ORIGINAL ARTICLE

AG-2021-201
doi.org/10.1590/S0004-2803.202202000-36

Validation of the RAND 36-Item Health Survey questionnaire in Brazil

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Received: 25 October 2021
Accepted: 7 December 2021

ABSTRACT – Background – Health-related quality of life is frequently used as an outcome measure that improves the quality of care. The SF-36 and RAND-36 were derived from the Medical Outcomes Study. **Objective** – The present study aimed to validate the RAND-36 in Brazil, in healthy individuals and patients with liver disease. **Methods –** Confirmatory factor analysis (CFA) was conducted by using JASP Software. The parameters of the items were estimated using the Robust Diagonally Weighted Least Squares (RDWLS) approach. Comparative fit index (CFI), Goodness-of-fit index (GFI), Tucker-Lewis Index (TLI) and the root mean square error of approximation (RMSEA) were evaluated. Internal consistency was measured using the Composite reliability index. Convergent validity between RAND-36 domains and Work Ability Index (WAI) was conducted. **Results –** This validation study included 763 individuals, 400 (52.4%) with chronic liver disease. The most prevalent liver diseases were hepatitis C (13.9%), alcoholic liver disease (11.8%), and steatosis (12.1%). The measurement model tested using the CFA obtained the following adjustment indicators: X^2 (df): 599.65 (498); CFI: 0.998; GFI: 0.998; TLI: 0.998; RMSEA: 0.016 (90%CI: 0.011–.021). Convergent validity of RAND-36 and total WAI ranged from medium to large correlation. **Conclusion –** The RAND-36 is effective in measuring the perception of health-related quality of life in individuals with and without chronic liver disease. The results of our study support the developer's claims for the reliability of the RAND-36 version 1 as a measure of health-related quality of life. The evidence for the construct validity of the RAND-36 was substantial.

Keywords – Quality of life; health-related quality of life; validation study.

INTRODUCTION

Health-related quality of life (HRQoL) has been acknowledged as a relevant health indicator because epidemiological measures such as mortality and morbidity rates only provide a restrict and partial understanding of public health needs. HRQOL is consistent with the public health scope, measuring dysfunction and disability of a population, and its association with chronic diseases, and comorbidities[1]. Quality of life measures have emerged from the biopsychosocial perspective on health, in which is important to identify psychological, social, and physical factors that may impact individuals' wellbeing[2].

HRQoL is frequently used as an outcome measure that evaluates the quality of care, while the Short Form-36 (SF-36) is a reliable tool that provide good reliability and validity for assessing the individuals' quality of life in different stages of an illness[3-11]. In August 2021, a search in PubMed (https://www.ncbi.nlm.nih.gov) database using the term "SF 36" retrieved 92,145 articles. The SF-36 has been translated into over 170 languages, and was a product of the Medical Outcomes Study (MOS)[12].

The MOS study was an observational study designed to evaluate the influence of providers, patients, and health systems on outcomes of care[13]. A 20-item short survey (SF-20) was derived from the original 149-item used in the MOS, but the developed scale was limited by floor effects[12,13]. In 1992, Ware and Sherbourne[14] published a new 36-item short form survey, comprising eight health concepts: physical functioning, pain, role limitations due to physical health problems, role limitation due to personal or emotional problems, general mental health, social functioning, energy/fatigue, and general health perceptions. This version was called as SF-36v1, also known as Ware-36, being ruled by the Medical Outcomes Trust, Inc. with strict adherence to the scoring and item wording to preserve the SF-36 trademark[12]. In sequence, Sherbourne, and Mazel[13] published a publicly available version of the 36-item short form, the RAND-36.

Nowadays, academic organizations are working in partnership with companies to increase the commercialization of their scientific research products. High fees have to be paid for, using and scoring the SF-36, and the high cost of the instrument can make its use unfeasible, particularly for users from developing countries[15]. The RAND-36 scoring, and use are publicly available on the RAND Corporation web site (www.rand.org). The original Ware-36, published in 1992, and the RAND-36, are composed by thirty-six identical items, and both instruments have been referred to as the "SF-36"[12]. The original version of SF-36v1 was cross-culturally adapted and translated into Brazilian Portuguese, but no psychometric properties of the instrument was evaluated[16]. The aim of the present study is to validate the RAND-36 in Brazil.

