BMJ Open

A Swedish version of the Dyspnoea-12

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-014490
Article Type:	Research
Date Submitted by the Author:	27-Sep-2016
Complete List of Authors:	Sundh, Josefin; School of medical Sciences, Örebro University, Department of Respiratory Medicine Ekström, Magnus
Primary Subject Heading:	Respiratory medicine
Secondary Subject Heading:	Research methods
Keywords:	dyspnoea, breathlessness, multidimensional, measurement, Swedish

SCHOLARONE™
Manuscripts

For peer review only

Title: A Swedish version of the Dyspnoea-12

Running title: Swedish version of D-12

Authors: Josefin Sundh, MD, PhD[1], Magnus Ekström, MD, PhD[2]

[1] *Department of Respiratory Medicine, School of Medical Sciences, Örebro University, Örebro, Sweden.*

[2] *Department of Clinical Sciences, Division of Respiratory Medicine & Allergology, Lund University, Lund, Sweden*

Corresponding author: Josefin Sundh, Department of Respiratory Medicine, School of Medical Sciences, Örebro University, Örebro, Sweden, E-mail josefin.sundh@oru.se, Phone +46702349517, Fax +4619186526

Word count for body of text: 1120

Word count for abstract: 197

Tables: 0; **Figures:** 1.

Key words: Dyspnoea; breathlessness, multidimensional, measurement, Swedish

For peer review only

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

ABSTRACT

Background: Dyspnoea consists of multiple dimensions including the intensity, unpleasantness, sensory qualities and emotional responses which may differ between patient groups, settings and in relation to treatment. Dyspnoea-12 is a validated and convenient instrument for multidimensional measurement in English. We aimed to take forward a Swedish version of Dyspnoea-12.

Methods: Translation and linguistic validation of the Dyspnoea-12 was performed (Mapi, Lyon, France). The standardised procedure involved forward and backward translations by two independent certified translators, and revisions after feedback from an in-country linguistic consultant, the developers, and three native physicians. The understanding and convenience of the translated version was evaluated using qualitative in-depth interviews with five patients with dyspnoea.

Results: A Swedish version of the Dyspnoea-12 was elaborated and evaluated carefully according to international guidelines. The Swedish version; "Dyspné-12", has the same layout as the original version, including 12 items distributed on seven physical and five affective items. The Dyspnoea-12 is copyrighted by the developer but can after permission be used free of charge for not industry-funded research.

Conclusion: A Swedish version of Dyspnoea-12 is now available for clinical validation and multidimensional measurement across diseases and settings with the aim of improved evaluation and management of dyspnoea.

For peer review only

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Article Summary

Strengths and limitations of this study

- Translation and linguistic validation of the Dyspnoea-12 to Swedish was performed in a structured multi-stage process in accordance with international guidelines
- Translation of the first version by two independent certified translators, with backwards translation for quality check by an in-country consultant and the developer
- Clinicians review and patients evaluation before establishing the final translated version
- A Swedish version of Dyspnoea-12 is now available for clinical validation across patient populations and settings

For peer review only

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

INTRODUCTION

Reduction of symptoms is a major treatment goal in chronic cardiac and respiratory diseases. Dyspnoea is the cardinal symptom in cardiopulmonary disease, including heart failure, chronic obstructive pulmonary disease (COPD) and interstitial lung diseases such as idiopatic pulmonary fibrosis (IPF). Dyspnoea is strongly associated with impaired health related quality of life in COPD (1) and IPF (2), and with increased mortality in COPD (3, 4), IPF (5, 6) and heart failure (7). Despite this fact, clinical practice often focuses on underlying diseases and not on management of the often chronic symptom of dyspnoea itself (8).

Multiple dimensions of dyspnoea

Traditionally, dyspnoea has been assessed as an indirect measure of functional limitation due to breathlessness, as with the Medical Research Council (MRC) scale (9), or using a single rating scale such as a visual analogue scale (VAS) (10) or Borg scale (11) during exercise tests. However, growing attention has been paid to the fact that dyspnoea consists of multiple important dimensions besides the overall intensity or unpleasantness, such as sensory and affective qualities, the associated emotional responses, and the functional impact on the person´s life (12). This makes it difficult to compare findings between patient populations and between differences in responses of separate treatments of dyspnoea (13). Thus, standardised measurements with different dimensions of dyspnoea are needed.

Dyspnoea-12

The Dyspnoea-12 instrument was developed to be a concise instrument for quantification of different aspects of dyspnoea, valid across different cardiorespiratory diseases (14). In the

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

original study establishing the final version of Dyspnoea-12, the instrument was associated with MRC in COPD, IPF and heart failure (14). The subsequent validation study showed a good internal reliability and test-retest reliability, and the Dyspnoea-12 was significantly correlated to Hospital Anxiety and Depression Scale (HADS), MRC, Forced Expiratory Volume in one second (FEV_1) and six minutes walking distance (6MWD) (14). After the initial validation, further studies have validated the use of Dyspnoea-12 in interstitial lung disease (15) and COPD (16), but also in asthma (17), pulmonary arterial hypertension (18), bronchiectasis and tuberculosis destroyed lungs (19).

The Dyspnoea-12 is available as English (14), Arabic (16, 20) and Korean (19) versions, but is to our knowledge not translated to any other European language except English. Until now, there has been no multidimensional instrument for measurement of dyspnoea available in Swedish. A Swedish version of Dyspnoea-12 should be of great importance for further research in the field of breathlessness, especially to be able to compare across populations. We therefore aimed to develop a linguistically validated Swedish translation of the Dyspnoea-12.

METHODS

The translation and linguistic validation of the Dyspnoea-12 to Swedish was performed in a structured multi-stage process in accordance with international guidelines (21, 22), in collaboration with a company specialized in translation and validation of patient-reported outcome measures (Mapi Linguistic Validation, Lyon, France; hereafter referred to as 'Mapi') (23). Permission to translate Dyspnoea-12 into Swedish was obtained from the developer.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Translation

The original instrument in British English was translated into Swedish by two independent certified translators. These forward-translations were analysed and reconciled by an in-country consultant to a first translated version. After quality check from Mapi, the first Swedish version was translated back to English and compared with the original version by the developer and by the in-country consultant, to establish a second translated Swedish version.

Clinicians review

The second translated version was reviewed by three native Swedish-speaking specialists in internal and/or respiratory medicine, including the authors of this paper, in order to provide detailed feedback on the wordings from a clinical perspective. The feedback from the clinicians was considered by Mapi again with input from the in-country consultant and the developer, resulting in a third translated Swedish version.

Patient interviews

The third translated version was evaluated using individual in-depth interviews with five Swedish patients with dyspnoea, recruited by Mapi and the in-country consultant, in order to investigate if the instrument was easy to understand, assimilate and accept. The feedback from the patients on their understanding and suggested alternative formulations for each item was used for revision and establishment of the final linguistically validated translation.

Ethics

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

The study was approved by the regional ethics committee at Lund University (DNr: 2016/16). Written informed consent was not required as no personal data on participants were collected.

RESULTS

The final certified, linguistically validated Swedish translation of the Dyspnoea-12 is found in Figure 1. The Swedish version; "Dyspné-12", has the same layout as the original version (Figure 2), including 12 items. The clinicians review resulted in several small linguistic adjustments, after which the instrument copies the original but uses the corresponding adequate clinical words and expressions in Swedish. The time period of measurement in the original version is "these days", which was translated to a corresponding word in Swedish.

DISCUSSION

The purpose of this project was to translate and linguistically validate a Swedish version of the Dyspnoea-12 instrument. The procedure has been performed according to international guidelines for patient-reported outcomes and have resulted in a convenient instrument for quantification of different aspects of breathlessness in Swedish research. The instrument could be used as brief and easy-to use alternative or complement to the instrument Multi-Dimensional Profile (MDP) (13, 24).

Major strengths of Dyspnoea-12 are that it brings a new possibility to deepen the understanding of breathlessness. Breathlessness is a complex symptom appearing in a spectrum of cardiorespiratory diseases and is often undertreated (8). Persistent disabling breathlessness despite treatment has been found common in COPD (25), and further research is needed to value the impact of different dimensions of breathlessness. The fact that we have

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

presented a Swedish version of Dyspnoea-12 means that we can compare and aggregate results from different populations and countries.

Use of the Dyspnoea-12

As described, the Dyspnoea-12 is a brief questionnaire including12 items rated on a Likert scale. The items form a two component-structure, where seven item constitute a "physical" part, and the remaining five items an "affect" part of the instrument. Each item is multiplied with three to get a final score of 0 to 36; the higher the worse. The author recommends that the instrument should not be used with more than three missing items. The idea is to get a general perception of the current state, and thus the term "these days" is suggested. However, the English version of Dyspnoea-12 has been used for the period of recent two weeks (Marie Williams, personal communication), and the Swedish version also need to be validated for different periods of time. The Dyspnoea-12 is copyrighted by the developers but can after permission be used free of charge for not industry-funded research.

Conclusion

A Swedish version of Dyspnoea-12 is now available for clinical validation and multidimensional measurement across diseases and settings with the aim of improved evaluation and management of dyspnoea.

