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: Maura Marcucci

Reviewer's report:

Comments to the authors

Hölzel and colleagues present the protocol of a randomized controlled trial on the usefulness of culture-sensitive health information material compared to standard translated information on depression or chronic low back pain for patients with a migration background living in Germany. The topic is surely interesting, and the background information describes a condition of equipoise and supports the rationale of the study. The protocol is well written and easily readable. The research question is quite well translated into appropriate methods. However, some relevant details to judge the internal and external validity of the study appear under-developed/reported throughout the protocol. See comments below.

Major Compulsory Revisions

#1 Setting. The information on the study setting (primary care) is missing in the abstract and in the formulation of the study question. In general, the importance of the setting is overlooked throughout the protocol, whereas it is fundamental for the interpretation and the generalizability of the future study results. The same interventions could be tested in a different healthcare setting, for example in specialist clinics or in health services specialized in the assistance of migrants. The findings of the current study will not be necessarily interchangeable with the findings of these hypothetical studies conducted in different settings, with different patient populations. The rationale of the choice of the primary care as setting for the study should be added to the “METHODS/DESIGN” (perhaps after the last paragraph on page 4).

#2 General practitioner recruitment. How the general practitioners participating to the study will be recruited by the study centers should be specified. What is the existing relationship between the study centers and the primary cares?

#3 Patient inclusion criteria and recruitment. The protocol should state more clearly if it is the participating general practitioner to assess patient eligibility and which data source for patient socio-demographic and clinical information he/she will rely on. It should also specify which sampling method will be used to enroll patients, whether a consecutive approach can be accomplished. In addition it is not clear if any patient with a migration background affected by depression/chronic low back pain will be considered for inclusion regardless of
the reason for the consultation, or if the reason for the index consultation needs to be related to one of the two targeted diseases. With regards to the inclusion criteria as currently specified, the investigators are invited to reflect on the risk of including typologies of patients whose response might lead to a dilution of the effects, due to: 1) no specification of the timing in the disease course when the patients are eligible (with the possible inclusion of patients with already a long experience with their disease); 2) the adoption as criteria for migration background of “being born in another country” or “having a parent who was born in a country other than Germany” (with the possible inclusion of people grown up in Germany, completely integrated in the German culture, even if able to read their parents’ tongue).

#4 Blinding. Please, add something on the blinding status of outcome assessors and statisticians.

#5 Study schedule. In the text and in table 1, please add the actual timing corresponding to –T1 and T1 (e.g. how many days, with T0 as reference). In addition, it sounds strange that demographic information (“additional parameters”), including information on migration background and mother tongue, is not collected until T1, i.e. after the enrolment and allocation. Please, add also how the patients have to return the prepaid envelope at T1.

#6 Sample size calculation. Considering a Cohen’s d of 0.3, a Type I error of 0.05 and a power of 80%, how could the investigator get the sample size of 280 (140 per group)? Based on a simple t-test, one would get about 90 per group. Did the investigators account/adjust for something not declared?

Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)

#7 Unit of recruitment. Please explicitly specify, in the abstract and early in the main text, that the patient is the unit of randomization.

#8 Rationale. In the rationale paragraph of the “METHODS/DESIGN” (page 4, last paragraph), the investigators justify the choice of depression and chronic low back pain as the two index diseases saying that the former represents “a predominantly mental disorder” and the latter “a somatic disorder”; with this choice, the generalizability of their findings would be enhanced. In fact, this justification sounds not completely valid. As a clinician, it is common to experience the “psychic” component of a chronic low back pain (in fact it is not uncommon to see the association of a chronic low back pain with a depressed mood). Therefore, the choice of those two index disorders appears appropriate since they are chronic, generally highly prevalent (and in particular among people with a migration background), they “require an active involvement of patients in their own health care”, and are expected to be sensitive to the cultural background; but if the investigators were looking for a chronic somatic disorder with these characteristics, there are other conditions, with these characteristics, that would fit more the definition of somatic disease than the low back pain (to make an example, diabetes mellitus and management of insulin therapy).
#9 Randomization. The randomization process, based on a computer-based algorithm, numbered sealed envelopes assigned consecutively to the enrolled patients, and 3 stratifying factors and blocks of variable size, seems quite complex. I would suggest describing it more clearly, specifying if it will be central or locally managed (e.g. each physician, provided in advance with his/her own envelopes, according to the disease and the migration background of the eligible patient, will simply hand to the patient the next envelope from the appropriate group of envelopes).

#10 Intervention. I would suggest the inclusion of some details on how the brochure looks like (length, inclusion of pictures, etc.).

#11 Outcomes. A) Some details on the content of the self-administered scale to assess “usefulness” should be provided. B) Among the feasibility issues of the study (Discussion), the high number of scales the patient needs to self-administer (with the risk of hindering patient response and increasing losses of follow up and missing data) might be recognized. C) Among the methodological issues of the study (Discussion), the use of several self-constructed scales, with unknown validity and reliability, might be recognized.

#12 Additional parameters on participating practitioners. The rationale and the objectives for collecting data on the participating practitioners should be added.

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 declare that I have no competing interests