Author’s response to reviews

Title: A Mobile Phone-based Program to Promote Healthy Behaviors among Adults with Prediabetes: Study Protocol for a Pilot Randomized Controlled Trial

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Author’s response to reviews:

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Gillian Lancaster, PhD
Editor-in-Chief
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Dear Dr. Lancaster:

We thank you and your team for the opportunity to revise and resubmit our manuscript titled, “A Mobile Phone-based Program to Promote Healthy Behaviors among Adults with Prediabetes: Study Protocol for a Pilot Randomized Controlled Trial” (PAFS-D-17-00024) for consideration for publication in BMC Pilot and Feasibility Studies. Based on the reviewers’ comments, we have made major revisions to our original submission and believe that these changes have substantially improved our manuscript. Our responses to the reviewers’ comments are described below.
Reviewer #1:

1. Thank you for the opportunity to review this paper and learn about the proposed study, which will generate some timely and useful evidence about managing the serious problem of diabetes.

   Thank you for these comments.

2. 'Leverage': this term is used in the abstract and main paper but it is not clear what it means. Please explain.

   We apologize for this confusion and have removed the word ‘leverage’ from our manuscript. Instead, we use synonymous phrases to indicate that the data should be used to inform subsequent interventions.

3. Different types of motivation are described in the abstract and main paper including autonomous and overall motivation. Autonomous motivation is explained clearly but there is no corresponding definition of overall motivation until the final paragraph of the paper. Please clarify these distinctions at the first opportunity to help the reader through the rest of the paper. Also, in the background, please explain what is 'competence' (line 32, p2 of background). Additionally, please explain 'purpose and values' (line 9, p3 of background) and whether the participant predefines these during the intervention. Finally, please explain 'proximal mediators'. In the abstract, it is unclear why these appear to relate to overall motivation and not all types of motivation. Could these sections be clarified please.

   Since the initial submission of this manuscript, we have modified our study outcomes such that change in autonomous motivation is our only primary outcome and change in overall motivation is a secondary outcome. Accordingly, we provide a detailed description of autonomous motivation in the Background.
We provide a citation for overall motivation in the Methods along with citations for all secondary measures so that interested readers may learn more about this measure.

We have substantially revised our Background section, and we have removed details that do not directly facilitate readers’ understanding of our study’s main objectives. In doing so, we have removed the words “competence”, “purpose” and “values” from the background, thus obviating the need to define these terms.

We apologize for the confusion related to use of the phrase “proximal mediator,” which was intended to describe that greater levels of autonomous motivation have been found to drive positive behavioral changes, and that we thus hypothesize that increases in levels of autonomous motivation will occur prior to other behavioral change measures (e.g. engagement in a program or weight loss). To clarify this point, we have replaced the phrase “proximal mediator” with the following:

“Increases in levels of autonomous motivation occur early along the path to behavioral change and may be a key signal that this intervention, if delivered on a larger scale, may lead to measurable changes in clinically relevant health outcomes such as body weight and physical activity.” (Lines 103 to 106)

4. Could the authors explain why this is a pilot study. Is this the first time JOOL Health is being evaluated? If so promising, why not undertake your research on a bigger scale?

While the acceptability of the JOOL Health has been evaluated among general app users (unpublished data from JOOL Health, Inc.), it is not known whether use of JOOL Health leads to changes in levels of autonomous motivation. Further, little is known about recruitment feasibility or intervention acceptability among our study population of adults who have refused participation in free formal diabetes prevention programs. Thus, we aim to test the mechanism by which JOOL Health promotes healthy behaviors in the context of a pilot study so that we can also gather information about the feasibility and acceptability of this mHealth program on our target population. Through semi-structured interviews with a purposive sample of participants (see #7), we will also gather information on ways to further improve and refine the intervention. Taken together, these data will inform a larger study.
5. Why is a 12-week intervention period chosen?

