ARTICLE DETAILS

TITLE (PROVISIONAL)

Process evaluation for the adaptation, testing and dissemination of a mobile health platform to support people with HIV and tuberculosis in Irkutsk, Siberia

AUTHORS

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VERSION 1 – REVIEW

REVIEWER

Tumuhimbise, Wilson
Mbarara University of Science and Technology

REVIEW RETURNED

18-Aug-2021

GENERAL COMMENTS

Thank you so much for the opportunity to review this manuscript which i found interesting and contributes to the body of knowledge for understanding practical considerations, challenges and lessons learned in the implementation of a multi-institution program to promote an integrated, mobile health-based approach for the care of people living with HIV and tuberculosis in Irkutsk, Siberia.

I generally found the work interesting and i believe if a few issues are clarified the paper would be a great contribution to the body of knowledge.

INTRODUCTION
Page 3, Line 5
It would be helpful to show this rate by stating the current statistics of both HIV and MDR.

METHODS
Page 5, Line 14 (Platform iteration and testing)
Did the smartphone come with an a pre-installed application, self installation, or the application was installed by the staff. Please provide more information about this.

I would incorporate the Tidier (Template for Intervention Description and Replication) Checklist as a supplementary file to give a full description of this smartphone app and a thorough overview, its content and delivery.

Provide more information whether the application was entirely internet based to run/ function or it was an offline version or had both the offline and online components. It would be great to clearly show this (the Word "a data plan if needed" in this statement
leaves one wondering about the specific parameters for internet usage as far as this application is concerned.

RESULTS
Page 6, Line 6 (Server management)
Provide more information on why the server experienced intermittent system crashes. Was it due to lack of skills in server configuration or Internet connectivity, the operating environment of the server

Page 6, Line 10
I would be specific about the provider of these services e.g Lenode or Amazon Web services. and was this at a free cost or you paid, this would offer more information and guidance on costs involved during the upgrading to the cloud based services.

Page 8, Line 34 (Usability and Acceptability)
It would be great to know how many participants interacted with the system regularly out of the 60 that were recruited in the study, this would ascertain whether the intervention was useful or not. This can be determined through quantifying the number of patients who interacted with system through posting messages on the community message board, viewing the posted messages, commenting or liking (depending on the functionalities) or logged into the system as required. Does the application track these details?, can this information be accessed from the metadata or web based portal by the system administrators. If the system was not meant to be capture these, then it would good for future consideration.
You might find that a few of the participants (I can call them dominant participants) actually interface with the system borrowing a leaf from common Whatsapp groups. I think its very important to understand this as it would provide a better perspective on the actual usability of the system

DISCUSSION
I would beef up the entire discussion section discussing all these constructs independently by stating the meaning and implication of each construct in regards to mHealth development for TB /HIV care, compare these constructs with the existing literature for similarity and difference in findings and document unanswered questions and areas of future research. Remember to clearly discuss the limitations of this study that must be born by the readers in mind when interpreting these results.

Page 10, Line 45
"The lower scored survey items (still above 3 out of 5) were both related to perceived usefulness of the platform in facilitating self-management ‘more quickly’ What does this imply in regards to the implementation of future mhealth interventions? describing this would provide guidance for future researchers.

Page 11, Line 44 on the challenges
Do we have participants who never actually used the application after the enrollment or had challenges with using the application, or abandoned the application e.g lack of internet among patients with low income, etc i think it would be great to know why if they are there.
For general consideration, you could consider formatting or adding the subheadings for the key words in your paper i.e Practical considerations Challenges Lessons learned These could emerge from your discussion section.

REVIEWER Mars, Maurice
University of Kwazulu-Natal, TeleHealth
REVIEW RETURNED 11-Dec-2021

GENERAL COMMENTS
This paper describes the process of taking an existing mobile phone platform designed for use with people living with HIV in the US and adapting it for use in Russia with people co-infected with HIV and tuberculosis. The platform was piloted and has since been scaled up and is widely used in the region.

