

# The Four Pillars Approach in managing pregnant women with anaemia in Yogyakarta-Indonesia

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<b>Registration date</b> 07/05/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/06/2014	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The Four Pillars Approach (FPA) is a new approach to anaemia in pregnancy combining four strategies to improve antenatal and delivery care. The main objective is to measure the effect of the FPA on pregnant women with anaemia.

### Who can participate?

A total of 360 pregnant women with anaemia will participate.

### What does the study involve?

The Four Pillars Approach was implemented in treatment groups and the usual care was implemented in control groups. The results of those interventions (Four Pillars Approach and usual care) were compared. The Four Pillars Approach is: healthy life style, social support, adequate skills and knowledge of nurse midwives of anaemia in pregnancy, and nurse midwives' caring behaviour. The participants in treatment groups were involved in parenting class and will receive a booklet of anaemia in pregnancy.

### What are the possible benefits and risks of participating?

The participants received a regular haemoglobin (Hb) measurement and free consultation. There are no risks.

### Where is the study run from?

The study ran from Yogyakarta, Indonesia.

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

The study started in mid 2012 and ran for a period of six months. The study can be extended if needed.

### Who is funding the study?

Funded by Indonesian Government

Who is the main contact?

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## Contact information

### Type(s)

Scientific

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## Additional identifiers

### Protocol serial number

1083202989605930

## Study information

### Scientific Title

The Four Pillars Approach in managing pregnant women with anaemia in Yogyakarta-Indonesia

### Acronym

FPA

### Study objectives

It is hypothesised that the Four Pillars Approach will be effective in improving the outcomes for pregnant women with anaemia vs. usual care.

The null hypothesis is that there will be no difference in outcomes between treatment and control groups, this may arise participant's compliance on the treatment is not monitored by the trained nurse-midwives.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

The Medical and Health Research Ethics Committee (MHREC), Ministry of National Education Faculty of Medicine Gadjah Mada University, December 15, 2011, ref: KE/FK/730/EC

**Study design**

Interventional case control study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Anaemia in pregnancy

**Interventions**

In an intervention study, the effectiveness of the Four Pillars Approach will be compared to usual care.

Training of the Four Pillars Approach to nurse midwives in treatment groups in Yogyakarta. The trained nurse midwives will implement the Four Pillars Approach to eligible participants during the period of six months. Participants will receive the booklet of anaemia in pregnancy and with their husbands or other family members will involve in parenting classes.

In this study, we use different location for treatment and control groups, but they have the similar characteristics of demography and population. We use 24 Public Health Center in each groups. Based on the sample size calculation, we need 360 participants totally. The participants enrollment will be done until the target number of participant in each Public Health Center is achieved. We use cluster for the target number of participants in each Public Health center in both groups, and we randomize the recruited participants.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

1. The difference of haemoglobin level
2. The number of antenatal care attendances
3. Skilled birth attendance at delivery

Haemoglobin level, the frequency of antenatal care will be measured at baseline (in first trimester of pregnancy) and after six months of intervention (in the third trimester of pregnancy); and the presence of skilled birth attendance during labour will be monitored in delivery process.

**Key secondary outcome(s)**

1. The barriers and facilitating factors of the implementation of the Four Pillars Approach
2. Patient's and nurse-midwives' satisfaction with the approach.

Evaluated after six months of intervention

**Completion date**

31/12/2012

## Eligibility

### Key inclusion criteria

1. Pregnant women with a haemoglobin (Hb) of less than 11 g/dl in the first trimester of pregnancy
2. Living with a husband or other family members

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

Female

### Key exclusion criteria

Pregnant women over twelve weeks of gestation will be excluded

### Date of first enrolment

01/05/2012

### Date of final enrolment

31/12/2012

## Locations

### Countries of recruitment

Indonesia

### Study participating centre

PSIK FK UGM

Yogyakarta

Indonesia

55281

## Sponsor information

### Organisation

Radboud University Medical Centre Nijmegen (Netherlands)

ROR

<https://ror.org/05wg1m734>

## Funder(s)

**Funder type**

Government

**Funder Name**

Directorate General of Higher Education Ministry of National Education of Republic of Indonesia (Indonesia) ref.: 369/E4.4/K/2011

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	07/05/2014		Yes	No