Author’s response to reviews

Title: Effects of adding psychosocial stimulation for children of lactating mothers using an unconditional cash transfer platform on neurocognitive behavior of children in rural Bangladesh: protocol for a cluster randomized controlled trial

Authors:

Sheikh Hossain (sheikh.jamal@icddrb.org)
Bharati Roy (bharati.roy@icddrb.org)
Nur-E- Salveen (n.salveen@icddrb.org)
Mohammad Hasan (imrul@icddrb.org)
S.M. Mulk Tipu (tipu.mulk@icddrb.org)
Shamima Shiraji (shamima.shiraji@icddrb.org)
Fahmida Tofail (ftofail@icddrb.org)
Jena Hamadani (jena@icddrb.org)

Version: 3 Date: 20 Jan 2019

Author’s response to reviews:

To
Editor
BMC Psychology

Subject: Request for consideration for publication of the attached manuscript (revised 1) on “Effects of Adding Psychosocial Stimulation for Children of Lactating Mothers using an Unconditional Cash Transfer platform on Neurocognitive Behaviour of Children in Rural Bangladesh: protocol for a cluster randomized controlled trial”

Dear Sir,

We are submitting the revised manuscript for your consideration for publication in your journal. Please see our response to the reviewers’ comments under each point:
Comment: 1) Thank you for submitting additional documents. However, we have since noted that the ethics approval from ICDDR,b expired on the 8th May 2018, prior to your submission. Before we can proceed with your submission, please forward copies of all original and signed documentation that details that ethical approval is currently in place and ongoing at all sites where the study will be conducted. These documents should be sent as email attachments to the following email address, BMCSeriesEditorial@biomedcentral.com. Please DO NOT upload these documents as additional files in the submission system. If your documents are not in English, please could you provide translated versions of the relevant parts. These should be endorsed and signed by a contactable person at the institution.

Response: Thank you for your noticed. We have sent the letter of continuation of the ethics approval from the International Centre for Diarrhoeal Disease Research Bangladesh (icddr,b) through email.

Comment: 2) Please provide further details on the method to randomise participants, and include this information in the Methods sections.

Response: It has been included in the method section with details. Please see the page number 08 line numbers 170-190.

“Participants Recruitment and randomization:

Eleven Unions will be randomly selected out of 14 Unions from Ullapara, Sirajgonj sub-district in rural Bangladesh. A Union is the lowest tier of local government system in the country. Three old Wards together make a Union. On an average there are 10 thousand populations in an old Ward. Many administrative and resource allocation are done considering the old Wards as a small unit in the health system of Bangladesh. This old Ward will be considered as a cluster for the study. A restricted randomization process will be followed where each of the three clusters of a Union will be randomly allocated to one of the three arms. Therefore, 11 Wards will fall under each of the three arms.

The participants will be the recipients of UCT -HE program or those eligible for the program but not receiving it. Since the Government is providing UCT -HE to 79 mothers in each Union, the research team is expecting to get approximately 26 participants in each cluster. On an average 18 participants will be recruited randomly in each cluster of the arm i) and ii).

We will collect a list to identify potential beneficiaries from the clusters of the comparison arm (arm iii) through survey following the eligibility criteria of the recipients for the UCT - HE
program. Then we will exclude the recipients of the UCT-HE program from the list through discussion with local government authority of Ullapara sub district. Finally, we will enrol 18 participants randomly in each cluster of this arm (arm iii). We will not impede providing GOB program in the comparison clusters due to ethical consideration and it is a limitation for the study. Permission from the GOB official will be obtained to use the information about the participants. The recruitment and randomization process has been shown in the trial flow chart (Fig I).”

Comment: 3) Please indicate in the exclusion/inclusion criteria section of the Methods the age of mothers who will participate in the study (as described earlier in the Methods).

Response: We mentioned in the “inclusion criteria” of the method section that the mothers will be recruited who are receiving or eligible to receive the Unconditional Cash Transfer (UCT) program- indeed, it includes all criteria for mothers to receive UCT program.

Comment: 4) Please indicate the intervention period in the abstract (both on the online submission form and in the abstract).

Response: This also has been included in both online and main document. Please see the page number 02 and line number 54.

“The intervention designed for one year includes UCT with HE for the poor as a safety net program in rural Bangladesh with or without PS”

Comment: 5) Figure 1 describes a ‘follow-up’ time-point although this is not mentioned in the manuscript. Please rephrase accordingly and please provide estimated durations/time-points for the ‘follow-up’ and ‘analysis’ points in the figure. Please also include the intended numbers of participants in the ‘allocation’ boxes of the flow-chart.

