

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	LIVING WITH LONG TERM CONDITIONS: VALIDATION OF A NEW INSTRUMENT FOR FAMILY CAREGIVERS IN A SPANISH-SPEAKING POPULATION
AUTHORS	Marín-Maicas, Patricia; Ambrosio, Leire; Corchon, Silvia; González-Moreno, Jesús; Portillo, Mari Carmen

VERSION 1 - REVIEW

REVIEWER NAME	Al-Rasbi, Samira
REVIEWER AFFILIATION	Sultan Qaboos University Hospital
REVIEWER CONFLICT OF INTEREST	none
DATE REVIEW RETURNED	23-Jun-2024

GENERAL COMMENTS	<p>The article presents a valuable study on the psychometric validation of the EC-PC-Fam scale for family caregivers of individuals with LTCs. It addresses a significant gap in the literature and has the potential to inform both clinical practice and further research. However, there are areas where clarity and depth could be improved, particularly in the methods and results sections. A more detailed explanation of the statistical analyses and a thorough discussion of the study's limitations would strengthen the manuscript. While there are areas for improvement, particularly in data presentation and ensuring a balanced sample, the study provides a valuable tool for assessing the quality of life and experiences of family caregivers of individuals with LTCs. Future research should build on these findings to further refine the scale and explore interventions to support caregivers effectively.</p> <p>Strengths:</p> <ol style="list-style-type: none">1. The study uses both qualitative and quantitative methods, including cognitive interviews, pilot testing, and various validated tools (EQ-5D-5L, WHODAS 2.0, Zarit Test, DUKE UNC Functional Social Support Questionnaire) for robust comparisons.2. Detailed exploration of reliability, validity, and acceptability, with the use of EFA and CFA, strengthens the scale's development.3. The study adheres to ethical standards with necessary approvals, informed consent, and data confidentiality. <p>Areas for Improvement:</p> <ol style="list-style-type: none">1. Improve readability by breaking down complex sentences and organizing the text with clear subsections.2. Provide more detailed demographic data and discuss potential sample biases.3. Enhance discussion on the findings' implications and comparisons with existing literature.
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	enhancing clarity, organization, and discussion depth would further improve the work. The EC-PC-Fam scale shows promise for research and clinical practice applications.
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REVIEWER NAME	Laranjeira, Carlos
REVIEWER AFFILIATION	Polytechnic Institute of Leiria, School of Health Sciences
REVIEWER CONFLICT OF INTEREST	None
DATE REVIEW RETURNED	07-Jul-2024

GENERAL COMMENTS	<p>I appreciate the opportunity to review this manuscript and hope my comments assist in the revision process. The material is interesting and the topic is timely and relevant. The method seems to have been followed faithfully and the authors were well-positioned to conduct the analysis. Despite these positives, in my view, the paper needs more work before it can be published and I have made some specific suggestions below.</p> <ul style="list-style-type: none"> - I suggest a keyword be Spanish-speaking population or Spanish version as research from there is hard to find. - Please revise the aim of study because doesn't fit well the content of your paper (authors only mention psychometric properties but they also included validation); - Explain how this/your study is increasing our understanding/knowledge regarding care of individuals with Long-Term Conditions. This would allow a better understanding of the importance of the topic. - Please provide the specific questions/hypotheses under study, it would be useful for the readers. <p>Method</p> <ul style="list-style-type: none"> - If this study is a part of a larger study with more variables. Has any of this data been published? Please provide more details of the broader study. - Authors stated that study is observational and cross-sectional. However it is also a methodological or instrumental study. Did you used a checklist of verification? (i.e. STROBE or COSMIN). - A Rationale is needed for the sampling procedure used. Why do you choose the mentioned different private health and social-health centers located in the province of Valencia? Based on what criteria? - Some subjects refused to participate. Response rate? - The process of analysis should be made as transparent as possible. Did you analyze any potential non-response bias? And early vs late bias? Did you check if data can suffer from common method bias? <p>Results</p> <ul style="list-style-type: none"> - A better visual structure of tables (boldface variables with statistical significance) would improve the readability. - Please provide all acronyms and statistical significances mentioned in the tables in footnotes. <p>Discussion</p> <ul style="list-style-type: none"> - Some of the contributions that are highlighted here could be flagged in the introduction for a more consistent narrative throughout the paper. Discussion can be improved if questions/hypotheses are outlined in the introduction, then answered suitably in this section, and the results interpreted appropriately. I believe there should be better integration of the results with the existing literature. - A stronger discussion of implications for future research and potential intervention work is needed. Identify recommendations for
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	<p>practice/research/education/management as appropriate, and consistent with limitations, to more fully allow readers to understand the extent to which the authors were able to answer the research questions and to grasp the limitations of this study. I suggest dividing these theoretical implications/ recommendations for action, in three ways: - individual actions; - community responsibilities; and policy implications.</p> <p>- Theoretical and methodological limitations should be emphasized more deeply.</p> <p>- The authors found sound psychometric properties of their instrument. However, following scientific recommendations in scale adaptation the authors fail to report detailed information about various other aspects: e.g. responsiveness and interpretability of the questionnaire, and predictive validity. Therefore, the authors should describe their results as preliminary information about the psychometric properties and relativize their conclusions.</p> <p>CHECKLIST FOR STYLE</p> <p>The manuscript will serve a broad audience of students, researchers, and practitioners, however, the manuscript needs to be carefully and attentively proofread because some sentences are awkwardly constructed, punctuation is deficient, and therefore reading is occasionally difficult to follow. That leads me to believe that it needs careful editing by a native English speaker.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Samira Al-Rasbi, Sultan Qaboos University Hospital

