Author's response to reviews

Title: The efficacy and safety of probiotics intervention in preventing conversion of impaired glucose tolerance to diabetes: study protocol for a randomized, double-blinded, placebo controlled trial of the Probiotics Prevention Diabetes Programme (PPDP)

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Editor's comments:1. Requesting ethics and funding proofs- As you may be aware, it is the policy of the journal not to peer review study protocols where ethical and external funding approval have been obtained, as these processes usually involve peer review and as there is little possibility to change a protocol after enrolment begins. Therefore, could you please respond to the following points below and provide the requested responses in your cover letter. A: Thank you for your professional advice and giving us an opportunity to improve our work. Please find below our responses to your comments. Hope it’s acceptable.a. Ethical and Funding Approval Documentation Before we can proceed with your submission, can you please forward copies of all ethical approval and funding approval for our records. 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. Please also include the original documents. Can you please confirm in your cover letter that you have forwarded the requested documentation to BMCSeriesEditorial@biomedcentral.com.A: The institutional review board of Shanghai East Hospital have reviewed and approved the protocol, ref: 2013-009. The study is funded by the Research Program of Shanghai (134119a3300), Key Specialty Construction Project of Pudong Health and Family Planning Commission of Shanghai (Grant No.PWZz2013-04) and Project of Science and Technology of Pudong Health and Family Planning Commission of Shanghai (Grant No. PKJ2014-Y13). The requested ethical and funding documentation of this study have been sent to BMCSeriesEditorial@biomedcentral.com in 6th Nov, 2015.b. Funding A study is considered to be externally funded if the authors have been awarded a grant for the study by a major funding body (e.g. governmental funding/ award from a charitable foundation). If a study has not received external funding, then the study protocol will be sent for peer-review with a member of our Editorial Board. If a study has received funding/assistance from a commercial organization, this should be clearly stated in the 'competing interests' section of your manuscript, and the study protocol will be sent for peer-review by a member of our Editorial Board. Can you please confirm whether your study protocol has undergone peer-review by the funding body.A:
The Probiotics Prevention Diabetes Programme has received financial support from governmental funding. Funding of RMB 300 thousand from the Science and Technology Commission of Shanghai Municipality (134119a3300) covers the cost of the study from June 2013-June 2016. Funding of RMB 170 thousand from the Project of Science and Technology of Pudong Health and Family Planning Commission of Shanghai (Grant No. PKJ2014-Y13) covers the programme delivery from October 2014 to October 2017. Further support from the Key Specialty Construction Project of Pudong Health and Family Planning Commission of Shanghai (Grant No.PWZzz2013-04) provided RMB 300 thousand to cover the programme delivery and trial recruitment in community. We have no competing interests to declare. The protocol has undergone peer-review by the Science and Technology Commission of Shanghai Municipality and the Project of Science and Technology of Pudong Health and Family Planning Commission of Shanghai. We have revised the competing interests' section in manuscript according to your advice.

c. Study status
The protocol must be for a study that is ongoing. An ongoing study is defined as one where the investigators are still collecting, or analyzing data. Can you please confirm what stage your study is currently at?
A: Participant recruitment started in September 2014. Baseline measurement started in October 2014 for the first enrolled subjects. Medicine interventions started in October 2014. The recruitment of subjects is continuing until October 2015. We have enrolled about one hundred subjects now and are still keeping collecting participants. We have added this part in the manuscript now. Please see Trial status after Discussion.

d. Related Articles
Can you please clarify whether any publications containing the results of this study have already been published or submitted to any journal. If so, can you please provide a list of the related articles?
A: We confirm that neither the entire work nor any part of the results of this study has been published or submitted to elsewhere.