The process outlines a patient-centred approach to assisting people with self-management of their HIV and TB. The steps taken included patient interviews to understand their health needs and their requirements and expectations of the platform, and provider interviews to determine how the platform could be adapted to meet the specific needs of the local patient populations. The findings of these interviews guided the redesign of the platform that had to incorporate TB management and take into account language and cultural issues. Redesign was an ongoing iterative process both during and after the trial. The intervention requires a smartphone for access and participants in the pilot trial were provided with a phone and data if required. After a six month pilot study the platform was well received by providers and patients. The smartphone requirement will unfortunately further disadvantage those who are least likely to own a smartphone.

The platform brought together those responsible for the management of HIV and TB in Irkutsk who had until then worked independently of each other. This led to collaboration and information sharing to the patients’ benefit.

The paper serves as a guide on good practice for those planning on setting up mHealth platforms.

Successful eHealth implementations are founded on sound eHealth readiness assessments of at least seven different stakeholder groups. The only reported weakness described in this paper was inadequate local IT technical support which should have been identified in advance. This resulted in server downtime, the extent of which was not documented and problems troubleshooting and upgrading the server. The solution was to move to a secure cloud service to host server data. This can be problematic as many countries, including Russia, do not allow their citizen’s data to be stored in offshore clouds. Presumably, the data is in a Russian cloud. This should be addressed in the paper.

REVIEWER Liu, Xinying
Georgia State University
REVIEW RETURNED 15-Dec-2021

GENERAL COMMENTS
This research investigated the re-build, testing, and iteration of a mHealth platform to meet the requirements of HIV and TB patients.
in Irkutsk, Siberia. In addition, this research examines the usability and acceptability of the adapted mHealth intervention from 47 patients. 18 of 20 items show scores above 4 on a scale from 1-5. This research makes its contributions in revealing the mHealth preferences of HIV and TB patients in Russia. Also, it provides knowledge about the health-related priorities those patients have, and the specialty of Russian healthcare provider and patient relationships. The valuable deliverable of the adapted mHealth platform is a good start point to be tested in a larger population and make further coordination. However, same as any other research, this research have improvements to make. Following are some issues.

1. This research has limited contribution. The motivation of the research is described as “no mHealth strategies have been studied to enhance delivery of HIV and TB care within the Russian Federation.” But there is limited discussion about the differences between the results from this research compared to other research in other contexts, making the research less unique and provide limited insights. Also, the description of why the integration of HIV and TB management platform should be conducted, and how the new adapted integrated platform works compare to the platform(s) for single disease is not discussed thoroughly. Since the original platform is for PLWH, and the newly adapted platform is anticipated to have broader implementation to PLWH regardless of TB co-infection status, I think it is important to have the in-depth discussion of uniqueness and potential generalization. I suggest the authors to provide more evidence in demonstrating the value of the research. What makes it so different from others, and what results indicate the differences and what are the potential generalization.

2. Only descriptive statistics makes certain statement less convincing. In the “Discussion” section, statement “notably, these survey items as well as others within the category of ‘perceived usefulness’ became somewhat redundant following language adaption of the survey.” There was no analysis of the construct validity of all the survey items. Thus, making the statement lack of evidence.

I suggest the authors to conduct the construct validity analysis to show the appropriateness of the survey items, especially in the adapted Russian context, and provide more convincible results about the acceptability and usability of the platform.

3. There is misalignment of the description of the targeted patient type. In the previous sections, especially the recruited survey participants, the descriptions show the targeted patient is HIV and TB co-infected population, but in the “Discussion” sections, it is described as “PLWH with or without TB.” Though in the “Platform Dissemination” part, it is mentioned that the platform has been disseminated to a broader population, but I still suggest the authors improve the alignment of the description.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Dr. Wilson Tumuhimbise, Mbarara University of Science and Technology
Comments to the Author:
Thank you so much for the opportunity to review this manuscript which I found interesting and contributes to the body of knowledge for understanding practical considerations, challenges and lessons learned in the implementation of a multi-institution program to promote an integrated, mobile health-based approach for the care of people living with HIV and tuberculosis in Irkutsk, Siberia.

I generally found the work interesting and believe if a few issues are clarified the paper would be a great contribution to the body of knowledge.

