Author's response to reviews

Title: Development of a Nursing Intervention to Facilitate Optimal Antiretroviral Treatment Taking among People living with HIV

Authors:

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Author's response to reviews: see over
Reviewer's report
Reviewer: Jill Francis

Reviewer's report:
Discretionary Revisions
1. Page 3: “overall needs” – I am unclear what this term means. Whose needs? Is need the issue or are there other types of factors that could be addressed?

Change has not been done.

2. At the top of Page 5, the sentence commencing, “the needs assessment ends with…” would benefit from a reminder to the reader of the basis of this work in intervention mapping (ref 16, 17).

Clarification has been done.

Minor essential revisions
1. Introduction: I agree that ARV treatments probably bring hope to people living with HIV-AIDS, but the first three publications cited did not measure hope and so, for a scientific publication, it is probably preferable to report only what was measured in these studies.

Correction has been made.

2. Page 3: “asses” should be “assess”.

Change has been done.

3. Mapping of the list of intervention mapping steps on to the structure of the paper: To be consistent the literature review (Page 4) should precede the “analysis of target population” (Page 3). Presenting the literature review first would strengthen the analysis section. For example, before referring to the lack of interventions to make taking antiretroviral treatments “easier” it would be helpful to have evidence that this factor is a predictor of the treatment taking behaviour.

In the IM approach, the first step is Needs assessment. At this stage two operations are performed in parallel: analysis of the target population and analysis behaviour. Interest for developing an intervention arose from an evident need in this population. As such we have given a succinct presentation of this before the literature review.

4. Page 4: The refusal of one (out of two) clinic to participate requires further comment. Can the authors provide any evidence that the clients of these two major centres do not differ significantly on measurable factors? This would have important implications for the potential generalisability of the intervention developed. Why was Montreal the only location selected? Are there other centre in the Province that could have provided variation in key variables and thus results in a more generalisable intervention? In
addition, this point is introduced too early as it relates only to Step 5. Hence, it is a distraction at this point.

This part has been removed. At this step our interest is not to generalize but to describe the intervention developed by means of the Intervention Mapping approach.

5. Page 4: “High perception of self-efficacy” – Self-efficacy is, by definition, a perception, so “perception of” is not needed in this phrase.

Change has been done

6. Page 4: Is there a difference between “attitudes” and “personal attitudes”? I think all attitudes are “personal”.

Change has been done. The term “attitudes” is used instead of “personal attitudes”.

7. Page 5: The desired behavioural outcome are specified as “enhance self-efficacy and positive attitudes to facilitate optimal antiretroviral treatment taking …”. I think that self-efficacy and attitudes are cognitive outcomes, not behavioural outcomes. It would be preferable to specify the behavioural outcome (i.e., optimal antiretroviral treatment taking) and reiterate that the proposed mediators of this change (self-efficacy and attitude) would be the proximal targets of the intervention.

Clarification has been added.

8. On Page 5, although I see the distinction between “behavioural outcomes” and “performance objectives”, I do not understand the shift from “behavioural” to “performance” here. Presumably these are “behavioural objectives”?

According to the Intervention Mapping approach the behavioural outcome, that is, optimal antiretroviral treatment taking, requires some sub-behaviours so that we called the performance objectives.

9. Table 1 and related text: This is rather confusing in its present state. First, it would be helpful if the POs in Column 1 matched the POs as described in the text. Second, I do not understand the sentence, “Change objectives were formulated by correlating the performance objectives with the predictors...”. The performance objectives and predictors were not measured as continuous variables and no correlations are reported. Do the authors mean to say that “Change objectives were formulated by examining the performance objectives in the light of the predictors”?

Yes, we do mean that “Change objectives were formulated by examining the performance objectives in the light of the predictors”. As such we reformulated this notion.

10. At this point, are “change objectives” the same as “intervention objectives”? If
so, consistent language should be used.

Change objectives are not the same as intervention objectives. Using IM to create a matrix of intervention objectives led us through several steps: specifying performance objectives, selecting predictors, and determining specific change objectives.

11. Page 5: I don’t fully understand the phrase “useful theory-based learning and behavioural-change strategies”. What is meant by ‘useful’? Do the strategies have to be evidence-based? What is the relationship between ‘learning strategies’ and ‘behavioural-change strategies’? I’m guessing that the former change knowledge and the latter change behaviour but I am not clear that both of these will be measured.

Clarification has been made.

12. I am not clear about what is an ‘intermediate theory’. I am guessing this refers to theories that might account for the identified predictors and propose mechanisms by which they influence behaviour.

Yes, the intermediate theory or middle-range theory refers to theories that might account for the identified predictors and propose mechanisms by which they influence behaviour.

13. Page 6: The authors twice state that Bandura “believes” a certain principle. Strictly, it is better to say that he “argues”, “proposes” or “theorises”, as these can be directly inferred from the publications and do not infer a current internal state. Similarly, I would recommend replacing “in Bandura’s opinion” with “According to Self-efficacy theory, …” and re-word the phrases, “He considers that ..” and similar phrases on Page 7: “Bandura sees”; “He considers”; “the author thinks’ etc. (Also, “consider” on Page 8.)

