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

<table>
<thead>
<tr>
<th>TITLE (PROVISIONAL)</th>
<th>Evaluating Process and Clinical Outcomes of a Primary Care Mental Health Integration Project in rural Rwanda: a Prospective Mixed-Methods Protocol.</th>
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<tr>
<td>AUTHORS</td>
<td>Smith, Stephanie; Misago, Claire; Osrow, Robyn; Franke, Molly; Iyamuremye, Jean Damascène; Dusabeyezu, Jeanne; Mohand, Achour; Anotole, Manzi; Kayiteshonga, Yvonne; Raviola, Giuseppe</td>
</tr>
</tbody>
</table>

VERSION 1 - REVIEW

| REVIEWER            | Francine Cournos  
                     | Professor of Clinical Psychiatry (in Epidemiology)  
                     | Mailman School of Public Health  
                     | Columbia University  
                     | United States  
                     | No competing interests. Of note is that I did work in Rwanda from 2009-2012 and met members of the involved organizations, but if anything this is probably helpful to reviewing this protocol. |
| REVIEW RETURNED     | 02-Oct-2016 |

GENERAL COMMENTS

Rwanda has been focused on integrating mental health care into medical settings (especially those caring for people with HIV infection) for some time now. After providing primary care nurses with basic education about mental disorders and their treatment, it’s clear that mentoring needs to follow, and that is not easy to implement. Therefore a trial like this is a great step to be taking and the results will be of considerable interest.

There are a few changes that would improve this protocol. One would be to use sites where implementation will be delayed as control sites on at least a few very simple variables, such as whether visits for mental illness increased at those sites over the same period of time. Another would be to build in a measure that tracks the improvement of epilepsy. I'm not familiar with the way response to epilepsy treatment is tracked since in the US and many other places outside of sub-Saharan Africa it's handled as a neurological disorder rather than a mental illness, but I would imagine tracking seizure frequency would be basic. The current measures are only indirectly informative about epilepsy outcomes. Finally, the protocol states that for qualitative interviews the research team will obtain the patient's assent and the relative's consent. Usually this is only done when the patient lacks capacity to consent, and capable patient's are allowed to consent for themselves, which is a more respectful approach.
This protocol describes the design of a study investigating the implementation and clinical outcomes of a program on integrating mental health care for severe mental disorders into primary health care in rural Rwanda. The program adapted a successful program of supported supervision for task shifting of HIV care in Rwanda.

Specific comments:
1. The title should reflect that this is a protocol.
2. Page 3, line 2: ‘Task sharing’ is now the preferred term to ‘task shifting’ given that it emphasizes the need for sharing of tasks between less specialized health workers and the need to ensure adequate supervision and support to avoid ‘task dumping’.
3. Page 4, lines 14-17: More detail on the training programme is suggested. In addition, were any guidelines made available for nurses e.g. the World Health Organization mhGAP Intervention Guide (mhGAP-IG) for mental, neurological and substance use disorders for non-specialist health settings?
4. Page 4, lines 25-28, the authors seem to be describing a quality improvement process. The authors are requested to elaborate on this process. For example, how were systems-based performance issues and ‘quality gaps’ identified. How were identified plans for improving these issues monitored?
5. Page 4, lines 33-38, the authors should reassess the use of the terms outcome and process evaluation. Outcome evaluation typically uses quantitative data to assess for changes in outcomes and process evaluation typically uses qualitative interviews to explore perceptions and experiences as well as process indicators to assess changes in the uptake of services etc as a result of the intervention.
6. Page 6, lines 14-31, a description of the outcome measures used and reasons for choosing the identified measures should be provided. Given the focus on severe mental disorders, the choice of the GHQ-12 is surprising given that it is commonly used as a screening instrument for common mental disorders, as well as being a more general measure of psychosocial well-being.
7. On page 7, line 15 – review heading “Qualitative outcomes evaluation specific aim” in light of point 3 above. The same goes for page 8, line 25.
8. Page 7, line 51. From the description of the analysis – it would seem that thematic analysis is being planned rather than content analysis.
topic and there is a need for rigorous implementation research in this area. The paper needs some reworking to improve the methodological detail and situate the intervention in the recent literature in this area.

Title:
1. Need to specify that this is a ‘protocol’

Abstract:
2. The abstract has very little methodological detail. For a protocol paper, it is necessary to expand the methods part. At the least to provide the objectives/hypothesis, and describe the study design for the quantitative component, the sample sizes and proposed approach to analysis.

