Effects of a maternal mentoring program on the iron status of pregnant women in Bantul, Indonesia: study protocol for a cluster randomized controlled trial

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SUMMARY

Nutrition and health during preconception period will affect pregnancy outcomes. Preconception preparation in terms of nutrition and health to deal with pregnancy is very important, but there has not been much attention regarding this issue. The aim of this study is to test the effectiveness of mentoring program carried out since preconception period on the iron status of pregnant women in Bantul District, Indonesia. The study design is a cluster randomized controlled trial involving 156 hamlets (pedukuhan) in three sub-districts: Sedayu, Pajangan and Pleret. The hamlets are grouped into 122 clusters and randomly divided into 61 intervention groups and 61 control groups. A total of 224 premarital women of reproductive age will be recruited into the study. They will be followed up until 12 weeks of pregnancy. The monitoring program will start in their premarital period that can be interpreted as preconception period. The program consists of preconception health education, monitoring of pregnancy status, reminder to immediately carry out the first antenatal care (ANC) visit, and reminder to take the iron supplements regularly. The primary outcome is the iron status of pregnant women in 13-16 weeks of pregnancy. Secondary outcomes are the timing of the first ANC, the timing of the first iron supplement consumption, the number of iron supplement consumed during their first trimester of pregnancy, knowledge of preconception health and nutrition, dietary intake, weight, and mid-upper arm circumference (MUAC). The maternal mentoring program is expected to be one of the alternative efforts to improve maternal and child health in Indonesia

1. Background

Maternal and child health is one of the problems that still need attention in Indonesia. This is based on the results of the 2015 Intercensus Population Survey (SUPAS) shows that the maternal mortality rate (MMR) has decreased slightly to 305 per 100,000 live births. This is still far from the target in the Sustainable Development Goals (SDGs), below 70 per 100,000 live births by 2030 (1). To be able to achieve the SDGs target, of course, serious handling is needed in an effort to improve maternal health status.

The nutritional status and health of the mother during pregnancy, even from the time of preparing for pregnancy or the preconception period, will greatly affect the nutritional status and health of the child to be born (2–4). The World Health Organization (WHO) emphasizes that preconception health services, including the condition of their nutritional status, are recommended to be part of maternal and child health services in all countries because they can have a positive impact on maternal and child health which of course will also affect the next life of the child. adolescence, adulthood, to the elderly (5).

A meta-analysis study that aims to look at the effect of anemia in pregnancy on pregnancy outcomes in developing countries gives the results that pregnant women who are anemic will have a higher risk for preterm birth, perinatal death, low birth weight babies, and low birth weight babies. mortality in infants and children compared to pregnant women who are not anemic. The proportion of these events is found to be higher in low-income countries (6). Anemia conditions experienced before pregnancy can also have a similar effect. In women who have preconception anemia will have a greater risk of giving birth to babies with low birth weight (7). Giving iron supplementation since before pregnancy and during pregnancy can improve conditions so as to reduce the risk of adverse pregnancy outcomes, including the baby's birth weight (8,9).

Data on iron tablet consumption in Indonesian pregnant women (2013) showed that 89.1% of pregnant women had consumed Fe during pregnancy, but only 33.3% had consumed it as recommended (>90 tablets during pregnancy) and there were even 10.9 % who did not take Fe tablets. The 2018 RISKESDAS report provides similar information that only 37.7% of pregnant women consume >90 tablets of Fe (10). This shows that there is a wide gap between the high coverage rate for Fe tablets and the low consumption rate. The occurrence of this gap can be caused by compliance with maternal consumption which is still low. Several factors that can affect adherence include maternal education level, family income level, frequency of ANC, presence or absence of counseling related to Fe consumption during pregnancy, history of anemia (11), forgetfulness, dislike factors, and the presence of side effects such as nausea after consuming Fe tablets (10,12,13).