We chose a 12-week intervention period for 2 key reasons. First, we hypothesize that changes in autonomous motivation that are attributable to JOOL Health will occur after weeks of app use and should therefore be observable within our study period. Second, we are interested in understanding the feasibility and acceptability of the intervention. Because this is, to our knowledge, the first lifestyle change program that aims to recruit individuals who declined formal Diabetes Prevention Program participation, it is difficult to predict rates of participation and adherence. A 12-week pilot study will provide this key information and inform a larger study.

6. Do all participants start at the same time and complete 12 weeks? If there is a fixed end date, how does the team include data from participants experiencing a shorter intervention period?

Participants will be recruited to the study on a rolling basis. Each participant will take part in the study for a total of 12 weeks. Data analysis will occur after all study participants have completed the follow-up survey.

7. Please provide references to evidence the rationale that focus group participants should be grouped according to level of change.

Since the initial submission of this manuscript, we have altered our plan for qualitative data collection. Rather than conducting focus groups, we will conduct semi-structured interviews with a purposive sample of JOOL-only and JOOL-plus participants within 2 weeks of study completion. This will reduce the potential for recall bias, which may have been greater among focus group participants given potential variability in the duration of time since study completion. We describe our current plan for qualitative, semi-structured interviews in the Methods:
“Following the intervention period, we will conduct semi-structured interviews with JOOL-only and JOOL-plus participants. For purposive sampling, we will interview individuals with differing levels of engagement with the intervention and change in autonomous motivation using cut-points for high and low levels of these determined following quantitative data analysis. We will conduct at least 20 interviews divided equally between JOOL-only and JOOL plus participants; additional interviews will be conducted if we do not reach thematic saturation after 20 interviews [39][40]. During the interviews, we will explore the participants’ experience with the JOOL Health application; we will also discuss the acceptability of the Fitbit activity tracker and scale with JOOL-plus participants. In this way, we will gain insight into the particular intervention characteristics (or combination of characteristics) that may have facilitated or hindered the participants’ ability to achieve the primary outcome. We will also solicit participants’ ideas regarding additional behavioral change supports and their recommendations on ways to improve the intervention.” (Lines 172 to 183)

8. The heading 'statistical analysis' is not correct - this section describes all analyses. Please amend.

We have changed the heading ‘Statistical analysis’ to ‘Data analysis.’ (Line 225)

9. Please reference the qualitative analysis methods. Please justify the use of grounded theory. This is a research method not just an analysis method. It is an inductive approach involving a data collection approach which is informed by findings in early data. It doesn't seem suitable for a pilot study where four focus groups are predefined.

We agree that a grounded theory approach to our qualitative data collection and analysis may not be appropriate. We believe that directed content analysis will be more appropriate, as our quantitative data will guide our initial codes. We have revised our Methods to indicate use of this approach:

“Semi-structured interviews will be recorded and subsequently transcribed verbatim. Interviews will then be imported into qualitative analysis software. Two investigators will independently
read and code transcribed interviews. Interviews will then be coded jointly using consensus conferences. Interviews will be analyzed using directed content analysis [49].” (Lines 233 to 236)

10. The paper would benefit from a consideration of the limitations of the protocol. The population is already known to be hard to reach but the challenges in recruiting people who have ignored previous encouragement to behaviour change are not acknowledged. Additionally, if this is generally an unwilling population, what effect will such a lengthy series of questions (table 1) have on their risk of dropping out? It is best practice to involve members of the public or patients who share characteristics and experiences of the target population, partly to ensure the research methods are optimised to achieve recruitment and minimise dropouts. Have the study team involved some people with prediabetes in planning this study and discussed recruitment and data collection methods and tools? If not, why not?

