



VALIDATION STUDIES

# Impact of rheumatoid arthritis on sexuality: adaptation and validation of the Qualisex questionnaire for use in Spain

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## Abstract

Patients with rheumatoid arthritis (RA) have a significantly increased risk of sexual dysfunction. However, it is not properly included in commonly used questionnaires to assess health-related quality of life in RA. Qualisex is a questionnaire developed in France to assess the impact of RA on patients' sexual function. Our aim was to adapt and validate this questionnaire for use with Spanish RA patients. Two independent translations and a backward translation were obtained. The final version was tested in a pilot study with 10 RA patients to detect any aspects that could hinder interpretation. The validity and reliability of the linguistically validated questionnaire were studied in a multicenter cross-sectional study, with a longitudinal component for reliability estimation. 125 RA patients were included. The response process, discrimination, internal consistency, internal structure, convergent validity (correlation with MGH-SFQ questionnaire, DAS-28, physician global assessment, patient global health assessment, RAID, HAQ, HADS and SF-12<sup>®</sup>) and reliability were analyzed. The inclusion of two extra items was proposed in the pilot study. The validity analysis detected responses for item 10 that were not coherent with responses for the rest of items. The Cronbach alpha coefficient was 0.971. The highest correlation (0.665) was obtained with MGH-SFQ (questionnaire measuring sexual functioning), followed by RAID (0.516). The intra-class correlation was 0.880 (95% CI 0.815; 0.923), higher than 0.85, which indicates excellent reliability. All parameters used to assess this questionnaire show highly acceptable values. Qualisex allows for a global score of RA patients' sexual functioning and can be self-administered.

**Keywords** Arthritis, rheumatoid · Sexuality · Surveys and questionnaires · Validation study · Quality of life · Patient reported outcomes

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## Introduction

The World Health Organization defines sexual health as a state of physical, mental and social well-being in relation to sexuality and defines sexuality as a central aspect of being human [1].

Patients with RA have a significantly increased risk of sexual disfunction [2]. The reasons are diverse. During periods of high disease activity, there may be a decrease in sexual desire due to pain, fatigue and stiffness. On the other hand, disillusionment with body image because of deformities can lead to loss of self-esteem and reduced sexual pleasure. Feeling pain during intercourse, erectile dysfunction and difficulty with certain body positions are physical issues that are also associated with sexuality. All this can lead to a significant loss of interest and decreased intercourse frequency [3–7].

A patient whose partner lacks an understanding of the illness or who, at times, is excessively cautious so as not to cause physical harm can also make satisfactory intercourse challenging [5].

Frequently, patient care is devoid of communication regarding sexuality [6]. Barriers to communication have been observed on the patient's side, which can stem from insecurity about broaching the subject, imagining that sexual problems do not count as illness, fear of judgment from the physician, or the belief that nothing can be done to solve it. Furthermore, sexuality is not often broached during medical consultations and it is not properly included in commonly used questionnaires to assess health-related quality of life [8–10].

An assessment of sexual problems requires valid, reliable, and easy-to-implement tools [11]. In this respect, a questionnaire called Qualisex has been developed and validated in France. It contains ten simple questions to assess the impact of RA on sexuality. The score for each item ranges from 0 to 10 and the total score is the mean of the results (but question 10 is scored on an opposite scale). Higher scores indicate more impact of RA on sexuality [12].

The adaptation and validation of the Spanish version of Qualisex will provide a tool that allows, both in clinical practice and in research, to assess the impact of RA on sexuality, obtaining a global score for RA patients' sexual function. The aim of this study was to adapt and validate this questionnaire for use in Spain.

## Materials and methods

### Translation and cultural adaptation [13]

After permission was obtained from the author, two translations were independently produced by Spanish native

speakers with adequate understanding of French language. Then, a backward translation was obtained by a French native speaker with adequate knowledge of Spanish language and uninformed about the final use of the translation. Participation of translators with and without experience in the management of musculoskeletal disorders was assured. Any discrepancies detected were resolved by consensus and the participation of an external translator. The final version resulting from this process was tested in a pilot study with RA patients to detect any aspects that might make interpretation of the questions and comparability of results difficult. Participants were RA patients aged  $\geq 18$  years, of different age groups, who were recruited by means of a purposive sampling based on their willingness to take part. Two discussion groups were formed, one with five women and the other with five men. Any proposals in the discussion groups were evaluated by two methodologists and the principal investigator.