INTRODUCTION
Page 3, Line 5
It would be helpful to show this rate by stating the current statistics of both HIV and MDR.

Thank you for this comment. An additional statistic explicitly stating annual incidence of HIV/TB co-infection based on the most recent surveillance we could find specifically for Irkutsk has been included in the introduction (lines 5-6, page 3).

METHODS
Page 5, Line 14 (Platform iteration and testing)
Did the smartphone come with an pre-installed application, self installation, or the application was installed by the staff. Please provide more information about this.

A sentence was added in the text to clarify that staff assisted patients with downloading the app onto their phones. Smartphones were provided only to patients who did not own one (ie 'if needed' as described in line 20 of page 5) and the app was downloaded with staff assistance either onto that phone or the patient’s personal smartphone (lines 21-22, page 5).

I would incorporate the Tidier (Template for Intervention Description and Replication) Checklist as a supplementary file to give a full description of this smartphone app and a thorough overview, its content and delivery.

Thank you for providing this helpful and essential resource. This template has been completed and will be uploaded as a supplementary file.

Provide more information whether the application was entirely internet based to run/ function or it was an offline version or had both the offline and online components. It would be great to clearly show this (the Word “a data plan if needed” in this statement leaves one wondering about the specific parameters for internet usage as far as this application is concerned.

Thank you for this comment, we agree that this is an important aspect of the platform to include in terms of replication. A sentence has been added, and describes the offline component, ie that users can interact with features, and activity is stored in the server, however intermittent connectivity is required for activity to be viewed by others using the platform (for example, users’ responses to daily queries are stored regardless of connectivity, but in order for staff or peers to review these responses, the user must intermittently have WiFi or cellular data for internet connectivity for these responses to be uploaded periodically, lines 25-28, page 4).

RESULTS
Page 6, Line 6 (Server management)
Provide more information on why the server experienced intermittent system crashes. Was it due to lack of skills in server configuration or Internet connectivity, the operating environment of the server

This line was clarified: crashes were experienced due to connectivity issues (line 13, page 6).
Page 6, Line 10
I would be specific about the provider of these services e.g Lenode or Amazon Web services. and was this at a free cost or you paid, this would offer more information and guidance on costs involved during the upgrading to the cloud based services.

The services were purchased from a Russian commercial vendor using program funding. This description was added to the Methods section (Lines 17-18, page 6).

Page 8, Line 34 (Usability and Acceptability)

It would be great to know how many participants interacted with the system regularly out of the 60 that were recruited in the study, this would ascertain whether the intervention was useful or not. This can be determined through quantifying the number of patients who interacted with system through posting messages on the community message board, viewing the posted messages, commenting or liking (depending on the functionalities) or logged into the system as required. Does the application track these details?, can this information be accessed from the metadata or web based portal by the system administrators. If the system was not meant to be capture these, then it would good for future consideration.

You might find that a few of the participants (I can call them dominant participants) actually interface with the system borrowing a leaf from common Whatsapp groups. I think its very important to understand this as it would provide a better perspective on the actual usability of the system.

Thank you for this comment, we agree that this is important information. We have published this information in the paper which is referenced in the manuscript: Hodges J, Zhdanova S, Koshkina O, et al. Implementation of a Mobile Health Strategy to Improve Linkage to and Engagement with HIV Care for People Living with HIV, Tuberculosis, and Substance Use in Irkutsk, Siberia. AIDS Patient Care STDS 2021;35(3):84-91. doi: 10.1089/apc.2020.0233. We focused on formative output in this publication, as usage patterns were examined as an outcome in the aforementioned publication. Included are details on month by month usage by participants, including the number of active users (usage of each feature one or more times per month), as well as total usage by the cohort over the 6 months following participants’ enrollment). We have added a summary of usage data to the results section (lines 44-49, page 8).

DISCUSSION

I would beef up the entire discussion section discussing all these constructs independently by stating the meaning and implication of each construct in regards to mHealth development for TB/HIV care, compare these constructs with the existing literature for similarity and difference in findings and document unanswered questions and areas of future research. Remember to clearly discuss the limitations of this study that must be born by the readers in mind when interpreting these results.