3. The abstract section on ‘ethics and dissemination’ does not seem to deal with these topics at all. Instead it seems to be describing potential impact of the study.

4. The structure of the abstract is unconventional, with key words included in the middle.

Introduction
5. Please define what you mean by severe mental disorder. In the methods it seems as if the programme is more generally targeted, also including depression and epilepsy (not conventionally understood to be SMD)

6. It is difficult to talk about integration of mental health care into primary care without referring to the World Health Organisation’s mental health Gap Action Programme.

7. There are several other initiatives underway in Africa to integrate mental health into primary care for people with severe mental disorder (if you expand to include depression then there are many more). The PRIME project is particularly relevant as it is an implementation research programme focused on rural districts in Ethiopia and Uganda. Look also at the work of Rachel Jenkins in Kenya. Please consider the following: (1-7)


Methods
8. The objectives of the study need to be specified clearly towards the beginning. At the moment there is a section entitled ‘overall objectives’ which just describes study methodology.

9. There is some confusion. The methods section starts with a description of where the intervention was implemented, but this is a protocol paper and should be describing the future planned intervention (which is an expansion of the intervention to new sites).

10. More detail is needed about the intervention, in particular how it relates to evidence-based guidelines published by the WHO (mhGAP Intervention Guide) and the PLoS medicine packages of care for schizophrenia in LMICs (Jair Mari et al.). As well as training for primary care workers, is there any community level case-finding? Without that the intervention might not lead to increased uptake of services. Who trained the primary care workers? (it looks as if it was the psychiatric nurse but not fully clear)

11. The study design for the quantitative component is not specified consistently. In the abstract it is described as a ‘prospective cohort’ but it is actually an intervention study so ‘uncontrolled before-after study’ would be more accurate.

12. Process evaluation aim 1 would be better described as an interrupted time series study.

13. For process evaluation aim 2 please specify the sample size for looking at change in checklist performance. This approach will give some indication of quality but the limitations need to acknowledge that this is obtained from routine recording and so the relationship with actual care is not known.

14. Before-after study
a. The cohort appears to be heterogeneous, including different disorders which makes it difficult to measure the relevant outcomes with sufficient power.

b. The WHODAS is relevant across disorders, but the GHQ will only be relevant to depression. Please provide information about the cultural validity and psychometric properties of the proposed scales.

c. What other co-variates/potential confounders are being measured – what about alcohol/substance use? And physical ill-health/disability?

d. With 6 months of follow-up and no control group the economic evaluation may be affected by seasonal effects.

15. Qualitative study
a. Reliance on ‘information rich’ respondents may not be appropriate in this case. People with SMD may struggle to engage in lengthy interviews and may not be ‘information rich’ in that sense but their perspective is clearly critical.

b. The topic guide doesn’t seem to cover cultural acceptability of care – will you be able to interview some people who dropped out of care?

16. Ethical considerations
a. The investigators will include people with SMD who are unable to answer for themselves due to illness. What safeguards will be employed for people who lack capacity to consent?
b. Under the section ‘patients’ (following the ethic section) the consent procedures are described. Patients are described as giving ‘assent’ (that is relevant for under-age patients but not for those who lack capacity) and caregivers providing consent, but patients may also be able to consent if they have decision-making capacity. How will capacity be evaluated?

**VERSION 1 – AUTHOR RESPONSE**

Reviewer: 1  
Reviewer Name: Francine Cournos  
Institution and Country: Professor of Clinical Psychiatry (in Epidemiology), Mailman School of Public Health, Columbia University, United States  
Please state any competing interests: No competing interests. Of note is that I did work in Rwanda from 2009-2012 and met members of the involved organizations, but if anything this is probably helpful to reviewing this protocol.

Please leave your comments for the authors below

-- Rwanda has been focused on integrating mental health care into medical settings (especially those caring for people with HIV infection) for some time now. After providing primary care nurses with basic education about mental disorders and their treatment, it's clear that mentoring needs to follow, and that is not easy to implement. Therefore a trial like this is a great step to be taking and the results will be of considerable interest.

-- There are a few changes that would improve this protocol. One would be to use sites where implementation will be delayed as control sites on at least a few very simple variables, such as whether visits for mental illness increased at those sites over the same period of time.

Process indicator one includes the tracking of routine data including service visits, unique visits and diagnosis, at all health centers in the district for six months following entry into the MESH MH program. As the process indicators were designed to record routine data and assess their change over time, each site serves as its own ‘control’, rather than other health centers in the district. No mental health services are currently offered at those health centers prior to the MESH MH program implementation, so comparing service use at these health centers with those who have the MESH MH program services, would not provide a meaningful comparison.

