PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (http://bmjopen.bmj.com/site/about/resources/checklist.pdf) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

| TITLE (PROVISIONAL) | Dyspnoea-12: A translation and linguistic validation study in a |
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| | Swedish setting |
| AUTHORS | Sundh, Josefin; Ekström, Magnus |
| | |
| | VERSION 1 - REVIEW |
| REVIEWER | Koichi Nishimura |
| KEVIEWEK | National Center for Geriatrics and Gerontology |
| | Department of Pulmonary Medicine |
| | JAPAN |
| REVIEW RETURNED | 01-Oct-2016 |
| REVIEW RETORNED | 01-0ct-2010 |
| | |
| GENERAL COMMENTS | Only the results obtained from the translation and linguistic |
| | validation of the Dyspnoea-12 to Swedish are described in the |
| | manuscript. To the best of my knowledge, the validation study on |
| | across patient populations and settings is necessary for the |
| | publication in the scientific journal. |
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| REVIEWER | Paula Meek |
| | University of Colorado |
| | Aurora Colorado USA |
| REVIEW RETURNED | 27-Oct-2016 |
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| GENERAL COMMENTS | The reviewer completed the checklist but made no further |
| SEIVERAE GOMMENTO | comments. |
| | · |
| DEVIEWED | Ingola Hanash |
| REVIEWER | Ingela Henoch |
| | Sahlgrenska Academy, institute of Health and Care sciences, |
| DEVIEW DETUDNED | University of Gothenburg, Sweden |
| REVIEW RETURNED | 03-Nov-2016 |

| GENERAL COMMENTS | Review of bmjopen-2016-014490 Thank you for giving me the opportunity to review the manuscript bmjopen-2016-014490, with the title "A Swedish version of the Dyspnoea-12". To properly assess such a delimiting symptom as dyspnea is very important. This study only concerns the translation and linguistic adaptation of the Dyspnea-12 and there is no validation. The authors could consider adding some empirical data and validating the Dyspnea-12 against some other instruments. |
|------------------|--|
| | Introduction The authors state that there has been no multidimensional instrument for measurement of dyspnea available in Swedish. I do |

not agree, the Cancer Dyspnea Scale is a multidimensional instrument that has been validated in Swedish lung cancer patients. (Henoch I., Bergman B. & Gaston-Johansson F. (2006). Validation of a Swedish version of the Cancer Dyspnea Scale. Journal of Pain and Symptom Management 31(4), 353-361.) The authors need to do a thorough literature review before giving a statement like this.

Method

In the method section, the Dyspnea-12 needs to be described. There is a description of the scale in the discussion, but some parts of that section need to be moved to the method section. If Dyspnea-12 is a multidimensional scale, the readers need to be informed about which dimension the scale is measuring and how the scoring of these dimensions is performed. The method section needs to start with a description of the Dyspnea-12.

The patient interviews need to be described. If it was in-depth interviews, the interview questions need to be provided. How long did the interviews take? Were they transcribed verbatim? How were they analyzed? There is also a need for a reference for the analysis. The authors state that informed consent was not required, but when interviewing patients you need to obtain informed consent. The roles of the authors of the study and the Mapi Company need to be clarified.

Results

The results section is very short. Changes that were made after the interview with the clinicians are reported in the results, but not changes made after the interviews with the patients. If in-depth interviews were performed, the results from them need to be reported.

Discussion

Strength about the Dyspnea-12 should not be discussed in the discussion section; this should be stated in the introduction, as a rationale for performing this study. Some of the description of the Dyspnea-12 should be moved to the method section.

It is mentioned in the discussion that the instrument should not be used with more than three items missing. Which authors recommend this? The authors of the present study or the authors of the original study? What is the rationale for this statement? This is very difficult for the reader to understand when there is no description of scales or factors.