Thank you for this comment, we agree that the implications of this work for mHealth and TB/HIV care should be more strongly emphasized. A segment has been added to the introduction (lines 29-31, page 3): A multi-faceted mHealth strategy designed to support patients beyond tracking of daily medication adherence has not been studied for HIV/TB or TB mono-infection, despite a pressing need identified in recent years. We have added an additional citation (Subbaraman et al 2018) to the introduction that provides an excellent review of the digital health interventions for TB, identifying the need for strategies that go beyond focusing on ‘pill in mouth’ tracking of adherence, and instead support patients by ‘meeting them where they are at,’ facilitating navigation of multiple psychosocial barriers. We have also added a citation highlighting the strategies used for TB mono-infection and their impact to date (Ngwatu et al 2018), which are all centered specifically on increasing patient medication adherence. To this end, in addition to describing the impact of PositiveLinks for HIV care in US-based cohorts (lines 34-36, page 3), we have also highlighted those aspects of the original PositiveLinks build that were retained in MOCT in lines 21-23, page 4 (a direct messaging feature for
low barrier communication with clinic care team members outside of clinic and a chat board which encourages peer support and assists patients with navigating stigma) which are novel in terms of digital health functionalities applied to TB care in any context, and to HIV care outside of the US. We have added to the discussion (lines 16-21, page 11) further observations we make about the low availability of mHealth functionalities for TB that are geared specifically toward holistic patient support, rather than tracking/encouraging medication adherence alone, citing recent reviews that identify this need as well as the need to design digital health interventions for TB that incorporate patient preferences. Finally, an additional segment was added to the conclusion (lines 25-29, page 12) highlighting the importance of these features in addressing HIV/TB.

Page 10, Line 45
"The lower scored survey items (still above 3 out of 5) were both related to perceived usefulness of the platform in facilitating self-management 'more quickly'" What does this imply in regards to the implementation of future mhealth interventions? describing this would provide guidance for future researchers.

Thank you for this comment. We hesitate to make significant inferences from these survey responses as our survey items have not been validated following translation, instead opting to make these observations while acknowledging the lack of validation of items later in the discussion as well as in our revised ‘strengths and limitations’ section.

Page 11, Line 44 on the challenges
Do we have participants who never actually used the application after the enrollment or had challenges with using the application, or abandoned the application e.g lack of internet among patients with low income, etc i think it would be great to know why if they are there.

For general consideration, you could considered formatting or adding the subheadings for the key words in your paper i.e Practical considerations Challenges Lessons learned These could emerge from your discussion section.

Thank you for this question. As noted in our previous response, usage patterns are discussed in further detail in our referenced publication describing outcomes of the pilot study (Hodges et al, AIDS Patient Care and STDs). Study activities did not support a rigorous evaluation of non-participation such as availability of internet connectivity, however we hope to study these considerations as well as other ‘implementation’ outcomes in future work following dissemination of the app using validated implementation science frameworks with a mixed methods approach. We have added this limitation to the ‘Strengths and Limitations’ section and the conclusion (line 32-34, page 12). Also, we have revised the title per editor request to simplify the description of the contents included in the paper.

Reviewer: 2
Prof. Maurice Mars, University of Kwazulu-Natal
Comments to the Author:
This paper describes the process of taking an existing mobile phone platform designed for use with people living with HIV in the US and adapting it for use in Russia with people co-infected with HIV and tuberculosis. The platform was piloted and has since been scaled up and is widely used in the region.

The process outlines a patient-centred approach to assisting people with self-management of their HIV and TB. The steps taken included patient interviews to understand their health needs and their requirements and expectations of the platform, and provider interviews to determine how the platform
could be adapted to meet the specific needs of the local patient populations. The findings of these
interviews guided the redesign of the platform that had to incorporate TB management and take into
account language and cultural issues. Redesign was an ongoing iterative process both during and
after the trial. The intervention requires a smartphone for access and participants in the pilot trial were
provided with a phone and data if required. After a six month pilot study the platform was well
received by providers and patients. The smartphone requirement will unfortunately further
disadvantage those who are least likely to own a smartphone.