-- Another would be to build in a measure that tracks the improvement of epilepsy. I'm not familiar with the way response to epilepsy treatment is tracked since in the US and many other places outside of sub-Saharan Africa it's handled as a neurological disorder rather than a mental illness, but I would imagine tracking seizure frequency would be basic. The current measures are only indirectly informative about epilepsy outcomes.

We have chosen the GHQ-12 and WHO-DAS brief because they are not specific to diagnosis and track psychological distress and disability in all of our included patients, who run the gamut from psychotic disorders to depressive disorders to epilepsy. This will allow us to ensure standardization in outcome measures regardless of diagnosis. We have chosen to use a general distress scale which can be used in all comers to the clinic as we are also assessing the accuracy of diagnosis provided by health center nurses as part of the study (please see table 2). Therefore, we do not want to choose outcome measures which are dependent on diagnosis, until we have assessed how accurate the diagnosis given by HC nurses actually are. Please also see edits in the text section entitled “Outcomes Evaluation (Quantitative Pre- and Post- Intervention Analysis), section Data collection,
measures and outcomes" to describe why these two scales were chosen.

--Finally, the protocol states that for qualitative interviews the research team will obtain the patient's assent and the relative's consent. Usually this is only done when the patient lacks capacity to consent, and capable patient's are allowed to consent for themselves, which is a more respectful approach.

This is correct that people with mental disorders should be allowed to consent for themselves to participate in studies, while this proposal specifies that we will obtain assent from patients and consent from families. However, the Rwanda National Ethics Committee has mandated that for this protocol, assent be acquired from patients and consent from families. They stipulate this because according to Rwandan law, a person with a mental disorder cannot consent for research endeavors. Thus, this consent/assent process is written as such because the Rwanda ethics review has required this specific process in order to proceed with this study. Of note, this study has been deemed exempt by the Harvard University Institutional Review Board.

Reviewer: 2
Reviewer Name: Inge Petersen
Institution and Country: University of KwaZulu-Natal, South Africa
Please state any competing interests: None declared

Please leave your comments for the authors below

--This protocol describes the design of a study investigating the implementation and clinical outcomes of a program on integrating mental health care for severe mental disorders into primary health care in rural Rwanda. The program adapted a successful program of supported supervision for task shifting of HIV care in Rwanda.

Specific comments:
1. The title should reflect that this is a protocol.

The title has been updated to reflect that this is a protocol.

2. Page 3, line 2: 'Task sharing' is now the preferred term to 'task shifting' given that it emphasizes the need for sharing of tasks between less specialized health workers and the need to ensure adequate supervision and support to avoid 'task dumping'.

Task-shifting has been changed to task-sharing in this line (page 3, line 13-14)

3. Page 4, lines 14-17: More detail on the training programme is suggested. In addition, were any guidelines made available for nurses e.g. the World Health Organization mhGAP Intervention Guide (mhGAP-IG) for mental, neurological and substance use disorders for non-specialist health settings?

Significantly more detail on the training program has been added, in addition to description of the use of mh-GAP (section entitled MESH MH program)

4. Page 4, lines 25-28, the authors seem to be describing a quality improvement process. The authors are requested to elaborate on this process. For example, how were systems-based performance issues and 'quality gaps' identified. How were identified plans for improving these issues monitored?

Identified plans for improving the issues were monitored by the systems facility checklist, and returned to on a weekly basis until the issue was resolved. This is now described in the text outlining more details on the program (page 4 line 13-21)
5. Page 4, lines 33-38, the authors should reassess the use of the terms outcome and process evaluation. Outcome evaluation typically uses quantitative data to assess for changes in outcomes and process evaluation typically uses qualitative interviews to explore perceptions and experiences as well as process indicators to assess changes in the uptake of services etc as a result of the intervention.

The terms outcomes and processes have been reassessed and terminology streamlined to make more clear the proposal for studying the implementation of this program. Specifically, the quantitative evaluation has been renamed the “Quantitative Outcomes Evaluation” and the program processes have all been renamed as one “Process Evaluation” including the process indicators of service use (Process Aim 1), quality of care (Process Aim 2), and the qualitative semi-structured interviews of nurses, patients and families’ experience of the program (Process Aim 3).

