



Original article

## Adaptation and validation of the Rheumatoid Arthritis Quality of Life Scale (RAQoL) to Mexican Spanish

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## ABSTRACT

**Objective:** To develop and validate the Mexican-Spanish version of the Rheumatoid Arthritis Quality of Life questionnaire (RAQoL).

**Methods:** The original UK English version of RAQoL was translated into Mexican-Spanish version by a bilingual translation panel. An independent lay panel reviewed the instrument's item phrasing to ensure comprehensiveness and appropriateness in colloquial Mexican-Spanish. Structured cognitive debriefing interviews were conducted with 15 Rheumatoid Arthritis (RA) patients to assess face and content validity. Finally, an independent sample of RA patients completed the RAQoL and additional assessments were performed to assess reproducibility and construct validity.

**Results:** Translation and adaptation was successful as both the lay panel and cognitive debriefing participants considered the new language version to be appropriate.

Fifty-seven patients were included in the final evaluation of the Mexican-Spanish version of RAQoL (73.8% female, mean age 52.4 years, SD 14.1, RA duration range 2–27 years). Cronbach's  $\alpha$  for the new RAQoL was 0.91 and the test-retest reliability 0.92, indicating that the measure has good internal consistency and low random measurement error. The Mexican-Spanish version of RAQoL could discriminate between patients who differed on their perception of disease activity, general health status, current rating of perceived RA severity and whether or not they were experiencing a disease flare.

**Conclusions:** The Mexican-Spanish version of RAQoL was well accepted by RA patients. The psychometric quality of the adapted questionnaire shows that it is suitable for use in clinical studies and trials of patients with RA.

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### Adaptación y validación del Rheumatoid Arthritis Quality of Life Scale (RAQoL) al español de México

## RESUMEN

**Objetivo:** Adaptar y validar la versión oficial del cuestionario Rheumatoid Arthritis Quality of Life (RAQoL) al español de México.

**Métodos:** La versión inglesa del RAQoL fue traducida al español por un panel bilingüe. Un segundo panel de individuos revisó y adaptó el fraseo de las preguntas al español cotidiano. Se realizaron entrevistas a 15 pacientes con artritis reumatoide (AR) para evaluar la validez de aspecto y contenido. El cuestionario fue aplicado en 2 ocasiones a 57 pacientes con AR para evaluar su reproducibilidad y validez de constructo.

**Resultados:** Se encontraron pocas dificultades en las etapas de traducción y adaptación del cuestionario. Las versiones preliminar y final fueron bien recibidas por el panel de referencia y por los pacientes entrevistados respectivamente. Un total de 57 pacientes participaron en la evaluación del instrumento final (73,8% mujeres, edad promedio 52,4 años, DE 14,1, duración de la AR de 2-27 años). El  $\alpha$  de Cronbach para el

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RAQoL en español de México fue de 0,91 y la fiabilidad aplicación-reaplicación de 0,92, lo que sugiere que el cuestionario muestra interrelación homogénea entre sus componentes y que tiene niveles bajos de errores aleatorios de medición. El RAQoL en español de México pudo discernir a pacientes que difirieron en relación con la percepción de la severidad de su enfermedad, estado general de salud, calificación de su enfermedad el mismo día y si cursaban o no con una recaída al momento de la evaluación.

**Conclusiones:** El RAQoL en español de México fue bien recibido por pacientes con AR. La calidad del cuestionario adaptado lo muestra como un instrumento útil para ensayos clínicos de pacientes con AR.

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Rheumatoid arthritis is an inflammatory disease of unknown origin that affects 1% of the adult population. Although it is a systemic disease, it shows a clear preference for provoking chronic synovial joint inflammation, causing destruction and deformity. It predominantly presents itself in females (in a ratio of 2–3 per male) and the most frequent age for presentation ranges from 30 to 50 years old.<sup>1–3</sup>

The disease has an impact on the patient's functionality in different ways. Pain dominates in early stages, with functional limitation and tiredness, which are associated to the inflammatory process. In more advanced stages, persistent inflammation is converted into structural changes that eventually lead to joint destruction, deformity and dysfunction. Quality of life is determined by the activity of the disease, functional capacity and other indirect factors such as depression, comorbidities, and RA impact on family, emotional and work spheres.<sup>4–7</sup> As well as these negative consequences, adverse effects of the medication reduce the patient's level of wellbeing.