### Study on the validity and reliability of the linguistically validated questionnaire

#### General design

Multicenter cross-sectional study to evaluate the questionnaire's validity, with a longitudinal component for reliability estimation.

#### Study population

- Inclusion criteria: Patients  $\geq 18$  years, diagnosed with RA according to ACR criteria, whose first nationality and native language was Spanish, with ability to answer the questionnaires.
- Exclusion criteria: Pathology limited to the genital tract with an impact on sexuality. Fibromyalgia. Patients stating that they were not sexually active due to any cause other than RA (different pathology, age, personal decision, or any other reason). Taking part in any clinical trial or research project that could prevent adequate participation in the study.

The Declaration of Helsinki and Good Clinical Practice Standards were followed. The study protocol and materials were approved by the Research Ethics Committee (REC) of Hospital Universitari de Bellvitge (ethics approval protocol number PR426/18) on 20 December 2018. Written informed consent was obtained from all participants. Patient data entered in the CRF were codified, and only researchers from each center, as well as the study monitor, could link these data with the corresponding medical history.

## Sampling and sample size

During regularly scheduled visits to the Rheumatology department, patients meeting the selection criteria were consecutively invited to participate. It was intended that at least 25% of participants were men (the approximate proportion of men in the RA patient population) and that all age ranges were included (at least 10% younger than 40, and at least 20% older than 65) [14].

Based on the wide variety of existing criteria used to establish a sample size for questionnaire validation studies, the recommendation to recruit ten patients per item was taken into consideration. Therefore, 100 patients had to be recruited, a sample size that also conforms with the minimum recommended by other authors [15].

Taking into account an incomplete questionnaire (2 or more unanswered items) rate of 20%, a sample size of 125 patients would ultimately be needed. Five centers from different Spanish regions (Catalonia, Valencia, Madrid, Andalusia and Basque Country) took part in this study.

## Variables

### 1. Socio-demographic variables:

- age, sex;
- marital status (single, married/domestic partnership, divorced/separated, widowed);
- partner (yes/no) and duration of relationship;
- level of education (basic: primary education, finished or not, and first part of secondary education; intermediate: high school diploma or intermediate vocational training or equivalent; higher: university degree or equivalent or higher vocational training or equivalent);
- employment status (no incapacity, temporary incapacity, permanent incapacity for work);
- religion (Catholic; Protestant; Orthodox Christian; Muslim; Jewish; agnostic; atheist; other; no response) and frequency of religious practice (practicing; non-practicing; no response).

### 2. Comorbidities, year of diagnosis and treatment: cardiovascular pathology, diabetes, Sjögren syndrome.

### 3. Disease variables: DAS28-ESR [16]. Physician global assessment of disease activity in the last week (scored 0 to 100). Patient global health assessment (PGA) in relation to their RA in the last week (with visual numeric scale; scored 0 to 100). Current treatment and over the past 3 months; start and end dates.

### 4. Questionnaires on disease impact, quality of life, functional capacity: RAID (Rheumatoid Arthritis Impact of Disease scale) [9], HAQ (Health Assessment Questionnaire) [10],

HADS (Hospital Anxiety and Depression Scale) [17], SF-12 v1 (12-item Short-Form Health Survey)® [18].

5. Questionnaires on sexual functioning: Qualisex questionnaire (linguistically validated version), MGH-SFQ (Massachusetts General Hospital-Sexual Functioning Questionnaire; self-administered questionnaire validated in the Spanish general population, with five items referring to sexual interest, arousal capacity, ability to achieve orgasm, ability to achieve and maintain erection (only for men) and overall sexual satisfaction. The score for each item ranges from 0-totally decreased- to 4-normal and the total score is calculated as the sum) [11].

## Data monitoring

Online monitoring of all patients included in the database was conducted to confirm that there were no inconsistencies or relevant data loss. After online monitoring, in-situ monitoring was performed for questionnaires from 96% of the recruited patients.