Declared conflict of interest of all authors: none
Disclosure of funding: no funding received
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METHODS

Sampling and data collection

This cross-sectional study, nested to a cohort, were performed at two institutions, Federal University of Bahia, and Bahiana School of Medicine and Public Health. Participants were individuals enrolled in the outpatient clinic for liver diseases at a university hospital and on a dentistry clinic, at Federal University of Bahia. The sample was calculated using the OpenEpi version 3, considering results from a pilot study with 135 patients, 75 with liver diseases, and 39 healthy subjects. We compared the mean of the HRQoL mental and physical summary components between groups, considering the confidence interval of 95% and a power of 95%. The highest value obtained was 285 per group. We inflated the total sample by 20%, which resulted in 684 individuals, 342 per group. Healthy individuals were included to prevent bias when analyzing a target population as individuals with liver diseases.

Two trained healthcare professionals with up to 5-years of experience in the outpatient clinic of liver disease applied the questionnaires. The examiners were blinded to each other's findings, they did not have access to scoring data, and they assessed data from the medical record only after collection. Data were collected from January 2017 to December 2019.

The RAND 36-Item Health Survey

The RAND-36 is a 36-item questionnaire which generates eight health-related quality of life domains: physical functioning (10 items), role limitations due to physical health (four items), role limitations due to emotional problems (three items), energy/fatigue (four items), emotional well-being (five items), social functioning (two items), bodily pain (two items), and general health (five items). A single item indicates individual self-perceived change in health[14]. There are some differences between the Ware-36 and RAND-36 scoring methods. Both questionnaires use the same 36-six items and answer choices, obtaining identical results in six of the eight domains, but they differ in the bodily pain and general health domains[12]. The RAND-36 domains are scored on a 0 to 100 range, so that a high score defines a more favorable health-related quality of life[13,17].

Statistical analysis and validation

Confirmatory factor analysis (CFA) was conducted by using JASP Software. We tested the measurement model composed by the eight theoretically predicted factors (physical functioning, role limitations due to physical health, role limitations due to emotional problems, energy/fatigue, emotional well-being, social functioning, bodily pain, and general health). The parameters of the items were estimated using the Robust Diagonally Weighted Least Squares (RDWLS) approach.

We observed the following indices of adherence of the model: chi-square (tests the difference between the empirical matrix and the theoretical model matrix, the higher is the value of X^2, the worse is the adjustment); comparative fit index (CFI), Goodness-of-fit index (GFI) e Tucker-Lewis Index (TLI) (the closer to 1.0 represent a better model quality). The root mean square error of approximation (RMSEA) was calculated. Values below 0.08 were considered acceptable[18,19]. Internal consistency was measured using the Composite reliability index. Values of ≥0.7 were considered satisfactory and values of ≥0.8, with high reliability[20]. Researchers applied the 11-item quality appraisal tool for studies of diagnostic reliability (QAREL) for assessing the quality and applicability of the present reliability study[21].

Convergent validity

Convergent validity between RAND-36 domains and Work Ability Index (WAI) was conducted. The WAI scale measures the self-perceived physical and mental health, and have been previously used in individuals with chronic liver disease, presenting good reliability[9,22]. The WAI total score ranges from 7 to 49, and high scores indicate good work ability[23]. Spearman correlation evaluated the degree of correlation between RAND-36 domains and the total WAI, and results were interpreted in line with Cohen's classification as follows: small correlation (0.10–0.29), medium correlation (0.30–0.49), and large correlation(0.50–1.0)[24].

Ethical approval

The study protocol was approved by the Ethics Review Board (protocol number 2.165.600) of the School of Medicine, Federal University of Bahia. The protocol is in accordance with Brazilian National Health Council Resolution 466/2012 and the World Medical Association Declaration of Helsinki 2013. All participants signed an informed consent form prior to their inclusion in the study.

RESULTS

The study included 763 individuals, 400 (52.4%) with chronic liver disease (CLD). Most of the participants were male (53.5%), racially mixed (54.7%), engaged in a stable relationship (62.3%), with up to 8 years of schooling (84.9%), and family income of up to two minimal wages (MW). The most frequent liver diseases were hepatitis C (13.9%), alcoholic liver disease (11.8%), and steatosis (12.1%). The mean age was 50.3±9.9 years (TABLE 1).