Comments to the Author:

The article presents a valuable study on the psychometric validation of the EC-PC-Fam scale for family caregivers of individuals with LTCs. It addresses a significant gap in the literature and has the potential to inform both clinical practice and further research. However, there are areas where clarity and depth could be improved, particularly in the methods and results sections. A more detailed explanation of the statistical analyses and a thorough discussion of the study's limitations would strengthen the manuscript. While there are areas for improvement, particularly in data presentation and ensuring a balanced sample, the study provides a valuable tool for assessing the quality of life and experiences of family caregivers of individuals with LTCs. Future research should build on these findings to further refine the scale and explore interventions to support caregivers effectively.

Strengths:

1. The study uses both qualitative and quantitative methods, including cognitive interviews, pilot testing, and various validated tools (EQ-5D-5L, WHODAS 2.0, Zarit Test, DUKE UNC Functional Social Support Questionnaire) for robust comparisons.
2. Detailed exploration of reliability, validity, and acceptability, with the use of EFA and CFA, strengthens the scale's development.
3. The study adheres to ethical standards with necessary approvals, informed consent, and data confidentiality.

Areas for Improvement:

1. Improve readability by breaking down complex sentences and organizing the text with clear subsections.

Many thanks for this comment. The paper has been reviewed by a professional English translation service and several grammatical mistakes have been addressed. However, following your comment we have proof read the paper again and removed some grammatical errors.

2. Provide more detailed demographic data and discuss potential sample biases.

Many thanks for this comment. Supplemental Material (Table 2) shows a detailed demographic data, focusing in sociodemographic variables and historical characteristics of the situation of the family caregiver in the sample. In addition, we have highlighted this limitation in the "Limitation and strength section" and we have incorporated a paragraph in the discussion that elaborates on the potential risk of bias in the sample analysed (see page 13).

3. Enhance discussion on the findings' implications and comparisons with existing literature.

enhancing clarity, organization, and discussion depth would further improve the work. The EC-PC-Fam scale shows promise for research and clinical practice applications.

Many thanks for this comment. This has been reinforced in the manuscript (see page 11-13).

Reviewer: 2

Dr. Carlos Laranjeira, Polytechnic Institute of Leiria

Comments to the Author:

I appreciate the opportunity to review this manuscript and hope my comments assist in the revision process. The material is interesting and the topic is timely and relevant. The method seems to have been followed faithfully and the authors were well-positioned to conduct the analysis. Despite these positives, in my view, the paper needs more work before it can be published and I have made some specific suggestions below.

- I suggest a keyword be Spanish-speaking population or Spanish version as research from there is hard to find.

Many thank for this recommendation, we have included your suggestion in the keywords (see page 1).

- Please revise the aim of study because doesn't fit well the content of your paper (authors only mention psychometric properties but they also included validation);

Thank you for this appreciation, we have refined the objective including your suggestion (see page 5).

- Explain how this/your study is increasing our understanding/knowledge regarding care of individuals with Long-Term Conditions. This would allow a better understanding of the importance of the topic.

Thank you for your comment. This has been reinforced in the manuscript (see page 4).

- Please provide the specific questions/hypotheses under study, it would be useful for the readers.

Many thank for this appreciation, we have provided the specific questions and hypotheses under study. See page 2.

Method

- If this study is a part of a larger study with more variables. Has any of this data been published? Please provide more details of the broader study.

Many thanks for this comment. This study is not a part of a larger study with more variables. Any data has been published.

- Authors stated that study is observational and cross-sectional. However, it is also a methodological or instrumental study. Did you use a checklist of verification? (i.e. STROBE or COSMIN).

Yes, we are using the COSMIN consensus of measurement properties for health-related patient-reported outcomes (reference number 47):

Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *J Clin Epidemiol* [Internet]. 2010 [cited 2024 Mar 7];63:737–45. Available from: <http://www.cosmin.nl>

- A Rationale is needed for the sampling procedure used. Why do you choose the mentioned different private health and social-health centers located in the province of Valencia? Based on what criteria?