6. Page 6, lines 14-31, a description of the outcome measures used and reasons for choosing the identified measures should be provided. Given the focus on severe mental disorders, the choice of the GHQ-12 is surprising given that it is commonly used as a screening instrument for common mental disorders, as well as being a more general measure of psychosocial well-being.

The GHQ-12 is a non-specific measure of psychological distress that can be used across a variety of diagnoses, and this is why it was chosen as our patient population consists of a heterogenous population. This is now more fully described in the section entitled “Outcomes Evaluation (Quantitative Pre- and Post- Intervention Analysis), section Data collection, measurement and outcomes”.

7. On page 7, line 15 – review heading “Qualitative outcomes evaluation specific aim” in light of point 3 above. The same goes for page 8, line 25.

The specific aims have been renamed to reflect the changes. The quantitative outcome analysis is now the primary outcome of the study, and the three process aims (service use, quality of care and qualitative process) have been renamed as such.

8. Page 7, line 51. From the description of the analysis – it would seem that thematic analysis is being planned rather than content analysis.

The qualitative analysis has been changed to thematic analysis rather than content analysis (see Process Evaluation Aim 3, Data analysis section).

Reviewer: 3
Reviewer Name: Charlotte Hanlon
Institution and Country: Addis Ababa University, College of Health Sciences, Department of Psychiatry & King's College London, Institute of Psychiatry, Psychology and Neuroscience, Centre for Global Mental Health
Please state any competing interests: None declared

Please leave your comments for the authors below

Evaluating a Primary Care Mental Health Integration Project in Burera District, Rwanda: A mixed methods outcome evaluation

The authors describe a protocol to evaluation of intervention of a model of integrating mental health into primary care for people with severe mental disorders in a rural African setting. This is a neglected
topic and there is a need for rigorous implementation research in this area. The paper needs some reworking to improve the methodological detail and situate the intervention in the recent literature in this area.

Title:
1. Need to specify that this is a ‘protocol’

The title has been changed to specify that this is a protocol.

Abstract:
2. The abstract has very little methodological detail. For a protocol paper, it is necessary to expand the methods part. At the least to provide the objectives/hypothesis, and describe the study design for the quantitative component, the sample sizes and proposed approach to analysis.

The abstract has been modified to include methodological detail as described in this comment (the hypothesis, study design, sample size and analysis approach). Please refer to edited abstract.

3. The abstract section on ‘ethics and dissemination’ does not seem to deal with these topics at all. Instead it seems to be describing potential impact of the study.

The ‘ethics and dissemination’ section has been edited appropriately to reflect the appropriate ethics approvals and dissemination plan.

4. The structure of the abstract is unconventional, with key words included in the middle.

Key words have been moved to the end of the strengths and limitations section.

Introduction
5. Please define what you mean by severe mental disorder. In the methods it seems as if the programme is more generally targeted, also including depression and epilepsy (not conventionally understood to be SMD)

The program is more generally targeted as mentioned by this reviewer. The text has been changed to reflect this and now uses the term ‘neuropsychiatric disorders’ to indicate the variety of diagnoses targeted by the program, rather than severe mental disorders.

6. It is difficult to talk about integration of mental health care into primary care without referring to the World Health Organisation’s mental health Gap Action Programme.

The mental health Gap Action Program has been cited in two places now in the text, to reflect its role in the MESH MH program development (references 7 and 15).

7. There are several other initiatives underway in Africa to integrate mental health into primary care for people with severe mental disorder (if you expand to include depression then there are many more). The PRIME project is particularly relevant as it is an implementation research programme focused on rural districts in Ethiopia and Uganda. Look also at the work of Rachel Jenkins in Kenya.

Please consider the following: (1-7)


The text has been updated to reflect ongoing global work in evaluation of integrated mental health programs across the globe (references 10-12 in the protocol).

Methods

8. The objectives of the study need to be specified clearly towards the beginning. At the moment there is a section entitled ‘overall objectives’ which just describes study methodology.

The study objectives have been clarified and listed in the “Study Objectives” section near the beginning of the proposal.

9. There is some confusion. The methods section starts with a description of where the intervention was implemented, but this is a protocol paper and should be describing the future planned intervention (which is an expansion of the intervention to new sites).

The protocol has been adapted to clarify the proposed study. The full program description which has been implemented is in the introduction section, and the description of the movement of the program to new health centers (where the intervention will be tested) is in the methods section in the section entitled “Study Design”.