ACKNOWLEDGEMENTS

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

The authors thank Bengt Dahlander, MD, Capio ASIH Nacka, who contributed to the clinical review of the Dyspnoea-12.

FUNDING

The study was supported by an unrestricted grant from the Swedish Heart-Lung Foundation (Nr 20150424).

REFERENCES

1. Bestall JC, Paul EA, Garrod R, Garnham R, Jones PW, Wedzicha JA. Usefulness of the Medical Research Council (MRC) dyspnoea scale as a measure of disability in patients with chronic obstructive pulmonary disease. Thorax. 1999;54(7):581-6.
2. Nishiyama O, Taniguchi H, Kondoh Y, Kimura T, Ogawa T, Watanabe F, et al. Health-related quality of life in patients with idiopathic pulmonary fibrosis. What is the main contributing factor? Respiratory medicine. 2005;99(4):408-14.
3. Nishimura K, Izumi T, Tsukino M, Oga T. Dyspnea is a better predictor of 5-year survival than airway obstruction in patients with COPD. Chest. 2002;121(5):1434-40.
4. Casanova C, Marin JM, Martinez-Gonzalez C, de Lucas-Ramos P, Mir-Viladrich I, Cosio B, et al. Differential effect of mMRC dyspnea, CAT and CCQ for symptom evaluation within the new GOLD staging and mortality in COPD. Chest. 2015.
5. Mura M, Porretta MA, Bargagli E, Sergiacomi G, Zompatori M, Sverzellati N, et al. Predicting survival in newly diagnosed idiopathic pulmonary fibrosis: a 3-year prospective study. The European respiratory journal. 2012;40(1):101-9.
6. Nishiyama O, Taniguchi H, Kondoh Y, Kimura T, Kato K, Kataoka K, et al. A simple assessment of dyspnoea as a prognostic indicator in idiopathic pulmonary fibrosis. The European respiratory journal. 2010;36(5):1067-72.
7. Ekman I, Cleland JG, Swedberg K, Charlesworth A, Metra M, Poole-Wilson PA. Symptoms in patients with heart failure are prognostic predictors: insights from COMET. Journal of cardiac failure. 2005;11(4):288-92.
8. Johnson MJ, Currow DC, Booth S. Prevalence and assessment of breathlessness in the clinical setting. Expert review of respiratory medicine. 2014;8(2):151-61.
9. Mahler DA, Wells CK. Evaluation of clinical methods for rating dyspnea. Chest. 1988;93(3):580-6.
10. Lansing RW, Moosavi SH, Banzett RB. Measurement of dyspnea: word labeled visual analog scale vs. verbal ordinal scale. Respiratory physiology & neurobiology. 2003;134(2):77-83.
11. Borg GA. Psychophysical bases of perceived exertion. Medicine and science in sports and exercise. 1982;14(5):377-81.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

12. Parshall MB, Schwartzstein RM, Adams L, Banzett RB, Manning HL, Bourbeau J, et al. An official American Thoracic Society statement: update on the mechanisms, assessment, and management of dyspnea. American journal of respiratory and critical care medicine. 2012;185(4):435-52.
13. Banzett RB, O'Donnell CR, Guilfoyle TE, Parshall MB, Schwartzstein RM, Meek PM, et al. Multidimensional Dyspnea Profile: an instrument for clinical and laboratory research. The European respiratory journal. 2015;45(6):1681-91.
14. Yorke J, Moosavi SH, Shuldham C, Jones PW. Quantification of dyspnoea using descriptors: development and initial testing of the Dyspnoea-12. Thorax. 2010;65(1):21-6.
15. Yorke J, Swigris J, Russell AM, Moosavi SH, Ng Man Kwong G, Longshaw M, et al. Dyspnea-12 is a valid and reliable measure of breathlessness in patients with interstitial lung disease. Chest. 2011;139(1):159-64.
16. Alyami MM, Jenkins SC, Lababidi H, Hill K. Reliability and validity of an arabic version of the dyspnea-12 questionnaire for Saudi nationals with chronic obstructive pulmonary disease. Ann Thorac Med. 2015;10(2):112-7.
17. Yorke J, Russell AM, Swigris J, Shuldham C, Haigh C, Rochnia N, et al. Assessment of dyspnea in asthma: validation of The Dyspnea-12. The Journal of asthma : official journal of the Association for the Care of Asthma. 2011;48(6):602-8.
18. Yorke J, Armstrong I. The assessment of breathlessness in pulmonary arterial hypertension: reliability and validity of the Dyspnoea-12. European journal of cardiovascular nursing : journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology. 2014;13(6):506-14.
19. Lee BY, Lee S, Lee JS, Song JW, Lee SD, Jang SH, et al. Validity and Reliability of CAT and Dyspnea-12 in Bronchiectasis and Tuberculous Destroyed Lung. Tuberculosis and respiratory diseases. 2012;72(6):467-74.
20. Al-Gamal E, Yorke J, Al-Shwaiyat MK. Dyspnea-12-Arabic: testing of an instrument to measure breathlessness in Arabic patients with chronic obstructive pulmonary disease. Heart & lung : the journal of critical care. 2014;43(3):244-8.
21. Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, et al. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research. 2005;8(2):94-104.
22. Wild D, Eremenco S, Mear I, Martin M, Houchin C, Gawlicki M, et al. Multinational trials-recommendations on the translations required, approaches to using the same language in different countries, and the approaches to support pooling the data: the ISPOR Patient-Reported Outcomes Translation and Linguistic Validation Good Research Practices Task Force report. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research. 2009;12(4):430-40.
23. 2016. Available from: http://mapigroup.com/.
24. Morelot-Panzini C, Gilet H, Aguilaniu B, Devillier P, Didier A, Perez T, et al. Real-life assessment of the multidimensional nature of dyspnoea in COPD outpatients. The European respiratory journal. 2016;47(6):1668-79.
25. Sundh J EM. Persistent disabling breathlessness in chronic obstructive pulmonary disease. International journal of chronic obstructive pulmonary disease. 2016: In press.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

University of Salford
A Greater Manchester University

Royal Brompton & Harefield NHS
NHS Foundation Trust

Dyspné-12

Detta frågeformulär är utformat för att hjälpa oss att ta reda på mer om hur din andning besvärar dig.

Läs varje påstående och kryssa sedan i den ruta som bäst stämmer överens med din andning överlag **på senare tid**. Om du inte upplever ett symtom, kryssa i rutan "Upplever inte alls". Vänligen svara på alla påståendena.

Namn: ..... ID: ..... Datum: ..... /..... /.....

Påstående	Upplever inte alls	Lindrigt	Måttligt	Svårt
1. Jag kan inte ta djupa andetag				
2. Min andning är ansträngande				
3. Jag känner mig andfådd				
4. Jag har svårt att hämta andan				
5. Jag får inte tillräckligt med luft				
6. Min andning är obehaglig				
7. Min andning är utmattande				
8. Min andning får mig att känna mig nedstämd				
9. Min andning får mig att känna mig olycklig				
10. Min andning är bekymmersam				
11. Min andning gör mig uppstressad				
12. Min andning är besvärande				

© Royal Brompton and Harefield Trust, London and University of Salford, Greater Manchester, alla rättigheter förbehålls

For peer review only

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

BMJ Open

Dyspnoea-12: A linguistic validation of a Swedish version

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-014490.R1
Article Type:	Research
Date Submitted by the Author:	29-Dec-2016
Complete List of Authors:	Sundh, Josefin; School of medical Sciences, Örebro University, Department of Respiratory Medicine Ekström, Magnus
Primary Subject Heading:	Respiratory medicine
Secondary Subject Heading:	Research methods
Keywords:	dyspnoea, multidimensional, measurement, Swedish, translation

SCHOLARONE™
Manuscripts

For peer review only

Title: Dyspnoea-12: A linguistic validation of a Swedish version

Running title: Swedish version of D-12

Authors: Josefin Sundh, MD, PhD[1], Magnus Ekström, MD, PhD[2]

[1] *Department of Respiratory Medicine, School of Medical Sciences, Örebro University, Örebro, Sweden.*

[2] *Department of Clinical Sciences, Division of Respiratory Medicine & Allergology, Lund University, Lund, Sweden*

Corresponding author: Josefin Sundh, Department of Respiratory Medicine, School of Medical Sciences, Örebro University, Örebro, Sweden, E-mail josefin.sundh@oru.se, Phone +46702349517, Fax +4619186526

Word count for body of text: 1544

Word count for abstract: 201

Tables: 0; **Figures:** 2.

Key words: Dyspnoea; multidimensional, measurement, Swedish, translation

For peer review only

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

ABSTRACT

Background: Dyspnoea consists of multiple dimensions including the intensity, unpleasantness, sensory qualities and emotional responses which may differ between patient groups, settings and in relation to treatment. The Dyspnoea-12 is a validated and convenient instrument for multidimensional measurement in English. We aimed to take forward a Swedish version of the Dyspnoea-12.

Methods: The linguistic validation of the Dyspnoea-12 was performed (Mapi Language Services, Lyon, France). The standardised procedure involved forward and backward translations by three independent certified translators, and revisions after feedback from an in-country linguistic consultant, the developers, and three native physicians. The understanding and convenience of the translated version was evaluated using qualitative in-depth interviews with five patients with dyspnoea.

