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Title: How will we scale up mHealth HIV interventions? Site and public health perspective (from research to scale up)

Reviewer #1

Overall:

This manuscript discusses the iTech center's approach for designing and testing interventions such that they are ready for scale-up, using P3, one of their interventions being tested in a current efficacy trial. The team brings valuable experience in developing and testing (ongoing) the mobile app. Overall, the idea of writing about this is strong, but the execution could be improved.

Currently the paper is formatted consistent with an empirical manuscript, and yet much of the manuscript reads as a "lessons learned" piece. Simultaneously, some of what is written is more reflection about what should be done moving forward, but pieces of this are in the results section, which, to this reviewer doesn't seem fitting. From my perspective, there are options about how to optimize this paper. One option is to call it a "lessons learned" paper and present the experiences/lessons accordingly outside of the structure of a traditional empirical manuscript. Another option is to keep the traditional manuscript subheadings but rearrange the text. This would mean the results section would be written in past tense and focus on reporting what the team actually did, in line with what is under the header "Development of P3 mobile app for support of PrEP scale-up." It would also include reworking some of the information about how the planning and trial phases of P3 were conducted. Ideally, the results would include [more] illustrative examples of how your efforts were fruitful. For example, under "Planning," you discuss how "potential implementers provide feedback." It would be great to illustrate some of the feedback the team received and discuss how it informed development. Such illustrations will likely be appreciated by the readers.

Reply Overall: The authors appreciate the thorough review from Reviewer #1. The authors have decided to reorganize as per Reviewer #1's first suggestion, "call it a "lessons learned" paper and present the experiences/lessons accordingly outside of the structure of a traditional empirical manuscript".

Specific comments follow:

Title

Comment 1: The title reads like a commentary and does not align terribly well with the content.

Reply 1: The title has been changed to read: Scale up mHealth HIV interventions: Site and public health perspective and lessons learned from development of P3, a mobile app for PrEP adherence.

Abstract

Comment 2: This part should be reassessed. The Background states that "we discuss an approach of focus on researcher, funders, and potential implementers...", yet the results section of the abstract does not speak to that. It seems to me that the purpose of the paper is to describe the processes of planning for scale-up during the P3 development and efficacy trial phases and related recommendations.

Reply 2:

The abstract has been changed to provide an overview of the manuscript in which authors discuss

designing for scale up and lessons learned from P3

Comment 3: Depending on how authors decide to respond to re-organization, the abstract will need re-worked to conform to the paper. The abstract could then be a brief summary of each section of the paper.

Reply 3:

As stated in Reply 2, the abstract has been changed to provide an overview of the manuscript in which authors discuss designing for scale up and lessons learned from P3

Introduction

Comment 4: Those new to m4RH may not realize how it relates to HIV prevention and care, so this should be explicated when it is mentioned.

Reply 4:

On page 3, an explanation of how m4RH is related to HIV prevention and care has been added.

Comment 5: The last paragraph on pg 2 mentions the mHealth adaptation model and the following paragraph introduces additional models, yet it is said that the current project has similar themes to the mHealth adaptation model. The introduction should set up the reader such that at the end of it, then can see why the project approach was taken. In this particular case, the mention of the other models is a distraction and leaves the reader wondering how those other models are relevant.

I believe it would be sufficient to note that multiple models and frameworks have been developed related to designing with scale-up in mind. Cite them, then note that one of few mhealth applications that has been successfully scaled up, m4RH, was scaled via the mHealth adaptation model (mAM, we'll say for short). Next, review the steps of the mAM, and point out that while P3 was developed prior to the publication of mAM, P3 was developed with similar basic principles, including iterative design and stakeholder engagement, with numerous opportunities for feedback and adaptation.

Reply 5:

One page 3, the authors have made the changes to the text as suggested by Reviewer #1.

Comment 6: I would not include the Damschroder model, as it does not seem it was central to the development of P3.

Reply 6:

The Damschroder model has been removed as suggested.

Comment 7: Statements about how “developers of mHealth interventions should have plans in mind for wide scale implementation through all stages of development” should include citations, as there are many authors who have suggested that previously (see the reference list below for some leads). That said, these statements only belong here as context for how P3 was conceived (that is, with the expectation that planning for scale-up starts at development and continues through the process).

Reply 7:

The authors have added in references for the idea of planning for scale-up throughout the development of an app. The manuscript style has been changed from an empirical manuscript to a lessons learned paper and so concepts of best practices are discussed along with descriptions of aspects of development of P3.

Comment 8: A new purpose statement is needed. Ideally, something about describing the process of developing an HIV prevention intervention, P3, with scale-up in mind, illustrating lessons learned.

Reply 8:

The following purpose statement was added: Our purpose is to discuss aspects of development of P3 using this framework of planning for scale-up and to discuss successes and lessons learned.

Methods

Comment 9: As noted, I am not sure if it makes sense to have a methods section. If you keep the methods section, I think the information currently there makes sense, for the most part. I would recommend changing the language around P3, though, to refer to what the team was trying to accomplish with P3 and what media were planned for engagement. If this is the approach, the “results” will be the processes used and the lessons learned.

Reply 9:

The Methods Section has been removed as the manuscript was reordered to be a lessons learned paper.

Results

Comment 10: It will be best to stay in past tense in the results section. This is not the best place to write about what should happen; rather, here, I recommend you discuss what did happen as it relates to preparing for scale-up during development and testing phases.

Reply 10:

The Results Section has been removed as the manuscript was reordered to be a lessons learned paper.

Comment 11: Depth can be added to the paper by including examples of what scale-up-related feedback was given at various stages and how it was incorporated into the intervention. Similarly, did the team include cost analysis early on? If yes, discuss what was learned from that. If not, take that out from this section and keep that as a recommendation for the discussion.

