

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form ([see an example](#)) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Investigating community ownership of a text message program to improve adherence to antiretroviral therapy and provider-client communication: a mixed methods research protocol
AUTHORS	Mbuagbaw, Lawrence; Ongolo-Zogo, Pierre; Thabane, Lehana

VERSION 1 - REVIEW

REVIEWER	Patrizia Carrieri, INSERM U912 - Marseille
REVIEW RETURNED	04-Apr-2013

THE STUDY	<p>The authors present here a protocol concerning the involvement of the HIV community for an intervention improving adherence in Cameroon. The intervention consists in the use of text messages to improve adherence to antiretroviral therapy and reduce treatment interruptions.</p> <p>The protocol is well written and is based on combining qualitative and quantitative methods to assess the community capacity to build and perform this intervention and quantitative methods to explore acceptability issues.</p> <p>The authors could better describe how the intervention is likely to be built: 1) what does "text messages" mean? 2) How are they going to tailor messages to be sent? Or to send always the same? Or to randomize a set of text messages?</p> <p>It is also unclear to me whether other interventions to improve adherence are likely to be conducted by the community under a "package" including text messages. Will it be combined with other interventions (ex for sexual prevention?) - The way the intervention is likely to be performed is not adequately described.</p> <p>The way the outcome measure will be built is not detailed in depth. The authors simply say that the data collection tool for the quantitative phase will be developed from the qualitative strand. However, in the literature there are already several measures concerning acceptability and satisfaction which could be adapted or validated here.</p> <p>It would be helpful for the reader to understand whether the authors wish to invent new measures (maybe not as they do not mention the psychometric process which enables the creation of a new scale) or just better establishing the questions to better characterize acceptability and satisfaction.</p> <p>Also the statistical analysis of the outcome is not very clear – the</p>
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	<p>author cite polynomial, then multinomial logistic regression – they need to better detail this point – they don't know yet whether the outcome will be dichotomous or qualitative or ordinal.</p> <p>The authors do not mention whether this intervention is likely no to be feasible on people living with HIV with very low education level/lowesources or less acquainted with text messages – who are these people?</p>
REPORTING & ETHICS	Due the specificity of the study I am unable to say whether or not this protocol is reported according to standard approaches (ex: Strobe?).
GENERAL COMMENTS	<p>Though there is more interest in protocols of cohort studies or randomized trials, in this case and considering the context, the protocol presented here could be of some interest for other countries which need to transfer some tasks from health staff to the community. The use of mixed approaches also allows taking into account the sociocultural context.</p> <p>To conclude I would shorten the length of the manuscript which is rather long.</p>

REVIEWER	<p>Rashmi J Rodrigues Assistant Professor Community Health St John's Medical College Bangalore, India</p> <p>And Division of Global Health Department of Public Health Sciences Karolinska Institutet, Stockholm Sweden</p> <p>Conflict of interest- None declared</p>
REVIEW RETURNED	10-Apr-2013

THE STUDY	<p>Reference No 30- is it necessary? Date last accessed for online publications</p>
REPORTING & ETHICS	The intent to obtain ethical approval by the authors is seen, however it is considered necessary to obtain ethical clearance prior to publication, and the same mentioned in the paper.
GENERAL COMMENTS	<p>Introduction: Well written</p> <p>Page 6: Research questions: Who are the stakeholders in this program. Will focus group discussions with only PLHIV be sufficient to achieve your objectives?</p> <p>By community are you referring specifically to “the community of PLHIVs”? Is this your working definition for this work?</p> <p>Page 7: Mixed methods research questions: Are the themes related to opportunities and challenges involved in the community ownership of a text message project among PLHIV in Yaoundé, Cameroon, generalizable to a larger sample of PLHIV in</p>