Results: A Swedish version of the Dyspnoea-12 was elaborated and evaluated carefully according to international guidelines. The Swedish version; "Dyspné-12", has the same layout as the original version, including 12 items distributed on seven physical and five affective items. The Dyspnoea-12 is copyrighted by the developer but can be used free of charge after permission for not industry-funded research.

Conclusion: A Swedish version of the Dyspnoea-12 is now available for clinical validation and multidimensional measurement across diseases and settings with the aim of improved evaluation and management of dyspnoea.

For peer review only

Article Summary

Strengths and limitations of this study

- The linguistic validation of the Dyspnoea-12 to Swedish was performed using a structured multi-stage process in accordance with international guidelines, involving translations by two independent certified translators, a backward translation for quality check, and review by clinicians and test on patients with dyspnoea before establishing the final Swedish version
- A Swedish version of the Dyspnoea-12 will enable to conduct clinical validation studies across patient populations and settings, and will bring a new possibility to deepen the understanding of breathlessness and to value the impact of different dimensions of breathlessness.
- The translated version of the Dyspnoea-12 still needs to be psychometrically validated in a clinical Swedish population.

For peer review only

INTRODUCTION

Reduction of symptoms is a major treatment goal in chronic cardiac and respiratory diseases. Dyspnoea is the cardinal symptom in cardiopulmonary diseases, including heart failure, chronic obstructive pulmonary disease (COPD) and interstitial lung diseases such as idiopathic pulmonary fibrosis (IPF). Dyspnoea is strongly associated with impaired health related quality of life in COPD (1) and IPF (2), and with increased mortality in COPD (3, 4), IPF (5, 6) and heart failure (7). Despite this fact, clinical practice often focuses on underlying diseases and not on the management of the often chronic symptom of dyspnoea itself (8).

Multiple dimensions of dyspnoea

Traditionally, dyspnoea has been assessed as an indirect measure of functional limitation due to breathlessness, as with the Medical Research Council (MRC) scale (9), or using a single rating scale such as a visual analogue scale (VAS) (10) or Borg scale (11) during exercise tests. However, growing attention has been paid to the fact that dyspnoea consists of multiple important dimensions besides the overall intensity or unpleasantness, such as sensory and affective qualities, associated emotional responses, and the functional impact on the person´s life (12). This makes it difficult to compare findings between patient populations and between differences in responses of separate treatments of dyspnoea (13). Thus, standardised measurements with different dimensions of dyspnoea are needed.

Dyspnoea-12

The Dyspnoea-12 instrument was developed to be a concise instrument for quantification of different aspects of dyspnoea, valid across different cardiorespiratory diseases (14). In the

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

original study establishing the final version of the Dyspnoea-12, the instrument was associated with the MRC scale in COPD, IPF and heart failure (14). The subsequent validation study showed a good internal reliability and test-retest reliability, and the Dyspnoea-12 was significantly correlated to the Hospital Anxiety and Depression Scale (HADS), the MRC scale, the Forced Expiratory Volume in one second (FEV_1) and the six minutes walking distance (6MWD) test (14). After the initial validation, further studies have validated the use of the Dyspnoea-12 in interstitial lung disease (15) and COPD (16), but also in asthma (17), pulmonary arterial hypertension (18), bronchiectasis and tuberculosis destroyed lungs (19).

The Dyspnoea-12 is available in English (14), Arabic (16, 20) and Korean (19), but has to our knowledge not been translated into any other European language except English. A multidimensional instrument for assessment of dyspnoea in cancer, the Cancer Dyspnoea Scale, has been developed (21) and validated in Swedish (22), and recently the Multidimensional Dyspnoea Profile (13) has been linguistically validated in Swedish (23). However, a brief and convenient multidimensional instrument that allows comparison across diseases would be of additional value. Until now, there has been no multidimensional instrument for measurement of dyspnoea available in Swedish. A Swedish version of Dyspnoea-12 should be of great importance for further research in the field of breathlessness, especially to be able to make comparisons across populations. We therefore aimed to develop a linguistically validated Swedish version of the Dyspnoea-12.

METHODS

The Dyspnoea-12 instrument

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

The Dyspnoea-12 instrument includes 12 descriptors assessed on a four-point scale such as none (score 0), mild (1), moderate (2) or severe (3), resulting in a total score from 0 to 36 where a higher score corresponds to more severe breathlessness. The first seven items constitute a physical domain assessing whether the breath does not go in all the way, the patient cannot get enough air, feels short of breath or has difficulty catching breath, and the breathing requires more work, is uncomfortable or exhausting. The remaining five items constitute an emotional domain where the items describe whether the breathing is distressing, irritating or makes the patient feel depressed, miserable or agitated. A physical and an emotional component score can be calculated, with maximum score of 21 and 15, respectively. A minimal important clinical difference (MCID) of 3 units has been recommended (24).

Linguistic validation

The linguistic validation of the Dyspnoea-12 into Swedish was performed in a structured multi-stage process in accordance with international guidelines (25, 26), in collaboration with a company specialized in translation and validation of patient-reported outcome measures (Mapi Language Services, Lyon, France; hereafter referred to as 'Mapi') (27). Permission to translate the Dyspnoea-12 into Swedish was obtained from the developer. The role of Mapi was to supply translators and to perform quality checks in collaboration with the developer. The whole process is summarised in Figure 1.

Translation

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Two independent certified translators, native speakers of Swedish and living in Sweden, translated the original instrument developed in British English into Swedish. These two forward-translations were analysed and reconciled by an in-country consultant into a first translated version. After a quality check from Mapi, the first Swedish version was translated back into English and compared with the original British version by the developer and by the in-country consultant, to establish a second translated Swedish version.

Clinicians' review

The second translated version was reviewed by three native Swedish-speaking specialists in internal and/or respiratory medicine, including the authors of this paper, in order to provide detailed feedback on the wordings from a clinical perspective. The feedback from the clinicians was considered by Mapi again with input from the in-country consultant and the developer, resulting in a third translated Swedish version.

Patients' interviews

The third translated version was evaluated using a validated method of individual in-depth interviews (27) with five Swedish patients with dyspnoea, recruited by Mapi and the in-country consultant, in order to investigate if the instrument was easy to understand, assimilate and accept. The patients were interviewed face-to-face by the local consultant. The patients were asked to complete the questionnaire and subsequently make general comments and answer two specific questions for each item. They were told that the intention was to assess whether the questionnaire was comprehensible and acceptable for them, but not to evaluate their answers to the items. The first question was "What does the

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

instructions/question/response choice mean for you?", and encouraged the respondents to reword the item using other words that those used or to give examples. The second question was "Did you have difficulty understanding the instructions/question/response choice?", and also included follow-up questions if there were words that were difficult to understand and suggested changes of the wording. The patients were encouraged to speak and to express their feelings about the questions without being interrupted. The consultant was attentive to any non-verbal or verbal signs betraying the way the respondents felt. The interviews took approximately one hour each, and were transcribed verbatim. The feedback from the patients on their understanding and suggested alternative formulations for each item was used for revision and establishment of the final linguistically validated translation.

Ethics

The study was approved by the regional ethics committee at Lund University (DNr: 2016/16). Written informed consent for the translation process and clinicians' review was not required as no personal data on participants were collected. Oral consent was received from the five patients for the in-depth interviews.

RESULTS

The final certified, linguistically validated Swedish translation of the Dyspnoea-12 is found in Figure 2. The Swedish version; "Dyspné-12", has the same layout as the original version , including 12 items. The clinicians review resulted in several small linguistic adjustments, after which the instrument was conceptually equivalent to the original but uses the corresponding adequate clinical words and expressions in Swedish. The in-depth interviews

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

with five patients did not result in any further changes. The time period of measurement in the original version is “these days”, which was translated into a corresponding word in Swedish.

DISCUSSION

The purpose of this project was to linguistically validate a Swedish version of the Dyspnoea-12 instrument. The procedure was performed according to international guidelines for patient-reported outcomes and have resulted in a convenient instrument for the quantification of different aspects of breathlessness in Swedish research. The instrument could be used as a brief and easy-to use alternative or complement to the instrument Multi-Dimensional Profile (MDP) (13, 28).

A major strength of our study was the structured multi-stage process in accordance with international guidelines, including translation two independent certified translators, backward translation for quality check, and clinicians’ and patients’ evaluations before establishing the final translation. Moreover, the Swedish version of the Dyspnoea-12 will enable the comparison and aggregation of results from different populations and countries, and the development of further research needed to value the impact of different dimensions of breathlessness. However, the translated version of the Dyspnoea-12 needs to be psychometrically validated in a clinical Swedish population. In addition, further linguistic validations in other languages would be of value and much welcome to develop multinational research.

Use of the Dyspnoea-12

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

The developer of the Dyspnoea-12 recommends that the instrument should not be used with more than three missing items. The idea is to get a general perception of the current state, and thus the term "these days" is suggested. However, the English version of the Dyspnoea-12 has been used with a recall period of " the recent two weeks" (Marie Williams, personal communication), and the Swedish version also need to be validated for different periods of time. The Dyspnoea-12 is copyrighted by the developers but can be used free of charge for not industry-funded research, after permission.

