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: 10 February 2014

Reviewer: Reitze Rodseth

Reviewer’s report:

Thank you for the opportunity to review this manuscript. In this protocol the authors have designed a trial that attempts to determine the impact of culturally-sensitive information material provided to primary care patients with a migration background suffering from depression or chronic lower back pain in comparison to the administration of non-culturally adapted information material.

Major compulsory

The design chosen for this study is a double-blind, randomized controlled multicentre trial. This design is appropriate to address the question being posed in the trial objectives. The broad inclusion criteria used make it very likely that the results seen in this trial will be generalisable to the broader medical community.

What I am not clear on is what exactly is meant by culturally-sensitive information. The target groups in this study are Turkish, Polish, Russian, and Italian. I can understand that these groups have different cultural norms to the German population. However, the degree of cultural variance with regard to the German population will obviously not be the same between the four groups. Reading the process by which the interventions will be developed I surmise that the interventions for each of the groups will differ from each other. One could further deduct that in populations where the material undergoes the greatest degree of modification you would then expect the greatest impact. All this would suggest that the intervention being studied would not have the same impact across the entire group.

The randomization and allocation process seem robust and the blinding method seems appropriate for the situation. I am not convinced that patients would not be able to identify culturally-sensitive material, however, if the data collection is blinded, which it is, this should be adequate.

The primary outcome of the trial is the perceived usefulness of the material. What
would constitute a clinically significant change in this usefulness score? This would be of vital importance when determining the sample size required for a successful trial. It is a pity that the trial has not been designed to address a more clinically robust outcome. Further, the score is being developed on an inpatient population and has not been validated outside the hospital. Why would the authors believe this score to perform as well in an outpatient population without having tested it?

Why will a one-sided t-test be used for scoring comparison? Surely it is possible that this material could result in patients perceiving it as less useful?

Please specify the direction that you expect to see in the sub-group analysis.

I am concerned about the method by which the sample size has been calculated. First, it is not clear what a clinically significant improvement usefulness would be. Second, as the score has not yet been developed I am not clear what the normal variance of such a score would be. Developing the score in an inpatient setting, and then using this score to design an outpatient study, without validating the score, is concerning. Third, there is a high likelihood that there will be a different treatment effect from the intervention across the four groups. When taking these factors into account, as well as the multi-factorial nature of this intervention I believe this to be an over optimistically small sample size. The dropout rate is probably realistic though.

Minor essential
The manuscript could be improved by minor language and grammar changes. For example “low back pain” should rather be written as “lower back pain”; “culture-sensitive” should read “culturally sensitive”. Words such as “operationalised” (pg 5) are not commonly used and alternative synonyms should be chose. Similarly the abstract states “...are only insufficiently reached by existing...” should read “... inadequately reached by existing...”

Summary
The trial seems to be robust, and sufficient details have been provided to allow replication of the work. However, the sample size would seem to be inadequate and I have serious reservation about the scale that is to be used to evaluate the primary outcome.

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

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

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

Declaration of competing interests:
No conflicts