Thank you for your comment. The selection of three private centres in the province of Valencia for this study was primarily driven by considerations of participant accessibility. Private institutions often have more flexible operational structures, which can facilitate more efficient and streamlined data collection compared to public centres, which may face more bureaucratic constraints. The selection aimed to capture diverse socio-health perspectives where family caregivers of individuals with chronic conditions are present: one in a hospital setting (Hospital QuironSalud), one with a purely social focus (Levante F. D.), and one integrating both perspectives (AFAV). The selected private centres together in this study offered a variety of services and attended different patient volumes, allowing for a more comprehensive evaluation of the study variables and providing a broader understanding of user's experiences and outcomes.

- Some subjects refused to participate. Response rate?

Many thanks for this comment because it gives us the opportunity to explain this question. The response rate was 96,48%. We offered participation to a total of 320 participants, of whom 9 declined the invitation claiming 'no time to respond' or 'no interest in responding to yet another survey'. When we explained that the purpose was aimed at the family caregiver and not the patient, it was generally well received with a high level of interest from the participants. In fact, a percentage of them ticked the option to get in touch again in case of further collaboration in future studies. This shows the social relevance of this study and this instrument in question.

- The process of analysis should be made as transparent as possible. Did you analyze any potential non-response bias? And early vs late bias? Did you check if data can suffer from common method bias?

Thank you very much for your comment. Regarding potential non-response bias and early versus late response bias, there are data points that unfortunately are not recorded. We have done everything possible to address it, but unfortunately, we have not been able to gather the information. We

acknowledge the importance of these aspects and thus, they are included as limitations of the study. On the other hand, we have included the calculation for common method bias. No factor exceeds the established criterion, so common method bias is not considered an issue in this study. All this information has been included in the manuscript (see page 12-13).

- A better visual structure of tables (boldface variables with statistical significance) would improve the readability.

Many thanks for this valuable comment, we completely agree with it. Therefore, we have put the variables in bold and highlighted the statistical significance (see page 8-11 and tables of the Supplementary Material Document).

- Please provide all acronyms and statistical significances mentioned in the tables in footnotes.

Thank you very much, we have included all acronyms used in the footnotes. Likewise, we have footnoted the statistical meanings mentioned in the tables. Please, see tables 2,3 and the tables of the Supplementary Material Document).

Discussion

- Some of the contributions that are highlighted here could be flagged in the introduction for a more consistent narrative throughout the paper. Discussion can be improved if questions/hypotheses are outlined in the introduction, then answered suitably in this section, and the results interpreted appropriately. I believe there should be better integration of the results with the existing literature.

Thank you for your valuable suggestion, this has been reinforced in the manuscript. We agree that highlighting certain contributions has created a more coherent narrative throughout the document. We have ensured that the questions and hypotheses are clearly presented in the introduction and appropriately addressed in the discussion section, with a thorough interpretation of the results and their integration with the existing literature. Please, see page 2-3, 11.

- A stronger discussion of implications for future research and potential intervention work is needed. Identify recommendations for practice/research/education/management as appropriate, and consistent with limitations, to more fully allow readers to understand the extent to which the authors were able to answer the research questions and to grasp the limitations of this study. I suggest dividing these theoretical implications/ recommendations for action, in three ways: - individual actions; - community responsibilities; and policy implications.

Thanks for your suggestion. According with this comment, this has been reinforced in the discussion of the manuscript (see page 12).

- Theoretical and methodological limitations should be emphasized more deeply.

Thanks for your suggestion, this has been reinforced in the limitations of the manuscript (see page 13).

- The authors found sound psychometric properties of their instrument. However, following scientific recommendations in scale adaptation the authors fail to report detailed information about various other aspects: e.g. responsiveness and interpretability of the questionnaire, and predictive validity. Therefore, the authors should describe their results as preliminary information about the psychometric properties and relativize their conclusions.

Thank you for this appreciation, you are right, we have made more cautions points in our conclusions (see page 13).

CHECKLIST FOR STYLE

The manuscript will serve a broad audience of students, researchers, and practitioners, however, the manuscript needs to be carefully and attentively proofread because some sentences are awkwardly constructed, punctuation is deficient, and therefore reading is occasionally difficult to follow. That leads me to believe that it needs careful editing by a native English speaker.

Thank you for this appreciation. The manuscript has been reviewed by a professional English translation service and several grammatical mistakes have been addressed. We have attached the certificated. Also, the manuscript has been revised by the co-authors, paying special attention to your points above (please note that some of the co-authors are residents in the UK).

VERSION 2 – REVIEW

REVIEWER NAME	Laranjeira, Carlos
REVIEWER AFFILIATION	Polytechnic Institute of Leiria, School of Health Sciences
REVIEWER CONFLICT OF INTEREST	None
DATE REVIEW RETURNED	16-Aug-2024

GENERAL COMMENTS	I believe that the review carried out has greatly improved the quality of the study. Also, I do think that the author(s) addresses the broad questions, appropriately which were asked.
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