We agree that this study has several important limitations, including the potential challenges of recruiting an unwilling population which is one reason we seek to conduct this pilot study of feasibility and acceptability. We have added the following limitations to our Discussion:

“This study has several important potential limitations. First, this is, to our knowledge, the first study to test a behavioral change program among individuals who previously declined DPP participation despite being invited to participate in either an in-person or web-based option at no out-of-pocket-cost. Accordingly, it is difficult to predict rates of recruitment or adherence among this population, as these individuals may be more reluctant to make lifestyle changes than the general population, and additional strategies may be necessary to encourage participation. We will thus collect data about the intervention’s feasibility and acceptability, and we will apply learned lessons to the subsequent larger study. Second, despite numerous mHealth applications to promote behavioral change and chronic disease management, rates of engagement with these applications over time are low [53], and use of mHealth devices may have unpredictable effects on the behaviors and outcomes they aim to modify [54] [55]. It is unknown whether study participants will engage with JOOL Health or whether use of the app will stimulate positive behavioral change among the study population. Encouragingly, JOOL Health possesses key features associated with app effectiveness (e.g. user-friendly design, real-time feedback, and individualized messages)[56], which we believe will facilitate app use and promote healthy behaviors. Lastly, our study population will only include members of the University of Michigan’s self-funded insurance plans, which may limit the generalizability of our findings. To
minimize this limitation, we will recruit from a random sample of health plan beneficiaries with prediabetes, which includes over 20,000 employees, dependents and retirees.” (Lines 260 to 277)

We did not involve the target population in the design and implementation of this intervention. However, we agree that understanding this population’s perspectives and preferences is critical. We therefore look forward to gaining this important insight during our qualitative, semi-structured interviews. These data will then inform the design and implementation of a larger study.

11. Also, how generalisable are the findings? Could some aspect of being a University of Michigan employee affect willingness to engage in DPP?

This is an important point that deserves attention in our manuscript. UM’s self-funded insurers (i.e. Premier Care Grad Care) provide healthcare benefits to over 85,000 employees dependents and retirees, and approximately 20,000 of these individuals are eligible for DPP participation. Given the size and diversity of this population and the prevalence of prediabetes, it is likely that our findings will be generalizable. However, we acknowledge this potential limitation in the Discussion:

“At lastly, our study population will only include members of the University of Michigan’s self-funded insurance plans, which may limit the generalizability of our findings. To minimize this limitation, we will recruit from a random sample of health plan beneficiaries with prediabetes, which includes over 20,000 employees, dependents and retirees.” (Lines 273 to 277)

12. There is evidence that targeted mobile health interventions can have the opposite effect than that intended. Could this be discussed please. See for example: Lyons R.A., Rodgers S.E., Thomas S., Bailey R., Brunt H., Thayer D., Bidmead J., Evans B.A., Harold P., Hooper M., Snooks H. (2016) Effects of an air pollution personal alert system on health service usage in a high-risk general population: a quasi-experimental study using linked data J Epidemiol Community Health doi:10.1136/jech-2016-207222
We agree that this important point warrants discussion in our manuscript. We have added the following to the Discussion:

“Second, despite numerous mHealth applications to promote behavioral change and chronic disease management, rates of engagement with these applications over time are low, [41] and use of mHealth devices may have unpredictable effects on the behaviors and outcomes they aim to modify [42] [43]. It is unknown whether study participants will engage with JOOL Health or whether use of the app will stimulate positive behavioral change among the study population. However, JOOL Health possesses key features associated with app effectiveness such as user-friendly design, real-time feedback, and individualized messages [44], which we believe will facilitate user engagement and promote healthy behaviors.” (Lines 267 to 273)

Abstract

13. L20: please explain what is meant by 'leverages'

We apologize for this confusion and have removed the word ‘leverage’ from our manuscript.

14. L41: please give mHealth in full

We now define ‘mHealth’ as ‘mobile health’ before using the abbreviation.

15. L48-57: unclear what is the difference between autonomous and overall motivation; behaviours listed are relevant to both outcomes

We have modified our study outcomes such that change in autonomous motivation is our only primary outcome and change in overall motivation is a secondary outcome. In the Background, we continue to provide a detailed explanation of autonomous motivation. However, we no longer reference overall motivation. We have provided citations for all secondary outcome
measures, including overall motivation, in the Methods so that interested readers may easily obtain additional information regarding these psychosocial constructs and their respective measurement tools:

“Additional exploratory outcomes will include change in the following measures: HbA1c; weight (kg) and/or BMI (kg/m2); change in overall level of motivation to prevent T2DM [33]; purpose in life [42] [43]; perceived competence to prevent type 2 diabetes [44]; social support [45]; eating behavior [46]; self-reported physical activity[47]; patient activation[48]; and willingness to participate in a Diabetes Prevention Program. Among participants in the JOOL-plus arm, we will also assess objective change in physical activity minutes and body weight as measured with the Fitbit activity tracker and scale from baseline (first two weeks of the intervention) to 12-weeks (last two weeks of the intervention).” (Lines 205 to 211)

Reviewer #2:

16. Thank you for asking me to review this interesting study which is addressing an important problem.

Thank you for this comment.

