

Cultural adaptation of the Rheumatoid Arthritis Quality of Life (RAQoL) for Portugal

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ABSTRACT

Background: Rheumatoid Arthritis (RA) is a chronic inflammatory disease that has a major impact on patients' quality of life. The Rheumatoid Arthritis Quality of Life (RAQoL) questionnaire is a patient-reported outcome measure, specific to RA. The aim of this study was to translate and perform the cross-cultural adaptation of the RAQoL into Portuguese.

Material and Methods: The dual panel methodology was used to translate the UK RAQoL into Portuguese. This involved conducting a bilingual panel (providing the initial translation into Portuguese), followed by a lay panel (where items are assessed for comprehension and acceptability). Cognitive debriefing interviews were conducted with Portuguese RA patients to determine the face and content validity of the translated scale.

Results: The translation panels produced a Portuguese version of the RAQoL that was easily understood and considered natural by native speakers. Twelve RA patients participated in the cognitive debriefing interviews. Patients considered the translated questionnaire to be clear, relevant and appropriate.

Conclusion: The Portuguese version of the RAQoL was found to be comprehensible and demonstrated excellent face and content validity. Research examining the psychometric properties of this Portuguese version of the RAQoL is underway.

Keywords: Rheumatoid Arthritis; Quality of life; RAQoL; Adaptation; Dual-panel

INTRODUCTION

Rheumatoid arthritis (RA) is a chronic inflammatory joint disease characterised by pain, stiffness, swelling, and tenderness of the synovial joints, ultimately leading to joint destruction, disability, reduced quality of life and increased mortality¹. The estimated prevalence of RA in the adult Portuguese population is 0.7%².

Substantial advances have occurred in the treatment of RA during the past two decades. This includes the introduction of new therapies³ and treatment strategies designed to reduce disease activity or initiate a remission (Treat-To-Target- T2T)⁴. Despite this, there is no cure to RA. The primary goal of treatment is to achieve control of symptoms, prevent structural damage, disability and premature death, normalise functional and social participation and improve the quality of life (QoL) of patients⁵⁻⁷.

Generic instruments such as the Nottingham Health Profile (NHP)⁸, Short Form Health Survey 36 (SF 36)⁹ and the EuroQoL 5D¹⁰ have been widely used in studies of RA. Because these instruments are intended for use in different disease populations, they are not sufficiently specific to RA patients. Such measures lack sensitivity to clinically relevant changes¹¹.

The Rheumatoid Arthritis Quality of Life questionnaire (RAQoL) is a patient-centric assessment of QoL specific to patients with RA. It was developed by researchers in the UK and the Netherlands for use in clinical trials and for monitoring individual patients in clinical practice¹². The content of the RAQoL was derived from qualitative interviews conducted with RA patients to ensure that its content was relevant to this patient group. Individual items were selected on the basis that they related to aspects of human needs reported as being unfulfilled by the interviewees. The instrument demonstrated good psychometric properties¹². The RAQoL has been translated into 37 languages¹¹, but not Portuguese. The availability of a European Portuguese version of the RAQoL would have benefits for clinical

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practice and research, allowing the enrolment of Portuguese patients in international studies.

When a questionnaire is translated to another language, an acceptable methodology should be used. A simple and direct translation of the questionnaire may lead to misinterpretation due to language and cultural differences¹³. Thus, a methodology must be used that produces a culturally equivalent version of the questionnaire^{14,15}.

“This study aimed to translate and perform the cross-cultural adaptation of RAQoL into Portuguese”

MATERIAL AND METHODS

The study adopted the standardised protocol for the adaptation of all needs-based measures. This was achieved using the dual-panel translation methodology¹⁶, followed by cognitive debriefing interviews. The study was carried out between December 2015 and November 2016.

TRANSLATION OF THE RAQoL

The two panels (bilingual and lay) were formed by individuals who did not have personal or professional experience with RA. The panels met independently and consecutively. Both panels were led by the same group leader whose first language was Portuguese and who was fluent in English. A Galen Research representative attended both meetings. His / her role was to explain the specific meaning of the English questionnaire items and to guarantee the smooth running of the adaptation procedure.

The purpose of the bilingual panel was to translate the instructions, items and response categories into the Portuguese language. Panel members were informed of the purpose of the panel and received a brief description of the RAQoL, the effects of the disease on QoL and the way in which the RAQoL is used with RA patients. The panel discussed alternative translations for the instructions and items before agreeing on a version to be presented to the lay panel. The bilingual panel could produce more than one translation for consideration by the lay panel if consensus could not be reached. Participants were encouraged to work as a team on the translation of the RAQoL.

The lay panel aimed to ensure that the final wording of the items was at an appropriate level for future

patients who would subsequently complete the measure, regardless of their socio-demographic background. This panel only had access to the translation produced by the bilingual panel. The bilingual panel's version of the questionnaire was then presented and discussed. Participants were asked to ensure that the items could be easily understood, and that the language used was acceptable and ‘natural’.