10. More detail is needed about the intervention, in particular how it relates to evidence-based guidelines published by the WHO (mhGAP Intervention Guide) and the PLoS medicine packages of care for schizophrenia in LMICs (Jair Mari et al.). As well as training for primary care workers, is there any community level case-finding? Without that the intervention might not lead to increased uptake of services. Who trained the primary care workers? (it looks as if it was the psychiatric nurse but not fully clear)

Significantly more detail has been added to the text about the intervention (please see response to reviewer #2 as well). Please refer to the section entitled “MESH MH Program” in the Introduction, which outlines where the curriculum came from (mhGAP and PIH materials) as well as details around the training and community based case-finding approaches.

11. The study design for the quantitative component is not specified consistently. In the abstract it is described as a ‘prospective cohort’ but it is actually an intervention study so ‘uncontrolled before-after study’ would be more accurate.
The study design has been consistently changed to a quantitative outcomes evaluation with a pre- and post- test design.

12. Process evaluation aim 1 would be better described as an interrupted time series study.

The process evaluation does not consist of a named study but rather an assessment consisting of changes in process indicators (service use and quality of care) over time, as well as the qualitative interviews. These process indicators are meant to be associated with the outcomes evaluation to increase the plausibility of associating program outcomes with program processes.

13. For process evaluation aim 2 please specify the sample size for looking at change in checklist performance. This approach will give some indication of quality but the limitations need to acknowledge that this is obtained from routine recording and so the relationship with actual care is not known.

Sample size for checklist performance was not calculated. The study was powered for the outcomes analysis, and not for the process indicators such as checklist performance, which are assessments consisting of changes in process indicators over time. Limitations of this approach (as process data collected from routine recording) has been added to the discussion section as well as the “strengths and limitations” section of the proposal.

14. Before-after study
a. The cohort appears to be heterogeneous, including different disorders which makes it difficult to measure the relevant outcomes with sufficient power.

The study is powered to detect before and after differences in GHQ and WHO-DAS scores for the entire cohort, which are our primary stated outcomes (please refer to the section entitled “sample size” in the Outcomes Evaluation (Quantitative Pre- and Post- Intervention Analysis) section. The reviewer is correct that the study will not be powered within each group e.g. age, gender, health center, diagnosis etc, but these were not stated outcomes in the proposal, as this would require a large enough sample to not be feasible within the constraints of our study.

b. The WHODAS is relevant across disorders, but the GHQ will only be relevant to depression. Please provide information about the cultural validity and psychometric properties of the proposed scales.

The GHQ is a general measure of psychological distress (Goldberg D, Hillier VF. A scaled version of the General Health Questionnaire. Psychol Med 1979;9:139–45.) and was chosen given the heterogeneity of our population; we anticipate having patients across the spectrum of affective and psychotic disorders, as well as epilepsy, so this scale was chosen as the most parsimonious scale to use for a single symptom based scale. The GHQ and WHO-DAS have both been shown to be valid and reliable across multiple cultural settings and languages (references 19 and 20), and this has been updated in the text in section “Outcomes Evaluation (Quantitative Pre- and Post- Intervention Analysis), section Data collection, measurement and outcomes”.

c. What other co-variates/potential confounders are being measured – what about alcohol/substance use? And physical ill-health/disability?

All patients in our pre-post test design study serve as their own control, and therefore, patient level confounding is not a concern. We did not measure alcohol or consider substance use as a subgroup analysis as our study is a quantitative evaluation of the efficacy of a real-world public sector integrated mental health program, which did not focus on the management of substance use disorders, and
therefore people with substance use disorders were excluded from the evaluation (please see page 5 line 37-38). Physical health and disability is captured by the WHO-DAS Brief and thus we did not use a separate scale for this measurement.

d. With 6 months of follow-up and no control group the economic evaluation may be affected by seasonal effects.

The economic evaluation has been removed from the primary outcome aim, which now focuses solely on clinical symptoms and functioning.

15. Qualitative study
a. Reliance on ‘information rich’ respondents may not be appropriate in this case. People with SMD may struggle to engage in lengthy interviews and may not be ‘information rich’ in that sense but their perspective is clearly critical.

Participants in the qualitative interview will be selected by stratified purposeful sampling (see Process Aim #3, Study Population/Recruitment). This will allow us to choose a subset of the patients who are able to participate in the interviews. Although some people with SMD may struggle to participate in interviews, we anticipate that following treatment, our study population will include a sufficient number of patients who can meaningfully participate in interviews.

b. The topic guide doesn’t seem to cover cultural acceptability of care – will you be able to interview some people who dropped out of care?