## Statistical analysis

- Study of the response process: Atypical response patterns, distribution of missing responses, distribution of responses for each item, analysis of responses by sex and age.
- Study of discrimination: 33% of patients with higher scores (upper tertile) and 33% of patients with lower scores (bottom tertile) in the Qualisex questionnaire were selected. In each group, the mean was calculated for each item. Then the discrimination index for each item was obtained by subtracting the mean of the bottom tertile from the mean of the upper tertile.
- Internal consistency: Cronbach alpha coefficient. The corrected item-total correlation and the Cronbach alpha coefficient when the corresponding item was eliminated were also calculated.
- Internal structure: adequacy of data was verified with the Kaiser–Meyer–Olkin test (sampling fitness) and the Bartlett's Test of Sphericity. An explorative factor analysis was conducted by principal components extraction with varimax rotation. Spearman correlations between the different items were also calculated.
- Convergent validity: Spearman coefficient was used to analyze any correlations between the Qualisex questionnaire values and the following: MGH-SFQ, DAS28-ESR, physician global assessment, PGA, RAID, HAQ, HADS and SF-12.
- Reliability: A group of patients answered again the Qualisex questionnaire after a period of 7–10 days. Patients selected to participate in this part of the study were those with no changes in treatment and stable according to their

rheumatologist, thereby facilitating an evaluation of the degree of score reproducibility. Any variations observed in the PGA were taken into consideration to compare stability since the first time the patient completed the Qualisex questionnaire. The intraclass correlation coefficient (ICC) was calculated using a two-factor mixed model (single measurement and absolute agreement).

IBM SPSS (Version 25.0, Armonk, NY) and Microsoft Excel 365 were used to perform the analyses.

## Results

### Translation

The French version served as the original version [12]. The version obtained after translation and backward translation was assessed by the participants of the discussion groups, and some changes suggested regarding the wording were adopted in the final version. In addition, the inclusion of the following two extra items was proposed: one concerning quality (satisfaction) of sexual intercourse and the other one concerning sex life deterioration due to sadness or depression. Both items were accepted.

Figure 1 shows the final version of the Qualisex questionnaire that was used for the validity and reliability study.

### Study on the validity and reliability of the qualisex questionnaire

#### Socio-demographic data and rheumatoid arthritis characteristics

The sample consists of 125 RA patients. Tables 1 and 2 summarize the socio-demographic characteristics, comorbidities and data on RA.

#### Disease impact, quality of life and functional capacity

The mean (SD) from scores obtained with RAID, HAQ, HADS-Anxiety and HADS-Depression and the physical component of SF-12 measured 3.6 (2.4), 0.8 (0.7), 9.6 (2.5), 8.7 (1.7), 40.1 (11.1), respectively, without statistically significant differences between men and women. The mean for the mental component of SF-12 was 51.4 (7.8) in men and 48.4 (10.5) in women, this difference being on the borderline of statistical significance ( $p=0.093$ ).

#### Sexual functioning

All the participants answered the questionnaire by themselves, with occasional need to clarify doubts.

Supplementary Data S1 shows the response frequency for each item of Qualisex. High values indicate higher impact (except for item 10, which utilizes a reverse scoring scale).

Table 3 shows the scores obtained with MGH-SFQ and Qualisex questionnaires, as well as scores from the two extra items that had been proposed in the pilot study. All Qualisex items were answered, except for one patient who did not answer item 2, which refers to treatment effects (0.8%), and six patients (4.8%) who did not answer items 5 and 6 due to not having a current partner. Whether the six patients who left two questions unanswered were included or not, the calculations remained unaffected (Table 3).

Regarding the distribution in scores obtained with Qualisex for the different age groups, a slight increase was observed, with a mean (SD) of 2.74 (3.25) for the group of patients aged under 40, 2.86 (2.63) for the group aged 40–60 and 3.41 (2.38) for the group aged over 60 ( $p<0.001$ ).

### Study on the validity and reliability of the qualisex questionnaire

The validity analysis for the Qualisex questionnaire detected responses for item 10 that were not coherent with the responses given for the rest of items (including the extra items). Item 10 was the only one where low values indicated worse sexual functioning, which may have led to some confusion when patients answered this item. For this reason, the value of item 10 was modified for those patients whose response was clearly incoherent with those given for the rest of the Qualisex items and the extra items (see Supplementary Data S1).

