Author's response to reviews

Title: The Four Pillars Approach in managing pregnant women with anaemia in Yogyakarta, Indonesia

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Author's response to reviews: see over
Dear Editor,

First of all, we would like to say thank you to you, the editor, and to your reviewers, for the positive response and comments on our manuscript. With this letter we would like to re-submit our revised manuscript entitled, “A randomised controlled trial on The Four Pillars Approach in managing pregnant women with anaemia in Yogyakarta – Indonesia: study protocol,” for the next process of publication in BMC Pregnancy & Childbirth.

With regard to the reviewers comments about our manuscript, here are the compulsory revisions:

1. Page 2 – Abstract/Methods – the primary sampling unit (cluster) or level of intervention is the facility. The presentation of 64 nurse-midwives and 180 women needs to be better explained in terms of this. More detail as to the number of facilities in intervention and control areas would be helpful.

Answer:

We have adjusted the method section as suggested by the reviewer. We have added the following text:

The Yogyakarta Special Province has a total of 24 Public Health Centres with emergency obstetric care which we will use in our study. Based on the population criterias (such as the prevalence of anaemia in pregnancy, cultural background, health insurance), demographic characteristics (such as accessibility and location of the Public Health Centre), and facilities (such as laboratory, medical devices, and emergency kit) available in the Public Health Centre with emergency obstetric care, we will choose another 24 Centres in Yogyakarta for our control group. Central Java Province has many similarities with Yogyakarta Special Province. The Provincial Health Offices of Central Java Province gave us the information about the Public Health Centres with obstetric emergency care in some districts of Central Java Province which surround Yogyakarta Province and which we could use as research fields. Based on this information, we will randomly choose the 24 Public Health Centres for our control group. In total, we will involve 48 Public Health Centres as our research field. Generally, there are about seven to ten nurse-midwives in every Public Health Centre. Based on the inclusion criteria, we will randomly select two or three nurse-midwives from every Public Health Centre be involved in this study. We aim to include at least 90% of the 144 nurse-midwives in this study.
The sample size calculation led us to recruit in total approximately 360 pregnant women with anaemia, 180 pregnant women from the intervention group and 180 pregnant women from the control group. The period of recruitment will be limited to three months, and every Public Health Centre will recruit at least seven pregnant women with anaemia consecutively.

2. Page 4-5 – Background: little is presented with regards to other determinants of anaemia other than pregnancy e.g. malaria, helminth infestation, HIV etc. If malaria for example is present in Indonesia (e.g. Iqbal RF Elyazar, Simon I. Hay, and J. Kevin Baird. Malaria Distribution, Prevalence, Drug Resistance and Control in Indonesia. Adv Parasitol. 2011; 74:41-175) this has implications for anaemia in pregnancy and is thus an important aspect in the background as well as in control (intervention design).

Answer:

We have revised our manuscript based on the reviewers comment on Background. We have added the results of some studies about anaemia related to infectious diseases in pregnant women in Indonesia.

3. Page 6 – Methods-Study design: I think this section needs to be clarified. Unless I’m mistaken the level of intervention is at the facility level. In a given facility in the intervention arm I presume all nurse-midwives were to be trained to avoid dilution of the effect? Where all facilities used or some randomly assigned to the two arms e.g. Setting – “Twenty four Public Health Centres with basic emergency obstetric care will be used as research field for the intervention group in Yogyakarta.” Are these all the “Public Health Centres with basic emergency obstetric care” in this province? The description of the control area (province) and selection of facilities needs to be similarly expanded.

Answer

We have revised the study design section and added the following text to the manuscript as suggested:

The nurse-midwives involved in the intervention group will be trained in the Four Pillars Approach prior to the implementation of this model. The nurse-midwives will follow a refresher course on current management of anaemia in pregnancy, therapeutic communication (counselling) and professional behaviour. They will also have practical guidance in the skills laboratory phase where they have to demonstrate their knowledge and skills to manage pregnant women with anaemia such as taking laboratory tests, carry out
physical examination on the signs and symptoms of anaemia, and communication in terms of giving health education to patients.

