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

Authors:

Dina Griauzde (dhafez@med.umich.edu)

Jeffrey Kullgren (jkullgre@med.umich.edu)

Caroline Richardson (caroli@med.umich.edu)

Michele Heisler (mheisler@med.umich.edu)

Version: 2 Date: 26 Oct 2017

Author’s response to reviews:

Reviewer #1:

1. Lines 89-95: Could the authors indicate whether there is any evidence relating to JOOL Health or similar apps in any population - usability, effectiveness, acceptability?

To our knowledge, no prior studies have published data regarding the usability, effectiveness, or acceptability of the JOOL Health app. However, JOOL Health has been tested among diverse groups including healthy volunteers and those with obesity and other chronic diseases. These unpublished results suggest that the app is acceptable and effective in the populations within which it has been tested. To address this important point, we have added the following to our Background:

“Importantly, the JOOL Health application has been tested among heterogeneous populations including healthy volunteers and individuals with chronic diseases. These unpublished data demonstrate high user engagement and statistically significant increases in self-reported health behaviors.” (Lines 95 to 98)
2. Lines 96-112: what evidence has informed the hypothesis for this study?

We have revised this section to provide evidence in support of our hypotheses:

“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). Given that JOOL Health draws on SDT to inspire behavioral change, we hypothesize that autonomous motivation to prevent T2DM will increase to a greater degree among individuals who use JOOL Health compared to individuals who only receive written educational materials about T2DM prevention. Because Fitbit devices can also enhance user motivation by fostering autonomy, competence, and relatedness (through sharing of fitness data)[38] – key SDT tenets of psychological need – we also hypothesize that autonomous motivation to prevent T2DM will increase to a greater degree among individuals who use JOOL Health in conjunction with Fitbit devices compared to individuals who use the JOOL Health application alone.” (Lines 99 to 109)

3. Lines 114-117: What is the funding source for this study?

The study is funded by the Blue Cross Blue Shield of Michigan Foundation. We added the following to our Methods:

“The study is funded by the Blue Cross Blue Shield of Michigan Foundation and it is registered on ClinicalTrials.gov (NCT03025607).” (Lines 122 to 123)
4. Lines 130-132: please give a reference to support the rationale for using qualitative data in this way.

A reference was provided.

5. Lines 134-137: please clarify that all participants are employees/students of the University of Michigan and state if any subgroup of this.

We added the following:

“All eligible study participants are employees, retirees, and students of this university or their dependents.” (Lines 151 to 152)

6. Lines 180-182: have the authors considered questions about why participants sign up for the intervention?

This is an important question that we will now plan to include in our qualitative interviews. We have added the following to our Methods section:

“During the interviews, we will explore the following: reasons participants chose to engage in this study; participants’ experience with the JOOL Health application; and participants’ experiences with the Fitbit activity tracker and scale, if applicable.” (Lines 205 to 208)
7. Lines 191-93: I understood from an earlier section that recruitment was by telephone. The account of different uptakes is therefore confusing. Please clarify how recruitment is undertaken and who the telephone subset is.

We apologize for this confusion. Recruitment will be conducted only by telephone. We anticipate that there will be a subset of the eligible population that we will be unable to contact (e.g. disconnected phone line) and they therefore will not be invited to participate in this study. To provide a more accurate estimate of the rate of program engagement, we will calculate the rate of uptake among individuals whom we reached during the telephone recruitment phase. To clarify this point, we have added the following:

“Because we may not be able to reach all eligible participants via telephone (e.g. disconnected phone line), we will also calculate the rate of intervention uptake among only those for whom we are able to contact.” (Lines 188 to 190)

8. Outcome measures: the authors should also look at participant characteristics - age, centre, income/education group, baseline weight, employment status etc) to see if that affects participation.

We will collect these data and report them in our Table 1. However, we will not have access to data on individuals who do not participate in our study. Therefore, we will be unable to assess the degree to which sociodemographic characteristics influence study participation.

9. Lines 204-210: how are these outcome data collected?

We have added the following to our Methods:
“We will collect these exploratory data at baseline and 12-weeks using survey instruments, which will administered using RedCap, a secure web application [52]. At baseline, we will also collect sociodemographic characteristics including age, gender, race, ethnicity, education, and income. Among JOOL Health users, we will also evaluate changes in charted daily health behaviors (e.g. sleep, eating, physical activity) from baseline (first two weeks of the intervention) to 12-weeks (last two weeks of the intervention). 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 216 to 223)

10. Line 171-182: these relate to data collection. Suggest moving to before line 201.

We made this change.

