Reviewer's report

Title: An educational intervention to reduce pain and improve pain management for Malawian people living with HIV/AIDS and their family carers: study protocol for a randomised controlled trial

Version: 1 Date: 6 May 2013

Reviewer: Eve Namisango

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Major Compulsory Revisions

Background
1. p.2: it is referred to as the APCA African POS (the authors dropped APCA)
2. p.4: I don't think Africa has 10% of world population but larger than that (15%?) and the authors need a reference.
3. p.5: second paragraph has a number of statements without supportive references.
4. p.6 The hypotheses being tested should be made more specific for example how is improved quality of life defined? Or how is reduced pain defined?
5. The hypotheses are too crowded and could be split further for clarity for example one hypothesis could focus on pain and quality of life (all are patient outcomes) then hypothesis 2 could focus on improved knowledge and skills in managing pain

Methods
6. p.6 Is there a justification for the selection of these study settings?
7. p.7: neurological health problems: who determines if these are present and how?
8. p.7 is there any exclusion criteria for carers?
9. The authors should appreciate the inherent challenge of incomplete data for most patients so it is important to document how the study participants will be selected. Will they rely on WHO staging based on existing records or patients will be staged on each clinic day?
10. The authors should also review literature on the incidence of pain and WHO clinical stage alongside the literature on pain intensity and WHO clinical staging. This should strengthen their argument on why HIV/AIDS in clinical stages 1 and 2 have to be excluded; pain occurs for patients in all clinical stages certainly.

Randomisation
11. It is also stated that after two weeks “participants receive a phone call
reminder to enquire whether they have any further questions after reading the leaflet” – how will this be handled for the illiterate which is a reasonable number in Africa.

Measures

12. The primary outcome is pain intensity measured using Brief pain Inventory – the authors should provide more details here; I guess pain intensity will be assessed for the sub-sample that will report pain during the study period but this is not well articulated in the paper.

13. It is also not clear if the primary outcome will be treated as continuous or ordinal outcome. Secondly the authors need to justify why they are opting for average pain.

14. How will a clinically significant change be defined?

15. How will quality of life be measured or are authors relying on items that look at the impact of pain of the various functional domains of the BPI? This should be stated explicitly.

16. What conceptual framework that guided the intervention which aims to improve pain management from the side of patients and carers? This component is not well articulated for readers to appreciate how the intervention may lead to improvement in pain management from patient/carer perspective.

In general this section is quite vague and unclear.

17. There are a number of tools described but no discussion re. their validation in SSA and, if they are not, what impact that could have and how it can be mitigated.

18. Yes there are 10 items in the APCA African POS but, 7 are for patients and 3 are for carers; as such, the score range is not 0-50 but (and assuming they reverse scores so they are all scored in the same direction), 0-35 for patients and 0=15 for carers.

19. The authors should align the analysis plan to the hypothesis being tested for example when the null is rejected for the various outcomes of interest, considering the central theme of clinical significance

Minor Essential Revisions

20. The negative impact of pain on quality of life has been documented in Africa as well so this literature should be incorporated

21. Gifford et al, 1998 ref; the authors are using a numerical referencing system so do not use both.

22. Reference to ‘randomly allocated’: can put in brackets that this is elaborated below.

23. What do authors mean by participants’ details?
Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no conflict of interest