Author’s response to reviews

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

Authors:

Jeannette Beasley (jeannette.beasley@nyulangone.org)
Lindsey Kirshner (lindsey.kirshner@nyumc.org)
Judith Wylie-Rosett (judith.wylie-rosett@einstein.yu.edu)
Mary Ann Sevick (Mary.Sevick@nyumc.org)
Laura DeLuca (Ldeluca@mail.yu.edu)
Joshua Chodosh (Joshua.Chodosh@nyumc.org)

Version: 3 Date: 10 Jul 2019

Author’s response to reviews:

PAFS-D-18-00143R1

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

Jeannette M Beasley, PhD, MPH, RD; Lindsey Kirshner, MPH; Judith Wylie-Rosett, EdD, RD; Mary Ann Sevick, ScD, MS, RN; Laura DeLuca; Joshua Chodosh, MD, MSHS, FACP

Pilot and Feasibility Studies

Reviewer reports:

Reviewer #1: I think this paper is improved by presenting it as a feasibility study. I suggest that any reference to 'pilot-testing' is removed as this is confusing double terminology specifically in the Abstract (background) and Methods (design). Please refer to this study as a feasibility study (only) throughout!

Response: We agree with the reviewer and now refer to the study exclusively as a feasibility study. The one instance where “Pilot” is used is to refer to the CONSORT checklist that includes “pilot” in the title.p5 Line 100 'Feasibility is defined as...' is not strictly correct. Please change to 'Measures used to assess feasibility were:'...

Response: We modified the description of feasibility and acceptability measures per the reviewer’s suggestion.

p6 Line 119 members of what? Please clarify in this sentence.
Response: We clarified the sentence to “community center members”.

Secondary Measures: I agree with the other reviewer about the questionable value of the pre post test results but the authors clearly wish to retain these data in the paper. I therefore suggest that the objective is presented as feasibility of 'using the measures' (please state this p7 Line 150) and to identify possible effect direction and magnitude. p8 Lines 165-166 need to be changed accordingly. Similarly Results may need to be edited to reflect this.

Response: We modified the methods and results per the reviewer suggestion.

p12 Line 227 It is unlikely that demographics would change. Rephrase.

Response: We removed this phrase.

p15 Line 15 should 'efficacious' be 'effective'?

Response: We clarified the sentence by including the phrase: “demonstrated lifestyle intervention reduced diabetes incidence by 58% (95% CI 48 to 66%)”

p16 Line 280 recruitment rates were VERY low

Response: We added “very” as a descriptor.

Reviewer #3: This study is interesting and definitely needed, given the increased risk of type 2 diabetes in older people. I think the paper should be published after some revisions:

We thank the reviewer for acknowledging the contribution this work can make to the literature.

* For clarity and consistency, please use type 2 diabetes (instead of diabetes) throughout the paper.

Response: We modified the text per the reviewer’s suggestion.

* Feasibility and pilot are used interchangeably. I think this is a feasibility study but you should choose one and be consistent.

Response: We agree with the reviewer and now refer to the study exclusively as a feasibility study. The one instance where “Pilot” is used is to refer to the CONSORT checklist that includes “pilot” in the title.

* I think in the methods you can add a few sentences on how the original DPP was adapted for this particular population.

Response: We did not adapt the DPP materials for this particular population. Rather, the purpose of the study was to deliver the DPP intervention and elicit feedback from focus groups regarding recommendations for how to adapt the DPP for older adults.

* As this is a feasibility study, it would be interesting to have a discussion on lessons learned around the lines of what worked (or not) for whom and why. Based on the questions
you asked at the focus groups, I expected more detailed analysis of barriers and facilitators to engaging with the program. I appreciate the numbers regarding weight loss, attendance etc. as they are promising but I think it is more important to discuss the actual feasibility of the study.

Response: We added a more detailed description of focus group responses to the results, including quotes from participants:

“Participants wanted “more substance” and “factual information” provided in the facilitated group sessions. A couple of participants requested the sessions be led by a dietician, so that more advanced information could be provided beyond what is available in the handouts.”

* I also think you should clarify how you analysed the data - did you group answers as per focus group questions?