	<p>Youndé? - What if they are not generalizable? How would this affect the next phase of your work? How do you plan to address such a situation?</p> <p>Methods and analysis: Overall well described</p> <p>Page 10</p> <p>Sampling:</p> <p>PLHIV with relevant experience related to community activities shall be selected based on any of the following criteria- Does this mean they needn't satisfy all the 3 criteria and could satisfy only one of them? And will they be included even if they are not willing to participate in a community owned text messaging program? Wouldn't it be necessary to have an opinion of those who do not wish to participate in such a program and identify reasons for the same? This would give an overall understanding of the motives and barriers to the program.</p> <p>Line 38: Narrative data is usually obtained when people relate experiences- they are not usually obtained from focus group discussions.</p> <p>Page 11: Data Collection: It may be advisable to mention audio recording earlier in the paragraph and subsequently refer to the same as the activity of the note taker.</p> <p>Page 12: Do you think you (as a community) are ready to run a text message project? - Would you be explaining to the group what the role of the community would be in running a text messaging project? Or do you expect the group to come up with their role and how they could contribute towards the project?</p> <p>Page 13: Quantitative strand: The questions will be close ended with simple yes or no responses. Wouldn't acquiescence be a problem with such expected responses? May be necessary to modify questions to obtain responses such that do not lead to acquiescence. These responses could then be converted to binary outcomes for analysis- do consider if possible.</p> <p>Page 13: Qualitative data analysis: Well described. However, is this a specific approach to data analysis? (ex. Qualitative content analysis)</p> <p>Additional comments: Consider including a brief discussion of the importance of community ownership of mobile phone text messaging in the context of Cameroon (mobile phone penetration, the role of the community in the project) and how the outcomes of this research could influence its development.</p>
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<p>Reviewer(s) Reports:</p> <p>Reviewer: Patrizia Carrieri, INSERM U912 - Marseille</p>	
<p>The authors present here a protocol concerning the involvement of the HIV community for an intervention improving adherence in Cameroon. The intervention consists in the use of text messages to improve adherence to antiretroviral therapy and reduce treatment interruptions. The protocol is well written and is based on combining qualitative and quantitative methods to assess the community capacity to build and perform this intervention and quantitative methods to explore acceptability issues.</p>	<p>We thank the reviewer for her positive comments.</p>
<p>The authors could better describe how the intervention is likely to be built: 1) what does "text messages" mean? 2) How are they going to tailor messages to be sent? Or to send always the same? Or to randomize a set of text messages?</p>	<p>We have provided a description of what we mean by "text messaging". See page 4, second paragraph, lines 3-4.</p> <p>The literature covers diverse ways of tailoring text messages, yet it is unclear which is most efficacious. We have highlighted the uncertainty in the optimal method of tailoring messages. See page four, last two lines and page 5, first line. We hope that community participation can improve tailoring of text messages.</p>
<p>It is also unclear to me whether other interventions to improve adherence are likely to be conducted by the community under a "package" including text messages. Will it be combined with other interventions (ex for sexual prevention?) - The way the intervention is likely to be performed is not adequately described.</p>	<p>We have provided more details on the intervention.</p> <p>The goal is to enhance adherence to medication, retention in care and communication between patients and health personnel. No other interventions will be added.</p> <p>We have provided a reference to our previous text messaging trial and a brief description of how we performed the intervention. See page 6, lines 2 and 3.</p>
<p>The way the outcome measure will be built is not detailed in depth. The authors simply say that the data collection tool for the quantitative phase will be developed from the qualitative strand. However, in the literature there are already several measures concerning acceptability and</p>	<p>This is an important limitation of the sequential exploratory mixed methods design. We don't know what concepts will arise from the focus group discussions.</p> <p>We are not going to be looking at satisfaction, but</p>

<p>satisfaction which could be adapted or validated here.</p> <p>It would be helpful for the reader to understand whether the authors wish to invent new measures (maybe not as they do not mention the psychometric process which enables the creation of a new scale) or just better establishing the questions to better characterize acceptability and satisfaction.</p>	<p>rather acceptability of ownership.</p> <p>We are not developing a new measure but building on the qualitative information to develop the quantitative section. We are going to establish the appropriate questions to gauge acceptability and preparedness. Participant acceptability will be measured based on the themes they generate as being important to acceptability in the qualitative strand.</p> <p>We will also borrow concepts from the existing literature and modify to suit our purpose. This has been clarified in the manuscript.</p> <p>See page 12 lines 10-11 and reference number 36.</p>
<p>Also the statistical analysis of the outcome is not very clear – the author cite polynomial, then multinomial logistic regression – they need to better detail this point – they don't know yet whether the outcome will be dichotomous or qualitative or ordinal.</p>	<p>We are going to measure different levels of acceptability on a Likert scale and will most likely use ordinal logistic regression. We have provided more detail on how we will analyse the quantitative data, and now use the term “ordinal” consistently. See Abstract, page 2, methods and analysis, line 4 and page 14, quantitative analysis, lines 4-5.</p>
<p>Due the specificity of the study I am unable to say</p> <p>The authors do not mention whether this intervention is likely to be feasible on people living with HIV with very low education level/low resources or less acquainted with text messages – who are these people?</p>	<p>The acceptability is an important component of the feasibility. We are measuring acceptability in a low-resource setting with widespread use of mobile phone text messaging. Acceptability will be lower in the people who are less acquainted with text messages and maybe in those with lower levels of education. We will therefore collect data on level of education, mobile phone ownership and familiarity with text messaging. See page 14, quantitative analysis, line 6.</p>
<p>Due the specificity of the study I am unable to say whether or not this protocol is reported according to standard approaches (ex: Strobe?).</p>	<p>This protocol is designed according to recommended guidelines for mixed-methods research.[1]</p>
<p>Though there is more interest in protocols of cohort studies or randomized trials, in this case and considering the context, the protocol presented here could be of some interest for other countries which need to transfer some tasks from health staff to the community. The use of mixed approaches also allows taking into account the sociocultural context.</p>	<p>We thank the reviewers for their positive comments.</p>
<p>To conclude I would shorten the length of the manuscript which is rather long.</p>	<p>Mixed-methods protocols are often quite lengthy, owing to the need to provide details on qualitative and quantitative research.</p>