Conclusion

A Swedish version of the Dyspnoea-12 is now available for clinical validation and multidimensional measurement across diseases and settings with the aim of improved evaluation and management of dyspnoea.

AUTHOR´S CONTRIBUTIONS

Conception and design: ME. First draft: JS. Participated in the translation and validation, revision for important intellectual content, and approval of the version to be published: JS and ME.

ACKNOWLEDGEMENTS

The authors thank Bengt Dahlander, MD, Capio ASIH Nacka, who contributed to the clinical review of the Dyspnoea-12.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

FUNDING

The study was supported by an unrestricted grant from the Swedish Heart-Lung Foundation (Nr 20150424).

REFERENCES

1. Bestall JC, Paul EA, Garrod R, Garnham R, Jones PW, Wedzicha JA. Usefulness of the Medical Research Council (MRC) dyspnoea scale as a measure of disability in patients with chronic obstructive pulmonary disease. Thorax. 1999;54(7):581-6.
2. Nishiyama O, Taniguchi H, Kondoh Y, Kimura T, Ogawa T, Watanabe F, et al. Health-related quality of life in patients with idiopathic pulmonary fibrosis. What is the main contributing factor? Respiratory medicine. 2005;99(4):408-14.
3. Nishimura K, Izumi T, Tsukino M, Oga T. Dyspnea is a better predictor of 5-year survival than airway obstruction in patients with COPD. Chest. 2002;121(5):1434-40.
4. Casanova C, Marin JM, Martinez-Gonzalez C, de Lucas-Ramos P, Mir-Viladrich I, Cosio B, et al. Differential effect of mMRC dyspnea, CAT and CCQ for symptom evaluation within the new GOLD staging and mortality in COPD. Chest. 2015.
5. Mura M, Porretta MA, Bargagli E, Sergiacomi G, Zompatori M, Sverzellati N, et al. Predicting survival in newly diagnosed idiopathic pulmonary fibrosis: a 3-year prospective study. The European respiratory journal. 2012;40(1):101-9.
6. Nishiyama O, Taniguchi H, Kondoh Y, Kimura T, Kato K, Kataoka K, et al. A simple assessment of dyspnoea as a prognostic indicator in idiopathic pulmonary fibrosis. The European respiratory journal. 2010;36(5):1067-72.
7. Ekman I, Cleland JG, Swedberg K, Charlesworth A, Metra M, Poole-Wilson PA. Symptoms in patients with heart failure are prognostic predictors: insights from COMET. Journal of cardiac failure. 2005;11(4):288-92.
8. Johnson MJ, Currow DC, Booth S. Prevalence and assessment of breathlessness in the clinical setting. Expert review of respiratory medicine. 2014;8(2):151-61.
9. Mahler DA, Wells CK. Evaluation of clinical methods for rating dyspnea. Chest. 1988;93(3):580-6.
10. Lansing RW, Moosavi SH, Banzett RB. Measurement of dyspnea: word labeled visual analog scale vs. verbal ordinal scale. Respiratory physiology & neurobiology. 2003;134(2):77-83.
11. Borg GA. Psychophysical bases of perceived exertion. Medicine and science in sports and exercise. 1982;14(5):377-81.
12. Parshall MB, Schwartzstein RM, Adams L, Banzett RB, Manning HL, Bourbeau J, et al. An official American Thoracic Society statement: update on the mechanisms, assessment, and management of dyspnea. American journal of respiratory and critical care medicine. 2012;185(4):435-52.
13. Banzett RB, O'Donnell CR, Guilfoyle TE, Parshall MB, Schwartzstein RM, Meek PM, et al. Multidimensional Dyspnea Profile: an instrument for clinical and laboratory research. The European respiratory journal. 2015;45(6):1681-91.
14. Yorke J, Moosavi SH, Shuldham C, Jones PW. Quantification of dyspnoea using descriptors: development and initial testing of the Dyspnoea-12. Thorax. 2010;65(1):21-6.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

15. Yorke J, Swigris J, Russell AM, Moosavi SH, Ng Man Kwong G, Longshaw M, et al. Dyspnea-12 is a valid and reliable measure of breathlessness in patients with interstitial lung disease. Chest. 2011;139(1):159-64.
16. Alyami MM, Jenkins SC, Lababidi H, Hill K. Reliability and validity of an arabic version of the dyspnea-12 questionnaire for Saudi nationals with chronic obstructive pulmonary disease. Ann Thorac Med. 2015;10(2):112-7.
17. Yorke J, Russell AM, Swigris J, Shuldham C, Haigh C, Rochnia N, et al. Assessment of dyspnea in asthma: validation of The Dyspnea-12. The Journal of asthma : official journal of the Association for the Care of Asthma. 2011;48(6):602-8.
18. Yorke J, Armstrong I. The assessment of breathlessness in pulmonary arterial hypertension: reliability and validity of the Dyspnoea-12. European journal of cardiovascular nursing : journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology. 2014;13(6):506-14.
19. Lee BY, Lee S, Lee JS, Song JW, Lee SD, Jang SH, et al. Validity and Reliability of CAT and Dyspnea-12 in Bronchiectasis and Tuberculous Destroyed Lung. Tuberculosis and respiratory diseases. 2012;72(6):467-74.
20. Al-Gamal E, Yorke J, Al-Shwaiyat MK. Dyspnea-12-Arabic: testing of an instrument to measure breathlessness in Arabic patients with chronic obstructive pulmonary disease. Heart & lung : the journal of critical care. 2014;43(3):244-8.
21. Tanaka K, Akechi T, Okuyama T, Nishiwaki Y, Uchitomi Y. Development and validation of the Cancer Dyspnoea Scale: a multidimensional, brief, self-rating scale. British journal of cancer. 2000;82(4):800-5.
22. Henoch I, Bergman B, Gaston-Johansson F. Validation of a Swedish version of the Cancer Dyspnea Scale. Journal of pain and symptom management. 2006;31(4):353-61.
23. Ekström M, Sundh J. Swedish translation and linguistic validation of the multidimensional dyspnoea profile. European clinical respiratory journal. 2016;3.
24. Yorke J, Lloyd-Williams M, Smith J, Blackhall F, Harle A, Warden J, et al. Management of the respiratory distress symptom cluster in lung cancer: a randomised controlled feasibility trial. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2015;23(11):3373-84.
25. Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, et al. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research. 2005;8(2):94-104.
26. Wild D, Eremenco S, Mear I, Martin M, Houchin C, Gawlicki M, et al. Multinational trials-recommendations on the translations required, approaches to using the same language in different countries, and the approaches to support pooling the data: the ISPOR Patient-Reported Outcomes Translation and Linguistic Validation Good Research Practices Task Force report. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research. 2009;12(4):430-40.
27. Mapigroup 2016. Available from: http://mapigroup.com/.
28. Morelot-Panzini C, Gilet H, Aguilaniu B, Devillier P, Didier A, Perez T, et al. Real-life assessment of the multidimensional nature of dyspnoea in COPD outpatients. The European respiratory journal. 2016;47(6):1668-79.

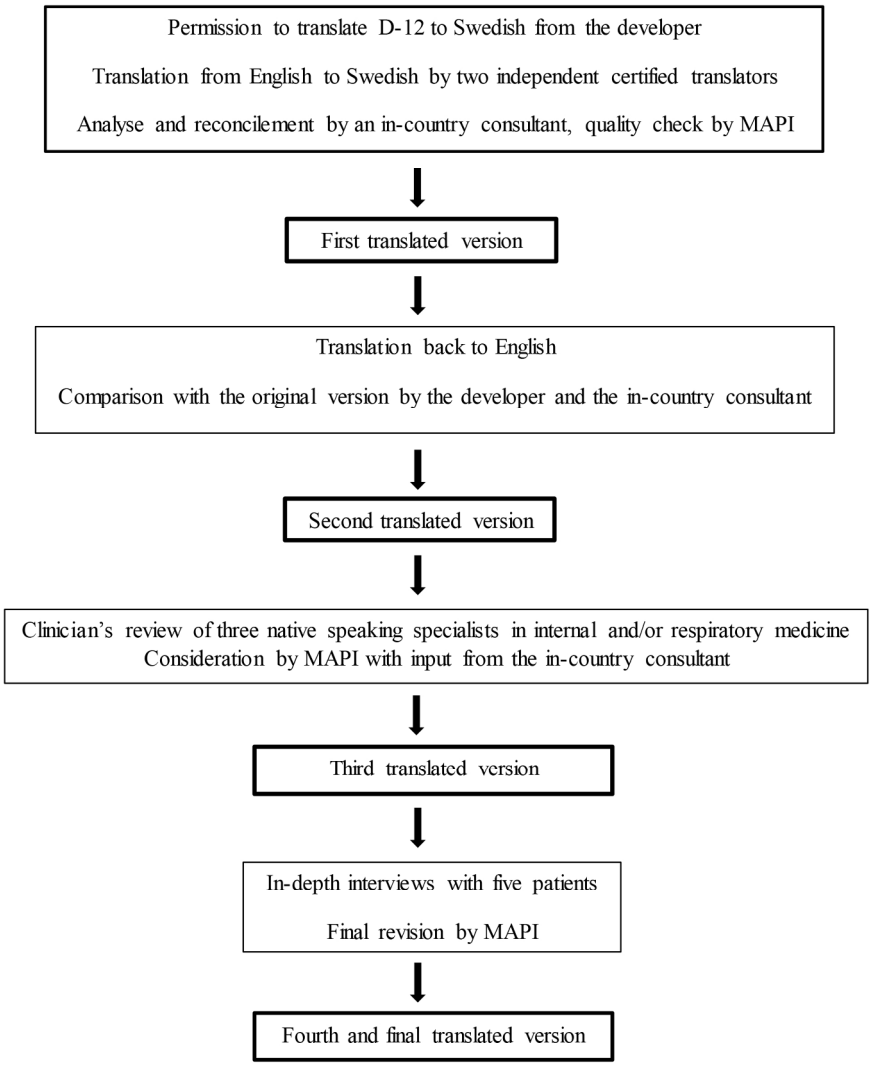
For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Figure legends (only captions needed)