Response: We clarified methods to address the reviewer’s question:

“Qualitative results were analysed by condensing transcripts from the two research assistants, grouping results by response, and summarizing major themes.”

* I am confused about the participation numbers - if 16 people took part and 12 were assessed for objectives, why did 23 people take part in the focus groups?

Response: We clarified in the abstract and methods that all 16 participants were invited to each of the two focus groups, and 13 and 10 chose to attend, respectively.

Associate Editor comments

In addition to Reviewer 1 and Reviewer 3 reports, please address the following points in any revised version of the manuscript:

Abstract

1. Please include the number of individuals recruited to the study in Results.

Response: We added “and 16 were recruited into the study.” to the first sentence of the abstract Results.

Secondary measures/Statistical Analysis/Results

2. The small number of participants in the study, and pre-post design, mean that it is inadvisable to carry out inferential testing on the quantitative measurement data. Reporting the results of t-test, chi squares and associated p-values is not informative given these study features (irrespective of whether the measures are described as primary or secondary) and the results of these have the potential to mislead. Please reconsider including these tests in any revision. Reviewer 1 has suggested a pragmatic approach where the quantitative measurements can meaningfully contribute to an understanding of the feasibility of the
program. I would anticipate that removing this focus on assessing statistically significant pre-post changes will also reduce the textual description of these in Results, which at present is disproportionate to the other aspects of feasibility reported. Please ensure that any changes made here are reflected throughout the manuscript (abstract, objectives, analysis, discussion etc.)

Response: We carefully considered the reviewers’ concerns regarding conducting inferential testing with our small sample size. However, in our protocol, which was peer reviewed and grant funded, we indicated we would use this analytic approach. Our clinicaltrials.gov record (https://clinicaltrials.gov/ct2/show/NCT03524404?term=Beasley&rank=1) record also describes that an aim of our study was to evaluate differences in diet, physical activity, and weight. So we retained these measures as secondary measures to remain true to our apriori specifications. We renamed “Statistical Analysis” to “Analysis” and now clearly prioritize the qualitative results.

Methods

3. L124. Remove ‘of’ from ‘comprised of’.

Response: Replaced “is comprised of” with “contains”.

4. L148. Qualitative data were used to shape the feasibility outcome measures. Please clarify the what is meant here or rephrase.

Response: Text was edited to “better understand participant perceptions of the intervention.”.

Focus groups

5. At present the focus group methods are not clearly described. Please provide further information to help readers understand more about the conduct of these important features of the study. Reporting guides (e.g. COREQ) will help to identify the key pieces of information to consider when reporting.

Response: Thank you for the suggestion to use the COREQ guide as a way to improve reporting of the focus group methods. We modified the abstract to clarify the study design and the methods to provide more details.

6. Please clarify the composition of the two focus groups. 23 took part over two focus groups, suggesting some of the 16 who received the intervention participated in both. Was the method (e.g. same set of topic questions) similar at both time points or did topics build on earlier stages? Were participants and their contributions tracked over time? If so, was their consistency over time or did participants' viewpoints change? Does it make sense to present findings by stage?

Response: Thank you for raising these points. We now clarify in the abstract and methods that all 16 participants were invited to attend both focus groups, and 13 chose to attend the first focus group while 10 chose to attend the second focus group. We also clarify that the
same set of topic questions were asked at each time point. We acknowledge in the discussion as a limitation that participants’ contributions were not tracked over time to assess changes in viewpoints. For this reason, we chose not to present findings by stage.

7. In Table 1 the 3rd to last question needs editing.

Response: We clarified the question to:

“Some of you shared ways that you track your food intake. How do you think using a nutrition smartphone application would change your participation in this program?”

8. Please ensure any strength or limitations to your approach to the focus groups are considered in your Discussion.

Response: We modified the discussion to include limitations of our focus group methodology.

Results

Flow diagram.

9. Please include the number of recruitment communications issued, with replies received as a proportion.

Response: We modified the flow diagram to include that 39/~2000 contacted responded to the recruitment email.

10. Please provide additional information in the 'assessment' stage to clarify which objectives were assessed and when (e.g. across all sessions or just at week 7).

