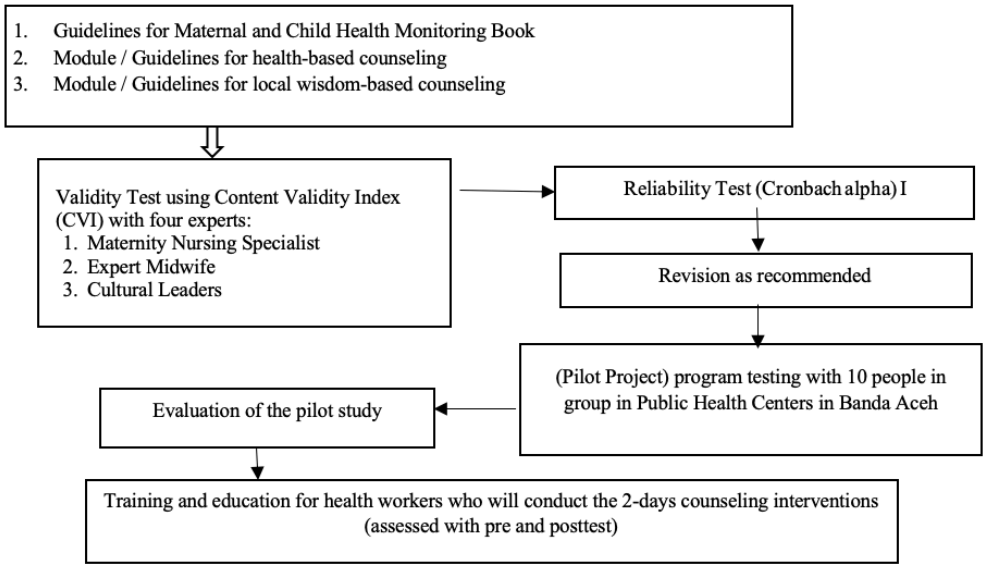

Figure 1 The intervention formulation, content, and program trials

5) Haemoglobinometer; haemoglobinometer will be used to measure the participants' hemoglobin levels. This measurement will be completed by Easy Touch GCHb, which is a digital health device produced by Nesco Multicheck. The Haemoglobinometer used in this study (Hb Meter) have shown high validity and reliability scores at .91 and .80, respectively (Ahmad et al., 2015; Pawlowski et al., 2015).

Program Intervention

Several activities, including an extensive review of relevant literatures, focus group discussions, observations, and consultation with experts in the field, had been completed in the development process of the intervention programs. Detail information about the implementation process of the intervention programs and how the results will be achieved are presented in Figure 2.

The Local Wisdom-based Counseling Intervention Group (LWCI Group) will provide participants' information about iron deficiency anemia prevention efforts appropriate to pregnant women in Aceh. This includes program introduction and research explanations (Session 1); Mutual trust building and pregnancy overview (Session 2); Counseling on iron deficiency anemia and explanation about Hb examination with the cultural approach (Session 3); Counseling on the iron tablets intake with the cultural approach (Session 4); Counseling on husband's supporting role for the iron tablets intake control with the cultural approach (Session 5); Review, follow up, and Hb examination (Session 6) (Sehhatie, Mirghafourvand, & Havizari, 2019). The program delivery method will include group counseling, with each group will consist of 7-9 participants. The intervention will be given to the participants for over 1 month (6 sessions) with 1-week intervals between sessions. The duration for each session will be 45-75 minutes.

The Health-based Counseling Intervention Group (HCI Group) was designed by combining WHO and GATHER counseling concepts (Philipines Department of Health, 2006; World Health Organization, 2009). Several information, including program introduction and research explanations (Session 1), mutual trust building and pregnancy overview (Session 2), counseling on iron deficiency anemia and explanation about Hb examination (Session 3), counseling on the iron tablets intake (Session 4), counseling on husband's supporting role for the iron tablets intake control (Session 5), and review, follow up, and Hb examination (Session 6) will be provided to participants. Program delivery method will include group counseling, with each group consists of 7-9 participants. The intervention program will last over 1 month (6 sessions) with 1-week intervals between sessions (Sehhatie et al., 2019). The duration for each session will be 45-75 minutes.

Participants in the control group will receive a standard antenatal counseling, based on information in the Maternal and Child Health Books published by the Indonesian Health Ministry. The duration, session number, and interval are the same as used for the LCWI and HCI above.

The program providers (counselors) in this research will be nurse-midwives who work at the selected PHCs. The providers will be recruited through a purposive sampling method. The inclusion criteria will include a diploma degree in midwifery/nursing and have working experience in a maternal and child health room as the nurse-midwife and in the antenatal services. One-day training will be given to providers, to ensure that they will be able to implement the interventions appropriately. Also, program modules will be provided to all providers.

Data Collection

A pre-test, post-test, and follow-ups measurements will be conducted. Pre-test will be administered before the first session of the intervention program started. Then, participants will receive the same test at the last session of the intervention (session 6). The follow-up will be conducted at 15 days and one month after the intervention program completion. The participants will also receive a hemoglobin measurement during the tests. All the tests will be carried out by the researchers, research assistants, and program providers in the selected Public Health Centers.