In the initial stages, assessment of therapeutic efficacy in RA focused on the impact of treatments on RA inflammatory activity measurements (pain, count of tender and inflamed joints, tiredness, acute phase reactants, etc.), assuming that their improvement would directly affect the other spheres. Later on, functional capacity assessment was included and the Health Assessment Questionnaire Disability Index (HAQ-DI)<sup>8</sup> became practically a standard. More recently, the quality of life assessment was included (as part of modern clinimetrics),<sup>9–11</sup> as well as radiographic study (assessing joint damage progression), which have become specific markers to define more systematic therapeutic objectives.

Instruments have been formulated that non-specifically or specifically assess the impact of RA or therapeutic interventions on the patients' quality of life.

In the beginning, quality of life measurements for patients with RA were carried out with instruments designed with a focus on other diseases and subsequently adapted. Eventually the need to have specific instruments became more evident. In 1997 Whalley et al<sup>12</sup> performed an analysis with indexes used up until then, including the Arthritis Impact Measurement Scales (AIMS and AIMS2),<sup>13,14</sup> the MOS 36-Item Short Form Health Survey (SF-36),<sup>15</sup> the EuroQoL,<sup>16</sup> the Sickness Impact Profile (SIP) and the SEIQoL.<sup>17</sup> Unsuitable methodological aspects were observed these scales, prompting the development of a new instrument called "Rheumatoid Arthritis Quality of Life Scale (RAQoL)."<sup>18</sup>

The RAQoL was brought about through direct free-form interviews with RA patients. This application was simultaneously conducted in 2 countries (United Kingdom and Holland) to reduce cultural bias. A panel of experts then selected a limited number of elements that were considered transcendental, to condense information.

The RAQoL is a questionnaire consisting of 30 elements (written as first person confirmations) that assess different aspects of the quality of life in people suffering from RA. This article describes the process of adapting RAQoL for use in the Mexican population and includes results produced by the translation panel, cognitive interviews and validation studies.

## Subjects and methods

### RAQoL Translation

The translation process adopted the dual panel methodology recommended by Hunt et al.<sup>19</sup> This methodology emphasises the importance of achieving conceptual equivalence between translated elements and the original; linguistic equivalence is of secondary importance. It is also vital for new elements to be expressed in a common language (colloquial) so that it is familiar to future polled people.

The RAQoL adaptation was undertaken in 3 stages: translation, cognitive interview and a validation poll.

The translation method does not require reverse translation. However, in non-English speaking countries, there are 2 panels: a bilingual panel that provides the initial translation to the language in question and a reference panel that refines the elements to improve their comprehension and takes care of language colloquialism.

### The bilingual panel

The bilingual panel consisted of a group of people with Spanish as their mother tongue, who had excellent knowledge of English. This panel's aim was to suggest translations for the instructions, elements and response categories. The panel members received the English version of this instrument a week before the meeting and the translation/adaptation work was supervised by one of the authors of the RAQoL original version, so as to guarantee that the original significance of the questions would be maintained in the translation.

The concepts were presented to the group one by one and their significance explained. The suggested alternative translations were considered by the complete panel. Each element was discussed until an agreement was reached. If an agreement was not reached, alternative versions were considered for each element, which were then put forward to the reference panel.

### Reference panel

The second translation panel consisted of monolingual people with an average or below-average educational level, considered representative of the target population. The translations produced by the bilingual panel were put to this panel and they were asked to discuss the comprehensibility and colloquialism of translated elements. The panel members were particularly asked if the item phrasing and language were acceptable or if they should be changed into a more natural language without altering their original significance. The reference panel members worked with the translated elements with no knowledge of the original British English version. It was also the group coordinator's role (who was also the bilingual panel coordinator) to ensure that the original significance was preserved in the final translation.

### Cognitive interviews

Cognitive interviews assessed the application, relevance and comprehensibility of the new instrument on patients with RA.<sup>20</sup> The interviews were personal and semi-structured; those questioned were asked to complete the instrument in front of an interviewer, who mentioned any difficulty or doubt that any specific element showed. Those interviewed were then questioned so as to clearly comment on the elements, instructions and format of the questionnaire replies. The participants were specifically asked whether they considered the elements relevant, applicable and comprehensible, and if they considered that any important aspects on how arthritis affects their lives had been omitted.

