

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Evaluating the implementation of a dynamic digital application to enable community-based decentralisation of rheumatic heart disease case management in Uganda: protocol for a hybrid type III effectiveness-implementation study
AUTHORS	Minja, Neema W.; Pulle, Jafesi; Rwebembera, Joselyn; de Loizaga, Sarah R.; Fall, Ndate; Ollberding, Nicholas; Abrams, Jessica; Atala, Jenifer; Kamarembo, Jenipher; Oyella, Linda; Odong, Francis; Nalubwama, Haddy; Nakagaayi, Doreen; Sarnacki, Rachel; Su, Yanfang; Dexheimer, Judith W.; Sable, Craig; Longenecker, Chris T.; Danforth, Kristen; Okello, Emmy; Beaton, Andrea; Watkins, DA

VERSION 1 – REVIEW

REVIEWER	van der Velde, Enno Leiden University Medical Centre, Cardiology
REVIEW RETURNED	17-Mar-2023

GENERAL COMMENTS	<p>This manuscript describes the study protocol of a project to implement a dynamic mobile application to enable community-based decentralization of rheumatic heart disease case management in Uganda. I think the manuscript is clear, well-written and complete.</p> <p>I think one of the many strengths of the project, as mentioned in the manuscript, is very important: "The study demonstrates the feasibility of integrating an electronic registry for RHD patient management at the primary health care (PHC) level in a low-resource setting".</p> <p>Clear overview in tables of: (1) comparison of current and proposed SAP delivery approaches; (2) Implementation strategies (3) Key metrics</p> <p>I have just a few minor comments:</p> <ul style="list-style-type: none">- in general: the manuscript makes many many times use of abbreviations that are not very common. In many cases I had to scroll down to the list of abbreviations to find the meaning. Maybe some of the abbreviations could be replaced by the full text. But in many cases I would leave the abbreviations as they are now. Maybe it is my shortcoming.- page 4/6, line 30: "the ACT application" : maybe add here: "(see below)".- page 7/9: ".. time and motion..": maybe add a reference here on this subject?- reference 27: there is no journal reference.
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REVIEWER	Mitchell, Alice
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GENERAL COMMENTS

Reviewers notes:

Strengthening the way secondary prophylaxis is delivered in locations that are strongly impacted by RHD is important because it adds to evidence that is accumulating with the increase in research around all aspects of RHD over the past two decades. This study will implement and evaluate activities for strengthening health systems in Uganda around RHD care, with decentralization and accompanying better care strategies hopefully improving outcomes for local people. Evidence from this evaluation is expected to provide understanding about ways to scale up decentralization and is thus an important study.

The protocol will be enhanced by the following suggestions.

General comments:

The design section of the protocol needs more clarity, especially for those readers who are not familiar with how the Ugandan health system is structured. One question that is not answered until after the Conclusion is the timeframe that this study will take place. The protocol would be enhanced by including the timeframes much earlier. Currently the study is planned to occur at some unspecified time in the future until readers get to the very end of the protocol. What years were the preparatory pilot activities undertaken? Figure 1 would have more value with some years/dates added to it.

I am not sure what "mobile" refers to in the ACT: mobile phone or a transportable system? Should this be web-based, or computer-based or electronic data based? Is it mobile phone-based, a mobile phone app? This is not clarified until the very end of the paper where technological limitations in Uganda are explained, as well as the inclusion of smart phones, and the related need for offline capacity for the ACT. This needs to come much earlier in the paper.

Title: Needs to include methodology in the title as well as clarify the dynamic mobile application. Some examples of a clearer title are provided for the authors to work with.

-“Evaluation of implementing a novel electronic tool to enable community-based decentralization of rheumatic heart disease case management in Uganda: a study protocol”.

Or,

-“Evaluation of implementing an electronic medical record application to enable decentralization of rheumatic heart disease case management in Uganda: a study protocol”-

Or

“Evaluation of a package of electronic tools and strategies implemented to enable decentralization of rheumatic heart disease care in Uganda: a study protocol”.

-Decentralization inherently infers moving out from large central care to community care.