17. It is clear that this is in fact a protocol not a report of a study and this should be clearer in the title.

We have changed the title from “A Mixed Methods Pilot Randomized Controlled Trial of a Mobile Phone-based Health Program among Adults with Prediabetes” to “A Mobile Phone-based Program to Promote Healthy Behaviors among Adults with Prediabetes: Study Protocol for a Pilot Randomized Controlled Trial.”
18. I think it would be helpful to refer the authors to the recently published CONSORT extension reporting checklist (Sandra M Eldridge, Claire L Coleman, Michael J Campbell, Christine M Bond, Sally Hopewell, Lehana Thabane, Gillian A Lancaster on behalf of the PAFS consensus group. CONSORT 2010 Statement: extension to randomised pilot and feasibility trials BMJ. 2016; 355: i5239). Although this is, as it says, a reporting checklist, the study protocol has to support the checklist items to be met when the study is reported. At the moment that is not the case.

Thank you for providing us with this very helpful reference, which we have carefully reviewed and used to revise our study as follows:

- As recommended above, we revised our title to clearly indicate that this is a study protocol for a pilot study.

- In the Abstract and Background, we clarify our aims, which include measurement of the intervention’s feasibility (recruitment and retention rates) and acceptability (adherence and qualitative experience).

- In the Background, we aim to provide a more succinct description of the JOOL Health application to better support our hypothesis that this app may lead to increased levels of autonomous motivation among our target population.

- In the Abstract, Background, and Discussion, we explicitly state our intention to use these pilot data to inform the design and implementation of a larger trial.

- In the Methods, we describe our outcome measures and give specific attention to the ways in which we will measure feasibility and acceptability of the intervention.

- In the Discussion, we describe potential limitations of this pilot study as well as our intention to use these data for a larger study, which will be powered to detect changes in clinically relevant outcomes such as weight loss.
19. The Background feels quite long. It is not exactly clear (as there is no aim) that this is a pilot study for a subsequent definitive study.

We have significantly revised the background to address these concerns. First, we shortened the length of this section by removing details and explanations that did not facilitate readers’ understanding of the purpose of this pilot study. Second, we revised the last paragraph of the Background to clarify our aims and our intention to use this data for a subsequent definitive study:

“We propose a pilot study to estimate the ability of JOOL Health – used alone and also in conjunction with Fitbit devices (i.e. activity tracker and wireless internet-enabled scale) – to increase autonomous motivation to prevent T2DM among individuals with prediabetes who declined participation in a formal DPP (i.e. DPP non-participants). We hypothesize that autonomous motivation to prevent T2DM will increase among individuals who use JOOL Health, and to a greater degree, among individuals who use JOOL Health plus the Fitbit devices compared to individuals who only receive written educational materials about T2DM prevention. Increases in levels of autonomous motivation occur early along the path to behavioral change and may be a key signal that this intervention, if delivered on a larger scale, may lead to measurable changes in clinically relevant health outcomes such as body weight and physical activity. Further, we aim to examine the feasibility of recruiting DPP non-participants and the acceptability (adherence and qualitative experience as reported during semi-structured interviews) of the intervention. We hypothesize that recruiting DPP non-participants may have unique challenges, as these individuals have already declined to participate in one lifestyle intervention. However, as compared to the DPP, this is a low-intensity intervention, which may appeal to individuals seeking a less time consuming program, and we believe that study participants will find the intervention acceptable. Taken together, these data will inform the design and implementation of a larger trial to test the effect of JOOL Health on clinically relevant outcomes, including weight loss, physical activity, and DPP engagement.” (Lines 97 to 113)