FACE AND CONTENT VALIDITY

The Portuguese RAQoL was tested in a representative sample of Portuguese RA patients through cognitive debriefing interviews.

A convenience sample was recruited from the Outpatient Rheumatoid Arthritis Clinic of the Centro Hospitalar e Universitário de Coimbra. Patients with a diagnosis of RA, who were able to read and to understand the questionnaire, who could communicate effectively and provide informed consent, were selected.

The patients completed the questionnaire in the presence of an experienced interviewer, who was asked to observe whether patients had any difficulties responding to the items. After completion of the questionnaire the interviewer enquired about any observed difficulties. Specific questions concerning the measure's comprehensiveness, relevance, and ease of completion were then asked. The interviewer also recorded the time taken by patients to complete the questionnaire.

Demographic information including age, gender, education level, work and marital status were collected, as well as patient-perceived general health and perceived disease severity.

The present study was conducted according to the Helsinki Declaration¹⁷. Patients who agreed to participate and provided signed informed consent were included.

RESULTS

BILINGUAL PANEL

The bilingual panel consisted of three males and two females aged between 22 and 73 years. All participants in the bilingual panel were native speakers of Portuguese and were fluent in English. The bilingual panel lasted just over two hours. The panel worked together as a team on the most appropriate translation of

the RAQoL, with equal participation and input from all participants.

Most questionnaire items were easily translated into Portuguese. Some items led to discussions.

For the item 'I avoid crowds because of my condition', the bilingual panel felt that the best translation for "crowd" should use the expression "a place with lot of people", to maximise comprehension by future patients. The item 'I have difficulty using a knife and fork' also evoked discussion. The bilingual panel considered that "talheres", meaning "flatware" in English, would be more appropriate in Portuguese compared to "faca e garfo" (knife and fork). The translation for 'depressed' from one of the items was considered acceptable but participants revealed some concern about whether the general population would interpret this as a medical condition or as an emotion. A similar situation was observed for another of the items, where the panel had difficulty finding a natural translation that captured the concept of to "go out and see people".

LAY PANEL

Five participants were included in the lay panel. Four participants were female, and ages ranged from 28 to 66 years. Participants considered the instructions and the questionnaire items to be clear and easy to understand.

The lay panel modified the bilingual panel's translation of "afraid", replacing this with a word that was considered more suitable and understandable by patients.

The final wording of this item was "Tenho medo que as pessoas me toquem" instead of "Tenho receio que as pessoas me toquem", which both mean "I'm afraid of people touching me". The bilingual panel suggested the translation "Por vezes sinto-me deprimido (a)" for the item 'I often get depressed'. However, the lay panel felt that "deprimido (a)" could be misunderstood as referring to clinical depression. Therefore, the lay panel decided that this should be replaced by "desanimado(a)" which better captured the intended meaning of feeling down and dispirited.

COGNITIVE DEBRIEFING INTERVIEWS

Twelve RA patients (2 male, 10 female), with a mean age of 62 (range 46 to 75) years took part in the cognitive debriefing interviews. Demographic and disease information of the patients is presented in Table I. The mean time taken to complete the RAQoL was 7.3 (\pm 3.5) minutes.

In general, all the participants found the questionnaire clear, easy to understand and to complete. The interviewees considered the items to be relevant and appropriate to their condition. No items stood out as being inappropriately worded or difficult to understand.

DISCUSSION

The current study produced a culturally acceptable

TABLE I. DEMOGRAPHIC AND DISEASE CHARACTERISTICS OF RA PATIENTS INCLUDED IN THE COGNITIVE DEBRIEFING INTERVIEWS

Gender	Age	Marital status	Working status	General Health	RA Severity	Time taken to complete (minutes)
Female	61	Married	Unemployed	Fair	Moderate	12
Female	65	Married	Homemaker	Fair	Quite severe	6
Female	60	Married	Retired	Poor	Moderate	5
Male	72	Married	Retired	Fair	Moderate	8
Female	75	Married	Retired	Fair	Moderate	12
Female	58	Married	Homemaker	Fair	Moderate	12
Female	69	Single	Retired	Fair	Moderate	8
Female	56	Married	Retired	Fair	Quite severe	5
Female	62	Married	Retired	Fair	Moderate	10
Male	62	Married	Retired	Very good	Mild	3
Female	46	Married	Full time	Fair	Mild	2
Female	58	Married	Retired	Fair	Moderate	5

Portuguese language version of the RAQoL. Most questionnaire items were easily translated into Portuguese. Patients considered the questionnaire to be relevant and easy to understand. The Portuguese version of the RAQoL demonstrates high face and content validity according to the cognitive debriefing interviews, showing good acceptability and feasibility.

In this study a dual-panel approach for translation was used, which is not the most commonly used method to translate questionnaires into Portuguese language^{14, 18}. The dual-panel approach utilizes “lay” people for the translation process, allowing a comprehensive check of whether the instructions and items in the measure will be understood by all potential respondents, regardless of their education level. The dual-panel approach has been shown to improve the quality of the linguistic, conceptual, and cultural adaptation of instruments, and to be more effective and efficient than the traditional forward–backward methodology^{14,18}.