The results obtained from the validity and reliability analysis after modifying item 10 and adding the extra items to the questionnaire, which will hereafter be referred to as Qualisex\_MA, are shown below. As in the original questionnaire, the global score was calculated as the mean of the responses for all 12 items (with item 10 scored using an opposite scale).

**Study on discrimination** Absolute values for the discrimination indexes ranked between 4.58 for item 5 and 7.23 for item 4. For all items,  $p$ -values for the difference in mean values between the group with the lowest global score and the group with highest global score in Qualisex\_MA were lower or equal to 0.001.

**Internal consistencies** The Cronbach alpha coefficient was 0.971; as it was higher than 0.7, it was classified as very satisfactory. Table 4 shows the mean values for each item, as well as the corrected item-total correlation and the Cronbach alpha coefficient when the corresponding item was eliminated. All corrected item-total correlations, including that for item 10, were higher than 0.4, which indicates that

**Fig. 1** Qualisex questionnaire.  
Final version used for the validity and reliability study

Estas preguntas se refieren a las consecuencias de la artritis reumatoide en su vida sexual. Por favor, en cada una de ellas marque el número que se ajuste mejor a su estado **durante los 3 últimos meses**.

1. Durante los 3 últimos meses, ¿su vida sexual ha empeorado debido a su estado de salud?

Nada					Muchísimo					
0	1	2	3	4	5	6	7	8	9	10

2. Durante los 3 últimos meses, ¿su vida sexual ha empeorado debido a los medicamentos que toma para la artritis reumatoide (por sus efectos secundarios)?

Nada					Muchísimo					
0	1	2	3	4	5	6	7	8	9	10

3. Durante los 3 últimos meses, ¿su deseo sexual ha disminuido debido a su estado de salud?

Nada					Muchísimo					
0	1	2	3	4	5	6	7	8	9	10

4. Durante los 3 últimos meses, ¿la frecuencia de sus relaciones sexuales ha disminuido debido a su estado de salud?

Nada					Muchísimo					
0	1	2	3	4	5	6	7	8	9	10

5. Durante los 3 últimos meses, ¿la relación sentimental con su pareja ha empeorado debido a su estado de salud?

Nada					Muchísimo					
0	1	2	3	4	5	6	7	8	9	10

☐ No tengo pareja

6. Durante los 3 últimos meses, ¿ha sentido una pérdida de autoestima que afecte a la relación con su pareja?

Nada					Muchísimo					
0	1	2	3	4	5	6	7	8	9	10

☐ No tengo pareja

7. Durante los 3 últimos meses, ¿se ha sentido menos atractivo debido a su estado de salud?

Nada					Muchísimo					
0	1	2	3	4	5	6	7	8	9	10

8. Durante los 3 últimos meses, ¿ha empeorado su vida sexual debido a los dolores causados por su artritis?

Nada					Muchísimo					
0	1	2	3	4	5	6	7	8	9	10

9. Durante los 3 últimos meses, ¿ha empeorado su vida sexual por estar cansado?

Nada					Muchísimo					
0	1	2	3	4	5	6	7	8	9	10

10. Durante los 3 últimos meses, ¿ha tenido una vida sexual globalmente satisfactoria?

Nada					Muchísimo					
0	1	2	3	4	5	6	7	8	9	10

#### (ÍTEM EXTRA)

Durante los 3 últimos meses, ¿la calidad (satisfacción) de sus relaciones sexuales ha disminuido debido a su estado de salud?

Nada					Muchísimo					
0	1	2	3	4	5	6	7	8	9	10

Durante los 3 últimos meses, ¿ha empeorado su vida sexual por estar triste/deprimido debido a su estado de salud?

