Author’s response to reviews

Title: THE ITALIAN VERSION OF THE CRANIOFACIAL PAIN AND DISABILITY INVENTORY IN PATIENTS WITH CHRONIC TEMPOROMANDIBULAR JOINT DISORDERS. Cross-cultural adaptation, reliability and validity

Authors:

Marco Monticone (mmonticone@gmail.com)

Barbara Rocca (barbara.rocca@icsmaugeri.it)

Paola Abelli (paola.abelli@icsmaugeri.it)

Simona Tecco (tecco.simona@hsr.it)

Tommaso Geri (marcotesta.unige@gmail.com)

Enrico Gherlone (gherlone.enrico@hsr.it)

Deborah Luzzi (deborah.luzzi@gmail.com)

Marco Testa (marco.testa@unige.it)

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Author’s response to reviews:

We would like to thank the editor and the reviewers for giving us the opportunity to improve the quality of our manuscript. Please find below our responses to the reviewers' criticisms and suggestions.

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Reviewer reports:

Esam Al-Moraissi (Reviewer 1):

Title

Reviewer. Why chronic TMD has been specified in title? While in the text authors did not mention it in abstract and in inclusion criteria?

Authors’ reply. Thanks for your suggestion. The chronicity of the condition was an inclusion criteria (pain history of at least 6 months prior to the study), however it was not made explicit in the text. We have modified the Methods, Patients paragraph, as provided below:

“The inclusion criteria were headache or facial pain attributable to TMD and a chronic condition defined as pain history of at least six months prior to the study, adult age, and confidence in Italian language; the exclusion criteria were systemic illness, psychiatric deficits, and recent cerebrovascular events or myocardial infarctions.

Authors’ reply. We have mentioned the subjects’ chronic condition also in the Abstract, results section, as follows:

“Two hundred and twelve patients with chronic TMD completed the tool.”

Introduction

Material and method

Inclusion criteria

Should specify what TMDs (muscular articular mixed and ), treated untreated, male female

Authors’ reply. We thank the reviewer for this suggestion and decided to add more details in the Introduction and Methods (inclusion criteria). There were no preclusions for males and females.

“…TMD due to untreated muscular, articular or mixed complaints”.

Results

Ok
Discussion

Reviewer. Well written paper which discuss very important. However, sample size is small to apply the results of this study.

Authors’ reply. Thank you for your appreciation. We collect data based on common sample size estimation from Kline (1993), the reference has been adjusted. However, we acknowledge your suggestion about the low external validity of our result and inserted it in the paper:

“This study shows some limits: it did not consider associations between TMD and physical tests as only self-reported measurements were utilised. Despite the sample size was calculated using previous recommendation [Kline 1993], a greater sample size without a high prevalence of females as in our sample, would have improved the generalizability of our results.”

Songlin He (Reviewer 2): The aim of this study was to develop an Italian form of the Craniofacial Pain Disability Inventory (CFPDI-I) and investigate its clinimetric abilities in patients with temporomandibular disorders (TMD). This is an interesting paper on cross-cultural validation. However, I strongly suggest the review of the statistics. Please, I recommend the careful reading of COSMIN manual

(http://www.cosmin.nl/images/upload/files/COSMIN%20checklist%20manual%20v9.pdf) to conduct the Confirmatory Factor Analysis in order to "confirm" the structure model obtained compared to the original version structure.

Authors’ reply. Thanks for your suggestion. We followed the procedure suggested in De vet [De Vet HCW, Terwee CB, Mokkink LB, Knol DL. Measurement in medicine: a practical guide [Internet]. Cambridge: Cambridge University Press; 2011] to perform CFA in order to confirm the factor solution proposed in the original version. Therefore, you will find the reporting of the structural validity of the questionnaire along the methods, results and discussion sections.

Reviewer. In general, there are a number of spelling, grammar and syntax errors throughout this manuscript, which would need to be addressed.

Authors’ reply. Thank you, we did our best to correct all the typos.