Data Analysis

IBM SPSS Statistics 23 will be used to analyze the data. Descriptive and inferential statistics will be completed to assess the intervention programs effects on participants' knowledge, attitude, behavior, and hemoglobin levels. Descriptive statistics will include frequency, percentage, mean and standard deviation, as appropriate. While the inferential statistic will include t-test and one-way ANOVA.

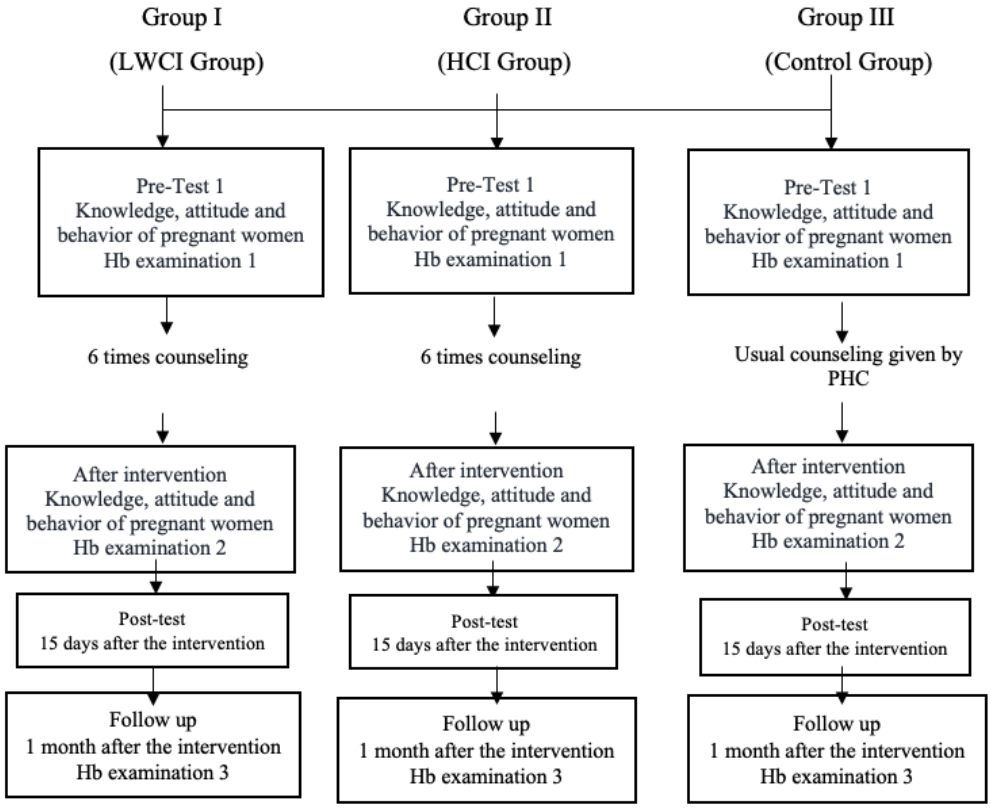

Figure 2 Development of the RCT interventions

Ethical Consideration

The study protocol was approved by the Nursing Ethics Committee of Nursing Faculty, Universitas Syiah Kuala (Approval ID: 113004111218). All participants will aware of the purpose of this study, supported by a signed informed consent document.

DISCUSSION

The incidence of iron deficiency anemia among pregnant women in Aceh especially Aceh Besar Regency requires serious attention and concrete action from the nurse-midwives who interact directly with the pregnant women through antenatal care. The nurse-midwife plays an important role in supporting pregnant women during the antenatal period, so they can carry out the pregnancy well and avoid complications, especially anemia (Septiani, 2017). Since Acehnese people strongly believe their traditional culture, we try to develop a counseling model that is based on the local wisdom, by integrating the aspects of Acehnese cultural beliefs into the pregnancy counseling program. The counseling program specifically designed to tackle the problem of iron-deficiency anemia during pregnancy.

The purpose of this study is to evaluate the local wisdom-based counseling in preventing iron-deficiency anemia during pregnancy,

where the increase of hemoglobin level is taken as the indicator. The positive change of knowledge, attitude, and behavior of pregnant women after the intervention is completed, are also taken as the successful indicators.

This local wisdom-based counseling will be implemented by the trained nurse-midwives in Public Health Centers in Aceh Besar Regency. The counseling will be conducted at every antenatal visit. We hope this model can be an effective way to reduce the iron deficiency anemia prevalence among pregnant women, thus suppressing maternal mortality as well as morbidity. The aims of this model also match the agenda of the Sustainable Development Goals (SDGs) in 2015-2030 (IAEG-SDGs, 2016). If this model is effective in preventing iron-deficiency anemia among pregnant women, this model also can be applied in other areas by adopting different observed cultures.

CONCLUSION

Local wisdom-based counseling in pregnant women has been designed in this study. It further will become a practical solution to overcome various problems in pregnancy, especially iron deficiency anemia. This project can be applied in a series of antenatal service activities in the other regions, by adopting the locally observed cultures.

Declaration if Conflicting Interest

The authors declare that they have no potential conflicts of interests to the research, authorship, and publication of this article.

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Authorship Contribution

The main author (DD) is the person who develop the theory and intervention plan, and also the person who conducts the research. NT, KH, and TT is the team that conceived the presented idea, directed the design of the study, and supervised the research conducted.

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