Reviewer's report

Title: Development and testing of culture-sensitive patient information material for Turkish, Polish, Russian and Italian migrants with depression or chronic low back pain in a double-blind randomised-controlled trial (KULTINFO): A study protocol

Version: 1 Date: 26 February 2014

Reviewer: Ashley Bonner

Reviewer's report:

This was a very well written protocol.

Major Compulsory Revisions:

1. Issue: The statistical analysis and sample size calculations for any trial fundamentally depends on the primary outcome. The manuscript in its current state does not provide sufficient details about the primary outcome to determine if the statistical analysis or sample size calculations are appropriate. The primary outcome for this trial is a measurement of perceived usefulness of the written patient information material. It is measured by the patient based on the Usefulness Scale for Patient Information Material (USE), that the authors mention is currently being developed. Requested resolution: Adding a description of the expected numerical range of this scale and nature of how the patients will respond to this scale would allow the analysis and sample size calculation portion of the manuscript to be interpreted and critiqued. Alternatively, if the development of the scale is at such a premature stage where this information is not known, adjustment of the statistical analysis section to include options, such as non-parametric tests if suitable for the outcome (e.g., Wilcoxon test), would be appropriate.

Minor Essential Revisions:

None

Discretionary Revisions:

None

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

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

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