Once their points of view had been considered, they were asked specific questions on the elements that had previously been chosen for discussion. These elements were alternative names for similar concepts and elements that were considered potentially problematic for some of the individuals questioned.

### Validation procedure

#### Aspect and content validity

To determine the validity of the aspect and contents of the questionnaire, the translation and adaptation that both panels carried out was applied to 15 patients with rheumatoid arthritis attending out-patient clinics. The patients completed the questionnaire in the presence of an interviewer, who observed if there were any difficulties in reading, understanding the questions or in the response process. Later on, they were specifically questioned on the questions and how easy it was to answer them.

#### Reproducibility

The psychometric properties of the translated questionnaire were assessed among out-patients patients at our RA clinic (a total of 57). These patients were randomly selected when attending the clinic and invited to take part in the study. Together with the RAQoL, patients also responded to the Nottingham Health Profile (NHP), HAQ-DI, demographic data and visual analogue scale (VAS) on pain and general state of the disease. They received an assessment on disease activity from a rheumatologist that included the HAQ-DI, an inflamed and tender joint count and the physician's VAS on the general state of the disease (Table 4). This assessment was repeated 2 weeks later, as this interval was considered an appropriate intermediate point; if it was longer the RA conditions could change and be considered as an under-assessment of real reproducibility, while shorter periods could have recall bias if the patient remembered the previous questions.

A high correlation indicates that the instrument provides a low error rate. Both applications of the questionnaire and the parallel assessment measures were undertaken at the same place and under the same conditions to reduce measurement errors.

The Spearman rank coefficient correlation ( $>0.85$ ) indicates that the instrument produces a low random error. This same coefficient was used to assess RAQoL reliability. The stability of ratings was later analysed, comparing the direct and median scores of the RAQoL rating at both times of application.

#### Construct validity

Convergent and divergent validity were determined to ascertain the association between the ratings obtained by RAQoL and other comparison measurements that measure related or non-related constructs, respectively. This investigation used NHP and HAQ-DI

for comparison, with the Spearman correlation coefficient. The NHP was chosen because it was excellent both in sensitivity to change and generic assessment of the quality of life.<sup>12</sup>

The convergent validation was performed using NHP as a comparison instrument, as in other RAQoL translation and validation exercises. The hypothesis examined was that RAQoL would show a low-moderate association (correlation coefficient between 0.4-0.6) in sleep disorder, emotional reactions and social isolation sections in the NHP, and a moderate-high association (around 0.6) in the 3 remaining sections.

Other clinical assessments were also used to test the convergent validity of the Mexican Spanish RAQoL. The correlation between the RAQoL results and some assessments by rheumatologists were undertaken, which included: number of inflamed joints, number of tender joints and the general state of health (VAS documented). Patients also reported pain (VAS) and general health level, as well as completing the Spanish version HAQ-DI.

#### Discriminant validity

Construct validity was based on the method of known groups. In this, the instrument to be validated must discriminate the group of patients according to a predefined categorisation of widely-accepted variables whose significance agrees with the expected measurements of the questionnaire.

The variables chosen in this investigation were patient assessment according to general health (*excellent/good/moderate/bad*), rheumatoid arthritis severity (*I have no discomfort/slight/moderate/severe/very severe discomfort*), current state of rheumatoid arthritis (*very good/good/bad/very bad*) and if the patient is suffering a flare up of his/her illness.

#### Statistical analysis

Internal consistency was assessed through Cronbach's  $\alpha$  coefficient. Alpha measurements were extended to inter-related elements on the scale. A low  $\alpha$  level ( $<0.7$ ) indicates that the elements do not work together to form the scale.

Non-parametric tests for independent samples were used for discriminant validity, so as to measure the difference of the groups assessed by RAQoL categorised by their results (Mann-Whitney U-Test for 2 groups or the Kruskal-Wallis test from the ANOVA method for 3 or more groups).

The Spearman correlation coefficient was used to assess RAQoL correlation to other measurements of activity for the disease.

#### Instruments used in the study

The RAQoL has 30 questions with a dichotomous response (*Yes/No*), producing a score from the sum of the "Yes" responses (range 0-30). The higher the qualification, the worse the quality of life is.

The HAQ-DI has 20 statements that assess 8 aspects of daily life. The statements are scored 1-3 and a higher score reflects a greater functional limitation.

