Author’s response to reviews

Title: Cross-cultural adaptation and validation of Spanish version of The Foot and Ankle Ability Measures (FAAM-Sp)

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Author’s response to reviews:
Dear Editor

Thank you for the possibility of replying all the questions done by the reviewers.
We have made some changes to the manuscript and we feel that this has improved the quality of the paper.
We have addressed each of the comments on a point by point basis – please see below.

Reviewer #1: Dear Authors,
I have read this revised manuscript, however, I am sorry I could not find a statement/ limitation related to the "Floor and Ceiling effect" as a response to my comment. Could you please indicate if such statement was expanded or the reason of their lack of?

In the discussion section we have rewritten a paragraph

Reviewer #2: Thank you for the opportunity to review this study, which aimed at adapting and validating the Foot and Ankle Ability Measure into Spanish.
The conduct of the study is very well written and the authors appear to have successfully adapted the FAAM and established a conceptual equivalence between the original and the Spanish version of the FAAN (FAAN-Sp).

Abstract
Background
When used for the first time PRO should be written in full The aim of this study was to cross-culturally adapt the FAAM into Spanish and… - you are not adapting the Spanish version. We have rewritten a sentence that you explain us

Methods
When written for the first time IPSOR should be written in full
The sentence beginning with 'Confirmatory factor analysis …' needs to be reworded as confirmatory factor analysis (CFA) was not assessed and it is an assessment itself

We have written IPSOR full
We have rewritten a sentence that you explain us

Results
The first sentence '…with a mean age was 38.86 …' replace 'was' with 'of'

We have changed

Conclusion

Is the FAAM-Sp valid for the Spanish-speaking patients outside Spain? We have included a new word to explain this

Main document

Introduction
If the authors want to incorporate the information on evidence-based practice in this section, it would be helpful to give a current definition of evidence-based practice and show how this relates to evaluating health-related quality of life. In the current section, I do not see the
relationship between evidence-based practice and evaluating health-related quality of life and it may even read better if they started this section with line 3: 'The Foot and Ankle Ability Measure (FAAM) is a …'

Does PRO stand for 'patient related outcome' or 'patient-reported outcome' measure or 'patient-reported outcome questionnaire'? It is important for the reader to see the difference between an outcome and an outcome measure.

We have rewritten a sentence that you explain us

Methods
Page 4 line 56, please supply the reference for ISIS guidelines We have included a new reference

Results

To help the reader follow the results easily and logically, the authors may want to consider changing the order of presenting the results and change some subheadings, thus: (i) Cross-cultural adaptation, (ii) construct validity, (iii) internal consistency, (iv) convergent validity and (v) test re-test validity.

We have rewritten a sub-section that you explain us

In the translation and adaptation section of the results, the authors could report the results of the readability tests.

We have rewritten a sub-section that you explain us

Figure 1. Consider changing 'direct translation' to 'Forward translation (English to Spanish)'

We have changed this

Construct validity

Table 1. Based on the aims of this study, I do not see the reason for categorising all patient characteristics by gender.

If there is a reason for testing differences between patient subgroups (hypothesis driven test), the authors may want to specify the test statistic (and degrees of freedom) before the p-values.
In page 8 line 24, the authors mention that the characteristics of the sample are presented in Table 1. If these tests were carried out with a hypothesis in mind, then key results should be reported within the text i.e. whether the differences between groups do/not exist.

Where there are more than two groups being tested (e.g. professional status, educational level, pain location), then the authors should also indicate where the difference lies.

- We have changed this

- We have done a new table 1 without gender

In table 1, under professional status, the term 'active' can be confusing to readers. If appropriate, the authors could amend this to 'employed' or 'employed + self-employed'. Please clarify and amend

On the same table (Table 1), is the 'VAS scale of QoL' the same as EQ5D VAS? Please specify the name of the scale to avoid confusing the readers.

On all table, could the authors replace the comma (,) with a full stop (.) for a decimal point?

- We have changed this

We have clarified this confusion

We have changed this

Since the number of item in the FAAM-ADL has been reduced from 21 to 15; to make it clearer and avoiding confusing the readers, the authors could consider amending the titles of tables 2 to 4 thus:

- Table 2. Initial factor matrix for the 21-item ADL FAAM-Sp
- Table 3. Item-item correlations matrix for the 15-item FAAM ADL-Sp
- Table 4: Inter-item correlation for each factor of the 15-item ADL FAMM-Sp

In Figure 2, the readers would want to know what F1, F2 and F3 in the ADL subscale represent. This information can be found hidden somewhere in the discussion and the authors could add a
legend at the bottom of the figure to specify this, or they consider adding a label against each of the three item groups.

Criterion-related validity
Since the authors have assessed only convergent (not divergent) validity, this could be reflected in the above sub-heading (change to convergent validity). For this test, the authors have correlated the FAAM-ADL and FAAM-Sports subscales with the EQ5D. It is important to specify whether it was the EQ5D descriptive or EQ5D VAS that was used in these analyses.

We have changed this

Test re-test validity
This information is combined in with the construct validity and internal consistency but it would be clearer for the reader if this was reported separately.

We have changed this

Discussion
The new information added in page 10 line 1-18 presents the results which should not be in this discussion section. Since table 1 now has the list of diagnoses, which indicate a clinical heterogeneity, I was expecting the authors to discuss if this has any implication for the use of the tool in different patient populations. Do they advise caution when using the tool for patients that were not well represented in their sample? Do they recommend this tool to be used as a generic quality of life tool?

Given that the group of patients is highly heterogeneous with a small number for each sub-group, and selection bias cannot be ruled out, are the authors going to be more cautious in their conclusion?

In the discussion section we have rewritten new paragraphs to explain this and we have removed this lines

We have clarified the conclusion with new words