20. The primary outcomes are not those you would expect of a pilot study as they seem to be efficacy of changing the mediating factors that might result in behavior change. The outcomes do not fully map onto the study objectives listed in the main text of the paper.
We appreciate these comments and agree that our objectives warrant further attention and clarification. First, we do aim to test the effectiveness of our intervention on autonomous motivation, as positive changes in this mediating variable will suggest JOOL Health’s potential to help individuals achieve clinically-relevant behavioral outcomes (e.g. weight loss or increased physical activity), which we would then test in a larger study. Importantly, because we anticipate a relatively large effect size, we will have statistical power to detect between-group differences in autonomous motivation despite a relatively small study sample (N=105). We have added the following to our manuscript:

“We propose a pilot study to estimate the ability of JOOL Health – used alone and also in conjunction with Fitbit devices (i.e. activity tracker and wireless internet-enabled scale) – to increase autonomous motivation to prevent T2DM among individuals with prediabetes who declined participation in a formal DPP (i.e. DPP non-participants). We hypothesize that autonomous motivation to prevent T2DM will increase among individuals who use JOOL Health, and to a greater degree, among individuals who use JOOL Health plus the Fitbit devices compared to individuals who only receive written educational materials about T2DM prevention. Increases in levels of autonomous motivation occur early along the path to behavioral change and may be a key signal that this intervention, if delivered on a larger scale, may lead to measurable changes in clinically relevant health outcomes such as body weight and physical activity.” (Lines 97 to 106).

“In this pilot study, we aim to test whether JOOL Health can increase autonomous motivation among individuals with prediabetes when used alone and also in conjunction with other mHealth tools. Because changes in individuals’ levels of autonomous motivation occur early along the path to behavioral change, we anticipate a large effect size from the intervention and will therefore have the power to detect between-group differences in this outcome in the context of a relatively small study (N=105). This will serve as an important indicator that a larger study may lead to measurable changes in clinically relevant health outcomes such as body weight, physical activity, and DPP engagement.” (Lines 249 to 255)

We fully intend to evaluate the feasibility and acceptability of the intervention, although we realize that we did not explain this in sufficient detail in our original manuscript. To clarify this intention, we have added the following to our manuscript:
“The second aim of this pilot study is to examine the intervention’s feasibility and acceptability.” (Lines 38 to 39)

“We will also collect data related to the intervention’s feasibility (recruitment and retention rates) and acceptability (adherence and qualitative experience) as well as changes in overall psychosocial outcomes, hemoglobin A1c, and weight.” (Lines 48 to 50)

“Further, we aim to examine the feasibility of recruiting DPP non-participants and the acceptability (adherence and qualitative experience as reported during semi-structured interviews) of the intervention. We hypothesize that recruiting DPP non-participants may have unique challenges, as these individuals have already declined to participate in one lifestyle intervention. However, as compared to the DPP, this is a low-intensity intervention, which may appeal to individuals seeking a less time consuming program, and we believe that study participants will find the intervention acceptable. Taken together, these data will inform the design and implementation of a larger trial to test the effect of JOOL Health on clinically relevant outcomes, including weight loss, physical activity, and DPP engagement.” (Lines 106 to 113)

“The feasibility of recruitment will be determined by calculating the intervention uptake rate, defined as the number of participants recruited to the intervention divided by the total number of eligible participants. We will also calculate the rate of intervention uptake among only those individuals for whom we reached by telephone (i.e., those aware of the intervention). Reasons for non-participation in this study will be recorded.” (Lines 190 to 194)

“Among JOOL-only and JOOL-plus participants, we will calculate rates of adherence to the JOOL Health application, defined as the number of app-usage days divided by the total number of days during the intervention period. Among JOOL-plus participants, we will calculate rates of participant adherence to the Fitbit activity tracker and scale, defined as the number of total days that each of these devices were used divided by the total number of days during the intervention period.” (Lines 195 to 199)

“Participant retention will be determined by calculating the completion rate for the 12-week survey.” (Lines 200 to 201)
“The acceptability of the intervention will be determined though semi-structured interviews following the 12-week intervention period. Participants will be asked about their experience with the intervention and also which component(s) of the intervention could be changed or improved.” (Lines 202 to 204)

21. The dual use of pre diabetes and occasional use of the term people at risk is confusing and a single term throughout the paper would help.