Analysis of the 1994-2007 IDHS data shows that consumption of Fe-Folate tablets during pregnancy can reduce the risk of death in children <5 years of age. The more Fe-Folate tablets consumed and the earlier the time to take them, the lower the risk of death. Pregnant women who consume 30-89 tablets of Fe-Folate during pregnancy have a 28% lower risk of dying in the first 5 years of life, compared to pregnant women who do not take Fe-Folate tablets. Meanwhile, for pregnant women who consumed more Fe-Folate tablets, i.e. 120 tablets during pregnancy, the risk of

their children dying at the age of <5 years decreased by 44%. Likewise with the first time consuming Fe-Folate tablets during pregnancy, in pregnant women who have consumed Fe-Folate tablets since the first trimester of pregnancy, the risk of death in their children decreased by 38%. Meanwhile, in pregnant women who have just started taking Fe-Folate tablets in the third trimester of pregnancy, the risk reduction is smaller by 26% (14).

Compliance with Fe tablet consumption is related to the frequency of ANC visits. When pregnant women make ANC visits early, exposure to information about health behaviors that are recommended to be carried out during pregnancy, including recommendations to take Fe tablets, will of course be received earlier as well. A study in Malawi based on data from the 2010 Malawi Demographic and Health Survey showed that initiating ANC visits in the first trimester of pregnancy was associated with an increased chance of taking more Fe tablets (≥90 tablets) during pregnancy compared to those who had only had their first ANC visit in the second or third trimester (15).

In this study, education was carried out in an integrated manner in a mentoring program for mothers from preparing for pregnancy (preconception) until during pregnancy. The mentoring program is embedded in a Community Health Surveillance System (SSKM), which is a program of CAPTURE (Community-Alma Ata Partnership Through Updated Research and Education), a collaboration between Alma Ata University Yogyakarta and the Bantul District Health Office and the Bantul District Government. The educational materials delivered included the importance of preconception health, education on healthy eating patterns, recommendations for routine and timely ANC, and taking Fe tablets from the beginning of pregnancy. In this assistance, there are also activities to remind to take Fe tablets and make ANC visits according to schedule (reminder), monitoring iron status, monitoring food intake, and monitoring the nutritional status of mothers during pregnancy. This mentoring program refers to the continuum of care, which is a concept of sustainable health services, starting from the preconception period, until childhood. Through the application of the continuum of care concept, it is hoped that services for mothers and children will not run partially and efficiency will occur in various sectors (16).

2. Study Objectives

Primary Objective: to assess the effect of maternal mentoring program on the iron status of pregnant women

Secondary Objectives: to assess the effect of maternal mentoring program on the timing of first ANC visit and first iron supplement consumption, and the number of iron supplement consumed by pregnant women

3. Methods

Study Design and Setting

This is a cluster-randomized control trial, using the hamlet, or small village, as the unit of randomization. The study will be carried out in three sub-districts of Bantul, Indonesia: Pleret, Pajangan, and Sedayu; where the prevalence of anemia in pregnancy is high, top of three in the last three years (2013-2015). These 3 sub-districts are divided into 122 clusters based on their geographical area. These 122 clusters are divided randomly into the intervention group (n=61) and the control group (n=61).

Study Populations

We aim to recruit up to 224 premarital women of reproductive age who registering their marriage in the District Office. Selection of subjects based on inclusion and exclusion criteria.

The inclusion criteria for this study are:

(1) women of reproductive age planning a pregnancy,

(2) plans to stay in the research area for at least the next 2 years,

(3) who are willing to take part in the research by signing the informed consent

The exclusion criteria for this study are:

(1) women who are already pregnant before the mentoring program begin,

(2) lost to follow up

Intervention

The intervention group received maternal mentoring from preconception until 12 weeks of pregnancy, whereas the control group received usual routine health services. Mentorship is provided either directly in the form of home visits or indirectly through short message service (SMS)/WhatsApp (WA). The following is an explanation for each stage of the intervention:

1. Stage 1, is carried out in the preconception period. The mentors make home visits to carried out the pre-test and provide counselling about preparation for pregnancy using a booklet that has been prepared in advance. The pre-test includes anthropometric measurements (weight, height,

and mid-upper arm circumference), dietary intake assessment, iron status measurements and measuring the level of knowledge of preconception health and nutrition.