Acceptability of care will be addressed in the qualitative interviews. We will not be able to interview those who dropped out of care as the study takes place during the course of regular care and ethics approval was not obtained to seek out patients who are no longer coming to the health center for care. However, we anticipate that these patients still in care will have meaningful information to share about the cultural acceptability of care, and as well, interviews with nurses about acceptability of care will also yield pertinent information about communities and the cultural acceptability of care delivered at the primary health centers.

16. Ethical considerations
a. The investigators will include people with SMD who are unable to answer for themselves due to illness. What safeguards will be employed for people who lack capacity to consent?

Although the risk of participation for patients is low (short interviews following routine mental health care), the research assistant will implement safeguards of our participants by emphasizing the voluntariness of patients’ participation to minimize risk of coercion, and as well, safeguards in case of increased patient distress will be addressed (please refer to Ethics and Dissemination section of proposal). Regarding patient consent: The Rwanda National Ethics Committee has mandated that all patients have a family member consent for patient participation in this study (please see responses to ethics comment by Reviewer #1 above). This removes the question of capacity as the RNEC has mandated that family consent must be obtained in addition to patient assent.

b. Under the section ‘patients’ (following the ethic section) the consent procedures are described. Patients are described as giving ‘assent’ (that is relevant for under-age patients but not for those who lack capacity) and caregivers providing consent, but patients may also be able to consent if they have decision-making capacity. How will capacity be evaluated?

The writers would like to highlight that this study was deemed exempt by the Institutional Review Board of Harvard University and therefore no specific consent process was required by Harvard
University. The Rwanda National Ethics Committee has mandated that all patients have a family member consent for patient participation in this study (please see responses to ethics comment by Reviewer #1 above and previous comment). This removes the need for capacity evaluation as the RNEC has assumed that at baseline, family consent must be obtained in addition to patient assent.

VERSION 2 – REVIEW

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>Francine Cournos</th>
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<tbody>
<tr>
<td></td>
<td>Mailman School of Public Health</td>
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<td>Columbia University</td>
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<tr>
<td>REVIEW RETURNED</td>
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GENERAL COMMENTS

I am following up on my previous comments:

My prior comment: There are a few changes that would improve this protocol. One would be to use sites where implementation will be delayed as control sites on at least a few very simple variables, such as whether visits for mental illness increased at those sites over the same period of time.

Authors' comment: Process indicator one includes the tracking of routine data including service visits, unique visits and diagnosis, at all health centers in the district for six months following entry into the MESH MH program. As the process indicators were designed to record routine data and assess their change over time, each site serves as its own ‘control’, rather than other health centers in the district. No mental health services are currently offered at those health centers prior to the MESH MH program implementation, so comparing service use at these health centers with those who have the MESH MH program services, would not provide a meaningful comparison.

My new comment: I'm fine with this answer. The authors are stating that there are no other forces at play that would lead to an increase in mental health services, and I assume that they are in a position to know this.

My prior comment: Another would be to build in a measure that tracks the improvement of epilepsy. I'm not familiar with the way response to epilepsy treatment is tracked since in the US and many other places outside of sub-Saharan Africa it's handled as a neurological disorder rather than a mental illness, but I would imagine tracking seizure frequency would be basic. The current measures are only indirectly informative about epilepsy outcomes.

Authors' comment: We have chosen the GHQ-12 and WHO-DAS brief because they are not specific to diagnosis and track psychological distress and disability in all of our included patients, who run the gamut from psychotic disorders to depressive disorders to epilepsy. This will allow us to ensure standardization in outcome measures regardless of diagnosis. We have chosen to use a general distress scale which can be used in all comers to the clinic as we are also assessing the accuracy of diagnosis provided by health center nurses as part of the study (please see table 2). Therefore, we do not want to choose outcome measures which are dependent on diagnosis, until we have assessed how accurate the diagnosis given by HC nurses actually are. Please also see edits in the text section entitled "Outcomes Evaluation (Quantitative Pre- and Post-..."
My new comment: I notice that the other two reviewers have also expressed concern about the measures being used. I think if the authors adhere to such nonspecific measures it will limit what they can conclude about outcomes. However, this study will hopefully be only one step in a series of steps to look at the effectiveness of the approach.

My prior comment: The protocol states that for qualitative interviews the research team will obtain the patient's assent and the relative's consent. Usually this is only done when the patient lacks capacity to consent, and capable patient's are allowed to consent for themselves, which is a more respectful approach.

