Author’s response to reviews

Title: BRInging the Diabetes prevention program to GEriatric populations (BRIDGE): A pilot study of feasibility

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Author’s response to reviews:

September 24, 2018

Dear Pilot & Feasibility Studies Editor,

On behalf of my co-authors, I am delighted to submit our revised article to Pilot & Feasibility Studies. Below we’ve responded to thoughtful comments from the editor, and the changes made to the manuscript improved the work substantively. Please address all correspondence concerning this manuscript to me at jeannette.beasley@nyulangonehealth.org. Thank you for your consideration of this manuscript.

Sincerely,

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1. Although the primary aim of your study is the feasibility of implementing an adaptation of an existing intervention, the study methodology and results are weighted towards the secondary aim of determining pre-post intervention weight and dietary change. Please note that this second aim is not a typical pilot or feasibility objective because studies of this type are often not sufficiently powered to reliably detect change. In any revision I would encourage a greater focus on issues of feasibility. We revised the manuscript to better communicate the primary objective of assessing feasibility and acceptability of the intervention and clearly defining the effectiveness measures as being of secondary interest. Verbiage was added in the introduction of the nature of the pilot study and interest in a future larger scale trial.

2. Please provide specific feasibility objectives. These should relate to the uncertainties to be addressed and should be distinct from the objectives of a future larger scale study. We now explicitly state that quantitative feasibility measures were the proportion of responses from emailed invitations, proportion of those screened who were eligible, intervention session attendance, and proportion of follow-up visits completed. Focus groups among participants were used to qualitatively characterize intervention acceptability and feasibility.

3. Please ensure the measurements and results reflect the main focus of the study on specific aspects of feasibility. I would also encourage a fuller reporting of the focus groups methods and analysis. In addition to the changes stated above, we further expanded on our methods (e.g. added Table 2), enhanced description of study procedures, and elaborated on findings to better convey that our main focus of the study was feasibility and acceptability.

4. Hypothesis testing should be treated as secondary to the main feasibility results. Where these are relevant to the feasibility objectives they should come with a clear reason and a caveat of caution if no power calculations have been performed. We downplayed the testing of efficacy outcomes throughout and discussed that the rationale was to estimate expected effect sizes for a sufficiently powered efficacy trial.

5. The conclusions to the manuscript should clearly state whether the objectives were met and if a future full-scale study will be going ahead based on the results. We stated that feasibility objectives were met and that we are incorporating what we learned into the development of a full-scale efficacy study.

6. Please include relevant reporting guidelines with your submission. The checklist and flow diagram for the CONSORT extension for pilot randomised controlled trials should be completed as far as is possible. Some sections will not be applicable to your study design, but many remain relevant and will improve the transparency of reporting. The flow diagram should be included in the main body of the text and the checklist should be provided as an additional file. Both should be referenced in the text. Please see: https://urldefense.proofpoint.com/v2/url?u=https-3A__pilotfeasibilitystudies.biomedcentral.com_articles_10.1186-s40814-2D016-2D0105-2D8&d=DwIGaQ&c=j5oPpO0eBH1ii048Dtse6B0Gmuw5jHLjgtN2r4ehE&r=x3pTo1z3jepbokVDSamlnPjpj4h7LgDnftFvAo3sb44&m=ntXgkpyb4O5epH1U3G0XTe4SDkhmqlIBN
B92LgYPEhVY&s=cbcaDeWGzGbEnuoEzK5ZUQzmjB1i_nPNNRcZfy nz1Zg&=&. Other reporting guidelines available from the EQUATOR Network may also be useful. We added the flow diagram to the manuscript and reference it in the text (page 11). We also completed the attached CONSORT checklist by indicating where elements are incorporated, or listing as “NA” in the checklist. This is now referenced in the text as Supplemental Material on page 6.

8. Please include (as appropriate) “pilot” or “feasibility” within your title. Updated title: BRInging the Diabetes prevention program to GEriatric populations (BRIDGE): A pilot study of feasibility and effectiveness.

9. With your revised submission please ensure you consult the submission criteria https://urldefense.proofpoint.com/v2/url?u=https://pilotfeasibilitystudies.biomedcentral.com/submission-2Dguidelines_preparing2Dyour2Dmanuscript_research&d=DwIGaQ&c=j5oPpO0eBH1io48Dtse dbOBGmuw5jHLjgvtN2r4ehE&r=x3pTo1zjepbobkVDSamlnPjpj4h7LgDnftFvA03sb44&m=ntXgkpyh4O5epH1U3G0XTe4SDkhmqiBNB92LgYPEhVY&s=8gIZALE00UXub5HG2NG u5OX1LcmArf9kL1GxtKR2Nn42A&=&.

Please also see Eldridge et al (2016) “Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework.” https://urldefense.proofpoint.com/v2/url?u=https://doi.org_10.1371_journal.pone.0150205&d=DwIGaQ&c=j5oPpO0eBH1io48Dtse dbOBGmuw5jHLjgvtN2r4ehE&r=x3pTo1zjepbobkVDSamlnPjpj4h7LgDnftFvA03sb44&m=ntXgkpyh4O5epH1U3G0XTe4SDkhmqiBNB92LgYPEhVY&s=i7skQ8Na-wJvVSpkFG94rTNLggKwupfuKp9X1n3Tq_s&=&

We read the suggested materials and compared our submission to the criteria.