Nada					Muchísimo					
0	1	2	3	4	5	6	7	8	9	10

**Table 1** Sample socio-demographic characteristics by sex

	Total ( <i>n</i> = 125)	Men ( <i>n</i> = 34)	Women ( <i>n</i> = 91)	<i>p</i> value
Age (years)	54.6 ± 11.8	54.9 ± 11.4	54.5 ± 12.0	0.889
Age range				0.096
< 40	14 (11%)	1 (3%)	13 (14%)	
40–60	68 (55%)	23 (68%)	45 (50%)	
≥ 60	43 (34%)	10 (29%)	33 (36%)	
Marital status				0.912
Single	9 (7%)	3 (9%)	6 (7%)	
Partner (living together)	101 (81%)	27 (79%)	74 (81%)	
Separated/divorced	15 (12%)	4 (12%)	11 (12%)	
Current partner	119 (95%)	31 (91%)	88 (97%)	0.198
Relationship duration (years)	28.7 ± 15.1	28.3 ± 13.2	28.8 ± 15.7	0.876
Education level				0.238
Basic	49 (39%)	14 (41%)	35 (39%)	
Intermediate	35 (28%)	12 (35%)	23 (25%)	
High	41 (33%)	8 (24%)	33 (36%)	
Work incapacity				0.180
No incapacity	100 (80%)	24 (71%)	76 (84%)	
Temporary	1 (1%)	-	1 (1%)	
Permanent	24 (19%)	10 (29%)	14 (15%)	
Religion				0.075
Catholic	94 (75%)	30 (88%)	64 (70%)	
Atheist/agnostic	20 (16%)	4 (12%)	16 (18%)	
Others/no response	11 (9%)	-	11 (12%)	

these items measure the same feature as the global scale does. When the corresponding item was eliminated, the Cronbach alpha coefficients for items 5 and 10 were close to the global Cronbach alpha coefficient, which could indicate that they were not providing extra input to the questionnaire.

**Internal structure** Based on the selection criteria of components that had eigenvalues greater than 1, only one component would be selected. This would explain a variance of 76.18% (eigenvalue = 9.142). Communalities were high for all items, with a variation between 0.501 (for modified item 10) and 0.898 (for second extra item). This would indicate that the questionnaire evaluates sexual functioning by utilizing a unidimensional structure.

Supplementary Table S1 shows the Spearman's rank correlations among the different items in Qualisex\_MA. All of them were significant and positive, which indicated a direct relationship between them.

**Convergent validity** Table 5 shows the Spearman's rank correlations and their *p*-values. Except for depression as measured by HADS, all were statistically significant. Considering that the physician global assessment of disease activity, PGA, RAID, HAQ and HADS-anxiety all indicate worsening conditions when the score increase, consistent

with the results of Qualisex, the correlations proved positive. This was not the case with physical and mental components of SF-12 and MGH-SFQ, which indicates a worsening condition when the score decrease. It is worth noting that the highest correlation (0.665) was obtained with MGH-SFQ (the other questionnaire measuring sexual function), followed by RAID (0.516).

**Reliability** A total of 95 patients, 28 men and 67 women, answered Qualisex a second time; although 6 patients did not have a partner and, therefore, did not answer items 5 and 6, they were included in the analysis. Out of the 95 patients, those who remained stable from the first to the second questionnaire were selected. Data on PGA were again collected to assess their stability. There were 17 patients with worse PGA based on more than 20 points, 3 patients with improved PGA based on more than 20 points and 2 patients who did not provide the needed information. Thus, a total of 73 patients took part in the reliability analysis.

Responses to item 10 were revised using the procedure outlined in Supplementary Data S1.

The intra-class correlation was 0.880 (95% CI 0.815; 0.923), higher than 0.85, which indicated excellent reliability.