Authors' comment: This is correct that people with mental disorders should be allowed to consent for themselves to participate in studies, while this proposal specifies that we will obtain assent from patients and consent from families. However, the Rwanda National Ethics Committee has mandated that for this protocol, assent be acquired from patients and consent from families. They stipulate this because according to Rwandan law, a person with a mental disorder cannot consent for research endeavors. Thus, this consent/assent process is written as such because the Rwanda ethics review has required this specific process in order to proceed with this study. Of note, this study has been deemed exempt by the Harvard University Institutional Review Board.

My new comment: I think the authors should explain this point in the manuscript since this is an atypical approach that does not recognize the fact that people with mental illness are usually just as capable as other populations to consent to research.
or not appropriate account is being taken of repeated measures. The participants will give written consent – what is the provision for non-literate participants?

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Francine Cournos
Institution and Country: Mailman School of Public Health, Columbia University
Please state any competing interests: None declared

Please leave your comments for the authors below

I am following up on my previous comments:

My prior comment: There are a few changes that would improve this protocol. One would be to use sites where implementation will be delayed as control sites on at least a few very simple variables, such as whether visits for mental illness increased at those sites over the same period of time.

Authors' comment: Process indicator one includes the tracking of routine data including service visits, unique visits and diagnosis, at all health centers in the district for six months following entry into the MESH MH program. As the process indicators were designed to record routine data and assess their change over time, each site serves as its own 'control', rather than other health centers in the district. No mental health services are currently offered at those health centers prior to the MESH MH program implementation, so comparing service use at these health centers with those who have the MESH MH program services, would not provide a meaningful comparison.

My new comment: I'm fine with this answer. The authors are stating that there are no other forces at play that would lead to an increase in mental health services, and I assume that they are in a position to know this.

As we (the authors of the study) represent both Partners In Health, the non-profit organization supporting MH service development in the district, as well as the Ministry of Health, who provides the services directly, we can definitively report that there are no other mental health service development initiatives occurring within the district at this time besides the one articulated here.

My prior comment: Another would be to build in a measure that tracks the improvement of epilepsy. I'm not familiar with the way response to epilepsy treatment is tracked since in the US and many other places outside of sub-Saharan Africa it's handled as a neurological disorder rather than a mental illness, but I would imagine tracking seizure frequency would be basic. The current measures are only indirectly informative about epilepsy outcomes.

Authors' comment: We have chosen the GHQ-12 and WHO-DAS brief because they are not specific to diagnosis and track psychological distress and disability in all of our included patients, who run the gamut from psychotic disorders to depressive disorders to epilepsy. This will allow us to ensure standardization in outcome measures regardless of diagnosis. We have chosen to use a general distress scale which can be used in all comers to the clinic as we are also assessing the accuracy of diagnosis provided by health center nurses as part of the study (please see table 2). Therefore, we do not want to choose outcome measures which are dependent on diagnosis, until we have assessed how accurate the diagnosis given by HC nurses actually are. Please also see edits in the text section entitled “Outcomes Evaluation (Quantitative Pre- and Post- Intervention Analysis), section Data collection, measurements and outcomes” to describe why these two scales were chosen.
My new comment: I notice that the other two reviewers have also expressed concern about the measures being used. I think if the authors' adhere to such nonspecific measures it will limit what they can conclude about outcomes. However, this study will hopefully be only one step in a series of steps to look at the effectiveness of the approach.

The GHQ-12 as well as the WHO-DAS Brief have been used in other settings for evaluation of clinical effectiveness for mental health care and neurological disorders in low resource settings (Lund et al. Outcomes of the Mental Health and Development Model in Rural Kenya: a 2-year prospective cohort intervention study, Int Health 2013;5:43-50). Although in an clinical trial setting we may potentially be able to have multiple scales and measures of clinical effectiveness, for feasibility purposes in our implementation study, we are using more general scales for psychological distress and functioning which will give us a more global impression of the symptom burden and functioning of patients pre- and post- intervention. As the reviewer mentions, this study will be the first of several looking at effectiveness, and we hope that our results will inform more specific evaluations in the future including epilepsy outcomes.

My prior comment: The protocol states that for qualitative interviews the research team will obtain the patient's assent and the relative's consent. Usually this is only done when the patient lacks capacity to consent, and capable patient's are allowed to consent for themselves, which is a more respectful approach.