11. Line 235: I suggest replacing the word explain with interpret since this better describes the way qualitative data are used alongside quantitative data. Also in line 256, interpret or understand would read better than explain. Also, it suggests that the qualitative data collection is developed and undertaken after the quantitative analysis, which does not appear to be the method proposed in this study.

We agree that “explain” was not the best word choice. We have replaced “explain” with “clarify”, as we hope that our qualitative findings will clarify our quantitative study results. For example, if we find that autonomous motivation scores are unchanged, we will explore reasons for this during the interviews. Perhaps scores are unchanged because the application does not work through the hypothesized pathway. Alternatively, individuals may not have used the application, in which case we will not be able to draw conclusions regarding JOOL Health’s mechanism of action.
12. Could the authors indicate the basis on which this feasibility study progresses to a full trial. If the results show no change in participants, how will the team respond?

This is, to our knowledge, the first intervention that aims to engage individuals with prediabetes who have declined formal Diabetes Prevention Program participation in another program to encourage healthy behaviors. Given that this patient population is presumed to be difficult to engage, it is possible that we may not find a difference in autonomous motivation levels between groups due to low levels of engagement or other reasons. However, this will still provide an important opportunity to understand the needs of this population. For this reason, we will conduct qualitative interviews with study participants so that we may explore preferences and desires for additional tools. We have added the following to our Discussion:

“It is also possible that we will not detect changes in autonomous motivation. For this reason, we will conduct qualitative interviews with study participants so that we can interpret our quantitative findings in the context of individual-level participant experiences. For example, it is possible that some individuals may desire additional support (e.g. brief counseling, nutritional advice, explicit exercise goals) to augment the JOOL Health experience. Some individuals may want more tailored messaging from the JOOL Health application while others may find the daily charting to be burdensome. Understanding participants’ experiences will enable us to refine and strengthen our program. In this way, we will tailor our intervention to better meet the individual-level needs of this previously overlooked population with prediabetes who have not engaged in a formal DPP.” (Lines 268 to 277)

“Importantly, we will also gain new insight into the feasibility of recruiting a target population that is presumed to be difficult to engage based on extremely low rates of uptake in offered DPP options. However, it is plausible that some individuals, although reluctant to engage in a year-long DPP, may be interested in a lower-intensity program such as this mHealth intervention. Relatively high levels of engagement in this intervention may suggest that this population is not as difficult to reach as presumed. Rather tailored strategies and varied options to encourage weight loss and increased physical activity may be needed to help such individuals prevent type 2 diabetes. In contrast, relatively low levels of engagement may confirm our suspicion that this is truly a difficult to engage population, and we could then consider focus groups and/or interviews with key stakeholders to explore best practices for engagement.” (Lines 278 to 287)
13. Patient and public involvement in research is best practice and encouraged when researching a population which is hard to reach such as this. Could the authors consider this?

Through this work, we will gain an understanding of how difficult it truly is to reach this population and of reasons for low engagement in offered programs. It is plausible that some individuals, although reluctant to engage in a year-long DPP, may be interested in a lower-intensity program such as this mHealth intervention. Our recruitment experience will provide this important insight. High levels of engagement in this program may suggest that this population is not as difficult to reach as presumed. Rather tailored strategies and varied options to encourage weight loss and increased physical activity may be needed to help individuals prevent type 2 diabetes. In contrast, low levels of engagement may confirm our suspicion that this is truly a difficult to engage population, and we could then consider focus groups and/or interviews with key stakeholders to explore best practices for engagement.

14. How will the authors know if the app is being used rather than just viewed or even glanced at. Is there a way of collecting data about how the participants interact with the app?

We will define usage as the number of days that JOOL Health users enter data into the application. To address this important point, we have added the following to our Methods:

“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 (defined as the number of days that users entered data into JOOL Health) 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 191 to 196)
Reviewer #3:

15. Thank you for the opportunity to review this manuscript. The paper describes the protocol for an evaluation of the JOOL Health application for increasing autonomous motivation to prevent type 2 diabetes among those with pre-diabetes. It also investigates the feasibility and acceptability of the intervention. This is an important area for research and an interesting and relatively novel approach to the problem. It appears that the approach used and foci of the study has changed quite substantially since the last round of reviews. The changes are well justified and appear to suit the study's research aims better.