There is a discussion about that it would be better to use the period of recent two weeks, and I agree. There could be differences in how patients perceive "these days".

| REVIEWER | Prof. Michael Kreuter |
|-----------------|---|
| | Center for interstitial and rare lung diseases |
| | Thoraxklinik, University of Heidelberg, Germany |
| REVIEW RETURNED | 20-Nov-2016 |

| GENERAL COMMENTS | Thanks to the authors for undergoing this demanding task of a |
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| | linguistic validation of this questionnaire. |
| | There are only 2 minor requests: |
| | -While the process has been conducted correctly, a figure showing |
| | how the linguistic validation has been performed (i.e. compare to |
| | Kreuter et al., Pneumologie 2016) would be helpful to readers and |
| | other scientists in validating other questionnaires. |

-Was a minimal important difference for this questionnaire already developed? I am not aware of this and nothing can be found in the literature. It should be added to the discussion in a short limitations paragraph on the Dyspnoea-12 that -if no MID has been reported so far- this may limit the broad application of this questionnaire. Another limitation is that this questionnaire is only avaible in 4 languages now and authors may request the scientific community to have other linguistic validations in other countries.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Koichi Nishimura

Institution and Country: National Center for Geriatrics and Gerontology, Department of Pulmonary

Medicine, JAPAN

Please state any competing interests: None declared

Please leave your comments for the authors below

Only the results obtained from the translation and linguistic validation of the Dyspnoea-12 to Swedish are described in the manuscript. To the best of my knowledge, the validation study on across patient populations and settings is necessary for the publication in the scientific journal.

Answer: We fully agree with the important comment that a clinical validation study of the translated version need to be performed, and have included this fact as a limitation of the study. However, we respectfully disagree that this fact disqualifies this paper, as the intention of the present paper was to report the linguistic validation of the Dyspnoea-12 to Swedish. In our opinion, this is important as it enables other researchers to use the instrument.

Reviewer: 2

Reviewer Name: Paula Meek

Institution and Country: University of Colorado, Aurora Colorado USA

Please state any competing interests: None

Please leave your comments for the authors below

Answer: We have received no comment from this reviewer.

Reviewer: 3

Reviewer Name: Ingela Henoch

Institution and Country: Sahlgrenska Academy, institute of Health and Care sciences, University of

Gothenburg, Sweden

Please state any competing interests: None declared

Please leave your comments for the authors below

Review of bmjopen-2016-014490

Thank you for giving me the opportunity to review the manuscript bmjopen-2016-014490, with the title "A Swedish version of the Dyspnoea-12". To properly assess such a delimiting symptom as dyspnea is very important. This study only concerns the translation and linguistic adaptation of the Dyspnea-12 and there is no validation. The authors could consider adding some empirical data and validating the

Dyspnea-12 against some other instruments.

Answer: We fully agree that the translated version need to be clinically validated. A validation study is ongoing, but the aim of the present paper was to report the linguistic validation of the Swedish version.

Introduction

The authors state that there has been no multidimensional instrument for measurement of dyspnea available in Swedish. I do not agree, the Cancer Dyspnea Scale is a multidimensional instrument that has been validated in Swedish lung cancer patients. (Henoch I., Bergman B. & Gaston-Johansson F. (2006). Validation of a Swedish version of the Cancer Dyspnea Scale. Journal of Pain and Symptom Management 31(4), 353-361.) The authors need to do a thorough literature review before giving a statement like this.

Answer: Thank you for this valuable comment. The intention of the mentioned statement was to describe that general multidimensional instruments in Swedish for assessment regardless of underlying diseases were missing. We have clarified this in page 5 lines 11 to 16, and also added a sentence referring to the Cancer Dyspnea Scale, and to the recently published linguistic Swedish validation of another multidimensional dyspnea instrument.

Method

In the method section, the Dyspnea-12 needs to be described. There is a description of the scale in the discussion, but some parts of that section need to be moved to the method section. If Dyspnea-12 is a multidimensional scale, the readers need to be informed about which dimension the scale is measuring and how the scoring of these dimensions is performed. The method section needs to start with a description of the Dyspnea-12.