The platform brought together those responsible for the management of HIV and TB in Irkutsk who
had until then worked independently of each other. This led to collaboration and information sharing to
the patients’ benefit.

The paper serves as a guide on good practice for those planning on setting up mHealth platforms.

Successful eHealth implementations are founded on sound eHealth readiness assessments of at
least seven different stakeholder groups. The only reported weakness described in this paper was
inadequate local IT technical support which should have been identified in advance. This resulted in
server downtime, the extent of which was not documented and problems troubleshooting and
upgrading the server. The solution was to move to a secure cloud service to host server data. This
can be problematic as many countries, including Russia, do not allow their citizen’s data to be stored
in offshore clouds. Presumably, the data is in a Russian cloud. This should be addressed in the
paper.

Thank you for your helpful comments. We agree that maximizing stakeholder representativeness is
critical, and hope to involve as many distinct groups as possible in future studies using
implementation science methods. We have added our intention to more rigorously study uptake/non-
participation using these methods to our ‘Strengths and Limitations’ and ‘Conclusions’ sections. We
have further clarified that system crashes occurred due to connectivity issues. While local manpower
related to general technical support was identified upfront and remained available throughout the
study, our technical lead played a role in troubleshooting server issues, the nature of which shifted
over time, hence we have included this detail in our process descriptions in the Methods and
Discussions sections. We have also clarified that the data were stored in an internal cloud rather than
an offshore cloud (Line 18, page 6). Regarding the concern of equity related to smartphone
penetration, while use of the MOCT app when the program is scaled relies on availability of
smartphones across the targeted patient population as well as at least intermittent internet
connectivity/data, the program also included several steps to increase integration of HIV/TB care and
identified treatment priorities of both patients and providers within Irkutsk, which collectively has the
potential to impact care more broadly, including for patients not using/without access to the tool itself.

Reviewer: 3
Dr. Xinying Liu, Georgia State University
Comments to the Author:

This research investigated the re-build, testing, and iteration of a mHealth platform to meet the
requirements of HIV and TB patients in Irkutsk, Siberia. In addition, this research examines the
usability and acceptability of the adapted mHealth intervention from 47 patients. 18 of 20 items show
scores above 4 on a scale from 1-5.

This research makes its contributions in revealing the mHealth preferences of HIV and TB patients in
Russia. Also, it provides knowledge about the health-related priorities those patients have, and the
specialty of Russian healthcare provider and patient relationships. The valuable deliverable of the
adapted mHealth platform is a good start point to be tested in a larger population and make further
coordination. However, same as any other research, this research have improvements to make.
Following are some issues.
1. This research has limited contribution. The motivation of the research is described as “no mHealth strategies have been studied to enhance delivery of HIV and TB care within the Russian Federation.” But there is limited discussion about the differences between the results from this research compared to other research in other contexts, making the research less unique and provide limited insights. Also, the description of why the integration of HIV and TB management platform should be conducted, and how the new adapted integrated platform works compare to the platform(s) for single disease is not discussed thoroughly. Since the original platform is for PLWH, and the newly adapted platform is anticipated to have broader implementation to PLWH regardless of TB co-infection status, I think it is important to have the in-depth discussion of uniqueness and potential generalization. I suggest the authors to provide more evidence in demonstrating the value of the research. What makes it so different from others, and what results indicate the differences and what are the potential generalization.

