Author’s response to reviews

Title: Cross-cultural validation of the Educational Needs Assessment Tool in RA in 7 European countries

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Author’s response to reviews: see over
The Editor,
BMC Musculoskeletal Disorders
BioMed Central Ltd

Dear Editor

Re: Cross-cultural validation of the Educational Needs Assessment Tool in RA in 7 European countries. MS: 1480950561481438

Thank you for your feedback on the above manuscripts. We are pleased to re-submit the above article for publication in the BMC Musculoskeletal Disorders having taken account of your comments and those of the two reviewers as detailed in the next page. All changes in the revised manuscripts are in a coloured font.

We hope you are satisfied with the revisions and look forward to your views.

Sincerely yours,

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Editor’s comments:

1. Ethics: Please provide a more specific statement on ethics. Please state that ethical approval was obtained rather than 'they followed procedures'. Experimental research that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (http://www.wma.net/e/policy/b3.htm), and any experimental research on animals must follow internationally recognized guidelines. A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.

   We have stated that ethical approval was obtained

2. Please also highlight (with 'tracked changes'/coloured/underlines/highlighted text) all changes made when revising the manuscript to make it easier for the Editors to give you a prompt decision on your manuscript.

   We have used a blue colour for the amended text

3. Please also ensure that your revised manuscript conforms to the journal style (http://www.biomedcentral.com/info/ifora/medicine_journals). It is important that your files are correctly formatted.

   The journal style followed throughout the revised manuscripts

Reviewer 1: Ayse Kucukdeveci

1. Is ENAT a questionnaire specific to arthritis or rheumatoid arthritis? This should be stated clearly in 3rd paragraph.

   This study validated the ENAT for rheumatoid arthritis. This has been specified in the revised manuscripts.

Methods:

2. Patients: What do the authors mean with the exclusion criteria “having other forms of rheumatic disease in addition to RA”? What does this “rheumatic disease” include? In ENAT there are questions about pain, movement, drug treatments etc., which will be influenced by other concomitant diseases. The questions in ENAT do not ask all the questions specifically for arthritis. So the authors should specify this patient exclusion criteria. For example did they include DM patients? What about drugs taken for Hypertension?

   We have modified the text to make theses exclusions more specific.

3. Measure: Although the adaptation of different versions of ENAT seems to be a part of this study, no information is given about the details of this procedure in each country or different adapted versions. Were the translations semantic and/or conceptual? Were there any cultural differences for any items? If yes, what sort of solution was found for which items, for which country?
We did lay out the basic cross-cultural adaptation process, but in the revised manuscript we have given more explanation of how the translation was performed.

4. How do the readers get access to different versions of the ENAT, including the original English version? These should be mentioned in this section.

We have added a statement as to how readers can obtain the ENAT.

5. Titles of 3 sections of methods coming after “measure” section are all explaining statistical analysis. Under the title statistical analysis, the authors explain Rasch analysis and go on explaining it in “strategies” as well. Also they mention DIF both in cross-cultural invariance section and also in “strategies” section. This confuses the reader. I think there should be one section of statistical analysis, under this section Rasch analysis should be explained then the steps of the analyses performed in this study should be given.

We have revised the methods section extensively to respond to these comments.

6. Results: It seems that only the pooled data results have been explained although country-specific results have been presented in table 2. It would be good to mention country-specific results as well in this section. So were the assumptions of Rasch analysis met for each country? For example the Portuguese version seems not to be unidimensional in Table 2. Do the authors have any comment for this?

We have added a paragraph to report the country-specific results.

Discussion:

7. The authors have written in results that the cross-cultural DIF is due to the Dutch data. However while they discuss cross-cultural DIF in the third paragraph, they have made general comments. How would the practical use of this instrument be in future? Would this “splitting items” be applied only when the Dutch version is used? Would adjustment be necessary for comparison among any other 6 countries also? These should be clarified in that paragraph.

We have examined this and found some DIF still to be present after the exclusion of the Dutch data. However we have added a paragraph on the interpretation of the magnitude of DIF found in the study.

Conclusion:

8. The statement “It satisfies the strictest standards of measurement” is somewhat exaggerated for the results of this study. For example one version did not confirm unidimensionality.

We have explicitly stated that the Portuguese data failed that test.

Minor Essential Revisions:

9. Tables: Title of Table 2: It should “Rasch analysis results”
The title for table 2 has been changed in the revised manuscripts as suggested.

Discretionary Revisions:

10. Discussion: Regarding the comments about the sample, the most striking characteristics of Dutch data compared with the other countries is the great proportion (%82) of the highly educated patients. This has not been mentioned.

