

Effects of a maternal mentoring program on the timing of the first antenatal care visit and iron status of pregnant women in Bantul, Indonesia

Submission date 21/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/06/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/04/2022	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Maternal mortality refers to deaths due to complications from pregnancy or childbirth. The Maternal Mortality Rate (MMR) in Indonesia according to the 2015 Indonesia Demographic and Health Survey (IDHS) data is still very high at 305 per 100,000 live births. It will take serious efforts to reduce MMR to reach the WHO Sustainable Development Goal target by 2030, which is 70 per 100,000 live births. One of the health problems that contributes to MMR is anemia in pregnancy, when the prevalence tends to increase. A mentoring program for mothers is expected to improve the iron status of the mother during pregnancy. The aim of this study is to determine the effect of the maternal mentoring program from the preconception period on the iron status of pregnant women in Bantul District.

Who can participate?

Women of reproductive age who are planning a pregnancy and stay in the study area for at least the next 2 years

What does the study involve?

The maternal mentoring program is carried out from the preconception period until 12 weeks of gestation. The intervention program consists of health and nutrition counselling in the preconception period, reminding women to immediately make an antenatal care visit after they feel the signs of pregnancy, and reminding them to consume iron supplements regularly when they get the iron supplement from the health workers.

Counselling is carried out once during the home visit in the preconception period using a booklet about health and nutrition to prepare for pregnancy. Antenatal care and iron supplement reminders text messages are sent to participants. The antenatal care reminder is carried out once after the participant feels the signs of pregnancy, while the iron supplement reminder is carried out twice a week starting when they first received iron supplements until 12 weeks of gestation.

The iron status of the pregnant women is measured at the end of the first trimester of

pregnancy. The timing of the first antenatal care visit and the first iron supplement consumption, the number of iron supplements consumed during their first trimester of pregnancy, knowledge of preconception health and nutrition, dietary intake, body weight, and mid-upper arm circumference are all measured.

What are the possible benefits and risks of participating?

Possible benefits for participants include increased knowledge about preconception health and nutrition, information about their iron status and nutritional status, and awareness about the importance of pregnancy preparations.

Taking blood samples may cause minor bruising or swelling at the injection site, or feeling dizzy /nausea when seeing the blood drawn. However, these side effects can be reduced by using competent health personnel to take blood samples.

Where is the study run from?

University of Alma Ata (Indonesia)

When is the study starting and how long is it expected to run for?

September 2018 to September 2020

Who is funding the study?

1. Indonesia Endowment Fund for Education (Indonesia)

2. University of Alma Ata (Indonesia)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

KE/FK/1289/EC/2018

Study information

Scientific Title

Effects of a maternal mentoring program on the timing of first antenatal care visit and iron status in the first trimester of pregnant women in Bantul, Indonesia: a cluster randomized trial

Study objectives

1. Pregnant women receiving mentoring program will have their first antenatal care (ANC) visit earlier than those who do not receive the mentoring program
2. Pregnant women receiving mentoring program will have their first iron supplement consumption earlier than those who do not receive the mentoring program
3. Pregnant women receiving mentoring program will consume a higher number of iron supplements during the first trimester of pregnancy than those who do not receive mentoring program
4. Maternal mentoring program increase the iron status of pregnant women in the first trimester

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 03/12/2018 (first approval) and 12/12/2019 (continuing review approval of approval), Medical and Health Research Ethics Committee (MHREC), Faculty of Medicine, Public Health, and Nursing, Universitas Gadjah Mada, Yogyakarta, Indonesia (Radiopoetro Building, 2nd floor, Jl. Farmako, Sekip Utara, Yogyakarta 55128, Indonesia; +62 (0)811 2666 869; mhrec_fmugm@ugm.ac.id), ref: KE/FK/1289/EC/2018, KE/FK/1456/EC/2019

Study design

Cluster randomized trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Iron status of pregnant women in the first trimester

Interventions

This study is a cluster randomized trial using the hamlet, or small village, as the unit of randomization. The clusters are divided randomly into the intervention group and the control

group, using a random number generator. The intervention group receive maternal mentoring from preconception until 12 weeks of pregnancy, whereas the control group receive 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 carry 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 reminder 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.
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 reminder 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.

Intervention Type

Behavioural

Primary outcome(s)

Iron status (haemoglobin/Hb and ferritin level), measured using cyanmethemoglobin method for Hb level and enzyme-linked immunosorbent assay (ELISA) for ferritin level, at baseline (preconception period) and after intervention (13-16 weeks of gestation)

Key secondary outcome(s)

1. Timing of the first ANC, measured by calculating 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 calculating the difference between the 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 a 25-item self-administered validated questionnaire at baseline (preconception) and after the intervention (13-16 weeks of gestation)
5. Dietary intake measured using a semi-quantitative food frequency questionnaire at baseline (preconception) and after the intervention (13-16 weeks of gestation)
6. Weight measured using an electronic body scale with an accuracy of 0.1 kg at baseline (preconception) and after intervention (13-16 weeks of gestation)
7. Mid-upper arm circumference measured using a 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)

Completion date

16/09/2020

Eligibility

Key inclusion criteria

1. Able to give informed consent
2. Planning a pregnancy
3. Planning to stay in the study area for at least the next 2 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

205

Key exclusion criteria

1. Suffering from a chronic disease that can affect iron status
2. Already pregnant at the time of data collection

Date of first enrolment

01/01/2019

Date of final enrolment

03/04/2020

Locations

Countries of recruitment

Indonesia

Study participating centre

Sedayu Sub-district

Bantul District, Yogyakarta Province
Indonesia
55752

Study participating centre

Pleret Sub-district

Bantul District, Yogyakarta Province

Indonesia
55791

Study participating centre
Pajangan Sub-district
Bantul District, Yogyakarta Province
Indonesia
55751

Sponsor information

Organisation
University of Alma Ata

Funder(s)

Funder type
Government

Funder Name
Indonesia Endowment Fund for Education, Ministry of Finance, Indonesia

Funder Name
University of Alma Ata

Results and Publications

Individual participant data (IPD) sharing plan
The participant data are confidential and held by the University of Alma Ata.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Timing of first antenatal care visit results	18/08/2021	12/04/2022	Yes	No

Other publications	baseline data analysis	01/02/2021	21/06/2021	Yes	No
Participant information sheet			08/07/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			08/07/2021	No	No