Implementation is the main activity in the study whereas evaluation is the methodology.

Abstract:

	<p>Introduction: line 38 suggest removing “at least maintain or”. If the intervention does not improve SAP adherence but only maintains current rates of adherence, then it begs the question as to the value in undertaking decentralized care. Non-inferiority is the statistical measure in the study which belongs in the Methods section. The authors have stated this in the Methods section in line 46.</p> <p>Keywords: suggest adding “evaluation” if evaluation is not inserted in the title.</p> <p>Introduction: End of first paragraph, line 37 should read- poor RHD knowledge among the healthcare workforce. Line 45, remove “However” at start of sentence because the next sentence also begins with “however”. Line 3 page 5- remove “however” at start of sentence. Line 13 page 5- suggest replacing “modern” with “new” and break the sentence as below: Demonstrating that a new approach to RHD care is effective and implementable is important for scaling RHD services more broadly. The capacity within the current centralized approach is insufficient to serve the approximately 200 - 400 thousand persons estimated to be living with RHD in Uganda.</p> <p>Aims and Hypothesis: The study is clearly described here as an evaluation. This is not so clear in other sections. Suggest this would read better as: This study aims to evaluate the effectiveness of a package of implementation strategies that includes assessment of site readiness, decentralization of service site, a new mode of electronic record-keeping, health care worker training, “purposefully re-examination of the implementation”, it is not clear what this means. I assume you mean “iterative feedback during the implementation” (feedback from implementation at the first two sites to the following sites), identification of champions and monitoring supply of medicines for improving SAP delivery for RHD care. Suggested change wording to: We hypothesize that this package of strategies will improve or be equal to current SAP adherence and related outcomes for clients in the decentralized study locations.</p> <p>Methods and Analysis: Study design: Line 40: Suggest inserting: “This is a mixed methods, hybrid type III effectiveness-implementation study...” Mixed methods because researchers will conduct interviews and observations to assess acceptability etc as well as statistically measure SAP adherence rates and other related outcomes. Line 46: utilization outcomes among registrants, -suggest change to “utilization outcomes among clients” or “registered clients” to avoid confusion as to whether the registrant is a clinic site or a client in this design. Line 48-suggested rewording: “The study will determine whether adherence to SAP is non-inferior post-implementation, with usual centralized care acting as the active control”.</p>
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	<p>There is no mention of sample size or confidence intervals for the analysis of adherence post implementation until right at the end of the paper. Elsewhere the authors have stated that the sample is not large enough for a randomised trial. An estimation of sample size should be included here and not just in the statistical considerations section.</p> <p>Study Setting: Line 12- typo-should be “subsequently” Line 28- suggested new wording for clarity: “In this study, decentralization is defined as the change of service site for delivery of SAP for RHD registry patients, from current regional hospitals to district level PHC facilities”.</p> <p>The Intervention: this section describes the intervention as BPG however BPG is not the new activity in this study, decentralization of care is the intervention. Suggest removal of this paragraph about BPG. This heading will not then be needed. The second paragraph in this section could be inserted into the following section which could be renamed “Preparation For Decentralization”.</p> <p>RHD Registry cleaning ... As many readers will not be familiar with Uganda’s health system, clarity in this section would be greatly enhanced by use of a further flow diagram separate from Figure 1; depicting the study relationships between the National Registry and the other decentralizing sites. Are Gulu and Lira part of the same area/district? Do both Lira and Gulu have 4 health centers each or are 4 selected from a larger number of health centers? Two health centers in Lira will receive the intervention, and after 4 weeks, the remaining 2 selected for the study will commence decentralized care. Then 3 months later replication will occur in Gulu. This could be depicted in the flow diagram to make it clearer for the readers. Additionally, it is not clear what HCIII/IV means to readers who are unfamiliar with the Ugandan health system. Please insert an explanatory sentence defining HCIII/IV for international readers. Figure 2. could be made clearer if the LRRH (purple circle) and Ober clinic (green circle) were more easily visible. Also, the legend should read H= health centre. There are no HC’s in the map diagram.