Introduction

Reviewer. 1. Please, include in the introduction one statement that convince reader about the importance to use CFPDI-I in TMD patients. It will increase the importance of the paper towards its innovative potential. The introduction could not quite convince the reader on the importance of the study.
Authors’ reply. Thank you for your suggestion. We tried to improve the rhetoric of the manuscript in the introduction section, underlying that the added value of the questionnaire resides in its developmental process. Please see the correction at the end of the introduction and detailed below:

“To the authors knowledge, an Italian form of the CFPDI has never been created by means of full cross-cultural adaptation and clinimetrically analysed. Therefore, Italian researchers and clinicians are restricted from interpreting the outputs available from this measure that, being developed from direct experience of patients with TMD and headaches, will help to capture the health condition of Italian people with craniofacial pain.”

Reviewer. 2. The introduction would benefit from an explanation as to why cross-cultural adaptation is necessary in the process of translation of an instrument. The provision of information regarding the details of cross-cultural adaptation would also be of interest perhaps in the discussion section. As well as, explain to readers why it is important to check validity, internal consistency and reliability of the translated version.

Authors’ reply. We thank the reviewer for this comment and added more explanations in the Introduction:

“Full cross-cultural adaptations are crucial in order to guarantee the meanings of the original items are adequately captured in the target language and to subsequently allow psychometric testing (such structural and construct validity, internal consistency and reliability) of the original questionnaire, thus allowing comparisons between the results of investigations and original or other countries’ findings.”

A brief sentence was also added to the initial part of the Discussion:

“…leading to a valid measure of another culture’s conception of health that allows data comparability and cross-national studies.”

Methods

Reviewer. 1. The reference which the authors cited to calculate the sample size is not correct.

Authors’ reply. Thank you. We have recognized the error in the referencing and cited the correct one, as it follows: Kline, P (1993) The handbook of psychological testing. London. Routledge

Reviewer. 2. How many patients were selected to calculate the stability of the scale?
Authors’ reply. We apologize for the possible misunderstanding. All of the patients were re-tested. We slightly changed the sentence to avoid possible miscommunication as detailed below:

“…to all of the patients included into the study 7-10 days later the first administration.”

Reviewer. 3. Were any of the issues patients had in completing the questionnaire that warranted consulting a research assistant during completion raised in the pre-testing phase?

Authors’ reply. Thank you for your suggestion, we did not experience any issues during the pilot testing of the questionnaire nor during the cognitive interviews performed afterwards. We believe that this may be an important point to our result and have therefore added this aspect in the result section, as it follows:

“The testing of the pre-final version shown no issues for patients during the completion of the questionnaire that warranted a consulting with a research assistant. The cognitive interviews confirmed the clarity and the cognitive correspondence of the adaptation without showing anything causing puzzlement.”

Results

Reviewer. The Cronbach alpha value are very high - this is not necessarily a good thing as it suggests there maybe be additional redundant items. This should have been acknowledged and discussed.

Authors’ reply. Thank you for your suggestion. Together with the results coming from the CFA, we recognized that the higher Cronbach alpha was due to local dependency between items. We have discussed this in the related section as follows:

Internal consistency was outside the range of the accepted values and had higher figures than the original versions (0.80 – 0.86) [4]. This aspect further confirms the high degree of inter-relatedness among the items, especially for items 8 and 9, which may refer to a similar construct that is not captured by the 2-factors solution. Indeed, the analysis of content of item 8, which refers to no ise when moving the jaw, and item 9, which refers to feel the jaw getting out of place or getting stuck, may suggest that for Italian people the two items may be re-conducted to a construct referring to as “articular instability”.

Discussion

Reviewer. 1. More importantly, there is little in the discussion section about the importance of this study. Why would anyone care to use the CFPDI-I? Are there any particular issues related to its use in patients with TMD?
Authors’ reply. Thank you, the same was noticed also by another reviewer. We added details on the importance of the study in the introduction section, as it follows:

“To the authors knowledge, an Italian form of the CFPDI has never been created by means of full cross-cultural adaptation and clinimetrically analysed. Therefore, Italian researchers and clinicians are restricted from interpreting the outputs available from this measure that, being developed from direct experience of patients with TMD and headaches, will help to capture the health condition of Italian people with craniofacial pain.”

