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

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Reviewer: James Paul

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

Methodology: multicenter (4 institutions in Germany), double-blind randomised-controlled parallel-group study

Population: 480 patients with a Turkish, Polish, Russian or Italian migration background with a diagnosis of depressive disorder or chronic low back pain will be included. The sample size was rationalized with an anticipated Cohen’s d of 0.3 which is a small treatment effect as it assumes the difference in the primary outcome will amount to one third of a standard deviation. In addition the authors allowed for a 40% loss to followup which is reasonable for a questionnaire study.

Intervention: Culture-sensitive patient information was handed to the patient at the end of the physician consultation.

Control: Standard translated patient information material will be administered.

Outcome(s) & Timeframe: Questionnaire after the physician consultation, and at 8 weeks and 6 months following the consultation. Primary outcome was subjective usefulness.

Analysis: The primary outcome (usefulness of written patient information material; USE) will be analyzed with a one-sided t-test comparing the scores on the USE between the intervention and the control group.

Instrument development:

Methodological Issues

Major Compulsory Revisions

1. It is possible that the intervention could reduce the perceived usefulness of the patient information, hence the primary analysis should use a two-sided t-test.

2. Reliability and validity of the Usefulness Scale on Patient Information (USE) needs to be evaluated, either during its current development or in the design of this trial. Test retest reliability should be assessed and so should construct validity. If the patient information package is deemed as useful by the patient then presumably the patient understands their disease better. Maybe the patients
can be tested on their disease, either by another questionnaire, and see if scoring well on the USE correlates with increased knowledge about their diagnosis.

3. The impact of the information package might differ between patients with depression and low back pain. Particularly, patients with depression might be less receptive to an information package, regardless of its quality, given the nature of their condition. Also, the impact of the information package might differ depending on their course with their condition. Patients doing well with treatment might rate the usefulness of the package better for example. It would be worth quantifying the results overall and by disease type to explore this. The sample size might have to be adjusted accordingly.

4. The intervention might have a different impact on different cultures, with some finding in more or less useful. This variability in results might also increase the required sample size.

5. As acknowledged by the study team, the planned intervention is quite complex, especially the cultural adaptation aspect. In order to aim for a consistent impact of the tool for all populations the cultural adaptation aspect should focus on presentation and not the content of the material.

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

**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:**

None.