The measurement model tested using the CFA obtained the following adjustment indicators: X^2 (df): 599.65 (498); CFI: 0.998; GFI: 0.998; TLI: 0.998; RMSEA: 0.016 (90%CI: 0.011–0.021). The factors loadings are shown in FIGURE 1, and the covariances between the factors in TABLE 2.

For convergent validity, the correlations between each of the eight domains of the RAND-36 and the total score of WAI scale were analyzed, evidencing large correlation for all domains, except Pain and Social Functioning domains that showed medium correlations (TABLE 3).

DISCUSSION

The SF-36, in both versions 1 and 2, is a general instrument, commonly used to assess health-related quality of life[15,25-27]. The SF-36 had been used to measure the HRQoL in healthy individuals, patients with chronic diseases, in rehabilitation, and as a health-related measure in the field of occupational health[28-34]. The SF-36v1[14] and RAND-36[13,17] are the same 36-items short form derived from the MOS study[12,13,17]. The SF-36v1 questionnaire has been translated and culturally adapted to Brazilian Portuguese[16]. Developers of the RAND-36 have argued that the differences in scoring between the original SF-36 and RAND-36 scales did not contribute to any relevant difference in scores in the MOS longitudinal study[13].

In the present study, we investigated the psychometric properties of RAND-36 in Brazil, by using confirmatory factor analysis

TABLE 1. Demographic and clinical characteristics of 763 participants, Salvador, Bahia, 2019.

Demographic and clinical characteristic	N=763
Age, mean (SD[a])	50.3 (9.9)
Sex N (%)	
Male	408 (53.5)
Female	355 (46.5)
Ethnicity N (%)	
Caucasian	156 (20.4)
Racially Mixed	417 (54.7)
Black	190 (24.9)
Marital status N (%)	
Stable relationship	475 (62.3)
No stable relationship	288 (37.3)
Educational status N (%)	
≤8 years	648 (84.9)
>8 years	115 (15.1)
Family income (minimal wages)[b] N (%)	
≤2 MW	587 (76.9)
>2 MW	176 (23.1)
Liver diseases	
Autoimmune liver diseases	21 (2.8)
Alcoholic liver disease	90 (11.8)
Nonalcoholic fatty liver disease	15 (2.0)
Hepatitis C virus	106 (13.9)
Hepatitis B virus	19 (2.5)
Primary biliary cirrhosis	2 (0.3)
Secondary biliary cirrhosis	2 (0.3)
Hepatocellular carcinoma	9 (1.2)
Steatosis	92 (12.1)
Other liver diseases	44 (5.8)
Without liver disease	363 (47.6)

[a]Standard deviation; [b]Family income (minimal wages): 210.0 USD.

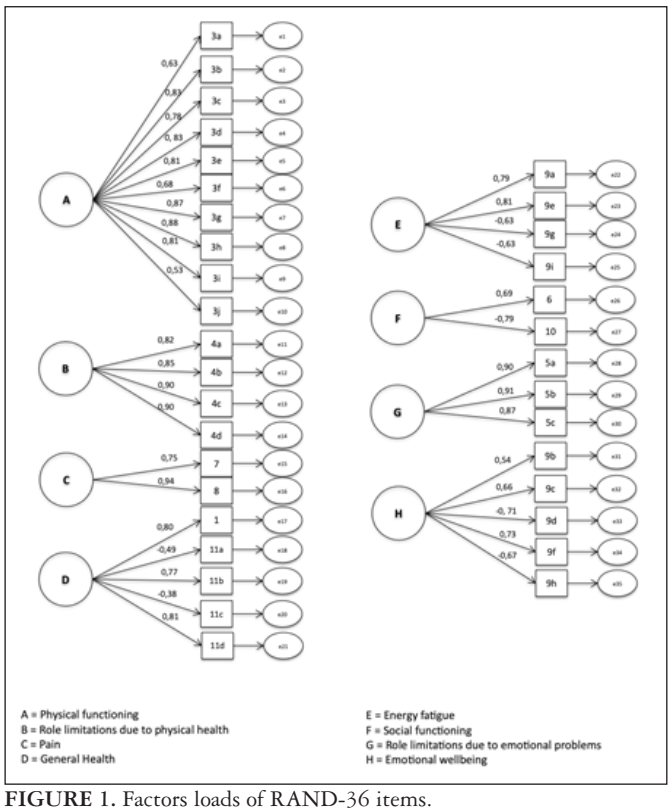

FIGURE 1. Factors loads of RAND-36 items.