Reviewer. 2. The authors did not refer to the potential effects of the fact that the majority of the study sample was females.

Authors’ reply. Thank you for your suggestion. We added a sentence in the limits section at the end of the discussion as hereby provided:

“Despite the sample size was calculated using previous recommendation [Kline 1993], a greater sample size without a high prevalence of females as in our sample, would have improved the generalizability of our results would have improved the generalizability of our results”.

Reviewer. 3. Please explain why you did not include the responsiveness of the CFPDI-I.

Authors’ reply. Thanks for this suggestion. The responsiveness of the questionnaire was not tested because the patients did not undergo any active treatment. The patients undergoing the reliability analysis who repeated the questionnaire were simply invited to fill up the questionnaire after a time interval of about 7-10 days. Hence, we did not added anything to the manuscript.

Alfonso Gil-Martinez (Reviewer 3): First, I would like to congratulate the authors of this article because is an interesting work in the field of Temporomandibular joint disorders. However, I have major considerations and recommendations for authors.

ABSTRACT

Reviewer. As I see it, Pearson’s correlations should be accompanied by p-values in the abstract.

Authors’ reply. Thank you for your suggestion. We added the p value in the abstract.
INTRODUCTION

Reviewer. It is a very weak introduction. The background and justify are almost inexistent. It seems a summary of original version included statistics data which could be deleted.

Authors’ reply. We agree with this suggestion and added some sentences in order to increase background and aims (please, see the new Introduction we submitted).

METHOD

Reviewer. One of the most important procedures in these designs are the Factorial Analyses (and Scree plot). This a is very important element to be considered for publication and it is needs to be included. That implies re-write results and discussion according Factorial Analyses.

Authors’ reply. Thank you for your suggestion. We added the confirmatory factor analysis to the methods section and reported the findings in the results and discussed afterwards, as described below:

METHODS

“Structural validity

A Confirmatory Factor Analysis (CFA) was performed to confirm the factor structure of the original version of the questionnaire [La Touche 2014], which suggested a 2 factors solution composed of, respectively, items 1, 2, 3, 4, 5, 6, 7, 8, 16, 17, 18, 19, 20, 21, and items 9,10,11,12,13,14,15. The model was fitted with lavaan version 0.6-3 [Rosseel 2012] in R version 3.4.1 (R core team, 2016). The estimation method was the Diagonal Weighted Least Square (DWLS) and the latent factors were standardized. The model fit was considered acceptable when the Comparative Fit Index (CFI) and the Tucker Lewis Index (TLI), were higher than, respectively 0.90 and 0.95 [Brown TA 2006] and the Root Mean Square Error of Approximation (RMSEA) was less than 0.05 and ideally close to 0. Modification indices and residuals were considered to explain the presence of local dependency among items.”
RESULTS

“Structural validity. The result of CFA confirmed the 2-factors solution of the original version. The TLI was 0.95, the CFI was 0.96. The RMSEA was higher than the predefined threshold of 0.05 (RMSEA = 0.07, 90%CI 0.06 – 0.08, p-value = 0). The factor loadings reported in Table 2 were all satisfactory except for items 8 and 9 that shown low loadings of the respective factor. The correlation between the 2 factors was 0.82 (p = 0), indicating the presence of a common variance components of both factors not explained by the model. The high RMSEA value and between-factor correlation were explained by the presence of local dependency, especially for items 8 and 9, shown by high residuals (res) and modification indices (mi) for items 8 with factor 2 (mi = 22.70), item 9 (res = 0.32, mi = 26.51), item 12 (res = 0.15, mi = 9.74), item 17 (res = 0.19, mi = 11.29), for item 9 with factor 1 (mi = 11.98) and item 14 (res = 0.19, mi = 10.26), and for item 17 with item 9 (res = 0.34, mi = 18.75).”

