

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Integrated multisectoral strategy to improve girls' and women's nutrition before conception, during pregnancy and after birth in India (Swabhimaan): protocol for a prospective, non-randomized controlled evaluation
<b>AUTHORS</b>	Sethi, Vani; Bhanot, Arti; Bhattacharjee, Sourav; Gope, Rajkumar; Sarangi, Debjeet; Nath, Vikash; Nair, Nirmala; Singh, Usha; Daniel, Abner; Parhi, Rabi; Sinha, Sonali; Loomba, Avinash; S, Somya; Purty, Apollo; Ali, Naushad; Mohapatra, Babita; Agarwal, Neeraj; Bhatia, Vikas; Ruikar, Manisha; Sahu, Bharati; RS, Reshmi; Pedgaonkar, Sarang; Dwivedi, Laxmi Kant; Saiyed, Farhat; Prajapati, Mahendra; Mishra, Preetu; Prost, Audrey; Kejrewal, Nita; Wagt, Arjan; Sachdev, Harshpal; Unisa, Sayeed

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Judith Stephenson Elizabeth Garrett Anderson Institute for Women's Health, UCL. UK
<b>REVIEW RETURNED</b>	20-May-2019

<b>GENERAL COMMENTS</b>	<p>This is clearly a very important and ambitious study protocol of an integrated multi-sectoral strategy to improve girls and women's nutrition before conception, during pregnancy and after birth in India.</p> <p>Main comments</p> <ol style="list-style-type: none"><li>1. It is pretty a complicated strategy, judging by the extent of the abbreviations alone! While the detail is mostly there, and Figure 1 looks comprehensive, some diagrams or maps explaining the integration between programmes and sectors in the 3 main areas would help convey the big picture.</li><li>2. What is driving the sample size? Did you start from an expected intervention-related outcome (e.g. x% reduction in % of underweight adolescents) and estimate the required sample size, or did you start with an existing study of known size (number of participants) or budget? In particular, you don't say what the expected changes in primary outcomes are based on e.g. 15% reduction in proportion of adolescents with BMI below 18.5. Does that estimate of 15% come from previous intervention studies?</li><li>3. How did you allocate clusters of villages to intervention and control group? What were the requirements for the allocation? You</li></ol>
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	<p>say that "The unit of assessment to intervention and control is an area comprising a defined number of villages." But on what did you base the number of villages for instance?</p> <p>4. It is not clear to me which parts of the evaluation will be based on 'surveys', and which on 'interviews' . Are any biological samples being taken? (It doesn't seem so, hence the comment about assessing anaemia below).</p> <p>4. Is clinical examination for signs of anaemia accurate enough, given that this relates to study outcomes (line 149)? Is there not some kind of digital method of assessing this now?</p> <p>5. Can you provide any data from the baseline survey conducted in 2016? such as response rates, or completeness of data for primary outcome analysis?</p> <p>6. The strengths of the study, listed at the end of the abstract, are impressive, but do not seem to be discussed in the protocol e.g. evaluation by an independent third party.</p> <p>7. In places, a little more detail would be helpful e.g. having a section on evaluation methods. Also I do not think there is enough information here to allow a statistician to judge the design adequately.</p> <p>8. The abstract should include a short description of the intervention.</p> <p>9. In summary this is clearly an important study protocol that should be published, but some aspects are hard to follow from the current manuscript. Adding a little more detail with clarity should fix that.</p> <p>Finally, I wish you every success with the study - it would be wonderful to achieve and demonstrate the outcomes you are aiming for.</p>
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<b>REVIEWER</b>	Michael Hambidge Professor Emeritus, Pediatrics University of Colorado USA
<b>REVIEW RETURNED</b>	29-Jul-2019

<b>GENERAL COMMENTS</b>	<p>Swabhimaan appears to be a very worthwhile challenging project which I found to be very interesting and informative. This research proposal addresses one major aspect of the program, the improvement of nutrition.</p> <p>Though not essential, it would be of interest to have some background on the participants---for example, pregnancy rates in adolescence and age at first conception; marital status.</p> <p>Purely from a research perspective, this project would perhaps be cleaner if it was more sharply focused on the adolescent population The secondary nutrition outcomes are clear and important and doable.</p>
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	A 15% reduction in the incidence of BMI <18. amounts to probably a 3-4% difference from baseline. It is uncertain if this is a meaningful or statistically significant improvement.
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## VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1

Reviewer Name: Judith Stephenson

Institution and Country:

Elizabeth Garrett Anderson Institute for Women's Health, UCL.

UK

This is clearly a very important and ambitious study protocol of an integrated multi-sectoral strategy to improve girls and women's nutrition before conception, during pregnancy and after birth in India.

Main comments

1. It is pretty a complicated strategy, judging by the extent of the abbreviations alone! While the detail is mostly there, and Figure 1 looks comprehensive, some diagrams or maps explaining the integration between programmes and sectors in the 3 main areas would help convey the big picture.

Our response

We have created a figure to explain the evaluation design across the three states. It is available as Figure 1.