Figure 1. Flow chart for the linguistic validation process

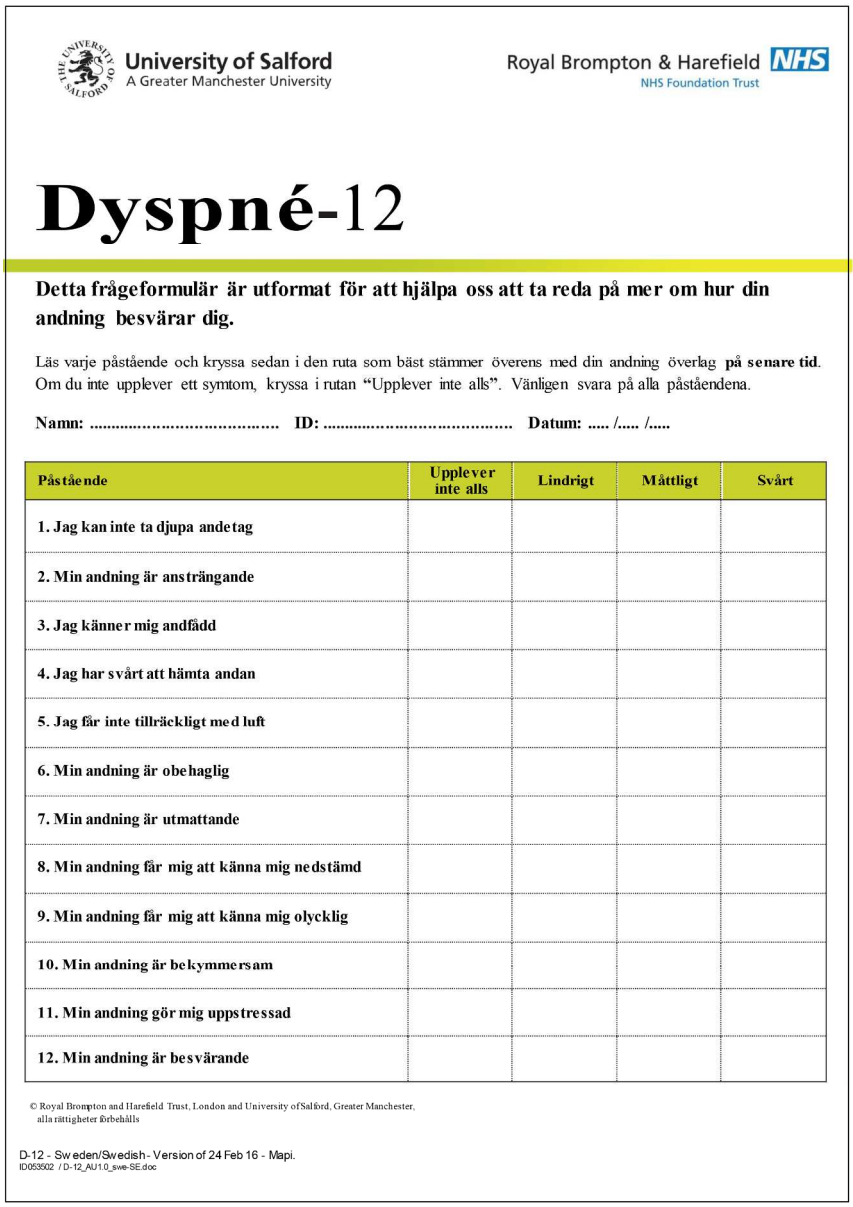
Figure 2. Swedish version of the Dyspnoea-12

For peer review only



Flow chart for the linguistic validation process

166x226mm (300 x 300 DPI)



University of Salford
A Greater Manchester University

Royal Brompton & Harefield NHS
NHS Foundation Trust

Dyspné-12

Detta frågeformulär är utformat för att hjälpa oss att ta reda på mer om hur din andning besvärar dig.

Läs varje påstående och kryssa sedan i den ruta som bäst stämmer överens med din andning överlag **på senare tid**. Om du inte upplever ett symtom, kryssa i rutan "Upplever inte alls". Vänligen svara på alla påståendena.

Namn: ..... **ID:** ..... **Datum:** ..... /..... /.....

Påstående	Upplever inte alls	Lindrigt	Måttligt	Svårt
1. Jag kan inte ta djupa andetag				
2. Min andning är ansträngande				
3. Jag känner mig andfådd				
4. Jag har svårt att hämta andan				
5. Jag får inte tillräckligt med luft				
6. Min andning är obehaglig				
7. Min andning är utmattande				
8. Min andning får mig att känna mig nedstämd				
9. Min andning får mig att känna mig olycklig				
10. Min andning är bekymmersam				
11. Min andning gör mig uppstressad				
12. Min andning är besvärande				

© Royal Brompton and Harefield Trust, London and University of Salford, Greater Manchester, alla rättigheter förbehålls

D-12 - Sweden/Swedish - Version of 24 Feb 16 - Mapi.
ID053502 / D-12_AU1.0_swe-SE.doc

Swedish version of the Dyspnoea-12

210x297mm (300 x 300 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract ***Yes***
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found ***Yes***
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported ***Yes***
Objectives	3	State specific objectives, including any prespecified hypotheses ***Yes***
Methods		
Study design	4	Present key elements of study design early in the paper ***Yes***
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection ***Yes***
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants ***N/A***
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case ***N/A***
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable ***Yes***
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group ***Yes***
Bias	9	Describe any efforts to address potential sources of bias ***Yes***
Study size	10	Explain how the study size was arrived at ***N/A***
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why ***N/A***

For peer review only

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding ***Yes***
		(*b*) Describe any methods used to examine subgroups and interactions ***N/A***
		(*c*) Explain how missing data were addressed ***N/A***
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy **N/A**
		(*e*) Describe any sensitivity analyses ***N/A***

Continued on next page

For peer review only

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed ***N/A***
		(b) Give reasons for non-participation at each stage ***N/A***
		(c) Consider use of a flow diagram ***Yes***
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders ***N/A***
		(b) Indicate number of participants with missing data for each variable of interest ***N/A***
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount) ***N/A***
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures ***Yes***
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included ***N/A***
		(*b*) Report category boundaries when continuous variables were categorized ***N/A***
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period ***N/A***
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses ***Yes***
Discussion		
Key results	18	Summarise key results with reference to study objectives ***Yes***
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias ***Yes***
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence ***Yes***
Generalisability	21	Discuss the generalisability (external validity) of the study results ***Yes***
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable,

For peer review only

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

for the original study on which the present article is based
Yes

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

For peer review only

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

BMJ Open

Dyspnoea-12: A translation and linguistic validation study in a Swedish setting

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-014490.R2
Article Type:	Research
Date Submitted by the Author:	09-Mar-2017
Complete List of Authors:	Sundh, Josefin; School of medical Sciences, Örebro University, Department of Respiratory Medicine Ekström, Magnus
Primary Subject Heading:	Respiratory medicine
Secondary Subject Heading:	Research methods
Keywords:	dyspnoea, multidimensional, measurement, Swedish, translation

SCHOLARONE™
Manuscripts

For peer review only

Title: Dyspnoea-12: A translation and linguistic validation study in a Swedish setting

Running title: Swedish version of D-12

Authors: Josefin Sundh, MD, PhD[1], Magnus Ekström, MD, PhD[2]

[1] *Department of Respiratory Medicine, School of Medical Sciences, Örebro University, Örebro, Sweden.*

[2] *Department of Clinical Sciences, Division of Respiratory Medicine & Allergology, Lund University, Lund, Sweden*

Corresponding author: Josefin Sundh, Department of Respiratory Medicine, School of Medical Sciences, Örebro University, Örebro, Sweden, E-mail josefin.sundh@oru.se, Phone +46702349517, Fax +4619186526

Word count for body of text: 1544

Word count for abstract: 201

Tables: 0; **Figures:** 2.

Key words: Dyspnoea; multidimensional, measurement, Swedish, translation

For peer review only

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

ABSTRACT

Background: Dyspnoea consists of multiple dimensions including the intensity, unpleasantness, sensory qualities and emotional responses which may differ between patient groups, settings and in relation to treatment. The Dyspnoea-12 is a validated and convenient instrument for multidimensional measurement in English. We aimed to take forward a Swedish version of the Dyspnoea-12.