DISCUSSION

“The result of the CFA confirmed that the CFPDI had a structural validity similar to the original version as the TLI and CFI indices were satisfactory. The RMSEA value higher than the predefined threshold was due to the presence of local dependency of items 8 and 9. This is not surprising considering that a similar problem was experienced also by the authors of the original version, in which item 9 was not assigned to any of the 2 proposed factors but it was held in the questionnaire for theoretical reasons [La Touche 2014]. Furthermore, the exploratory factor analysis of the original version produced a scree plot with an inflexion point between 2 to 3 factors but with eigenvalues higher than 1. A 3-factors solution has been reported in the Brazilian portuguese validation of the CFPDI after comparison with solution at 2 and 4 factors [Greghi 2018]. Therefore, the structural validity of the CFPDI still needs to be confirmed in future studies analysing the factor structure of the questionnaire.”

Reviewer. Can you explain why Migraine Disability Assessment Score Questionnaire (MIDAS) has been used in this work? The authors have included headaches in general.

Authors’ reply. In Italy there are not validated questionnaires evaluating headache in general and therefore we decided to include this tool despite possible clinical limitations. We added a limit:

“The MIDAS is not fully adequate to evaluate headache in general; however, we use it given the lack of other tools available in the Italian language.”

Reviewer. In sample size. Can you explain deeper why 10 patients per item are involved?

Authors’ reply. Thank you. Ten patients per item is the usual number chosen for validation based on Classical Test Theory. No change was made to the manuscript.
RESULTS

Reviewer. In general, results are very poor in Scale properties. This section must be developed in detail and showing specific data of the most important results. Should be adapted to Factorial Analyses. Why do you suppose that Italian version present 2 factors? These analyses should be done.

Authors’ reply. Thank you for your suggestion. The CFA has been performed and reported. Please see our replies above.

Reviewer. Please add the standard error of measurement (SEM) and minimal detectable change (MDC).

Authors’ reply. Thank for your suggestions. MDC were already reported in the previous version, but SEM and LOA were missing and they would certainly contribute to improve the quality of the manuscript. Therefore, we inserted SEM values in the results section and table 3 as suggested and calculated 95%CI limits of agreement as proposed by Bland and Altman (1986). We added the following text to the methods and result section, respectively:

Methods

The absolute reliability between the two measurements was assessed with the 95% limits of agreement (LOA) and Bland and Altman plots (Bland & Altman, 1986) calculated in R (R core team, 2016) using the package BlandAltmanLeh version 0.3.1 (Lehnert, B 2015).

Results

). For the absolute reliability, the LOA of the total scale ranged from -6.0 to 16.8 points with a mean difference of 5.4 points (Figure 1). The LOA of the pain and disability subscale ranged from -4.2 to 11.44 points with a mean difference of 3.6 points (Figure 2). The LOA of the jaw functions subscale ranged from -2.9 to 6.4 points with a mean difference of 1.8 points (Figure 3).

Reviewer. Perhaps, the use of Blond Altman plot illustrating the test-retest reliability of the CF-PDI could be interesting.

Authors’ reply. Thank fou your suggestion, LOA has been added as aforementioned.
DISCUSSION

Reviewer. Discussion is inconsistent and very weak. Statistical data is not needed in this section. Should be adapted to Factorial Analyses and rest of changes proposed.

Authors’ reply. We agree with the suggestion and decided to further increase this section by discussing our findings on structural validity as well as most of the other psychometric properties. Moreover, the limits section was largely revised (please, see the new Discussion section).

Reviewer. As informed by authors, TSK for TMD is not available in Italian version. This is an important limitation and must be discussed.

Authors’ reply. We added a limitation to the study.

“The TSK was not previously tested and validated in Italian patients suffering from TMD, limiting the interpretation of the correlations with the Italian CF-PDI”

Reviewer. The use of drugs and presence of comorbidities in the sample are high. Could this be a limitation? Please discuss it.

Authors’ reply. We added an additional limit, as requested:

“The use of drugs and the presence of comorbidities were high based on the sample included, probably affecting pain perception, disability, as well as pain beliefs; further analyses in samples suffering from lower levels of drugs use and comorbidities are therefore advised.”

REFERENCES

Reviewer. Some references are incomplete or wrong (in example: 4 or 23). Please revise it.

Authors’ reply. Thank you for your advice. References were thoroughly revised following the journal standards