Response: Follow-up time point is mentioned both in the manuscript and in the figure. Please see the “intervention section” of the manuscript; page number 06 line numbers 138-141. Intended numbers of participants are included in the boxes of the figure.
“The intervention includes:

i) Psychosocial stimulation and

ii) UCT (Maternity allowance) with HE awareness program

Psychosocial stimulation: The participants will receive fortnightly sessions of psychosocial stimulation at home by community female play leaders for one year. The play leaders will be selected from the same locality and will be trained on the curriculum of psychosocial stimulation for 2 weeks. They will visit children’s homes carrying home-made toys and picture books and will demonstrate play activities to the mothers. The toys will be left in the homes at each visit and exchanged with new toys on the following visit. The play leaders will also convey messages on language development and nutritional care for the children. The curriculum was first developed and used in Jamaica and then a culturally modified and translated version was developed for use in Bangladesh (16). The curriculum is based on improving the mother-child interaction and providing developmentally appropriate activities for the child. The curriculum has already been used in Bangladesh by Child Development Unit of icddr,b and has shown significant benefits to children’s development (11-13, 15) and growth (12, 15).

Unconditional Cash Transfer (Maternity allowance) with Health education awareness program: MOWCA provides maternity allowance of taka 500 ($6.25) for each targeted poor pregnant mother under safety net program of the GOB. The mothers receive the cash every six months for two years through banking channel. The objectives of the allowance are to help improving mothers and children’s health and wellbeing. The eligibility criteria for getting UCT and HE are:

1) mother’s age is equal to or more than 20 years; 2) mother is pregnant during UCT enrolment; 3) the mother has no child or one child; 4) monthly income of the mother is less than Taka 1500; 5) the family owns a residence only or lives in residence of others; 6) the mother or the family do not have agricultural land or pond for fish culture and 7) poor and disabled women will have priority to receive UCT.

All mothers in each union under the UCT (maternity allowance) program will receive training by designated local NGOs (LNGOs) or community based organizations (CBOs) through MOWCA, GOB funding. HE programme is designed to educate mothers on theirs and their children’s health and nutrition, women’s right and welfare in a broad way. The mothers are also motivated to spend the allowance for improving their and their child’s health and welfare. MOWCA developed and approved the curriculum for HE program, which the mothers are supposed to receive in 13 sessions over two years of the UCT program. The number of eligible mothers to receive UCT with HE is larger than those who receive it, because of resource constraints of GOB.”
Comment: 6) With reference to your response letter, please rephrase that necessary administrative permissions from the GOB has been obtained for your study in the past tense, so as to ensure that readers are aware that the required permissions are in place at the time of submission of your protocol. As previously, this information should be included in the Methods and in the section “Ethics approval and consent to participate” in the Declarations.

Response: We have added a sentence to meet your guideline. Please see the page number 08 and line number 188.

“Permission from the GOB official will be obtained to use the information about the participants.”

Comment: 7) Please rephrase ‘icddr,b’s Institutional Review Board’ to ‘the International Centre for Diarrhoeal Disease Research Bangladesh Institutional Review Board’ in the “Ethics approval and consent to participate” section of the Declarations, for clarity.

Response: We have made the changes. Please see the page number 13 and line number 292.

“Ethics approval and consent to participate

Necessary administrative permission of GOB will be obtained to access and use the information of the study participants before field implementation. Prior to submission of this protocol for funding, a discussion was held with GOB officials. Participation will be completely voluntary and at any time the participants can withdraw participation. Before enrolment, objectives, process, importance, risk and benefits of the study will be explained to all participants and their written informed consent will be obtained.

If we find any disability of the participants during our study, we will inform the parents by a clinical psychologist confidentially and refer the child to a proper health centre for treatment.

All participants will have unique identification number to conceal participants’ address. The hard copies will be under lock and key and will be accessed by designated person only. The results of this study will be disseminated in aggregates and identification of individual participants will not be disclosed.
This study has been approved by the International Centre for Diarrhoeal Disease Research Bangladesh (icddr,b) Institutional Review Board (PR-17009).”

Comment: 8) Please remove Figure titles and legends from the Figures and place these in a dedicated section following the references. Please ensure that these are numbered accordingly.

Response: We have made the changes as per your guidelines.

Comment: 9) Please rename Methods/Design in your manuscript as Methods.

Response: Methods/Design has been renamed as Methods in the manuscript. Please see the page number 04 and line number 98.

Comment: 10) Please remove the ‘Trial Status’ section following the List of Abbreviations and integrate this information in the Methods section.

Response: “Trial Status” has been included as per your guidelines. Please see the page number 11 and line numbers 250.

Comment: 11) As your manuscript does not contain data from any individual person, please state “Not applicable” in the Consent for publication section of the Declarations.

Response: The statement has been included. Please see the page number 13 and line number 295.

Comment: 12) At this stage, please upload your manuscript as a single, final, clean version that does not contain any tracked changes, comments, highlights, strikethroughs or text in different colours. All relevant tables/figures/additional files should also be clean versions. Figures (and additional files) should remain uploaded as separate files.
Response: We have done as per your guidelines.

Thank you.