The NHP is a measurement of the state of health that assesses changes in 6 areas: energy level, pain, mobility, sleep, social isolation and emotional reactions. It includes 38 dichotomous responses (*Yes/No*). Each section is independently scored and a percentage of the affirmative answers is obtained, yielding a score by section that goes from 0-100. Consequently, the greater the percentage, the greater the alteration in this area is.

The study protocol was approved by the corresponding local ethical committees following the guidelines of the Helsinki declaration.

All patients included in the study received sufficient information and gave informed written consent to take part in it.

## Results

### Translation

The bilingual panel and the reference panel were both managed by the same coordinator (CPT). The bilingual panel was supervised by a Galen Research representative who supplied information about each element.

The bilingual panel was made up of 4 females (27–28 years old) who had Mexican Spanish as their mother tongue, had a degree in English language, and managed and spoke English fluently. The supervisory panel set out the meeting agenda and supplied information on: rheumatoid arthritis disease in adults, the repercussions of the disease on the quality of life and the significance of the RAQoL questionnaire in evaluating the quality of life in patients that suffer from RA.

Before the meeting, each bilingual panel member received a copy of the original RAQoL and could ask questions about and discuss alternative translations for the instructions or its elements. The members were informed that the questionnaire translation would also be presented to the reference panel members, together with the alternative translations produced when no unanimous agreement was reached.

The panel members discussed using a literal English translation and using alternative phrasing for the majority of elements and words. The phrasing options were used in elements 5, 9, 17 and 21 of the RAQoL questionnaire to give a proper translation to Mexican Spanish.

### Reference panel

This panel consisted of 5 people (3 female and 2 male) with ages ranging from 32–62 years old. They had not seen the original RAQoL English version. Although the panel carried out some modifications and adaptations to questionnaire statements, these were minor in all cases.

### Cognitive interviews

A total of 15 patients with RA took part in the cognitive interviews. The group was predominantly female (87%), with an age of 47.4±9.9 years and disease evolution of 5.1±6.3 years on average. They were all recruited from local clinics and were over 18 years of age.

The majority of the adapted RAQoL questions were accepted by the patients and considered as relevant to their illness. All participants were able to complete the questionnaire without difficulty.

### Statistical description

The patients that took part in the validation stage were similar to those of the reference panel, not only in their demographic

**Table 1**

Descriptive characteristics of patients in the Validation Panel

	Validation panel
Male n (%)	6 (10.5)
Female n (%)	51 (89.5)
Mean age in years (SD)	52.4 (14.1)
Age range, years	21–83
Full-time Employees n (%)	19 (33)
Part-time Employees n (%)	5 (9)
Unemployed n (%)	34 (59)
Patients in remission n (%)	7 (12)
Patients in relapse n (%)	11 (19)
Mean duration of the disease in years (SD)	9.0 (6.5)
Range of the duration of the disease, years	2.0–27.0
General State of Health, %:	
Excellent and good	27 (47.3)
Regular	22 (38.5)
Bad	8 (14.0)
Current state of arthritis, %:	
Very good	7 (12.2)
Good	44 (77.2)
Very bad	6 (10.5)

n=number.

characteristics but also in aspects related to RA (Table 1). The RAQoL and NHP scores suggested that the patients had a moderate level of disease activity ([Table 2] and [Table 3]).

### Convergent and discriminant validity

In Table 3, the correlations between RAQoL and the different NHP sections are presented. The association profile is consistent with the hypothesis, which is that the correlation would be less in the sleep disorder and social isolation sections. In the rest of cases, correlation is acceptable, and therefore convergent validity was confirmed.

### Validity in known groups

The RAQoL was able to discriminate between patients according to their age group (older or younger than the mean) as patients over 48 years old had higher scores. There were no statistical differences in this panel's patients when compared to those of cognitive interviews in relation to gender, marital status or working situation. The RAQoL could discriminate patient groups according to the scores obtained for the general state of health, disease severity and current intensity

**Table 2**

Descriptive statistics of the questionnaire scores

	Mean (SD)	Min-Max	Minimum score %	Maximum score %
<i>First application</i>				
RAQoL	10.7 (7.3)	0–24	5.5	1.8
HAQ-DI	0.92 (0.8)	0–3	15.5	1.7
NHP Energy level	35.7 (30.8)	0–100	31.6	7.0
NHP Pain	36.4 (31.5)	0–100	29.3	1.7
NHP Emotional reactions	31.8 (22.0)	0–100	47.4	3.5
NHP Sleep disorders	22.8 (28.9)	0–100	28.9	7.2
NHP Social isolation	20.3 (30.8)	0–100	60.3	5.2
NHP Physical mobility	36.4 (28.0)	0–100	19.0	1.7
<i>Second application</i>				
RAQoL	11.0 (7.5)	0–26	5.9	2.0