</p> <p>Line 6 on page 7: currently reads, “to allow incorporation of planned formative feedback from decentralization in the Lira district”. This is the iterative component of the intervention. Need to state that feedback will inform activities in Gulu. If for instance, adherence is dropping in Lira due to an unintended, unforeseeable entity (e.g., electricity supply cuts, a pandemic, staff changes, a community issue), then the intervention in Gulu will be adjusted in light of this.</p> <p>Second paragraph, line 54- it is not clear what the “two registry sites” are for the baseline data collection. What is meant by registry site?</p> <p>Provider Education: Line 35- remove “overtime” Line 39- “from published provider health care interviews”, change to “in published healthcare provider interviews” Second paragraph, first sentence-change to “is not undertaken systematically”</p>
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	<p>Line 44- suggested change in wording: “The pilot identified deficiencies in specific areas that were instrumental in tailoring educational materials for pre-decentralization training”</p> <p>Line 52- would read better as: “Additionally, a standard operating procedure (SOP) was developed, which will serve as the guideline for all decentralization procedures in health facilities in both districts”.</p> <p>Line 56- The description of Champions for this study is a little hazy. What attributes do Champions have that lead to their selection? Motivation, confidence, experience in giving BPG etc? Can you define please? Do the authors expect Champions to be recruited in each district or HC?</p> <p>Line 56- reads better if you remove “one of the implementation strategies” from this sentence.</p> <p>Inclusion of medical records representatives: would read better as, “Inclusion of medical records personnel was not initially planned for. However, the pilot training revealed that these personnel are more technologically competent and including them would facilitate support at the health centers throughout the implementation”.</p> <p>Study population and recruitment: Suggest first sentence would read better as: All eligible RHD registrants will be approached by trained study staff. After an explanation of the study is provided, the registrants will be invited to participate in decentralization.</p> <p>Participant Eligibility: The paragraph beginning with the sentence “Registrants consenting to decentralization...” needs a reworking of the English expression for clarity and conciseness.</p> <p>Implementation Outcomes: Second paragraph, Line 55: “acceptability, adoption, penetration, and implementation cost”. These each need a short definition in addition to info in Table 4, for the study. For example, what does acceptability entail? How will the costs be measured? (I see it is later described as a time and motion study- needs a brief description here).</p> <p>Paragraph starting on line 57 with “Pre-implementation, formative research was planned...” is very difficult to read because past and present tenses are used interchangeably. For example, stating that something “was planned” or “was planned to”, gives the impression that the task was undertaken. But a following sentences states that a task will be done, indicating it is yet to be done. Please review this paragraph for English expression.</p> <p>Paragraph starting on line 17 of page 9 with “Database queries...” add interviews and observations to the list of data sources that will be used to evaluate the intervention. The term “challenges” is commonly used in speech in African countries, but it is not specific enough for publications such as this protocol. Challenges and successes are usually referred to in the literature as barriers and enablers. This term is also used in the conclusion where it could be changed to barriers.</p> <p>Discussion: Line 36 page 10. “Firstly, the study design was not according to conventional methods for establishing causality for the reasons previously mentioned” I am clear what this sentence means and it could be deleted.</p>
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	<p>The descriptions of the ACT and how it was modified based on the pilot study are much clearer in this section than at any point earlier in this paper. The protocol would be enhanced with more complete descriptions of the ACT and how it was modified due to setting characteristics (discomfort with technology) earlier in the paper.</p> <p>Conclusion: The mention of “poor health-seeking” behaviour is a system-centric judgmental way of describing community people’s actions. There are always complex reasons behind why people act in certain ways, and I don’t find it helpful to infer that clients have deficiencies. The study is addressing access and system change rather than patient’s behaviours. Suggest deleting this term. The final sentence in the conclusion is predicting results of the evaluation as being due to prior relationships. This sentence would be better worded that, rather than the relationships becoming a steppingstone to successful decentralization, that the relationships have facilitated implementation of the study.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Enno van der Velde, Leiden University Medical Centre