Methods: The linguistic validation of the Dyspnoea-12 was performed (Mapi Language Services, Lyon, France). The standardised procedure involved forward and backward translations by three independent certified translators, and revisions after feedback from an in-country linguistic consultant, the developers, and three native physicians. The understanding and convenience of the translated version was evaluated using qualitative in-depth interviews with five patients with dyspnoea.

Results: A Swedish version of the Dyspnoea-12 was elaborated and evaluated carefully according to international guidelines. The Swedish version; "Dyspné-12", has the same layout as the original version, including 12 items distributed on seven physical and five affective items. The Dyspnoea-12 is copyrighted by the developer but can be used free of charge after permission for not industry-funded research.

Conclusion: A Swedish version of the Dyspnoea-12 is now available for clinical validation and multidimensional measurement across diseases and settings with the aim of improved evaluation and management of dyspnoea.

For peer review only

Article Summary

Strengths and limitations of this study

- The linguistic validation of the Dyspnoea-12 to Swedish was performed using a structured multi-stage process in accordance with international guidelines, involving translations by two independent certified translators, a backward translation for quality check, and review by clinicians and test on patients with dyspnoea before establishing the final Swedish version
- A Swedish version of the Dyspnoea-12 will enable to conduct clinical validation studies across patient populations and settings, and will bring a new possibility to deepen the understanding of breathlessness and to value the impact of different dimensions of breathlessness.
- The translated version of the Dyspnoea-12 still needs to be psychometrically validated in a clinical Swedish population.

For peer review only

INTRODUCTION

Reduction of symptoms is a major treatment goal in chronic cardiac and respiratory diseases. Dyspnoea is the cardinal symptom in cardiopulmonary diseases, including heart failure, chronic obstructive pulmonary disease (COPD) and interstitial lung diseases such as idiopathic pulmonary fibrosis (IPF). Dyspnoea is strongly associated with impaired health related quality of life in COPD (1) and IPF (2), and with increased mortality in COPD (3, 4), IPF (5, 6) and heart failure (7). Despite this fact, clinical practice often focuses on underlying diseases and not on the management of the often chronic symptom of dyspnoea itself (8).

Multiple dimensions of dyspnoea

Traditionally, dyspnoea has been assessed as an indirect measure of functional limitation due to breathlessness, as with the Medical Research Council (MRC) scale (9), or using a single rating scale such as a visual analogue scale (VAS) (10) or Borg scale (11) during exercise tests. However, growing attention has been paid to the fact that dyspnoea consists of multiple important dimensions besides the overall intensity or unpleasantness, such as sensory and affective qualities, associated emotional responses, and the functional impact on the person´s life (12). This makes it difficult to compare findings between patient populations and between differences in responses of separate treatments of dyspnoea (13). Thus, standardised measurements with different dimensions of dyspnoea are needed.

Dyspnoea-12

The Dyspnoea-12 instrument was developed to be a concise instrument for quantification of different aspects of dyspnoea, valid across different cardiorespiratory diseases (14). In the

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

original study establishing the final version of the Dyspnoea-12, the instrument was associated with the MRC scale in COPD, IPF and heart failure (14). The subsequent validation study showed a good internal reliability and test-retest reliability, and the Dyspnoea-12 was significantly correlated to the Hospital Anxiety and Depression Scale (HADS), the MRC scale, the Forced Expiratory Volume in one second (FEV_1) and the six minutes walking distance (6MWD) test (14). After the initial validation, further studies have validated the use of the Dyspnoea-12 in interstitial lung disease (15) and COPD (16), but also in asthma (17), pulmonary arterial hypertension (18), bronchiectasis and tuberculosis destroyed lungs (19).

The Dyspnoea-12 is available in English (14), Arabic (16, 20) and Korean (19), but has to our knowledge not been translated into any other European language except English. A multidimensional instrument for assessment of dyspnoea in cancer, the Cancer Dyspnoea Scale, has been developed (21) and validated in Swedish (22), and recently the Multidimensional Dyspnoea Profile (13) has been linguistically validated in Swedish (23). However, a brief and convenient multidimensional instrument that allows comparison across diseases would be of additional value. Until now, there has been no multidimensional instrument for measurement of dyspnoea available in Swedish. A Swedish version of Dyspnoea-12 should be of great importance for further research in the field of breathlessness, especially to be able to make comparisons across populations. We therefore aimed to develop a linguistically validated Swedish version of the Dyspnoea-12.

METHODS

The Dyspnoea-12 instrument

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

The Dyspnoea-12 instrument includes 12 descriptors assessed on a four-point scale such as none (score 0), mild (1), moderate (2) or severe (3), resulting in a total score from 0 to 36 where a higher score corresponds to more severe breathlessness. The first seven items constitute a physical domain assessing whether the breath does not go in all the way, the patient cannot get enough air, feels short of breath or has difficulty catching breath, and the breathing requires more work, is uncomfortable or exhausting. The remaining five items constitute an emotional domain where the items describe whether the breathing is distressing, irritating or makes the patient feel depressed, miserable or agitated. A physical and an emotional component score can be calculated, with maximum score of 21 and 15, respectively. A minimal important clinical difference (MCID) of 3 units has been recommended (24).

Linguistic validation

The linguistic validation of the Dyspnoea-12 into Swedish was performed in a structured multi-stage process in accordance with international guidelines (25, 26), in collaboration with a company specialized in translation and validation of patient-reported outcome measures (Mapi Language Services, Lyon, France; hereafter referred to as 'Mapi') (27). Permission to translate the Dyspnoea-12 into Swedish was obtained from the developer. The role of Mapi was to supply translators and to perform quality checks in collaboration with the developer. The whole process is summarised in Figure 1.

Translation

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Two independent certified translators, native speakers of Swedish and living in Sweden, translated the original instrument developed in British English into Swedish. These two forward-translations were analysed and reconciled by an in-country consultant into a first translated version. After a quality check from Mapi, the first Swedish version was translated back into English and compared with the original British version by the developer and by the in-country consultant, to establish a second translated Swedish version.

Clinicians' review

The second translated version was reviewed by three native Swedish-speaking specialists in internal and/or respiratory medicine, including the authors of this paper, in order to provide detailed feedback on the wordings from a clinical perspective. The feedback from the clinicians was considered by Mapi again with input from the in-country consultant and the developer, resulting in a third translated Swedish version.

Patients' interviews

The third translated version was evaluated using a validated method of individual in-depth interviews (27) with five Swedish patients with dyspnoea, recruited by Mapi and the in-country consultant, in order to investigate if the instrument was easy to understand, assimilate and accept. The patients were selected by convenience. No patients denied participating. Data saturation was not discussed, as the number of patients were decided according to Mapi:s guidelines on linguistic validation. Two of the patients were males and three females, and their main conditions were asthma, heat failure or anxiety disorder.The patients were interviewed face-to-face by the local consultant, and the interviews took place at the

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

consultant´s office during the 7th to 10th of August 2015. The consultant was female, her occupation was physiotherapist, and she had 20 years of experience of patient interviews. The consultant had no personal relationship to the patients and no bias to report to the patients before the interviews. No one else except the consultant and the patient was present during the interviews. The patients were asked to complete the questionnaire and subsequently make general comments and answer two specific questions for each item. They were told that the intention was to assess whether the questionnaire was comprehensible and acceptable for them, but not to evaluate their answers to the items. The first question was "What does the instructions/question/response choice mean for you?", and encouraged the respondents to reword the item using other words that those used or to give examples. The second question was "Did you have difficulty understanding the instructions/question/response choice?", and also included follow-up questions if there were words that were difficult to understand and suggested changes of the wording. The patients were encouraged to speak and to express their feelings about the questions without being interrupted. The consultant was attentive to any non-verbal or verbal signs betraying the way the respondents felt. The interviews took approximately one hour each, and were transcribed verbatim. Notes were made by hand in Swedish and translated to English after the interviews. No audio recording was used. The transcripts of the interviews were not returned to the patients and the interviews were not repeated. The feedback from the patients on their understanding and suggested alternative formulations for each item was used for revision and establishment of the final linguistically validated translation. As the purpose of the interviews was only to test the understanding of the Swedish version of Dyspnoea-12, the results of the interviews were not coded or presented in themes or using quotations. The questions used in the interviews were pilot tested in the original English version.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Ethics

The study was approved by the regional ethics committee at Lund University (DNr: 2016/16). Written informed consent for the translation process and clinicians' review was not required as no personal data on participants were collected. Oral consent was received from the five patients for the in-depth interviews.

RESULTS

The final certified, linguistically validated Swedish translation of the Dyspnoea-12 is found in Figure 2. The Swedish version; "Dyspné-12", has the same layout as the original version, including 12 items. The clinicians review resulted in several small linguistic adjustments, after which the instrument was conceptually equivalent to the original but uses the corresponding adequate clinical words and expressions in Swedish. The in-depth interviews with five patients did not result in any further changes. The time period of measurement in the original version is "these days", which was translated into a corresponding word in Swedish.