For an explanation about the Public Health Centres with emergency obstetric care in the intervention and control groups, please refer to explanation No. 1.

4. Methods – were pregnant women checked for other confounding causes of anaemia at baseline e.g. malaria, worm infestation, HIV status? How are pregnant women with severe anaemia (Hb, 7 g/dl) dealt with in the study?

Answer:

There is an agreement between obstetric and gynecologist specialists and nurse-midwives in Indonesia. It is agreed that:

- pregnant women with any kind of disease or infection during their pregnancy should be treated by the specialist.

- Pregnancy with anaemia can be managed by the nurse-midwives as long as no invasive treatment (such as: transfusion or specific medication) is required. Severe anaemia can be managed by the nurse-midwives under specialist supervision and nurse-midwives have to refer the client to the hospital if the progress report is getting worse.

Based on this agreement, we will exclude the pregnant women with any kind of disease or infection. But we will recruit pregnant women with severe anaemia if they do not need to be hospitalized and supervised by a doctor.

5. Page 10 – Methods – data analysis: model building, diagnostic and fit assessment are not mentioned. Please include this in the analysis plan. Any plans to check for interaction between factors?

Answer:

We have added the information about model building, diagnostic and fit assessment in the analysis plan.

We do plan to check for interaction between factors depending on the findings.

6. Page 10-11 – Sample size – The adjustment for intracluster correlation (i.e. within facilities) is correct but I think that the calculated sample size (required clusters) needs to be better aligned with the total number of eligible public health centres (i.e. how does “6 clusters of 24 patients in each group” align with the facilities and how this unit is chosen i.e. multistage sampling/) and if a subset of facilities are used as clusters then how where they selected i.e. randomly we presume.
Answer:

We have revised the explanation in our sample size as suggested by the reviewer.

We need a total of 360 pregnant women with anaemia: (1) to detect a minimum difference of Hb = 0.5 g/dl between the intervention and control groups after assuming a standard deviation of 1.01, with $\alpha = 0.05$, a power of 0.80, ICC of 0.10 and a dropout percentage of 20%; (2) to detect an increase of 20 percentage points in skilled birth attendance in labour, with a baseline (control) percentage of 50% and an Intra Class Correlation Coefficient (ICC) of 0.10 with $\alpha = 0.05$, power of 0.80 and a dropout of 20%; and (3) to detect a mean difference in antenatal attendances of one visit between the intervention and control groups with standard deviation 2.1, with $\alpha = 0.05$ and power 0.80, ICC of 0.10 and a dropout of 20%. The sample size of 360 pregnant women with anaemia will consist of 180 pregnant women from intervention and other 180 pregnant women from control groups. The period of recruitment will be limited to three months, and every Public Health Centre will recruit consecutively at least seven pregnant women with anaemia.

7. Minor Essential revisions : the manuscript requires a language edit.

Answer:

The revised manuscript has been edited again by a native speaker.

8. Other corrections:

a. In the previous manuscript we said that we want to do face to face interviews to the nurse-midwives and nurse-midwives coordinators to investigate the barrier and the facilitators of the Four Pillars Approach implementation (secondary outcome). We changed the method, we decided to use focused group discussion because by doing focused group discussion we expected that one participant can stimulate other participant to speak up and also can remind the others to what they have done during the implementation of the Four Pillars Approach. The manuscript has been changed accordingly.

b. In page page 10 (Data analysis). It was written that “ATLAS.ti will be used to analyze the qualitative data from the semi structured interviews on Training Need Assessment, as the barriers and facilitating factors of the implementation of the Four Pillars Approach.”

We have adjusted the text as follows:
“ATLAS.ti will be used to support the analysis of the qualitative data from the semi structured interviews on nurse-midwives’ perception of their experiences in managing pregnant women with anaemia, as well as the barriers and facilitating factors of the implementation of the Four Pillars Approach.”

Thank you for giving us a chance to publish our manuscript in your journal. We appreciate your time and we are looking forward to your response.

Best regards,

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Enclosure: the manuscript: “A randomised controlled trial on the Four Pillars Approach in managing pregnant women with anaemia in Yogyakarta – Indonesia: study protocol”. (revision)