VERSION 2 – REVIEW

REVIEWER	<p>Reviewer: Rashmi J Rodrigues Assistant Professor Community Health St John's Medical College Bangalore, India</p> <p>And Division of Global Health Department of Public Health Sciences Karolinska Institutet, Stockholm Sweden</p> <p>Conflict of interest- None declared</p>
REVIEW RETURNED	09-May-2013

THE STUDY	<p>The manuscript complies with guidelines for mixed methods.</p> <p>Some minor language edits may be necessary prior to publication</p> <p>Clarity regarding the sample size based on outcome measure is necessary- this has been described in the general comments section</p>
REPORTING & ETHICS	<p>Though i would prefer an IERB approval even for a protocol, if the journal does not need ethics approval for protocol publication, its ok by me.</p>
GENERAL COMMENTS	<p>First of all, I appreciate your effort at addressing the concerns of both the reviewers in a way that you considered most suitable,</p> <p>I however continue to have some concerns</p> <p>1. Abstract: Effects of many mobile phone interventions are often reduced by human resource shortages- this sentence does not appear later in your introduction. Neither have I come across reports that mention this disadvantage.</p> <p>I bring up this issue as recently developed mobile phone interventions; especially those that are SMS based are computerized requiring a human component only for the purpose of monitoring the intervention and follow-up with the patient. These follow ups can usually be planned with the counselor who routinely conducts counseling sessions with patients at pill refill visits.</p> <p>In this light I refer to the issue of stakeholders. While all beneficiaries are stakeholders not all stakeholders may be beneficiaries.</p> <p>I however understand that you have addressed this issue in the</p>

introduction.

2. Further, expecting an individual to constantly SMS another in the long run will involve several issues, one of which is the cost. While I understand that your study itself will provide answers regarding the costs a person is willing to bear for the intervention, it may be necessary to acquaint the readers with minimum costs of a call and SMS in the study setting and if possible the socioeconomic background of HIV infected individuals in this setting.

Also, in response to my question regarding mobile phone penetration you have added a sentence in the introduction- this sentence however does not seem to fit in with the rest of the text in the paragraph. Also a growth of mobile phones that you have indicated of 270% may indicate a growth from 10users/100 people to 40users/100people and hence does not give the right picture. Hence it may be advisable to do away with the sentence.

3. Sample size, quantitative strand:

My apologies for not having picked this up earlier.

The following are the issues identified:

You have used the Cochran's formula, however it is not clear if you have made sample size estimations based on whether your primary outcome is continuous, categorical or ordinal, especially as you say you have used a p of 5% margin of error for (categorical data) and standard deviation of 0.5 (7 point scale).

For categorical data with binary outcomes the formula is (maximum sample size):

$(Z)^2 pq/d^2$ where, Z is the alpha error, p is the proportion, $q = 1-p$ and $d = \text{precision of the estimate}$.

For the largest possible sample size q is considered to be 0.5. For categorical data usually a precision estimate of 5% is used. Using this formula, based on the values that you have provided we get a sample size of 384, which is, reduced 363 based on the finite correction. With the 10% refusal rate that you have considered we get a sample of about 400.

Another point to note here is that refusals cannot be considered in

the sample, i.e. they are completely excluded from the sample, therefore you cannot adjust for 10% refusal as these are not participants (in follow up studies a 10% drop out rate is used which is not the same as refusal rate).

For continuous data the formula is: $Z^2 s^2 / d^2$, where 's' is the standard deviation. However unlike for proportions of categorical data a standard deviation of >0.5 will yield a greater sample size and it does not seem logical to use a standard deviation of 0.5 unless there is a specific reason (previous evidence) to do so.

Therefore it is important for you to decide whether you want to consider your variable categorical or continuous and if categorical then for Cochran's formula you will have you measure it as binary and not on a 7point scale.