Comments to the Author:

This manuscript describes the study protocol of a project to implement a dynamic mobile application to enable community-based decentralization of rheumatic heart disease case management in Uganda. I think the manuscript is clear, well-written and complete.

I think one of the many strengths of the project, as mentioned in the manuscript, is very important: "The study demonstrates the feasibility of integrating an electronic registry for RHD patient management at the primary health care (PHC) level in a low-resource setting".

Clear overview in tables of: (1) comparison of current and proposed SAP delivery approaches; (2) Implementation strategies (3) Key metrics

I have just a few minor comments:

- in general: the manuscript makes many many times use of abbreviations that are not very common. In many cases I had to scroll down to the list of abbreviations to find the meaning. Maybe some of the abbreviations could be replaced by the full text. But in many cases I would leave the abbreviations as they are now. Maybe it is my shortcoming.

Thanks for this relevant concern – we have tried to keep abbreviations to a minimum and have further reduced the number of abbreviations to make it easier for the reader.

- page 4/6, line 30: "the ACT application" : maybe add here: "(see below)".

This has been added

- page 7/9: ".. time and motion..": maybe add a reference here on this subject?

We agree that adding a reference here will be more insightful. We have added “Gold, H.T., McDermott, C., Hoomans, T. *et al.* Cost data in implementation science: categories and approaches to costing. *Implementation Sci* **17**, 11 (2022). <https://doi.org/10.1186/s13012-021-01172-6>”

- reference 27: there is no journal reference.

This is currently awaiting publication in *Applied Clinical Informatics*, Manuscript ID ACI-2022-12-RA-0339.R1. We have included this information.

Reviewer: 2

Dr. Alice Mitchell

Comments to the Author:

Reviewers notes:

Strengthening the way secondary prophylaxis is delivered in locations that are strongly impacted by RHD is important because it adds to evidence that is accumulating with the increase in research around all aspects of RHD over the past two decades. This study will implement and evaluate activities for strengthening health systems in Uganda around RHD care, with decentralization and accompanying better care strategies hopefully improving outcomes for local people. Evidence from this evaluation is expected to provide understanding about ways to scale up decentralization and is thus an important study.

The protocol will be enhanced by the following suggestions.

General comments:

The design section of the protocol needs more clarity, especially for those readers who are not familiar with how the Ugandan health system is structured. One question that is not answered until after the Conclusion is the timeframe that this study will take place. The protocol would be enhanced by including the timeframes much earlier. Currently the study is planned to occur at some unspecified time in the future until readers get to the very end of the protocol. What years were the preparatory pilot activities undertaken? Figure 1 would have more value with some years/dates added to it.

This is an important suggestions that we have considered carefully and made some changes. Figure 1 and 2 are both re-done to give an overview of the study setting and context as well as timelines for project activities.

I am not sure what “mobile” refers to in the ACT: mobile phone or a transportable system? Should this be web-based, or computer-based or electronic data based? Is it mobile phone-based, a mobile phone app? This is not clarified until the very end of the paper where technological limitations in Uganda are explained, as well as the inclusion of smart phones, and the related need for offline capacity for the ACT. This needs to come much earlier in the paper.

The ACT application is an app that can be used on the phone, tablet, computer or just accessed from a web-browser. We have changed the terminology “mobile” to digital. Mobile is used in reference to digital or m-health innovations but may be confusing as it has other specific meanings.

Title: Needs to include methodology in the title as well as clarify the dynamic mobile application.

Some examples of a clearer title are provided for the authors to work with.

-“Evaluation of implementing a novel electronic tool to enable community-based decentralization of rheumatic heart disease case management in Uganda: a study protocol”.

Or,

-“Evaluation of implementing an electronic medical record application to enable decentralization of rheumatic heart disease case management in Uganda: a study protocol”-

Or

“Evaluation of a package of electronic tools and strategies implemented to enable decentralization of rheumatic heart disease care in Uganda: a study protocol”.

-Decentralization inherently infers moving out from large central care to community care.

Implementation is the main activity in the study whereas evaluation is the methodology.

Opted to change “mobile” to digital application and we would like it to be understood as an electronic

application in this case used for health care/services. We also included the evaluation in the title to add clarity.