2. What is driving the sample size? Did you start from an expected intervention-related outcome (e.g. x% reduction in % of underweight adolescents) and estimate the required sample size, or did you start with an existing study of known size (number of participants) or budget? In particular, you don't say what the expected changes in primary outcomes are based on e.g. 15% reduction in proportion of adolescents with BMI below 18.5. Does that estimate of 15% come from previous intervention studies?

Our response

The targets for primary outcomes were set based on available estimates of BMI from population based surveys and for MUAC using rapid assessments done in Bihar. The level of reduction was based on trends observed in reduction as well as authors experiences from other community based studies. The sample size was decided based on adequacy to assess achievement of all three primary outcomes – 15% reduction in proportion of adolescent girls and mothers of children under two with BMI <18.5 and 0.4cm increase in MUAC among pregnant women. We considered 5% loss to follow up and design effect of 1.5. We have edited the manuscript to reflect these changes as seen in lines 194 to 199 and 205 to 208 in clean copy of the re-submitted manuscript.

3. How did you allocate clusters of villages to intervention and control group? What were the requirements for the allocation? You say that "The unit of assessment to intervention and control is an area comprising a defined number of villages." But on what did you base the number of villages for instance?

Our response

As the programme is based on a large scale government livelihood programme the clustering of villages were as per the livelihood programme administrative structures. We have explained this in lines 183 to 186 in clean copy of the re-submitted manuscript

4. It is not clear to me which parts of the evaluation will be based on 'surveys', and which on 'interviews' . Are any biological samples being taken? (It doesn't seem so, hence the comment about assessing anaemia below).

Our response

We have added a section on tools (lines 223 to 231) which explain the interview schedules and anthropometric measurements. These were done for the entire sample and sample coverage is also presented in lines 232 to 235.

4. Is clinical examination for signs of anaemia accurate enough, given that this relates to study outcomes (line 149)? Is there not some kind of digital method of assessing this now?

Our response

The clinical examinations are done by community workers not authorized to undertake biochemical tests. However, as Swabhimaan has a systems strengthening arm, diagnostic tests are undertaken to confirm anemia. This is now explained in lines 257 to 259.

5. Can you provide any data from the baseline survey conducted in 2016? such as response rates, or completeness of data for primary outcome analysis?

Our response

We have include sample coverage data in lines 232 to 235.

6. The strengths of the study, listed at the end of the abstract, are impressive, but do not seem to be discussed in the protocol e.g. evaluation by an independent third party.

Our response

We have strengthened the conclusion and implication section of the protocol to address this.

7. In places, a little more detail would be helpful e.g. having a section on evaluation methods. Also I do not think there is enough information here to allow a statistician to judge the design adequately.

Our response

We feel that the modifications made on sample size, selection and figure on evaluation methods will address this concern.

8. The abstract should include a short description of the intervention.

Our response

Description of the intervention has been added.

9. In summary this is clearly an important study protocol that should be published, but some aspects are hard to follow from the current manuscript. Adding a little more detail with clarity should fix that.

Finally, I wish you every success with the study - it would be wonderful to achieve and demonstrate the outcomes you are aiming for.

Our response

Thank you and we hope to have addressed your comments satisfactorily

Reviewer: 2

Reviewer Name: Michael Hambidge

Institution and Country:

Professor Emeritus, Pediatrics

University of Colorado

USA

Swabhimaan appears to be a very worthwhile challenging project which I found to be very interesting and informative. This research proposal addresses one major aspect of the program, the improvement of nutrition.

Though not essential, it would be of interest to have some background on the participants---for example, pregnancy rates in adolescence and age at first conception; marital status.

Our response

At this point we have shared the response rates. We are in process of releasing findings from baseline through peer-reviewed publications and sharing findings here may be in conflict of those agreements.

Purely from a research perspective, this project would perhaps be cleaner if it was more sharply focused on the adolescent population

Our response

The programme aims to inform the women' nutrition policy covering preconception, pregnancy and post-pregnancy nutrition. This will not be achievable with a limited target group.

The secondary nutrition outcomes are clear and important and doable.

A 15% reduction in the incidence of BMI <18. amounts to probably a 3-4% difference from baseline. It is uncertain if this is a meaningful or statistically significant improvement.

Our response

We have a three year intervention period. The targets are set based on trends witnessed over last decade as well as authors' previous experience in community based studies in India and South Asia region.

#### VERSION 2 – REVIEW

<b>REVIEWER</b>	Judith Stephenson UCL Elizabeth Garrett Anderson Institute for Women's Health, UCL, London, UK
<b>REVIEW RETURNED</b>	02-Sep-2019

<b>GENERAL COMMENTS</b>	This is my review of the revised manuscript. I recommend review by a statistician and providing that is satisfactory, I regard this paper as good for publication without further amendments or review.
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<b>REVIEWER</b>	Michael Hambidge University of Colorado
<b>REVIEW RETURNED</b>	24-Oct-2019

<b>GENERAL COMMENTS</b>	No additional comments. The Swabhimaan project is already well underway and presumably adequately funded. The prospective, non-randomized controlled evaluation presented here appears appropriate and adequate.
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