For the 7-point ordinal (Likert) scale, the correlation co-efficient rho, variance and the number of points on the scale are included the equation, i.e. a different formula could be used. There is also some reference to a simpler formula for an ordinal scale i.e. $Z^2 s^2 / (db)^2$ where 's' is the standard deviation and 'b' is the number of points on the Likert scale- this is best checked with a statistician.

4. In ordinal regression you will probably obtain proportional odds ratios.

5. You have mentioned best case and worst-case scenario approach- this is usually used in quantitative data analysis and not qualitative. Further bracketing is used in "phenomenology" in qualitative analysis. Here the researcher tries to analyse qualitative data in an unbiased manner by trying to mitigate possible preconception on the part of the interviewer during the interview.

6. How do you plan to ensure gender equity in your study, will your sample (both qualitative and quantitative) have equal numbers of men and women or will it be representative of the population of HIV infected individuals in Cameroon.

7. In the abstract it should be ordinal regression and not ordinal multivariable regression.

VERSION 2 – AUTHOR RESPONSE

Comment	Response
<p>From the managing editor:</p> <p>Ethics clearance will be required before we publish the protocol.</p>	<p>We are pleased to inform you that we have approval from the IRB of the Yaounde Central Hospital. N°288L/MINSANTE/SG/DHCY/Stages on the 16th May 2013.</p> <p>We have added this to the manuscript. See abstract and page 18, ethics and dissemination.</p>
<p>Reviewer: Reviewer: Rashmi J Rodrigues</p>	
<p>Some minor language edits may be necessary prior to publication</p>	<p>The entire manuscript has been revised by a native English speaker. Additional edits by the editorial team are welcome.</p>
<p>Clarity regarding the sample size based on outcome measure is necessary.</p>	<p>See responses below.</p>
<p>Though i would prefer an IERB approval even for a protocol, if the journal does not need ethics approval for protocol publication, its ok by me.</p>	<p>We are pleased to inform you that we have approval from the IRB of the Yaounde Central Hospital. N°288L/MINSANTE/SG/DHCY/Stages on the 16th May 2013.</p> <p>We have added this to the manuscript. See abstract and page 18, ethics and dissemination.</p>
<p>First of all, I appreciate your effort at addressing the concerns of both the reviewers in a way that you considered most suitable,</p> <p>I however continue to have some concerns</p>	<p>We have addressed these comments below.</p>

<p>1. Abstract: Effects of many mobile phone interventions are often reduced by human resource shortages- this sentence does not appear later in your introduction. Neither have I come across reports that mention this disadvantage.</p> <p>I bring up this issue as recently developed mobile phone interventions; especially those that are SMS based are computerized requiring a human component only for the purpose of monitoring the intervention and follow-up with the patient. These follow ups can usually be planned with the counselor who routinely conducts counseling sessions with patients at pill refill visits.</p>	<p>We appreciate the reviewer highlighting this point, and agree that it requires some clarification.</p> <p>The point we are trying to make here is that the maximum benefits of SMS interventions cannot be achieved if human resource shortages like insufficient staff for counselling, home visits, or timely medication dispensing are not resolved.</p> <p>We have other published material describing the accrued demands on the health care system when two-way communication using text messages is established. We invite the reviewer to see the manuscript in question:</p> <p><i>Mbuagbaw L, Thabane L, Ongolo-Zogo P. Opening communication channels with people living with HIV using mobile phone text messaging: Insights from the CAMPS trial. BMC Res Notes. Apr 4 2013;6(1):131.</i></p> <p>We have rephrased the abstract and introduction. See page 5, lines 8-9.</p>
<p>In this light I refer to the issue of stakeholders. While all beneficiaries are stakeholders not all stakeholders may be beneficiaries.</p> <p>I however understand that you have addressed this issue in the introduction.</p>	<p>This is true indeed. The beneficiaries are mostly involved in the evidence generation, while we involve all the other stakeholders in our dissemination plans.</p>
<p>2. Further, expecting an individual to constantly SMS another in the long run will involve several issues, one of which is the cost. While I understand that your study itself will provide answers regarding the costs a person is willing to bear for the intervention, it may be necessary to acquaint the readers with minimum costs of a call and SMS in the study setting and if possible the socioeconomic background of HIV infected individuals in this setting.</p>	<p>We do not intend for individuals to constantly SMS each other but to manage the content, timing and subscription to an automated service.</p> <p>We have added details on the cost of mobile communication in Cameroon.</p>
<p>Also, in response to my question regarding mobile phone penetration you have added a sentence in the</p>	<p>This sentence has been replaced by a more informative reference, "Cameroon also has a high mobile phone</p>

