Reviewer's report

Title: GoLBeT [Gojjam Lymphoedema Best practice Trial] - Evaluation of effectiveness of treatment for podoconiosis (non-filarial elephantiasis): study protocol for a randomised controlled trial

Version: 2 Date: 9 April 2015

Reviewer: Achim Hoerauf

Reviewer's report:

Major Compulsory Revisions:

Table 1 and Endpoints and Outcomes and measurements:
Is it possible for you to describe in more detail, how you plan to assess the number of acute attacks, especially in patients who are not able to write and therefore will have difficulties to write their own diary?

Table 1:
Regarding the clinical stage of disease you mention a scale specifically developed for use in podoconiosis patients. Could you please add a reference or describe the staging in more detail?

Table 1:
Who developed the scale to measure the perceived stigma? Could you please add a reference?

Sample size and statistical methods:
Could you please describe how you calculated the 40% increase to enable adjustment for 4 confounders? What will be the statistical method to analyse your primary outcome? This should be stated in the statistical methods.

Randomisation:
It is not clear how you plan to do the randomisation, are you going to randomise per kebele or per patient. If you randomise per patient, how do you plan to avoid a bias resulting from the fact that a participant for example, who is in the immediate treatment group shows his neighbour, who is in the delayed treatment group, what soap or ointment to use and how to apply the hygiene interventions? It is also not clear, why you do not randomise after checking the eligibility criteria as you state it in your study timeline (table 3). Table 3 and the text are contradictory.

Blinding and statistical methods:
In the Blinding paragraph you write that you will define an a priori analytical plan to avoid bias. That sounds as if you would develop the plan before starting with the study. But reading the statistical methods part it becomes clear that you want
to develop the plan before starting the analysis. Please state it more precisely.

Adverse event monitoring:
It would be more understandable for the reader if you write that you decided not to include a DSMB and then start with your arguments. This fact was not clear until one of the last sentences of the paragraph. Also in this paragraph you write that the control arm is standard of care, or no intervention. What do you mean with standard of care?

Minor Essential Revisions:
Last paragraph of outcomes and measurements:
the sentence structure is not clear.

In table 2, exclusion criteria 3, a bracket is missing, and exclusion criteria 4, the semicolon has to be deleted.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**
I have no competing interests.