Abstract:

Introduction: line 38 suggest removing “at least maintain or”. If the intervention does not improve SAP adherence but only maintains current rates of adherence, then it begs the question as to the value in undertaking decentralized care. Non-inferiority is the statistical measure in the study which belongs in the Methods section. The authors have stated this in the Methods section in line 46.

There are several other benefits of decentralization besides potentially improving adherence which would put non-inferiority still in favor of decentralization (short distance to health center for patients, possibility of reducing out of pocket costs for patients, decongesting larger hospitals etc.)

Keywords: suggest adding “evaluation” if evaluation is not inserted in the title.

We have now included evaluation in the title as per suggestions

Introduction:

End of first paragraph, line 37 should read- poor RHD knowledge among the healthcare workforce.
Changed

Line 45, remove “However” at start of sentence because the next sentence also begins with “however”.

Changed

Line 3 page 5- remove “however” at start of sentence.

Changed

Line 13 page 5- suggest replacing “modern” with “new” and break the sentence as below:

Demonstrating that a new approach to RHD care is effective and implementable is important for scaling RHD services more broadly. The capacity within the current centralized approach is insufficient to serve the approximately 200 - 400 thousand persons estimated to be living with RHD in Uganda.

Changed

Aims and Hypothesis:

The study is clearly described here as an evaluation. This is not so clear in other sections.

Suggest this would read better as:

This study aims to evaluate the effectiveness of a package of implementation strategies that includes assessment of site readiness, decentralization of service site, a new mode of electronic record-keeping, health care worker training, “purposefully re-examination of the implementation”, it is not clear what this means. I assume you mean “iterative feedback during the implementation” (feedback from implementation at the first two sites to the following sites), identification of champions and monitoring supply of medicines for improving SAP delivery for RHD care.

Modified

Suggested change wording to: We hypothesize that this package of strategies will improve or be equal to current SAP adherence and related outcomes for clients in the decentralized study locations.

Modified

Methods and Analysis:

Study design:

Line 40: Suggest inserting: “This is a mixed methods, hybrid type III effectiveness-implementation study...” Mixed methods because researchers will conduct interviews and observations to assess acceptability etc as well as statistically measure SAP adherence rates and other related outcomes.
Modified

Line 46: utilization outcomes among registrants, -suggest change to “utilization outcomes among clients” or “registered clients” to avoid confusion as to whether the registrant is a clinic site or a client in this design.

We take the point that the term registrants is unclear. We have thought on this further and agreed to use enrolled patients.

Line 48-suggested rewording: “The study will determine whether adherence to SAP is non-inferior post-implementation, with usual centralized care acting as the active control”. Reworded to “The study will determine whether adherence to SAP post-implementation is non-inferior to the current standard centralized care.”

There is no mention of sample size or confidence intervals for the analysis of adherence post implementation until right at the end of the paper. Elsewhere the authors have stated that the sample is not large enough for a randomised trial. An estimation of sample size should be included here and not just in the statistical considerations section.

Edited to include estimated sample size here.

Study Setting:

Line 12- typo-should be “subsequently”

Corrected

Line 28- suggested new wording for clarity: “In this study, decentralization is defined as the change of service site for delivery of SAP for RHD registry patients, from current regional hospitals to district level PHC facilities”.

Updated

The Intervention: this section describes the intervention as BPG however BPG is not the new activity in this study, decentralization of care is the intervention. Suggest removal of this paragraph about BPG. This heading will not then be needed. The second paragraph in this section could be inserted into the following section which could be renamed “Preparation For Decentralization”.

Thank you for noting this. Naming conventions in the IS community distinguish between the evidence-based intervention (EBI) and implementation strategies – which are designed to improve the access and delivery of EBIs. In this study, we are thus evaluating the implementation strategies (decentralization of care to PHCs, use of a dynamic electronic application for care management, etc.) to improve the delivery/uptake of SAP for RHD, not testing the EBI.

To address the confusion, we have clarified this and made the following changes:

1) clarified on the intervention terminology and reworded to evidenced based practice (EBP).