TABLE 3. Correlations between RAND-36 domains and total WAI.

RAND- 36 domains	WAI[a]	*P*[b]
Physical functioning	0.676	0.001
Role limitations due to physical health	0.592	0.001
Pain	0.454	0.001
General Health	0.601	0.001
Energy fatigue	0.585	0.001
Social functioning	0.490	0.001
Role limitations due to emotional problems	0.500	0.001
Emotional well-being	0.512	0.001

WAI: aWork Ability Index; bSpearman's correlation

TABLE 2. Mean and standard deviations, composite reliability, and scale intercorrelations of the RAND-36, by factor.

RAND- 36 domains	M±SD	1	2	3	4	5	6	7	8
1-Physical functioning	75.30±26.81	(0.94)							
2-Role limitations due to physical health	65.43±43.26	0.56[a]	(0.92)						
3-Pain	72.95±27.39	-0.54[a]	-0.47[a]	(0.84)					
4-General Health	66.27±22.47	-0.63[a]	-0.56[a]	0.59[a]	(0.80)				
5-Energy fatigue	67.48±23.85	-0.74[a]	-0.60[a]	0.70[a]	0.80[a]	(0.81)			
6-Social functioning	82.75±23.17	-0.62[a]	-0.67[a]	0.52[a]	0.67[a]	0.73[a]	(0.71)		
7-Role limitations due to emotional problems	71.42±41.56	0.37[a]	0.82[a]	-0.39[a]	-0.47[a]	-0.49[a]	-0.48[a]	(0.92)	
8-Emotional well-being	78.20±19.64	0.57[a]	0.46[a]	-0.67[a]	-0.76[a]	-0.88[a]	-0.70[a]	0.52[a]	(0.80)

M: mean; SD: standard deviations. [a]*P*<0.001 composite reliability index is in brackets.

estimating the parameters of the items with the Robust Diagonally Weighted Least Squares method. The option for using CFA was because a previous theoretical model for the distribution of items was already available, as well as evidence of the model's validity in other contexts[13,35,36]. To the best of our knowledge, this is the first study that evaluated the psychometric properties of RAND-36 in Brazil.

The overall fit of the model was excellent, and CFI, GFI and TLI were higher than 0.9, and the RMSEA was below 0.08. All composite reliability values of RAND-36 domains were higher than 0.8 (high reliability), except for Social Functioning that was higher than 0.7, considered as acceptable. Concerning factor loadings, all items loaded satisfactorily in the domain to which they belong[13]. Only item 11c ("I think my health will get worse"), which makes up the General Health dimension, had a slightly lower charge than expected (0.38). When analyzing the contents of the items in the general health dimension, the referred item is the only one mentioning a future event, which may have been responsible for making it less representative of the factor.

Convergent validity of RAND-36 and total WAI evidenced large correlation for all domains, except Pain and Social Functioning domains with medium correlations. Significant correlations between WAI and other HRQOL instrument has been reported. WAI was associated with overall quality of life, physical health, psychological, social relations and environment domains of WHOQOL BREF[37]. Therefore, the correlation indices obtained in the present study provide important additional evidence of the psychometric quality of the RAND-36. Our findings on reliability and validity of the RAND-36, showed consistent validation results for the use of RAND-36 for measuring HRQoL outcomes in Brazil. Our findings are similar to those reported for the Dutch translation of the RAND-36. In the Dutch study, reliability values of RAND-36 domains ranged from 0.71 to 0.93, while, in the present study, reliability ranged from 0.71 to 0.94.