We have made this change and now use the term ‘prediabetes’ throughout the paper.

22. I found the text on page 2 of the background lines 16-50 helpful but the following text on the JOOL was rather complex and I really wonder if people would find the JOOL of value. Of course that is what early feasibility and pilot work is about but I would have expected some earlier study showing how that the components of this complex intervention can work together in a way that is acceptable to participants. This would not be about effectiveness but acceptability. It seems premature to go straight into a randomised pilot.

We agree that our initial description of the JOOL Health application was unnecessarily complex and would likely cause confusion among readers. While the app is technically sophisticated and uses complex algorithms to deliver personalized messaging, the user’s experience is simple and straightforward. We have revised our description of JOOL Health as follows:

“JOOL Health is a mobile phone-based health application that uses principles from SDT to help users connect certain health behaviors (e.g. sleep, diet, physical activity) with personal values in specific life domains (e.g. family, work) [36]. JOOL Health integrates user-entered information with contextual data (e.g., weather, day of the week) and then delivers tailored messages to help individuals gain awareness of and control over the factors that contribute to their well-being and ability to engage in self-care behaviors. In this way, JOOL Health aims to cultivate autonomous sources of motivation to initiate and maintain healthy behaviors.” (Lines 90 to 96)
We hope that our response to comment #20 has adequately addressed this reviewer’s concerns about our aims and decision to undertake a pilot study.

23. The link between the pilot work and the planned subsequent study is not explicit.

We have revised the Discussion to clearly convey our intent to use this work to inform a subsequent larger study:

“A mixed methods approach to data analysis will help to explain the participant-level experiences and perspectives that led to our study outcomes. Taken together, these data will help to refine the intervention and inform a larger subsequent trial.” (Lines 257 to 259)

“To reduce the public health burden of prediabetes and T2DM, novel strategies are need to promote healthy behaviors among individuals with prediabetes. The information gathered through this study will inform subsequent work to identify clinically effective, cost-effective and highly-scalable approaches to prevent or delay the onset of T2DM and enhance the population health impact of existing Diabetes Prevention Programs.” (Lines 278 to 282).

24. The study objectives are not what would be expected of a pilot trial. The first is about efficacy which a pilot trial should not be addressing (see the CONSORT extension for pilot studies paper). The second is about acceptability and feasibility but details of feasibility such as confirming size of likely population, getting estimates of consent, recruitment, retention, completion of measures, fidelity to intervention are not measured.

We hope that we have adequately addressed these concerns in our responses to comments #18, #19, #20, and #23.
25. The description of JOOL plus should make clear the digital scales are internet enabled.

We made this change and now refer to ‘wireless internet-enabled scale’ rather than ‘digital scale’.

26. The Discussion feels more like the background. The authors could consider having some predetermined progression criteria which they would apply to decide whether or not to progress to the subsequent definitive study.

We have substantially revised the Discussion to address these concerns. First, we have added a limitations section, which highlights several potential challenges to this intervention; please see our response to comment #10 for further details and manuscript text. Progression to a subsequent definitive study will be guided by the data gathered in this pilot study, including change in autonomous motivation, recruitment feasibility, and intervention acceptability.

27. As I note this study has already been funded the funders should be notified if the protocol changes, and likewise the IRB.

We will notify the funders and the IRB of any changes to our protocol.

28. In summary this is an interesting behaviour change initiative in important health area but I think more non randomised feasibility work should be undertaken prior to a pilot RCT.

Thank you for these comments. We hope that our responses above have adequately addressed this concern.
We hope we have satisfactorily addressed these very helpful comments and suggestions. The topic of this manuscript, we believe, is both timely and important. We thank you for considering it.

Sincerely,

Dina H. Griauzde MD, MSc