Thank you for these comments.

16. As the target population are people with apparent low motivation already (having declined participation in DPP either face to face or online), are this group comparable to the wider patient population? Also, there may be significant retention problems, though the trial itself will identify whether this is actually an issue or not.

Although our target population may be difficult to engage, they unfortunately represent the majority of individuals with prediabetes who are given the opportunity to participate in a DPP. Specifically, less than 10 percent of individuals with prediabetes engage in DPP after invitation to participate, which means that at least 90 percent of invited individuals do not engage in or benefit from the DPP. This study will provide invaluable insight into the barriers to recruiting and engaging this population to a less intensive intervention that encourages healthy behaviors and aims to increase autonomous motivation for diabetes prevention.

17. The control group (group) are not a true control group as they are receiving some form of intervention. They are more of a comparison group. Consider editing the terminology.

We agree that “comparison group” is a more accurate description than “control group.” We have changed the terminology throughout the manuscript.
18. Should the University of Michigan be mentioned. Could this impact on confidentiality? Could this be masked slightly, e.g., by "our study protocol will only include members of a single university's self-funded insurance plans". This masks the university employees while also making clear the sample.

We have made this change.

19. Abstract:

"which helps users connect certain health behaviors (e.g. sleep, diet) with personal values in specific life domains (e.g. family, work)." Has this actually been determined, or is this the aim of the application?

This is the aim of the JOOL Health application. To clarify this point, we have revised this sentence of the Abstract as follows:

“One promising mobile phone-based application is JOOL Health, which aims to help users connect certain health behaviors (e.g. sleep, diet) with personal values in specific life domains (e.g. family, work).”  (Lines 34 to 36)

20. Background:

"To reduce the incidence of T2DM and improve population health, novel strategies are needed to increase autonomous motivation to prevent T2DM among individuals with prediabetes" - this is difficult to follow and feels almost as if there are two purposes to the sentence (the change from reduce incidence of T2DM and prevent T2DM). Consider rewriting for clarity.

We apologize for the confusion. We have revised this section of the Background as follows:
“New strategies are needed to motivate individuals with prediabetes to engage in healthy behaviors to prevent T2DM.” (Lines 79 to 80)

21. Please provide a reference for self-determination theory.

A reference was provided.

22. The section on the aims and hypotheses for the study is difficult to follow, and at times it is not clear why the hypotheses are placed. For instance, why is it believed that the participants will find the intervention acceptable? And why is it hypothesized that the Fitbit condition will be more effective? More rationale needs to be included to justify these predictions.

We apologize for this confusion. We revised this section of the Background as follows:

“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). Given that JOOL Health draws on SDT to inspire behavioral change, we hypothesize that autonomous motivation to prevent T2DM will increase to a greater degree among individuals who use JOOL Health compared to individuals who only receive written educational materials about T2DM prevention. Because Fitbit devices can also enhance user motivation by fostering autonomy, competence, and relatedness (through sharing of fitness data)[38] – key SDT tenets of psychological need – we also hypothesize that autonomous motivation to prevent T2DM will increase to a greater degree among individuals who use JOOL Health in conjunction with Fitbit devices compared to individuals who use the JOOL Health application alone.” (Lines 98 to 109)
23. Methods: The rationale for the qualitative aspect as detailed in the design section is not aligned to that stated in the hypotheses. I think that this is a matter of wording; acceptability/feasibility versus experiences/perspectives. Consider editing to increase congruence.

We have changed this section to make it clear that the qualitative interviews will be used to assess the intervention’s acceptability:

“All additionally, through qualitative interviews, we will explore the acceptability of the JOOL Health application among JOOL-only participants and the acceptability of the JOOL Health application and Fitbit devices among the JOOL-plus participants.” (Lines 138 to 140)

24. Discussion:

As with the previous reviewers' comments, it is still not entirely clear how the current study will inform the larger study. Make the links between the two much clearer - emphasize which aspects of the current study (outcomes, methods) will inform the future trial.

We hope that we have adequately addressed this important point in our response to comment #12.