The RAND-36 is a free generic HRQoL instrument distributed by RAND corporation, which can be administered electronically or by telephone. The survey takes approximately 7–10 min and presents alternative forms of administration (recall period) and different modes of administration (electronically, by telephone or in person)[35,38]. The questionnaire includes the same items as those in the SF-36, although the scoring is slightly different for the pain and general health domains. Regardless of these differences, literature reports the correlations of 0.99 in the MOS panel sample, when the questionnaires were scored using the SF-36 versus the RAND-36 scoring methods[14,35]. The RAND-36 includes the same items as those in the SF-36, which were translated into Brazilian Portuguese and transculturally adapted[16]. The availability of a free HRQoL instrument increases the opportunities for researchers from low-income countries to assess HRQoL, making possible to perform studies in the field without payment of extra costs.

This study has some limitations. First, this is a cross-sectional study nested to a cohort study. Unfortunately, it was not possible to follow up RAND-36 interviews due to COVID-19 pandemics. However, the sample size was adequate to the model and the results of validation were consistent.

CONCLUSION

The RAND-36 is an effective tool to measure the perception of health-related quality of life in individuals with and without chronic liver disease. The results of our study support the developer's claims for the reliability of the RAND-36 version1 as a measure of health-related quality of life. The evaluation of the construct validity of the RAND-36 was consistent.

ACKNOWLEDGMENT

This study was financed in part by the *Coordenação de Aperfeiçoamento de Pessoal de Nível Superior* – Brazil (CAPES) – Finance Code 001.

Authors' contribution

All co-authors included in this paper fulfill the criteria of authorship and all co-authors have critically reviewed it and approved its last version for publication. Lins-Kusterer L, Menezes MS, Quarantini LC, Cotrim HP and Brites C worked on the study conception. Lins-Kusterer L and Aguiar I have written the paper, worked on acquisition, analysis and interpretation of data Santos-Lins LS, Lins-Rocha M and Cotrim HP worked on acquisition, interpretation of data and critically reviewed the manuscript. Sampaio AS, Aguiar CVN, Quarantini LC, Menezes MS and Brites C have worked on analysis and interpretation of data and revised the paper critically; All co-authors have critically reviewed the paper and approved its last version for publication.

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Lins-Kusterer L, Aguiar I, Santos-Lins LS, Lins-Rocha M, Aguiar CVN, Menezes MS, Sampaio AS, Quarantini LC, Cotrim HP, Brites C. Validação do questionário *RAND 36*-Item *Health Survey* no Brasil. Arq Gastroenterol. 2022;59(2):193-7.

RESUMO – Contexto – A qualidade de vida relacionada à saúde é frequentemente usada como uma medida de resultado que melhora a qualidade da atenção à saúde. O SF-36 e o RAND-36 foram derivados do *Medical Outcomes Study*. **Objetivo** – O presente estudo teve como objetivo validar o RAND-36 no Brasil, em indivíduos saudáveis e pacientes com doença hepática. **Métodos –** A análise fatorial confirmatória (AFC) foi realizada usando o software JASP. Os parâmetros do elemento foram estimados usando o método *Robust Diagonally Weighted Least Squares* (RDWLS). O índice de ajuste comparativo (CFI), o índice de adequação (GFI), o índice de Tucker-Lewis (TLI) e o erro quadrático médio de aproximação (RMSEA) foram avaliados. A consistência interna foi medida pelo índice de confiabilidade composta. A validade convergente foi realizada entre os domínios do RAND-36 e o Índice de Capacidade para o Trabalho (ICT). **Resultados –** Este estudo de validação incluiu 763 indivíduos, 400 (52,4%) com doença hepática crônica. As doenças hepáticas mais prevalentes foram hepatite C (13,9%), doença alcoólica do fígado (11,8%) e esteatose (12,1%). O modelo de medida testado com a AFC obteve os seguintes indicadores de ajuste: X^2 (gl): 599,65 (498); CFI: 0,998; GFI: 0,998; TLI: 0,998; RMSEA: 0,016 (90%CI: 0,011–0,021). A validade convergente do RAND-36 e do ICT total variou de média a grande correlação. **Conclusão –** O RAND-36 é eficaz para medir a percepção da qualidade de vida relacionada à saúde em indivíduos com e sem doença hepática crônica. Os resultados do nosso estudo apoiam as afirmações dos desenvolvedores sobre a confiabilidade do RAND-36 versão 1 como uma medida de qualidade de vida relacionada à saúde. A evidência para a validade do construto do RAND-36 foi substancial.

Palavras-chave – Qualidade de vida; qualidade de vida relacionada à saúde; estudo de validação.

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