We have also taken the suggestion to have a broader subsection “Preparation for decentralization” to encompass the second paragraph and the subsequent sub section.

RHD Registry cleaning ...

As many readers will not be familiar with Uganda’s health system, clarity in this section would be greatly enhanced by use of a further flow diagram separate from Figure 1; depicting the study relationships between the National Registry and the other decentralizing sites. Are Gulu and Lira part of the same area/district? Do both Lira and Gulu have 4 health centers each or are 4 selected from a

larger number of health centers? Two health centers in Lira will receive the intervention, and after 4 weeks, the remaining 2 selected for the study will commence decentralized care. Then 3 months later replication will occur in Gulu. This could be depicted in the flow diagram to make it clearer for the readers.

We find this a very useful suggestion to enhance the understanding of the system in Uganda for international audiences. Lira and Gulu are two separate districts in Uganda. Four Health centres were selected in the district using density maps based on patients' residence (within 20km) in each district. The implementation strategies were planned to be rolled out in a staggered manner, starting with two clinics in Lira, followed by the other 2 after a 2-4 week gap. This would then be replicated in Gulu after 4- 6 months in the same stepwise manner.

To clearly depict this, we have taken this suggestion and changed/added to the figures as follows:

1. Figure 1 Changed to an overview map of Uganda with the two districts highlighted and modified to include Lira and Gulu separately, showing the hospital and health centres in relation to RHD patients. Further clarity added to the legends.
2. Figure 2 is now the previous figure 1 - modified to focus and demonstrate the staggered decentralization pattern in the two districts.

Additionally, it is not clear what HCIII/IV means to readers who are unfamiliar with the Ugandan health system. Please insert an explanatory sentence defining HCIII/IV for international readers. This has been added in the main document.

Figure 2. could be made clearer if the LRRH (purple circle) and Ober clinic (green circle) were more easily visible. Also, the legend should read H= health centre. There are no HC's in the map diagram. These changes have been incorporated in the new revised figure.

Line 6 on page 7: currently reads, "to allow incorporation of planned formative feedback from decentralization in the Lira district". This is the iterative component of the intervention. Need to state that feedback will inform activities in Gulu. If for instance, adherence is dropping in Lira due to an unintended, unforeseeable entity (e.g., electricity supply cuts, a pandemic, staff changes, a community issue), then the intervention in Gulu will be adjusted in light of this.

Agreed, this was the intention. The sentence in the end says "Thereafter, this will be replicated in Gulu after a period of three months to allow incorporation of planned formative feedback from decentralization in the Lira district. The staggered approach in Lira and then Gulu after some months is to allow this information from Lira to feed into Gulu.

Second paragraph, line 54- it is not clear what the "two registry sites" are for the baseline data collection. What is meant by registry site?

Clarified to include Lira and Gulu regional hospitals where the RHD patient registry and care is based.

Provider Education:

Line 35- remove "overtime"

Done

Line 39- "from published provider health care interviews", change to "in published healthcare provider interviews"

Modified

Second paragraph, first sentence-change to "is not undertaken systematically"

Suggestion incorporated

Line 44- suggested change in wording: “The pilot identified deficiencies in specific areas that were instrumental in tailoring educational materials for pre-decentralization training” Modified

Line 52- would read better as: “Additionally, a standard operating procedure (SOP) was developed, which will serve as the guideline for all decentralization procedures in health facilities in both districts”. Modified

Line 56- The description of Champions for this study is a little hazy. What attributes do Champions have that lead to their selection? Motivation, confidence, experience in giving BPG etc? Can you define please? Do the authors expect Champions to be recruited in each district or HC? We have also modified this for easy understanding.

Line 56- reads better if you remove “one of the implementation strategies” from this sentence. Modified

Inclusion of medical records representatives: would read better as, “Inclusion of medical records personnel was not initially planned for. However, the pilot training revealed that these personnel are more technologically competent and including them would facilitate support at the health centers throughout the implementation”.