Correction has been made.


Change has been done.

15. Page 6: Re-wording is also advisable at “the most influential form of learning about self-efficacy”, as the point is not that individuals learn about self-efficacy. Rather, mastery experiences increase individuals’ self-efficacy.

Change has been done.

16. On Page 7, why does the term “self-efficacy” change to “personal efficacy”? Consistent wording would be preferable.

Change has been done.

17. Page 8: “resistance to change” should be “resistant to change”.
Change has been done.

18. Page 9: I am not clear about what is a “theoretical method”. Perhaps “theory-based method” is better.

In the Intervention Mapping Approach the expression used is “theoretical method”.

19. Page 9: The “philosophy of empowerment”. I do not think one needs both a theory and a philosophy in this situation. The construct, self-efficacy is absolutely about the individual’s control over his/her own situation and behaviour and increments in self-efficacy are presumably the same as “empowerment”. The presentation of a theory-based approach to intervention development is, I think, undermined by a sudden recourse to a philosophy. I have no quarrel with philosophies or value systems but the theory already described appears sufficient for this argument.

The theory of self efficacy is an intermediary one that specifies strategies to put forth to optimize taking treatments. However, it is a philosophy of empowerment that has encouraged us in making our intervention operational in the sense that we have defined the roles of care giver and receiver. In this way, the individual is viewed as an active participant in managing the health condition and the professional is a partner who guides and equips him or her.

20. Page 14: in what sense is the intervention “adapted”? What has it been adapted from? I think perhaps the authors mean “designed”.

Change has been done.

21. Page 14: [Health professionals] “believe” [the intervention to be important]: As for an earlier point about inferring “belief” above, it would be better to say that they report that the intervention is acceptable etc.

Change has been done.

22. Page 15: I do not understand that phrase “almost entirely based on the component of information they provide”.

Clarification has been made.

23. Page 16: That prior evidence shows benefit of intervening with individuals rather than groups is surely important and should have featured earlier, as the basis for some of the decisions about how to deliver the intervention (page 9)?

The intervention was developed before the publication of this article.
24. Page 16: The idea of the Rueda’s “three criteria of efficacy” is introduced here but needs explanation.

In the preceding paragraph we put together the three criteria of efficacy.

Major compulsory revisions
1. Rationale: That no previous interventions have been “based on a theoretical framework that provides a comprehensive understanding of the behaviour …” is a strong rationale for the study. The fact that no intervention has been developed for Quebec is less persuasive. The other persuasive factor, to me, would be if the authors argued that that the five interventions that have been demonstrated to have a clinical effect are inadequate or could be optimised.

This intervention was developed in response to an important need; Supporting PLHIW in taking their antiretrovirals. The consequences of not taking this medication optimally are well documented. When the intervention was developed (2004-07) little conclusive data existed about the efficacy parameters of an intervention. In view of the fact that there were no systematic interventions in Quebec, we developed such an intervention in concert with researchers, clinicians and individuals living with HIV.

2. On page 5, five “performance objectives were formulated”. What were the methods used to formulate these objectives? Are they replicable and robust?

We used the Intervention approach to formulate the performance objectives. Performance objectives are sub-behaviours that detail what an individual needs to do to reach the behavioural outcome.

3. Figure 1: This is an effective figure but requires re-formatting. It would be a lot easier to understand if the outcome variable (treatment taking) is presented on the right hand side of the page, with predictors on the left, and intervention strategies and mediators in between predictors and outcomes. The use of “coping” in this figure could be updated: I think the authors are referring to what is now commonly referred to as “coping plans”.

Figure 1 is a schema or representation of the theoretical structure of the intervention. That structure is explained in greater depth in the text. As per the recommendation of one reviewer, we have added labels to the boxes to make it easier to understand the figure.

4. Page 9: Intervention description. I am assuming that the authors are presenting a scientific method for designing and intervention but I am not clear about the methods by which the authors move from the “methods” and “strategies”, or behaviour change techniques, listed in table 2 to the description of how these will be delivered (four 45- to 60-minute sessions with nurse, etc).

We developed the content of our intervention using practical strategies which have been transposed into a clinical context by a nurse and other health professionals, as well as
support personnel for persons living with HIV who are members of the membership committee of the coalition des organismes communautaires de lutte contre le SIDA.

5. Page 9: intervention description. I would like to see much more specific descriptions of what is actually said in each session (for example, presented in a Box). Alternatively, are the authors intending to upload the intervention manual or protocol that might include this kind of information?

After the completion of the RCT, our intervention manual will be made available.

6. Page 14: Importance ratings by health professionals and by HIV-positive individuals: these data, and quotations from their comments, should be reported in a Results section.

Section has been added in the implementation part.

7. Page 15: The evaluation is an important step. I assume that this paper is reporting the evaluation plans rather than the evaluation itself. These plans should include an indication of how the key variables will be assessed. What will be the measure of “taking treatment in an optimal manner”? How will the proposed mediators be measured? Will participants be randomised and how will contamination effects between intervention and control groups be avoided?

Section has been added in the implementation part.

Quality of written English: Needs some language corrections before being Published

The entire paper has been edited.