DISCUSSION

The purpose of this project was to linguistically validate a Swedish version of the Dyspnoea-12 instrument. The procedure was performed according to international guidelines for patient-reported outcomes and have resulted in a convenient instrument for the quantification of different aspects of breathlessness in Swedish research. The instrument could be used as a brief and easy-to use alternative or complement to the instrument Multi-Dimensional Profile (MDP) (13, 28).

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

A major strength of our study was the structured multi-stage process in accordance with international guidelines, including translation two independent certified translators, backward translation for quality check, and clinicians' and patients' evaluations before establishing the final translation. Moreover, the Swedish version of the Dyspnoea-12 will enable the comparison and aggregation of results from different populations and countries, and the development of further research needed to value the impact of different dimensions of breathlessness.

A limitation of the study is that the evaluation of the translated instrument was limited to a smaller number of clinicians and patients. The linguistic validation was performed in accordance with international guidelines, but we cannot exclude the possibility that an evaluation in a larger population could have identified a need to change some of the wordings in the Swedish translation. However, the aim of the present evaluation was to explore if the wordings were comprehensible, not to validate the wordings per se. The translated version of the Dyspnoea-12also needs to be psychometrically validated in a clinical Swedish population. In addition, linguistic validations in other languages would be of value and much welcome to develop multinational research.

Use of the Dyspnoea-12

The developer of the Dyspnoea-12 recommends that the instrument should not be used with more than three missing items. The idea is to get a general perception of the current state, and thus the term "these days" is suggested. However, the English version of the Dyspnoea-12 has been used with a recall period of " the recent two weeks" (29) , and the Swedish version also need to be validated for different periods of time. The Dyspnoea-12 is copyrighted by the developers but can be used free of charge for not industry-funded research, after permission.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Conclusion

A Swedish version of the Dyspnoea-12 is now available for clinical validation and multidimensional measurement across diseases and settings with the aim of improved evaluation and management of dyspnoea.

AUTHOR´S CONTRIBUTIONS

Conception and design: ME. First draft: JS. Participated in the translation and validation, revision for important intellectual content, and approval of the version to be published: JS and ME.

ACKNOWLEDGEMENTS

The authors thank Bengt Dahlander, MD, Capio ASIH Nacka, who contributed to the clinical review of the Dyspnoea-12.

DISCLOSURE STATEMENT

The authors have no financial or other competing interests related to the material of the present study.

FUNDING

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

The study was supported by an unrestricted grant from the Swedish Heart-Lung Foundation (Nr 20150424).

DATA SHARING STATEMENT

Data available from the Dryad Digital Repository: http://dx.doi.org/10.5061/dryad.sd879

REFERENCES

1. Bestall JC, Paul EA, Garrod R, Garnham R, Jones PW, Wedzicha JA. Usefulness of the Medical Research Council (MRC) dyspnoea scale as a measure of disability in patients with chronic obstructive pulmonary disease. Thorax. 1999;54(7):581-6.
2. Nishiyama O, Taniguchi H, Kondoh Y, Kimura T, Ogawa T, Watanabe F, et al. Health-related quality of life in patients with idiopathic pulmonary fibrosis. What is the main contributing factor? Respiratory medicine. 2005;99(4):408-14.
3. Nishimura K, Izumi T, Tsukino M, Oga T. Dyspnea is a better predictor of 5-year survival than airway obstruction in patients with COPD. Chest. 2002;121(5):1434-40.
4. Casanova C, Marin JM, Martinez-Gonzalez C, de Lucas-Ramos P, Mir-Viladrich I, Cosio B, et al. Differential effect of mMRC dyspnea, CAT and CCQ for symptom evaluation within the new GOLD staging and mortality in COPD. Chest. 2015.
5. Mura M, Porretta MA, Bargagli E, Sergiacomi G, Zompatori M, Sverzellati N, et al. Predicting survival in newly diagnosed idiopathic pulmonary fibrosis: a 3-year prospective study. The European respiratory journal. 2012;40(1):101-9.
6. Nishiyama O, Taniguchi H, Kondoh Y, Kimura T, Kato K, Kataoka K, et al. A simple assessment of dyspnoea as a prognostic indicator in idiopathic pulmonary fibrosis. The European respiratory journal. 2010;36(5):1067-72.
7. Ekman I, Cleland JG, Swedberg K, Charlesworth A, Metra M, Poole-Wilson PA. Symptoms in patients with heart failure are prognostic predictors: insights from COMET. Journal of cardiac failure. 2005;11(4):288-92.
8. Johnson MJ, Currow DC, Booth S. Prevalence and assessment of breathlessness in the clinical setting. Expert review of respiratory medicine. 2014;8(2):151-61.
9. Mahler DA, Wells CK. Evaluation of clinical methods for rating dyspnea. Chest. 1988;93(3):580-6.
10. Lansing RW, Moosavi SH, Banzett RB. Measurement of dyspnea: word labeled visual analog scale vs. verbal ordinal scale. Respiratory physiology & neurobiology. 2003;134(2):77-83.
11. Borg GA. Psychophysical bases of perceived exertion. Medicine and science in sports and exercise. 1982;14(5):377-81.
12. Parshall MB, Schwartzstein RM, Adams L, Banzett RB, Manning HL, Bourbeau J, et al. An official American Thoracic Society statement: update on the mechanisms, assessment, and management of dyspnea. American journal of respiratory and critical care medicine. 2012;185(4):435-52.

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

13. Banzett RB, O'Donnell CR, Guilfoyle TE, Parshall MB, Schwartzstein RM, Meek PM, et al. Multidimensional Dyspnea Profile: an instrument for clinical and laboratory research. The European respiratory journal. 2015;45(6):1681-91.
14. Yorke J, Moosavi SH, Shuldham C, Jones PW. Quantification of dyspnoea using descriptors: development and initial testing of the Dyspnoea-12. Thorax. 2010;65(1):21-6.
15. Yorke J, Swigris J, Russell AM, Moosavi SH, Ng Man Kwong G, Longshaw M, et al. Dyspnea-12 is a valid and reliable measure of breathlessness in patients with interstitial lung disease. Chest. 2011;139(1):159-64.
16. Alyami MM, Jenkins SC, Lababidi H, Hill K. Reliability and validity of an arabic version of the dyspnea-12 questionnaire for Saudi nationals with chronic obstructive pulmonary disease. Ann Thorac Med. 2015;10(2):112-7.
17. Yorke J, Russell AM, Swigris J, Shuldham C, Haigh C, Rochnia N, et al. Assessment of dyspnea in asthma: validation of The Dyspnea-12. The Journal of asthma : official journal of the Association for the Care of Asthma. 2011;48(6):602-8.
18. Yorke J, Armstrong I. The assessment of breathlessness in pulmonary arterial hypertension: reliability and validity of the Dyspnoea-12. European journal of cardiovascular nursing : journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology. 2014;13(6):506-14.
19. Lee BY, Lee S, Lee JS, Song JW, Lee SD, Jang SH, et al. Validity and Reliability of CAT and Dyspnea-12 in Bronchiectasis and Tuberculous Destroyed Lung. Tuberculosis and respiratory diseases. 2012;72(6):467-74.
20. Al-Gamal E, Yorke J, Al-Shwaiyat MK. Dyspnea-12-Arabic: testing of an instrument to measure breathlessness in Arabic patients with chronic obstructive pulmonary disease. Heart & lung : the journal of critical care. 2014;43(3):244-8.
21. Tanaka K, Akechi T, Okuyama T, Nishiwaki Y, Uchitomi Y. Development and validation of the Cancer Dyspnoea Scale: a multidimensional, brief, self-rating scale. British journal of cancer. 2000;82(4):800-5.
22. Henoch I, Bergman B, Gaston-Johansson F. Validation of a Swedish version of the Cancer Dyspnea Scale. Journal of pain and symptom management. 2006;31(4):353-61.
23. Ekström M, Sundh J. Swedish translation and linguistic validation of the multidimensional dyspnoea profile. European clinical respiratory journal. 2016;3.
24. Yorke J, Lloyd-Williams M, Smith J, Blackhall F, Harle A, Warden J, et al. Management of the respiratory distress symptom cluster in lung cancer: a randomised controlled feasibility trial. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer. 2015;23(11):3373-84.
25. Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, et al. Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research. 2005;8(2):94-104.
26. Wild D, Eremenco S, Mear I, Martin M, Houchin C, Gawlicki M, et al. Multinational trials-recommendations on the translations required, approaches to using the same language in different countries, and the approaches to support pooling the data: the ISPOR Patient-Reported Outcomes Translation and Linguistic Validation Good Research Practices Task Force report. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research. 2009;12(4):430-40.
27. Mapigroup 2016. Available from: http://mapigroup.com/.
28. Morelot-Panzini C, Gilet H, Aguilaniu B, Devillier P, Didier A, Perez T, et al. Real-life assessment of the multidimensional nature of dyspnoea in COPD outpatients. The European respiratory journal. 2016;47(6):1668-79.
29. Williams MT JD, Frith P. Comparison of the Dyspnoea-12 and Multidimensional Dyspnoea Profile in people with COPD. ERJ 2017 49: 1600773. 2017.