The RAQoL is a disease-specific questionnaire that is easy to administer, complete and score. The time required to fill the questionnaire is less than 10 minutes. No specific training or analytical ability is required to administer and score the measure. These characteristics make the RAQoL suitable for use in routine clinical practice. The availability of the Portuguese version will allow Portuguese patients to participate in international research, allowing for the comparison between Portuguese RA patients' QoL with RA patients from other countries.

Further research is necessary to establish the psychometric characteristics of this Portuguese language version of the RAQoL.

CONCLUSION

A Portuguese version of the RAQoL was successfully produced, which was shown to be comprehensible and well-received, with high face and content validity. The RAQoL is a potential instrument to be implemented in Portuguese RA patients' evaluation, both in clinical and research settings. Research examining the psychometric properties of this Portuguese version of the RAQoL is underway.

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REFERENCES

1. Studenic P, Smolen JS, Aletaha D. Near misses of ACR/EULAR criteria for remission: effects of patient global assessment in Boolean and index-based definitions. *Annals of the rheumatic diseases*. 2012;71(10):1702-1705.
2. Branco JC, Rodrigues AM, Gouveia N, Eusebio M, Ramiro S, Machado PM, et al. Prevalence of rheumatic and musculoskeletal diseases and their impact on health-related quality of life, physical function and mental health in Portugal: results from EpiReumaPt- a national health survey. *RMD open*. 2016;2(1):e000166.
3. Owens GM. Optimizing Rheumatoid Arthritis Therapy: Using Objective Measures of Disease Activity to Guide Treatment. *American health & drug benefits*. 2015;8(7):354-60.
4. Smolen JS, Breedveld FC, Burmester GR, Bykerk V, Dougados M, Emery P, et al. Treating rheumatoid arthritis to target: 2014 update of the recommendations of an international task force. *Annals of the rheumatic diseases*. 2016;75(1):3-15.
5. Singh JA, Saag KG, Bridges SL, Jr., Akl EA, Bannuru RR, Sullivan MC, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2016;68(1):1-26.
6. Smolen JS, Landewe R, Bijlsma J, Burmester G, Chatzidionysiou K, Dougados M, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. *Annals of the rheumatic diseases*. 2017;76(6):960-977.
7. Duarte C, Sousa-Neves J, Agueda A, Ribeiro P, Daniel A, Eugenio G, et al. Portuguese Recommendations for the use of biological therapies in patients with rheumatoid arthritis- 2016 update. *Acta reumatologica portuguesa*. 2017;42(2)(Apr-Jun): 112-126.
8. Hunt SM, McKenna SP, McEwen J, Williams J, Papp E. The Nottingham Health Profile: subjective health status and medical consultations. *Social science & medicine Part A, Medical sociology*. 1981;15(3 Pt 1):221-229.
9. Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical care*. 1992;30(6):473-483.
10. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation*. 2011;20(10):1727-1736.
11. Zlatkovic-Svenda M, Rouse M, Radak-Perovic M, Stojanovic R, Vujasinovic-Stupar N, Lazovic-Popovic B, et al. Adaptation and validation of the Rheumatoid Arthritis Quality of Life (RAQoL) questionnaire for use in Serbia. *Rheumatology international*. 2017;37(4):641-646.
12. de Jong Z, van der Heijde D, McKenna SP, Whalley D. The reliability and construct validity of the RAQoL: a rheumatoid arthritis-specific quality of life instrument. *British journal of rheumatology*. 1997;36(8):878-83.
13. Ramada-Rodilla JM, Serra-Pujadas C, Delclos-Clanchet GL.

- [Cross-cultural adaptation and health questionnaires validation: revision and methodological recommendations]. *Salud publica de Mexico*. 2013;55(1):57-66.
14. Chang FH, Liou TH, Brodersen J, Comins JD. Adaptation of the Activity Measure Post-Acute Care (AM-PAC) from English to Mandarin using the dual-panel translation approach. *Disability and rehabilitation*. 2017:1-6.
 15. Hagell P, Hedin PJ, Meads DM, Nyberg L, McKenna SP. Effects of method of translation of patient-reported health outcome questionnaires: a randomized study of the translation of the Rheumatoid Arthritis Quality of Life (RAQoL) Instrument for Sweden. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research*. 2010;13(4):424-430.
 16. Hunt SM, Alonso J, Bucquet D, Niero M, Wiklund I, McKenna S. Cross-cultural adaptation of health measures. European Group for Health Management and Quality of Life Assessment. *Health policy (Amsterdam, Netherlands)*. 1991;19(1):33-44.
 17. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *The Journal of the American College of Dentists*. 2014;81(3):14-8.
 18. Swaine-Verdier A, Doward LC, Hagell P, Thorsen H, McKenna SP. Adapting quality of life instruments. *Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research*. 2004;7 Suppl 1:S27-30.