**Reviewer’s report**

**Reviewer:** Gerjo Kok

1. Authors missed a relevant article: de Bruin et al., 2005, AIDS PATIENT CARE and STDs, 19, 384-394.

The above interesting pilot study was assessed in our reflections on the development of our intervention. We did not cite it because it was a pilot study and in the article we make reference to randomized trials.

2. Some details of the IM application are a little bit confusing, the last sentence of step 1 mentions the behaviors and the influencing factors, while the outcome is only described in terms of behaviors. Both are OK but they should be correspondend.

Clarification has been done.

3. In table 2, the distinction between methods and strategies is not always clear because the description of the strategies is too short, for instance: feedback, reward, which would
in IM be seen as methods. I would suggest to use some more words to describe the actual practical strategy in these cases.

While some authors do consider feed-back to be a method, we think that a method is a theory-based technique of influencing behaviour and that a strategy is a way of organizing an intervention and making it operational. For example, verbal persuasion can be a source of a feeling of self-efficacy and, as such, is a method. We begin to put this method into operation with constructive feed-back on the acquisition of skills.

**Reviewer's report**
**Reviewer:** Gozde Ozakinci

**Major compulsory revisions:**
1. The paragraph before Step 2 tries to identify the outcome of this intervention which is framed in terms of behavioural change. However, they report in that sentence that the outcomes relate to enhancing self-efficacy and positive attitudes. The ultimate outcome of this intervention sounds like is increasing adherence. However, this is aimed to be achieved by self-efficacy and attitude change. The authors need to be clear about outcomes and potential mediators and moderators.

Clarification has been added.

2. The authors report the work they have done in the Step 5 (Implementation). It would be quite useful to provide the data that support their conclusions that the intervention is acceptable, feasible etc.

Section in the implementation has been added.

**Minor essential revisions:**
1. The authors mention "adverse effects" under Analysis of Behaviour (I assume behaviour refers to 'adherence to treatment regimen' here). It's not clear what these 'adverse effects' mean.

« Adverse effects » has been change for Side effect.

2. The theoretical background is described in detail. Would it be worth to shorten these sections?

This section has been edited.

3. In second paragraph of Self-efficacy Theory heading, the authors put Bandura in parantheses without referencing it.

Change has been made.
4. The sentence in the second paragraph of the Persuasion Theory that begins with Petty and Caccioppo is confusing and would benefit from revising.

Text has been edited.

**Reviewer's report**

**Reviewer:** Mary Wells

**Minor essential revisions**

1. Figure 1 does not appear under the title. I assume it is the figure on p24. It might be helpful to add further labels e.g. Predictors to relevant boxes, and to delineate between the empirical and theoretical components, to aid clarity.

We have added labels to the boxes to make it easier to understand the figure.

2. Some minor revisions to Table 1 would help to reduce possible confusion. Table 1 presents and example of 2 performance objectives rather than a complete matrix of intervention objectives – this should be made clear. The text on p5 discusses “component parts of behavioural interventions” “change objectives” and “performance objectives”. However Table 1 uses the terminology of “Predictors” and does not specify that the objectives are “change objectives”. Sentence 2 of the text under Step 2 on p5 talks about “so called performance objectives” and it is not clear whether this refers to functional capabilities or change objectives.

Clarification and correction have been made.

3. There are a couple of typos e.g. trails on p16. I have some queries over some of the references e.g. should ref at top of p16 be 14 not 15?; should ref for mnemonic DECIDE on p16 really be Bandura?

Correction has been made. Bandura suggests using a mnemonic phrase to help remember but it was us who recommend the phrase DECIDE.

4. The strengths and limitations of the IM approach should be discussed at least briefly.

**Strengths have been briefly discussed in the “discussion part”**.

**Discretionary revisions**

1. Can the authors comment on how IM relates to/differs from other models/ frameworks e.g. logic modelling, REAIM (Glasgow et al), MRC framework for the evaluation of complex interventions (which is in common use in UK)? For an international audience this would be useful, and would help those interested in intervention development (but not the specific area of antiretroviral medication) to engage more effectively with the paper.
This is an interesting observation but it goes beyond the scope of this article: i.e., to describe an intervention and its process of development.

2. Considerable detail is given for the theoretical and empirical basis of the content of the intervention. It would be helpful if the authors could comment on the characteristics of the nurse, training and supervision required and on the choice of intervention structure e.g. why 4 sessions?

We plan to elaborate more on the characteristics of the nurse in our final paper which will report on the result of RCT.

3. Some further detail about the target population and risks re engagement with the intervention itself. For instance, what are the sociodemographics of the population (other than that they are mostly gay men)?

The purpose of this article is to describe the intervention and the process of its development. We plan to elaborate on sociodemographics of the sample in the next paper in which the results of the RCT will be reported.

4. Could the authors comment on the sustainability of the intervention beyond the trial?

This issue will be discussed in the next article reporting the results of the trial.

5. Could the authors refer to the literature on concordance in their background section, illustrating how the evidence on antiretroviral treatment taking fits with evidence and theories related to concordance?

We are not familiar with the literature on concordance. However we will take it into consideration.