**Table 3**  
Correlations between RAQoL and NHP

NHP categories	Correlation with RAQoL
Energy level	0.49 (n=55)*
Pain	0.61 (n=55)*
Emotional reactions	0.61 (n=55)*
Sleep disorders	0.48 (n=54)*
Social isolation	0.67 (n=55)*
Physical mobility	0.65 (n=55)*

\*The statistical significance of the correlation is less than 0.01.

**Table 4**  
Correlations between RAQoL and variables of disease activity

Variables of the disease's activity	Correlation with RAQoL
HAQ-DI	0.47* (n=55)
Tender joint count	0.48* (n=55)
Inflamed joint count	0.48* (n=55)
VAS pain	0.45* (n=55)
VAS general RA state (patient)	0.49* (n=55)
VAS general RA state (doctor)	0.49* (n=55)

\*The statistical significance of the correlation is less than 0.01.

of symptoms ([Figure 1], [Figure 2] and [Figure 3]). In the 3 cases, a higher RAQoL score was associated to a less favourable situation for the patient; this discerning capacity was statistically significant in comparing the 3 scales (general state of health [ $P<.001$ ], the severity of the disease in general [ $P<.05$ ] and the current intensity of symptoms [ $P<.004$ ]).

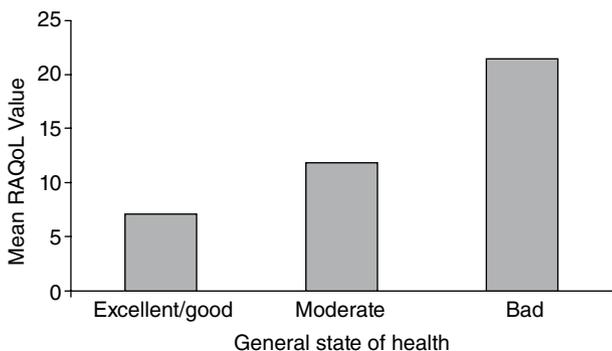
**Construct validity**

There was also a correlation between the RAQoL score and the different markers of RA activity. Statistically significant correlations were seen between the RAQoL score on tender and swollen joints count, VAS pain, VAS general state of health evaluated by the patient, VAS general state of health by the doctor and HAQ-DI score.

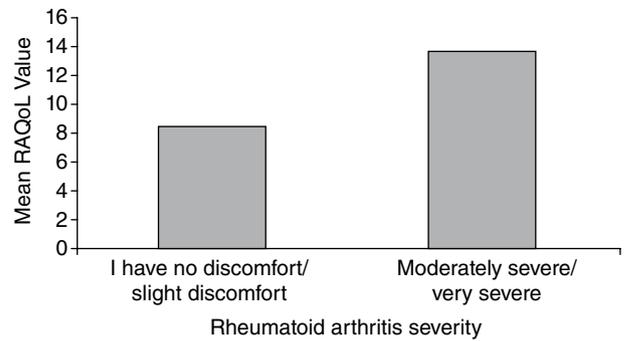
**Internal consistency and test-retest reliability**

The Cronbach  $\alpha$  coefficient for the RAQoL in Mexican Spanish was 0.91 (n=55) on visit 1 and 0.92 (n=51) on visit 2. This indicates that the new language version has excellent internal consistency between its elements.

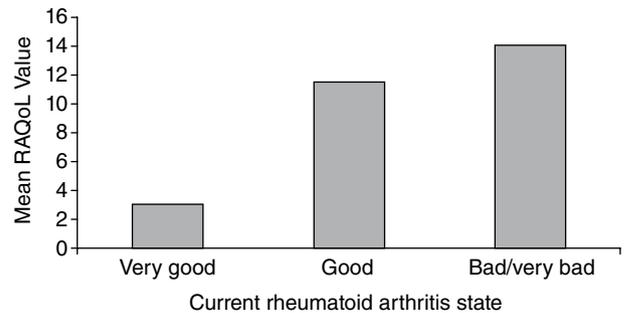
The RAQoL test-retest reliability in Mexican Spanish was 0.92 (n=51), indicating very low levels of random error. Finally, RAQoL showed excellent test-retest reliability (Figure 4).