Answer: We full agree and have added a more detailed description of the Dyspnoea-12 instrument in the method section, including moving some of the information from the discussion to the method section.

The patient interviews need to be described. If it was in-depth interviews, the interview questions need to be provided. How long did the interviews take? Were they transcribed verbatim? How were they analyzed? There is also a need for a reference for the analysis.

Answer: Thank you for this valuable comment. We have deepened the description of the in-depth interviews in the paragraph in page 7 line 15 to page 8 line 10.

The authors state that informed consent was not required, but when interviewing patients you need to obtain informed consent.

Answer: Our intention was to describe that informed consent was not needed for the translation process and for the clinicians' review, as no patients were involved. However, we fully agree informed consent was needed for the five patients in the in-depth interviews. We have clarified this in page 8 lines 15 to 16.

The roles of the authors of the study and the Mapi Company need to be clarified.

Answer: We have added a sentence clarifying the role of Mapi in the beginning of the method section page 6 lines 18 to 19. A paragraph stating the contributions of the authors has beed added in the end of the paper.

Results

The results section is very short. Changes that were made after the interview with the clinicians are reported in the results, but not changes made after the interviews with the patients. If in-depth interviews were performed, the results from them need to be reported.

Answer: No changes were made after the interviews. A sentence adding this information has been added in page 8 line 23 to page 9 line 1.

Discussion

Strength about the Dyspnea-12 should not be discussed in the discussion section; this should be stated in the introduction, as a rationale for performing this study. Some of the description of the Dyspnea-12 should be moved to the method section.

Answer: We agree and have rewritten the strengths and limitations section of the discussion in order to focus on the results of our study, and have moved some of the general sentences about the Dyspnoea-12 to the introduction.

It is mentioned in the discussion that the instrument should not be used with more than three items missing. Which authors recommend this? The authors of the present study or the authors of the original study? What is the rationale for this statement? This is very difficult for the reader to understand when there is no description of scales or factors.

Answer: This is a recommendation from the developer of Dyspnoea-12. We have clarified this in page 10 lines 1 to 2.

There is a discussion about that it would be better to use the period of recent two weeks, and I agree. There could be differences in how patients perceive "these days".

Answer: Thank you for this comment.

Reviewer: 4

Reviewer Name: Prof. Michael Kreuter

Institution and Country: Center for interstitial and rare lung diseases, Thoraxklinik, University of

Heidelberg, Germany

Please state any competing interests: None declared in relationship to this manuscript

Please leave your comments for the authors below

Thanks to the authors for undergoing this demanding task of a linguistic validation of this questionnaire.

There are only 2 minor requests:

-While the process has been conducted correctly, a figure showing how the linguistic validation has been performed (i.e. compare to Kreuter et al., Pneumologie 2016) would be helpful to readers and other scientists in validating other questionnaires.

Answer: Thank you for this valuable suggestion. We have constructed a flow chart of the translation and linguistic validation (Figure 1).

-Was a minimal important difference for this questionnaire already developed? I am not aware of this and nothing can be found in the literature. It should be added to the discussion in a short limitations paragraph on the Dyspnoea-12 that -if no MID has been reported so far- this may limit the broad application of this questionnaire. Another limitation is that this questionnaire is only avaible in 4 languages now and authors may request the scientific community to have other linguistic validations in other countries.

Answer: Thank you for this important comment. We fully agree and have added the information on MCID in page 6 lines 10 to 11.

VERSION 2 – REVIEW

| REVIEWER | Michael Kreuter |
|-----------------|--|
| | Center for interstitial and rare lung diseases, Thoraxklinik, University |
| | of Heidelberg, Germany |
| REVIEW RETURNED | 05-Jan-2017 |

| GENERAL COMMENTS | Thanks to the authors, all issues sufficiently addressed |
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