<p>introduction- this sentence however does not seem to fit in with the rest of the text in the paragraph. Also a growth of mobile phones that you have indicated of 270% may indicate a growth from 10users/100 people to 40users/100people and hence does not give the right picture. Hence it may be advisable to do away with the sentence.</p>	<p>penetration, with 52 mobile cellular subscriptions per 100 people in 2012". See page 5, line 10.</p>
<p>3. Sample size, quantitative strand: My apologies for not having picked this up earlier. The following are the issues identified: You have used the Cochran's formula, however it is not clear if you have made sample size estimations based on whether your primary outcome is continuous, categorical or ordinal, especially as you say you have used a p of 5% margin of error for (categorical data) and standard deviation of 0.5 (7 point scale). For categorical data with binary outcomes the formula is (maximum sample size): $(Z)^2pq/d^2$ where, Z is the alpha error, p is the proportion, $q = 1-p$ and $d = \text{precision of the estimate}$. For the largest possible sample size q is considered to be 0.5. For categorical data usually a precision estimate of 5% is used. Using this formula, based on the values that you have provided we get a sample size of 384, which is, reduced 363 based on the finite correction. With the 10% refusal rate that you have considered we get a sample of about 400.</p>	<p>This is the formula we used. We have specified that it is for a binary outcome. See page 11, line 12.</p> <p>We would like to draw the reviewer's attention to the uncertainty in the kinds of variables that may emerge from the qualitative strand of this study.</p> <p>We opt for a binary outcome which will provide us with the largest possible sample size.</p>
<p>Another point to note here is that refusals cannot be considered in the sample, i.e. they are completely excluded from the sample, therefore you cannot adjust for 10% refusal as these are not participants (in follow up studies a 10% drop out rate is used which is not the same as refusal rate).</p>	<p>We agree that we cannot adjust for refusal as they are not part of the sample. The idea here is to invite participants until we achieve the required sample size. Our plans, in terms of time and resources will include the possibility that 10% of the people approached with decline to participate. Such anticipation is recommended for cross-sectional surveys in statistical texts:</p> <p><i>See: Bartlett JE, Kotrlík JW, Higgins CC. Organizational research: Determining appropriate sample size in survey research. Information Technology, Learning, and Performance Journal 2001;19(1):43-50</i></p>
<p>For continuous data the formula is: Z^2s^2/d^2, where 's' is the standard deviation. However unlike for proportions of categorical data a standard deviation of >0.5 will yield a greater sample size and it does not seem logical to use a standard deviation of 0.5 unless there is a specific reason (previous evidence) to do so.</p>	<p>We are not using a continuous outcome.</p>

<p>Therefore it is important to for you to decide whether you want to consider your variable categorical or continuous and if categorical then for Cochran's formula you will have you measure it as binary and not on a 7point scale.</p>	<p>We have modified this section to reflect our use of Cochran's formula for a binary outcome. See page 11, line 12.</p>
<p>For the 7-point ordinal (Likert) scale, the correlation coefficient rho, variance and the number of points on the scale are included the equation, i.e. a different formula could be used. There is also some reference to a simpler formula for an ordinal scale i.e. $Z^2s^2/(db)^2$ where 's' is the standard deviation and 'b' is the number of points on the Likert scale- this is best checked with a statistician.</p>	<p>We consulted a statistician on this question.</p> <p>The correlation coefficient in this formula refers to repeated measures, in which the responses in pre-post interviews are correlated because they are from the same person.</p> <p>Our study is cross-sectional and data will be collected only once.</p>
<p>4. In ordinal regression you will probably obtain proportional odds ratios.</p>	<p>For a binary primary outcome we will use binary logistic regression.</p>
<p>5. You have mentioned best case and worst-case scenario approach- this is usually used in quantitative data analysis and not qualitative. Further bracketing is used in "phenomenology" in qualitative analysis. Here the researcher tries to analyse qualitative data in an unbiased manner by trying to mitigate possible preconception on the part of the interviewer during the interview.</p>	<p>We appreciate this comment. In this paragraph (page 15, last paragraph) we are simply listing our analytic options in case the data are conflicting.</p>
<p>6. How do you plan to ensure gender equity in your study, will your sample (both qualitative and quantitative) have equal numbers of men and women or will it be representative of the population of HIV infected individuals in Cameroon.</p>	<p>Our sample will be representative of people living with HIV in Cameroon. Almost three times more women are in infected.</p> <p>However, gender is one of the socio-demographic variables we will be looking at to determine its effects on community readiness and ownership.</p>
<p>7. In the abstract it should be ordinal regression and not ordinal multivariable regression.</p>	<p>We have modified the abstract. It is now binary logistic regression.</p>