**Figure 1.** Patient group discrimination by RAQoL according to the scores that the patients gave to disease severity and general state of health.



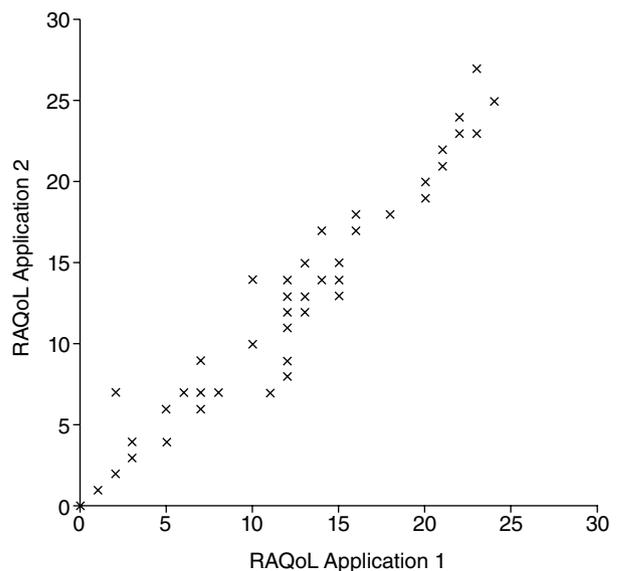
**Figure 2.** Patient group discrimination by RAQoL according to the scores that the patients gave to symptom intensity and general state of health.



**Figure 3.** Patient group discrimination by RAQoL according to the scores that the patients gave to disease severity and general state of health.

**Discussion**

The adaptation of RAQoL to Mexican Spanish was successful and was performed following the methodology previously used in adaptations to other languages. The adaptation process was carried out without any problems during its stages and the final product was well received by the patients, not only in the cognitive interview stages but also in the trial where its validity and reproducibility were assessed. This RAQoL version is a reliable, valid and sensitive instrument.



**Figure 4.** RAQoL reliability between the first and second application.

There are other specific generic instruments that have been used to measure quality of life in RA. Some include multi-functional scales such as AIMS and AIMS2, SF-36, EuroQoL and SIP. Their limitations have been reviewed previously and showed the need to consider an instrument designed specifically for patients with RA under the McKeena and Hunt premise, so as to assess the impact of the disease on various aspects of life, especially on covering needs instead of primarily focusing on repercussions on patient functionality.

The development of the RAQoL brought to light some aspects patients indicated as relevant in the impact of RA, such as mobility limitation, loss of dexterity, frustration, depression and anger, and feelings of humiliation or embarrassment at having to ask for outside help for some tasks. Patients referred to difficulty in concentrating, tiredness and severe interference from the illness in social and family activities. All these aspects are assessed by RAQoL.

The syntax and relevance of the questions was well received by the patients and gives it suitable validity regarding aspect and contents.

The methodology used in the translation and adaptation of the British English RAQoL to Mexican Spanish utilised a pre-established methodology comparable to previous adaptations of RAQoL to other English versions (Canadian, Australian)<sup>21,22</sup> or other languages (Estonian, Swedish, Turkish, Danish).<sup>23-27</sup> The user acceptance parameters and correlation to validation strategies (construct, parallel and main groups) are very similar. This suggests (in view of the RAQoL development process) that disease impact maintains a parallel affection profile in the different societies from which patients forming part of these exploration groups are drawn, despite local cultural differences.

For some reason, RAQoL correlations with the different NHP sections in our population showed smaller correlation (although acceptable) with the energy level section. This is worthy of note, as tiredness is a measure of RA impact on patients, especially in disease stages of great activity and there are scales that specifically explore it.<sup>28</sup>

## Conclusions

The quality of life assessment in RA patients should be carried out with a valid instrument, which is disease-specific, reliable and sensitive to the variations presented in the patient's quality of life.

Due to the changing activity of the disease, the adaptation of the RAQoL for its use in our population surely represents a good alternative in assessing our patients.

The parameters obtained in this adaptation indicate that RAQoL application in our population is feasible.

## Conflict of interest

The authors declare no conflict of interest.

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