2. Stage 2, is carried out in the pregnancy period. When the respondent is already confirmed to be pregnant, they will be given a reminding message via SMS/WA to book their first ANC visit to the doctor/midwife immediately. Confirmation of pregnancy is done via SMS/WA once a month to ask if there are any signs of pregnancy felt.
3. Stage 3, is carried out after the respondents make their first ANC visit and get the iron supplements from the health workers. Respondents will be sent reminding text messages via SMS/WA twice a week to consumed the iron supplements regularly. This reminding process is carried out until 12 weeks of gestation.

Outcomes

The primary outcome is iron status (hemoglobin/Hb and ferritin level) of pregnant women, measured using cyanmethemoglobin method for Hb level and enzyme-linked immunosorbent assay (ELISA) method for ferritin level. It measured at baseline (preconception period) and after intervention (13-16 weeks of gestation). The secondary outcomes are: (1) timing of the first ANC, measured by calculate the difference between the date of the first ANC visit and the mother's first day of last menstruation, expressed in terms of the mother's gestational age in 'days'; (2) timing of the first iron supplement consumption, measured by calculate the difference between date of the first iron supplement consumption and the mother's first day of last menstruation, expressed in terms of the mother's gestational age in 'days'; (3) the number of iron supplement consumed during their first trimester of pregnancy, measured by asking the respondents at 13-16 weeks of gestation; (4) knowledge of preconception health and nutrition, measured using 25-item self-administered validated questionnaire, at baseline (preconception) and after intervention (13-16 weeks of gestation); (5) dietary intake, measured using semi quantitative food frequency questionnaire, at baseline (preconception) and after intervention (13-16 weeks of gestation); (6) weight, measured using electronic body scale with an accuracy of 0.1 kg, at baseline (preconception) and after intervention (13-16 weeks of gestation); and (7) mid-upper arm circumference, measured using plastic measuring tape by looping the tape at the mid-point between the tip of the shoulder and the tip of the elbow of the left upper arm, at baseline (preconception) and after intervention (13-16 weeks of gestation).

Sample size

We calculated sample size using a method that takes into account the design effect (DE) of clustering. We assumed an intra-cluster correlation (ICC) of 0.05 and the average cluster size was 2.64, resulting in a DE of 1,082. We use a power of 80% to detect a 10% difference in the proportion of first time ANC visits between the two groups, resulting in a minimum sample size of 112 respondents per group.

Data collection

Premarital women who met the eligibility criteria and who were willing to participate in the research study were recruited as respondents. Demographic data and information regarding timing of the first ANC visit were collected using a structured questionnaire. Data on level of preconception health knowledge were obtained from a questionnaire that we have validated, containing 25 questions related to preconception nutrition, and summed to get a total score, ranging from 0-100 (internal consistency Cronbach's alpha= 0.7). Anthropometric data (weight, height, MUAC) were collected using standardized instruments.

Statistical analysis

Data analysis was performed by bivariate and multivariate analysis. Bivariate analysis aims to determine the effect of mentoring since the preconception period on the first time and frequency of consumption of Fe tablets, time of first ANC visit, and iron status. The test used independent t-test to see the difference in mean scores between the intervention group and the control group, and paired t-test to see the difference in the pre-test and post-test scores. For data that are not normally distributed, alternative tests are used, namely Mann-Whitney and Kruskall-Walis. Chi Square test was also conducted to determine the relationship between two variables whose measurement parameters have been categorized. The multivariate analysis used multiple logistic regression, to determine the factors that influenced the time of the first ANC visit. In addition, as an effort to ascertain the effects of modifications or confounding variables, a stratification analysis was carried out.

Ethical considerations

Before the research is conducted, an application for research ethics feasibility is submitted to the Ethics Commission of the Faculty of Medicine, Public Health and Nursing (FKKMK) UGM (Ethical

clearance No. KE/FK/1289/EC/2018 and No. KE/FK/1456/EC/2019). Furthermore, the processing of research permits is carried out by submitting application letters to related institutions, such as BAPPEDA Bantul Regency, Bantul District Health Office, as well as sub-districts and sub-districts of the research area. Before starting data collection, respondents who were met and met the inclusion and exclusion criteria were given an explanation of the stages, benefits, and risks of this study, then when the respondent was willing to participate in the study, they were asked to sign an informed consent. At the explanation stage, information is also given that the confidentiality of the data will be guaranteed, and the respondent also has the right to withdraw from this research at any time.

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