Modified

Study population and recruitment:

Suggest first sentence would read better as:

All eligible RHD registrants will be approached by trained study staff. After an explanation of the study is provided, the registrants will be invited to participate in decentralization. Modified

Participant Eligibility:

The paragraph beginning with the sentence “Registrants consenting to decentralization...” needs a reworking of the English expression for clarity and conciseness.

Modified

Implementation Outcomes:

Second paragraph, Line 55: “acceptability, adoption, penetration, and implementation cost”. These each need a short definition in addition to info in Table 4, for the study. For example, what does acceptability entail? How will the costs be measured? (I see it is later described as a time and motion study- needs a brief description here).

The explanations for these are given in the referenced paper, proctor et al (36), However, we think it is a good consideration to add a short description from the literature. This has been added as the second column in the Table.

Acceptability – will look at the perceptions around suitability and agreeability of decentralization and satisfaction among stakeholders. Analysis will be at the patient and provider level.

Adoption – defined as the intention to take up an innovation; “uptake and utilization”. In this study will be measured from provider level at the health facility using pre/post decentralization qualitative interviews and monthly health facility surveys.

Penetration- “defined as the integration of a practice within a service setting and its subsystems” and looks at the assimilation of the innovation in question. In this study will be measured at the provider level from the interviews, observations, time and motion study and monthly health facility surveys.

Costs – This will be done under a separate economic analysis and will look at the cost per patient visit from a societal perspective incurred under the two models of service delivery – decentralized care at health facilities and the current centralized care at regional hospitals in the two districts.

Paragraph starting on line 57 with “Pre-implementation, formative research was planned...” is very difficult to read because past and present tenses are used interchangeably. For example, stating that something “was planned” or “was planned to”, gives the impression that the task was undertaken. But a following sentence states that a task will be done, indicating it is yet to be done. Please review this paragraph for English expression.

Thank you for pointing this out – here the initial task of formative research with stakeholders was done prior to study start to inform the study activities. The sentences following refer to different activities – this paragraph has been modified to add clarity on events and hence tenses.

Paragraph starting on line 17 of page 9 with “Database queries...” add interviews and observations to the list of data sources that will be used to evaluate the intervention. The term “challenges” is commonly used in speech in African countries, but it is not specific enough for publications such as this protocol. Challenges and successes are usually referred to in the literature as barriers and enablers. This term is also used in the conclusion where it could be changed to barriers.

The sentence referring to database queries is in addition to what has already been mentioned in the previous paragraphs; ‘further’ is added to avoid repeating everything explained prior (interviews, facility surveys already mentioned in the previous paragraphs). The paragraph is also joined to the previous one – as it is a continuation.

We have also opted to use determinants, specific to implementation science language instead of challenges.

Discussion:

Line 36 page 10. “Firstly, the study design was not according to conventional methods for establishing causality for the reasons previously mentioned” I am clear what this sentence means and it could be deleted.

We have removed this sentence and kept the limitations of the methods in the section “Strengths and Limitations of this Study”

The descriptions of the ACT and how it was modified based on the pilot study are much clearer in this section than at any point earlier in this paper. The protocol would be enhanced with more complete descriptions of the ACT and how it was modified due to setting characteristics (discomfort with technology) earlier in the paper.

Modified

Conclusion:

The mention of “poor health-seeking” behaviour is a system-centric judgmental way of describing community people’s actions. There are always complex reasons behind why people act in certain ways, and I don’t find it helpful to infer that clients have deficiencies. The study is addressing access and system change rather than patient’s behaviours. Suggest deleting this term.

Very pertinent point, we have highlighted instead the barriers from health systems and modified accordingly. This has been incorporated in the discussion as per journal requirements.

The final sentence in the conclusion is predicting results of the evaluation as being due to prior relationships. This sentence would be better worded that, rather than the relationships becoming a steppingstone to successful decentralization, that the relationships have facilitated implementation of the study.

Thank you, we have opted to leave this out as we are advised by editorial team not to include a conclusion section.

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VERSION 2 – REVIEW

REVIEWER	Mitchell, Alice
REVIEW RETURNED	10-Jul-2023
GENERAL COMMENTS	Thank you for adjusting the article according to suggested edits. I look forward to reading the published paper.