Response: We now include more detailed information in the “assessment” stage of the flow diagram.

Discussion

11. Please comment on the delivery of 6/12 of the DPP sessions. Is there evidence (eg from focus group or the wider literature) to support the assumption that findings from 6 sessions would hold for a longer program?

Response: We added to the discussion (Page 18, line 303): “The 6-week intervention period was abbreviated from the year-long DPP intervention; however, the average number of DPP sessions attended in a large healthcare organization is six(35).


12. In the Conclusion please include a clear statement on future plans for a full scale study based on the study results. At the moment this is included earlier in the Discussion. However, please ensure that you consider whether any additional aspects of feasibility or piloting are
necessary before moving to a more definitive study type. For example, would randomisation to DPP (vs. another arm) be a likely feature and are there any possible issues to explore (eg identifying a suitable control arm, clustering vs. individual allocation etc.).

Response. To provide a more detailed description of next steps for this research, we modified the conclusion to: “Before evaluating a Medicare-reimbursable 12-month DPP intervention model, we are partnering with social support services such as the home-delivered meals program to investigate the feasibility of delivering a telehealth adaptation of the DPP within this population.”

--

Please also take a moment to check our website at https://urldefense.proofpoint.com/v2/url?u=https3A__www.editorialmanager.com_pafs_l.asp3Fi3D10194926l3D0PIDTPEK&d=DwIGaQ&c=j5oPpO0eBH1iio48DtsedeElZfc04rx3ExJHeIIZuCs&r=InC7fOhujuG3zVnvF2EaxR_TsRfrqZRNswoIFe&m=dmNzM2FSckQ3SV7D3uWRzE2tyAIx6tdNEwQXH7nRG5s&s=Csk11JiwZWDLMSk0los2w-QA0ceixUb9d_rNxwenlc&e= for any additional comments that were saved as attachments. Please note that as Pilot and Feasibility Studies has a policy of open peer review, you will be able to see the names of the reviewers. If improvements to the English language within your manuscript have been requested, you should have your manuscript reviewed by someone who is fluent in English. If you would like professional help in revising this manuscript, you can use any reputable English language editing service. We can recommend our affiliates Nature Research Editing Service (%CUSTOM_NATURE_EDITING_SERVICE_URL%) and American Journal Experts (%CUSTOM_AMERICAN_JOURNAL_EXP_URL%) for help with English usage. Please note that use of an editing service is neither a requirement nor a guarantee of publication. Free assistance is available from our English language tutorial (%CUSTOM_SPRINGER_ENG_LANG_TUTORIAL_URL%) and our Writing resources (%CUSTOM_BMC_WRITING_RESOURCES_URL%). These cover common mistakes that occur when writing in English. Recipients of this email are registered users within the Editorial Manager database for this journal. We will keep your information on file to use in the process of submitting, evaluating and publishing a manuscript. For more information on how we use your personal details please see our privacy policy at https://urldefense.proofpoint.com/v2/url?u=https-3A__www.sprin-2Dprivacy2Dpolicy&d=DwIGaQ&c=j5oPpO0eBH1iio48DtsedeElZfc04rx3ExJHeIIZuCs&r=InC7fOhujuG3zVnvF2EaxR_TsRfrqZRNswoIFe&m=dmNzM2FSckQ3SV7D3uWRzE2tyAIx6tdNEwQXH7nRG5s&s=YYfDVHaeRCscudtj6Msz-3wGs4BdzGnIIHY0FCuQX4&e=. If you no longer wish to receive messages from this journal or you have questions regarding database management, please contact the Publication Office at the link below.

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL:
n.asp3Fa3Dr&d=DwIGaQ&c=j5oPpO0eBH1iio48DtsedeElZfc04rx3ExJHeIIZuCs&r=InC7f
OhujUqGIT3DzVnvF2EaxR_TsRfrqZRNswoIFE&m=dmNzM2FSckQ3SVD3uWRzE2tyAJ
x6tdNEwQXH7nRG-5s&s=Bt9eL2QYfhwM_NPXms45ZdOgsT3losw5Kmqdjq4EFQ&e=
). Please contact the publication office if you have any questions.