This observation needs to be interpreted with much care for the following reasons: (i) the formal education systems across European countries are different and even within individual countries; these have changed over the years making the suggested direct comparison difficult (ii) the educational background question on the ENAT was asked differently across countries to reflect their formal education system. For example in the UK, patients were asked “how old were you when you left school?” but in some other countries such as The Netherlands and Finland, this question was more detailed, asking patients to indicate their highest educational level using options ranging from primary, middle and high school, middle professional training to higher professional training and University. Consequently, the countries that used these descriptors of educational background (Finland & Holland) appeared to have a greater proportion of “highly educated” patients; over-interpretation of which is likely to be misleading.

11. It would be better to give the percentages in education row in Table 1, such the gender presentation.

To avoid the potential misleading interpretation above (10) we have described the actual numbers of patients in the two main categories (basic & post-basic education) without putting the percentages.

Reviewer 2: Åsa Lundgren-Nilsson

This article describes the use of Rasch analysis to assess the Educational Needs Assessment Tool in RA and the cross-cultural DIF across 7 European countries. The study has a potential important contribution to furthering our understanding of the psychometric properties of the scale, particularly given its use in cross-cultural studies. Although the study appears to be worthwhile, the paper would require a major rewrite before it becomes acceptable for publication. The logic order of the analysis is poor, new results in the discussion. Data supporting the analysis within countries is missing. All this makes it hard for readers to judge the findings.

Minor Essential Revisions:

1. The order and names of authors in the attached file and on the website is not the same. Which are the correct names and order?

The revised manuscripts and the BMC Musculoskeletal Disorders web contain the correct order of authorship.
Abstract:

2. This will need to be rewritten after the revision of the paper.

   The abstract has been revised accordingly.

Background: Minor Essential Revisions

3. The last sentence in the first paragraph is hard to understand: Do you mean that the improvement in QoL depends on patients’ willingness to undertake self-care activities? If so please explain this more.

   The text has been modified in the revised manuscripts for more clarity.

4. Third paragraph needs some more details on how the ENAT is supposed to used. Is a sum score for all the 39 items used or are the domains summed separately? Give max and min for the scale. How would scores be interpreted?

   We have added text to explain this.

5. Please give reference for the first study with 20 patients.

   This is given in the revised manuscripts.

Methods:


   We have shortened the Rasch description and changed the reference.

Major Compulsory Revisions

7. In the analytic strategy add overall fit statistics as 1). Analysis of each country must first be performed following the analytic strategy before pooling of data can be done. This must be clearly described and followed. The Person Separation Index (PSI) is not equivalent to Cronbach’s alpha but can be interpreted in the same way. The DIF analysis is only described for testlets on pooled data. DIF analysis has to be firstly performed within countries before it can be done with pooled data. Please revise this part.

   This part has been addressed in the revised manuscripts.
Results:

8. Start with the analysis of each country. Give the results for fit, thresholds, DIF and unidimensionality. This will also give you information for your pooled analysis.

   This has been revised as described above.

9. DIF by age, gender, education and disease duration is stated to be likely to cancel out but this has to be proven. Please provide this or revise your conclusion.

   There appears to be interaction in the DIF groups such that, when country DIF is accommodated, other DIF is no longer present only two instances of borderline DIF is present. This has been included in the revised manuscripts.

10. The reason for disregarding disorder thresholds is not supported in the methods. Were thresholds disordered in the country specific analyses as well?

   Threshold ordering was marginal and rescoring worsened fit in this instance. As all items were subsequently made into testlets, where threshold ordering is no longer an issue, no rescoring was undertaken, thus leaving the original score range intact.

11. Calibration of the ENAT into interval scale: In this process it is important that you have the full score range of instrument in your dataset before you rescore. Was this the case?

   Yes

Discussion:

12. First part in the discussion is results. First discuss the results that are most important to you following the aim of this paper, cross-cultural validation. What was the difference between countries, do you have an idea why, can this be supported? Then address questions like local dependency and clinical use. In the end of paragraph three you talk about DIF by age, this is a new result and should be in the result section.

   We have extensively modified the discussion to take into account these points.

Conclusion:

Major Compulsory Revisions

13. Here it should be made clear that in the present format the ENAT can not be used in cross-cultural studies unless DIF is taken into account. It is not proven if the ENAT works in the same way for different ages, educational levels. This is also of importance in the clinic.

   We have modified the text to explain the limitation of using the ENAT.