Authors' comment: This is correct that people with mental disorders should be allowed to consent for themselves to participate in studies, while this proposal specifies that we will obtain assent from patients and consent from families. However, the Rwanda National Ethics Committee has mandated that for this protocol, assent be acquired from patients and consent from families. They stipulate this because according to Rwandan law, a person with a mental disorder cannot consent for research endeavors. Thus, this consent/assent process is written as such because the Rwanda ethics review has required this specific process in order to proceed with this study. Of note, this study has been deemed exempt by the Harvard University Institutional Review Board.

My new comment: I think the authors should explain this point in the manuscript since this is an atypical approach that does not recognize the fact that people with mental illness are usually just as capable as other populations to consent to research.

We agree with the assertions of reviewer FC, however the stipulations of the Rwanda National Ethics Committee have determined our consent process as articulated above. This has now also been articulated more clearly in the text, in the section “Ethics and Dissemination”.

Reviewer: 3
Reviewer Name: Charlotte Hanlon
Institution and Country: Addis Ababa University, College of Health Sciences, School of Medicine, Department of Psychiatry & King's College London, Institute of Psychiatry, Psychology and Neuroscience, Centre for Global Mental Health.
Please state any competing interests: None declared

Please leave your comments for the authors below

2nd review of BMJ Open paper
The authors have responded to most of my queries. The heterogeneity of the sample remains a concern in terms of the interpretability of the findings (after 6 months, most people with depression will remit, but one does not expect the same for psychosis.
Indeed, one does not necessarily expect high levels of ‘distress’ symptoms in people with psychosis. Our goal for this evaluation is to determine, across a heterogeneity of diagnoses and mental disorders, whether general distress has decreased and functioning increased in our patients, relative to program implementation. As expressed in the limitations, our study is not an RCT of an intervention compared with a control group, but rather an evaluation of implementation and clinical effectiveness of a task shared program capacitating primary care nurses to care for (almost all) comers to public primary care clinics in a real world setting. Our hypothesis is that regardless of diagnosis, distress will decrease and functioning will increase with quality care delivery by primary care nurses—rendering plausible the idea that the program has contributed to these outcomes.

It is generally preferred to use a term like ‘service user’ rather than ‘patient’.

We have changed the term “patient” to “service user” throughout the text.

The authors state that people with substance use problems will be excluded, which appears to be an important limitation. Many people with mental health problems have co-morbid substance use and this has an important bearing on outcome.

We are only excluding those with a primary substance use problem and no other diagnosed affective or psychotic disorder, so we do not anticipate that this will affect our results significantly as the vast majority of patients attending our services currently have a primary affective or psychotic disorder, or epilepsy. This has been clarified in our “Study Population/Recruitment” section.

It is a limitation of the study that the measure of psychological distress has not undergone cultural validation.

We have added this limitation to our discussion.

How is the ‘quality of diagnoses’ measured? (process aim 1)

Quality of diagnosis will be measured by the number of specific diagnoses occurring after implementation of the MESH MH program. As stated in the manuscript, we hypothesize that MESH MH supervision will lead to improvements in the number of individuals with specific mental health diagnoses post-MESH MH (compared with the current practice of diagnosing “mental trouble” across multiple diagnoses).

It is not clear from the description of the data analysis plan whether or not appropriate account is being taken of repeated measures.

We will not conduct repeated measures analyses. Alternatively, as described in the manuscript, we will quantify within-person change between baseline and each of the two follow-up points and test whether each the mean change is different than 0. This approach does not require adjusting the variance for multiple measurements within the same individual. In this version of the manuscript we clarify that we will identify variables associated with improvement at the end of follow-up only.

The participants will give written consent – what is the provision for non-literate participants?

Non-literate participants will use a thumbprint as is customary in Rwanda for consent by non-literate individuals within the health system. This has been added to the “Ethics and Dissemination” section.
<table>
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<tr>
<th>REVIEWER</th>
<th>Francine Cournos</th>
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<td>Columbia University</td>
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<td>REVIEW RETURNED</td>
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**GENERAL COMMENTS**

It's very important that you added the explanation for why people with mental disorders assent rather than consent to research in Rwanda. (Although unrelated to your study, revising these regulations to permit capable patients to consent to research would be a small step toward reducing the stigma of mental illness.)
Evaluating process and clinical outcomes of a primary care mental health integration project in rural Rwanda: a prospective mixed-methods protocol

Stephanie L Smith, Claire Nancy Misago, Robyn A Osrow, Molly F Franke, Jean Damascene Iyamuremye, Jeanne D'Arc Dusabeyezu, Achour A Mohand, Manzi Anatole, Yvonne Kayiteshonga and Giuseppe J Raviola

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