Thank you for this comment, we agree that the implications and novelty of this work for mHealth and TB/HIV care should be more strongly emphasized. This observation was similar to the constructive critique provided by Reviewer #1 and we have modified the manuscript similarly. As we have responded previously, a segment has been added to the introduction (lines 28-30, page 3): A multi-faceted mHealth strategy designed to support patients beyond tracking of daily medication adherence has not been studied for HIV/TB or TB mono-infection, despite a pressing need identified in recent years. We have added an additional citation that provides an excellent review of the digital health interventions for TB, identifying the need for strategies that go beyond focusing on ‘pill in mouth’ tracking of adherence, and instead support patients by ‘meeting them where they are at,’ facilitating navigation of multiple psychosocial barriers. To this end, in addition to describing the impact of PositiveLinks for HIV care in US-based cohorts (lines 33-35, page 3), we have also highlighted those aspects of the original PositiveLinks build that were retained in MOCT in lines 20-23, page 4 (a direct messaging feature for low barrier communication with clinic care team members outside of clinic and a chat board which encourages peer support and assists patients with navigating stigma) which are novel in terms of digital health functionalities applied to TB care in any context, and to HIV care outside of the US. We have added to the discussion (lines 16-21, page 11) further observations of the low availability of mHealth functionalities for TB that are geared specifically toward holistic patient support, rather than tracking/encouraging medication adherence alone, citing recent reviews that identify this need as well as the need to design digital health interventions for TB that incorporate patient preferences. An additional segment was added to the conclusion (lines 25-29, page 12) highlighting the importance of these features in addressing HIV/TB.

Distinct from our response to Reviewer #1, we wish to emphasize that we now have more strongly highlighted in the introduction the importance of integrating HIV/TB care, as these syndemics lead to very high mortality and often TB patients are under-engaged by health care systems for their HIV infection (lines 36-38, page 3). These changes are made in addition to the existing portions of the manuscript which outline existing mHealth strategies limited to single features without demonstrable impact on patient outcomes (lines 22-32, page 3), in addition to the discussion section (lines 25-37, page 11) and the ‘Platform Iteration’ section which discuss the unique components of the platform rebuild specific to added TB-related functionalities. We detail shared priorities as well as differences in patient preferences during user testing in the ‘Platform Iteration’ section which highlight important differences in patient preferences related to the platform when compared to those testing the original platform build prior to adaption, or PositiveLinks, which are important for replication of US-based mHealth platform adaptations in international settings where patients face different needs. This type of platform adaptation process for a multi-feature app is not well described. We have emphasized this point further in our edits in the ‘strengths and limitations’ section, along with emphasizing the novelty of additional patient support features beyond medication adherence provided by MOCT for HIV/TB care (and TB care in particular) in the discussion (lines 16-21, page 11).
2. Only descriptive statistics makes certain statement less convincible. In the “Discussion” section, statement “notably, these survey items as well as others within the category of ‘perceived usefulness’ became somewhat redundant following language adaption of the survey.” There was no analysis of the construct validity of all the survey items. Thus, making the statement lack of evidence. I suggest the authors to conduct the construct validity analysis to show the appropriateness of the survey items, especially in the adapted Russian context, and provide more convincible results about the acceptability and usability of the platform.

Thank you for this comment. We agree that the survey lacks rigorous validation following translation, which we have re-emphasized in the ‘Strengths and Limitations’ section in addition to the comments we provided later in the discussion section (Lines 13-17, page 12). We have published an analysis of patient usage patterns over time separately (Hodges et al, AIDS Patient Care and STDs), however we added a summary in the ‘Usability and Acceptability’ section (lines 44-48, page 8). We have also removed the sentence described in the comment.

3. There is misalignment of the description of the targeted patient type. In the previous sections, especially the recruited survey participants, the descriptions show the targeted patient is HIV and TB co-infected population, but in the “Discussion” sections, it is described as “PLWH with or without TB.” Though in the “Platform Dissemination” part, it is mentioned that the platform has been disseminated to a broader population, but I still suggest the authors improve the alignment of the description.

Thank you for this comment. The pilot study (including the survey distributed as part of the pilot study activities following patient participation) was conducted with HIV/TB patients with specific attention paid to ways to build in TB-specific functionalities in addition to tailoring the existing HIV functionalities for this patient population/context, whereas broader platform dissemination occurred within patients with HIV/TB as well as HIV mono-infection throughout Irkutsk. We clarify this point with the first edited bullet point of the ‘Strengths and Limitations’ section.

### VERSION 2 – REVIEW

| REVIEWER       | Tumuhimbise, Wilson               |
|----------------|-----------------------------------|
| Mbarara University of Science and Technology |                |
| REVIEW RETURNED | 25-Jan-2022                       |
| GENERAL COMMENTS | I would like to thank the authors for taking their quality time to address the comments raised which have greatly improved the manuscript. I have no further comments. |