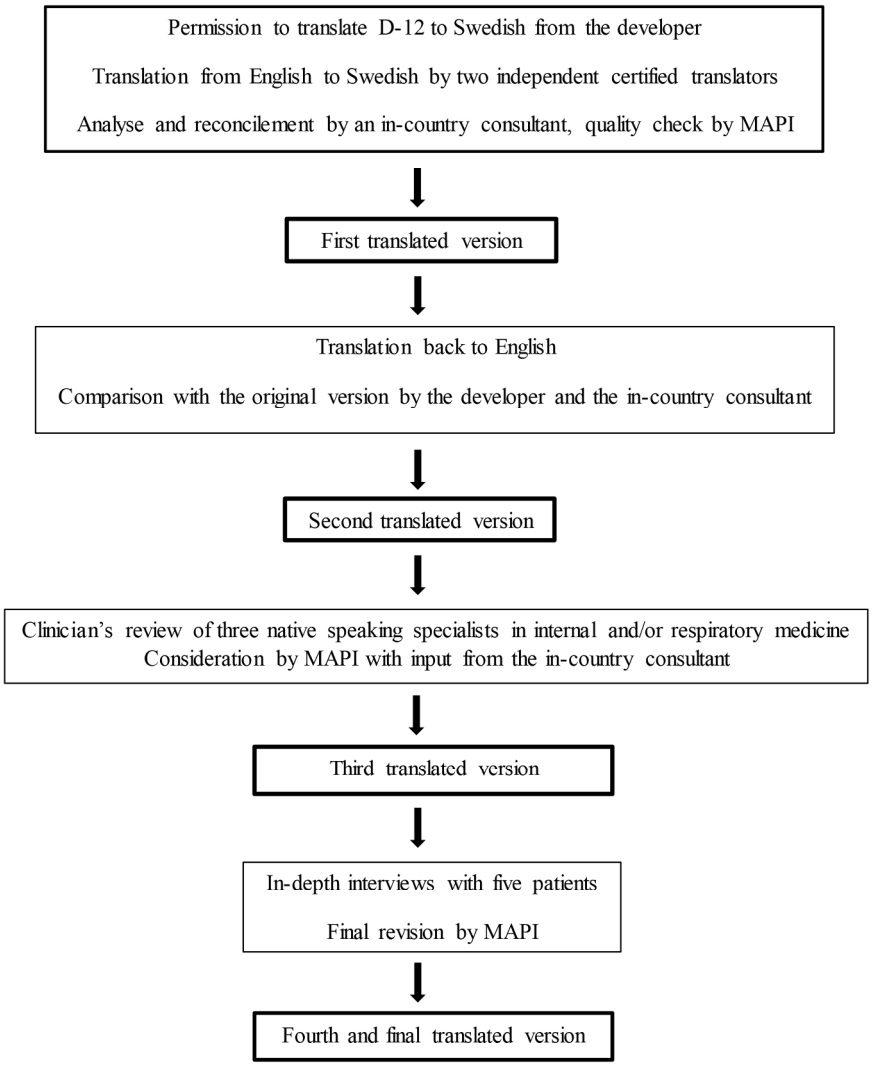
For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Figure legends (only captions needed)

Figure 1. Flow chart for the linguistic validation process

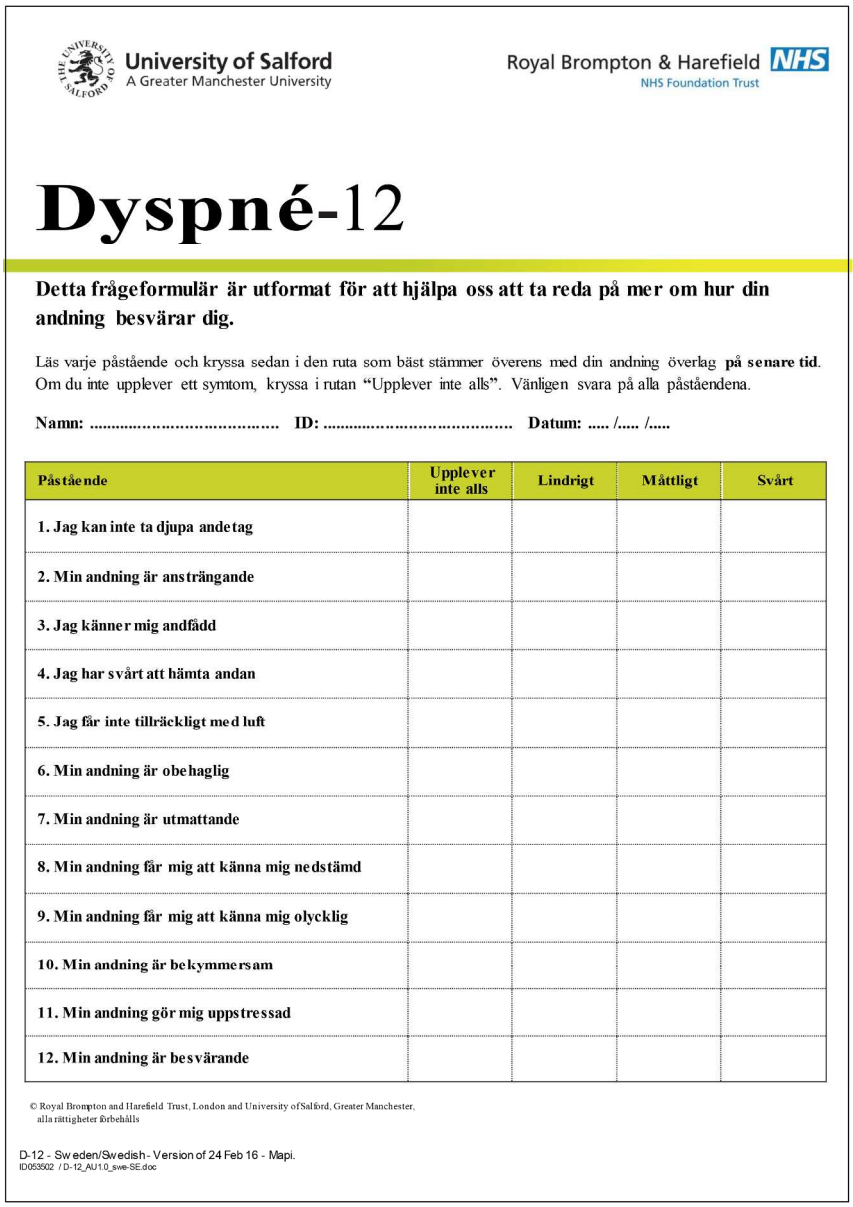
Figure 2. Swedish version of the Dyspnoea-12

For peer review only



Flow chart for the linguistic validation process

166x226mm (300 x 300 DPI)



University of Salford
A Greater Manchester University

Royal Brompton & Harefield NHS
NHS Foundation Trust

Dyspné-12

Detta frågeformulär är utformat för att hjälpa oss att ta reda på mer om hur din andning besvärar dig.

Läs varje påstående och kryssa sedan i den ruta som bäst stämmer överens med din andning överlag **på senare tid**. Om du inte upplever ett symtom, kryssa i rutan "Upplever inte alls". Vänligen svara på alla påståendena.

Namn: ..... **ID:** ..... **Datum:** ..... /..... /.....

Påstående	Upplever inte alls	Lindrigt	Måttligt	Svårt
1. Jag kan inte ta djupa andetag				
2. Min andning är ansträngande				
3. Jag känner mig andfådd				
4. Jag har svårt att hämta andan				
5. Jag får inte tillräckligt med luft				
6. Min andning är obehaglig				
7. Min andning är utmattande				
8. Min andning får mig att känna mig nedstämd				
9. Min andning får mig att känna mig olycklig				
10. Min andning är bekymmersam				
11. Min andning gör mig uppstressad				
12. Min andning är besvärande				

© Royal Brompton and Harefield Trust, London and University of Salford, Greater Manchester, alla rättigheter förbehålls

D-12 - Sweden/Swedish - Version of 24 Feb 16 - Mapi.
ID053502 / D-12_AU1.0_swe-SE.doc

Swedish version of the Dyspnoea-12

210x297mm (300 x 300 DPI)

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	8
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	8
Occupation	3	What was their occupation at the time of the study?	8
Gender	4	Was the researcher male or female?	8
Experience and training	5	What experience or training did the researcher have?	8
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	8
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	8
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	8
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	7
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	7
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	7
Sample size	12	How many participants were in the study?	7
Non-participation	13	How many people refused to participate or dropped out? Reasons?	7
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	7-8
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	8
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	7
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	8
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	8
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	8
Field notes	20	Were field notes made during and/or after the inter view or focus group?	8
Duration	21	What was the duration of the inter views or focus group?	8
Data saturation	22	Was data saturation discussed?	7
Transcripts returned	23	Were transcripts returned to participants for comment and/or	8

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	8
Description of the coding tree	25	Did authors provide a description of the coding tree?	8
Derivation of themes	26	Were themes identified in advance or derived from the data?	8
Software	27	What software, if applicable, was used to manage the data?	8
Participant checking	28	Did participants provide feedback on the findings?	8
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	8
Data and findings consistent	30	Was there consistency between the data presented and the findings?	9
Clarity of major themes	31	Were major themes clearly presented in the findings?	8
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	8

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

For peer review only