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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

Registration date
22/06/2021

Overall study status
Completed

Last Edited
12/04/2022

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)

Prevention

Participant information sheet
See additional files

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 measure
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)

Secondary outcome measures
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)

Overall study start date
01/09/2018

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

Age group
Adult

Sex
Female

Target number of participants
122 clusters, 2 participants in each cluster

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
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Sponsor information

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Sponsor type
University/education

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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

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal
2. The analysis of baseline data has been published

Intention to publish date
30/06/2021

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?
Other publications	baseline data analysis	01/02/2021	21/06/2021	Yes	No
Participant information sheet			08/07/2021	No	Yes
Protocol file			08/07/2021	No	No
Results article	Timing of first antenatal care visit results	18/08/2021	12/04/2022	Yes	No