Reply 11:

Authors have changed the style of the paper away from an empirical article because P3 is still being evaluated in a clinical trial where cost analysis is taking place. The reordering of the manuscript, as suggested by the reviewer, has moved the discussion of cost analysis.

Comment 12: Pg 6 has a list of questions that might be asked with potential implementers. Again, were these used in the P3 work? If yes, note that, and maybe include examples of what you learned from those questions. If not, this goes in the discussion. Either way, this list would make a good table for the paper.

Reply 12:

The information from page 6 has been moved to the discussion.

Comment 13: Similarly, were policy makers and funders engaged as you suggested on pg7?

Reply 13:

The reordering of the manuscript has helped to clarify this issue. The lessons learned section for P3 outlines that funding for scale-up was an area that was underdeveloped.

Comment 14: The subsection on analysis and dissemination should be more focused on how your team

used analysis in conjunction with stakeholders. If you haven't done it yet, this should be part of the discussion, too.

Reply 14:

The manuscript has been reordered as suggested by Reviewer 1.

Comment 15: The subsection on scale up and localized personalization also reads like recommendations rather than "results." Move to discussion unless you can talk about how you did this.

Reply 15:

This subsection has been moved to the discussion.

Comment 16: Pg 8 currently has the reporting on the development of P3, but that should probably be the beginning of the "results" section. More examples and clarity this section will strengthen this part tremendously. For example, "theoretical basis" is noted but it is not clear what theories were applied. "Trial design has been altered"—give examples of how and why throughout. The concept of centralized adherence coach appears to be mentioned here for the first time, but the reader doesn't know anything about that yet.

Reply 16:

Authors have changed the style of the paper away from an empirical article because P3 is still being evaluated in a clinical trial. Information about the centralized adherence coach has been added to the P3 app description section.

Comment 17: Considerations that were not made in P3 development should be saved for the discussion.

Reply 17:

This change has been made.

Discussion

Comment 18: This section will likely become much longer if you follow my suggestions about reformatting the paper.

Reply 18:

The discussion is longer because the manuscript has been reformatted as suggested.

Comment 19: First sentence of discussion needs citations. That said, that may not be the best first sentence of the discussion. Consider summing up the results briefly here. Then you can talk about how the experiences both complement existing literature and add to it.

Reply 19:

The discussion section has a summing up of concepts with further discussion of them. A conclusion section has been added and references have been cited in the first sentence of the conclusion section.

Comment 20: The paper states "public health policy makers and funders must see the value in the mHealth approach and be committed to enact policy and health systems changes...." I couldn't agree more! This should be explored further and should refer to other literature that supports that assertion.

Reply 20:

Two new references and a sentence addressing this further has been added on page 13.

Tables

Comment 21: Table 1 says it is “recommendations for ACTIONS” but not all bullets are actions. To keep the language parallel, start all bullets with words

Reply 21:

The authors appreciate this suggestion. The bullets all now start with action words.

Comment 22: Table 2 is confusing. What is the purpose of the “applicability to scale-up column?”

Reply 22:

The heading of the column has been changed to more accurately describe the column contents. The new column heading is “Aspects of Development Important to the Plan for Scale-Up”

Figures

Comment 23: As noted, I recommend removing the Damschroder framework.

Reply 23:

The Damschroder framework has been removed.

Comment 24: Suggested references to include/review:

Chambers, D. A., Glasgow, R. E., & Stange, K. C. (2013). The dynamic sustainability framework: addressing the paradox of sustainment amid ongoing change. *Implementation Science*, 8(1), 117.

Cohen, E. L., Head, K. J., McGladrey, M. J., Hoover, A. G., Vanderpool, R. C., Bridger, C., ... & Winterbauer, N. (2015). Designing for dissemination: lessons in message design from “1-2-3 pap”. *Health communication*, 30(2), 196-207.

Eckman, M., Gorski, I., & Mehta, K. (2016). Leveraging design thinking to build sustainable mobile health systems. *Journal of Medical Engineering & Technology*, 40(7-8), 422-430.

Gerhardt, U., Breitschwerdt, R., & Thomas, O. (2017). Engineering sustainable mHealth: the role of Action Research. *AI & SOCIETY*, 32(3), 339-357.

Matthew-Maich, N., Harris, L., Ploeg, J., Markle-Reid, M., Valaitis, R., Ibrahim, S., ... & Isaacs, S. (2016). Designing, implementing, and evaluating mobile health technologies for managing chronic conditions in older adults: a scoping review. *JMIR mHealth and uHealth*, 4(2), e29.

Pankomera, R., & van Greunen, D. (2018). A model for implementing sustainable mHealth applications in a resource-constrained setting: A case of Malawi. *The Electronic Journal of Information Systems in Developing Countries*, 84(2), e12019.

Peiris, D., Miranda, J. J., & Mohr, D. C. (2018). Going beyond killer apps: building a better mHealth evidence base.

Prochaska, J. J., Fromont, S. C., Hudmon, K. S., & Cataldo, J. K. (2009). Designing for dissemination: development of an evidence-based tobacco treatment curriculum for psychiatry training programs. *Journal of the American Psychiatric Nurses Association*, 15(1), 24-31.

Sundin, P., Callan, J., & Mehta, K. (2016). Why do entrepreneurial mHealth ventures in the developing world fail to scale?. *Journal of medical engineering & technology*, 40(7-8), 444-457.

Tomlinson, M., Rotheram-Borus, M. J., Swartz, L., & Tsai, A. C. (2013). Scaling up mHealth: where is the evidence?. *PLoS medicine*, 10(2).

Reply 24:

These references have been reviewed and many have been included in the manuscript