**Table 2** Comorbidities and RA characteristics by sex

	Total (n = 125)	Men (n = 34)	Women (n = 91)	p value
Comorbidities				
Cardiovascular	27 (22%)	9 (26%)	18 (20%)	0.419
Diabetes mellitus	6 (5%)	3 (9%)	3 (3%)	0.343
Sjögren syndrome	9 (7%)	2 (6%)	7 (8%)	0.728
Rheumatoid arthritis				
Time of evolution (years)				0.593
< 5	34 (27%)	11 (32%)	23 (25%)	
5–10	16 (13%)	3 (9%)	13 (14%)	
> 10	75 (60%)	20 (59%)	55 (60%)	
NTJ28				0.882
0	71 (58%)	21 (62%)	50 (56%)	
1	14 (11%)	4 (12%)	10 (11%)	
2	15 (12%)	3 (9%)	12 (13%)	
3 or more	24 (19%)	6 (17%)	18 (20%)	
NSJ28				0.153
0	98 (79%)	30 (88%)	68 (76%)	
1	11 (9%)	3 (9%)	8 (9%)	
2 or more	15 (12%)	1 (3%)	14 (15%)	
ESR <sup>a</sup>	9 (4; 19)	5.5 (3.7; 11.7)	13 (5; 22)	0.014
DAS28-ESR <sup>a</sup>	2.4 (1.5; 3.2)	2.1 (1.3; 2.9)	2.5 (1.7; 3.4)	0.058
Categorized DAS28				0.452
≤ 3.2	93 (75%)	28 (82%)	65 (73%)	
3.3–5.1	28 (23%)	6 (18%)	22 (25%)	
> 5.1	2 (2%)	-	2 (2%)	
Global assessment <sup>a</sup>				
Patient	30 (10; 50)	20 (10; 50)	30 (10; 50)	0.341
Physician	10 (1; 40)	10 (10; 21.2)	20 (0; 40)	0.336
Treatment				
Last 3 months				
Corticosteroids	59 (48%)	13 (39%)	46 (51%)	0.310
Conv. DMARDs	90 (73%)	26 (76%)	64 (71%)	0.655
Biologic agents	70 (56%)	17 (50%)	53 (59%)	0.420
Currently				
Corticosteroids	56 (45%)	12 (35%)	44 (49%)	0.226
Conv. DMARDs	88 (71%)	26 (76%)	62 (69%)	0.508
Biologic agents	69 (56%)	17 (50%)	52 (58%)	0.544

NTJ number of tender joints, NSJ number of swollen joints, ESR erythrocyte sedimentation rate, conv. = conventional

<sup>a</sup>Data show the median (P<sub>25</sub>; P<sub>75</sub>)

## Discussion

An assessment of RA patient sexuality problems requires valid, reliable and easy-to-implement tools [11]. In this promoted by the Spanish Society of Rheumatology, the Qualisex questionnaire [12] was adapted and validated for the Spanish population suffering from RA and showed high reliability and consistency.

The Qualisex questionnaire was also adapted and translated into Spanish by an Argentinian group for use in patients with axial spondyloarthritis [19]. A total of 50 patients (40 of them men) took part in that validation process. The modest number of participants is a limitation. On the other hand, as they were patients with spondyloarthritis, the proportion of men (80%) does not represent the RA population in Spain [14].

**Table 3** Scores from the MGH-SFG and Qualisex questionnaires on sexual functioning

	Total ( <i>n</i> = 125)	Men ( <i>n</i> = 34)	Women ( <i>n</i> = 91)	<i>p</i> value
<b>MGH-SFQ</b>				
Men (0–20)/ Women (0–16)		16.16 ± 5.27	9.76 ± 5.75	
MGH-SFQ (0–4)	2.61 ± 1.39	3.05 ± 1.20	2.44 ± 1.43	0.030
Desire	2.59 ± 1.48	2.94 ± 1.32	2.46 ± 1.51	0.106
% Desire ≤ 3	69 (55%)	16 (47%)	53 (58%)	
Arousal	2.62 ± 1.45	3.09 ± 1.21	2.45 ± 1.49	0.028
% Arousal ≤ 3	70 (56%)	16 (47%)	54 (59%)	
Orgasm	2.66 ± 1.49	3.18 ± 1.36	2.46 ± 1.49	0.016
% Orgasm ≤ 3	59 (47%)	11 (68%)	36 (40%)	
Erection		3.19 ± 1.17	–	
% Erection ≤ 3		13 (42%)	–	
Satisfaction	2.59 ± 1.42	3.12 ± 1.14	2.40 ± 1.47	0.005
% Satisfaction ≤ 3	52 (42%)	19 (58%)	33 (37%)	
<b>QUALISEX</b>				
Qualisex (0–10)	3.04 ± 2.61	2.61 ± 2.56	3.20 ± 2.63	< 0.001*
Qualisex (0–10) <sup>a</sup>	2.40 (0.6; 4.9)	1.25 (0.5; 6.6)	2.70 (0.7; 5.0)	0.297
Qualisex (0–10) <sup>b</sup>	3.10 ± 2.63	2.67 ± 2.58	3.26 ± 2.65	< 0.001*
% Patients with at least one item higher or equal to 9	90 (72%)	24 (71%)	66 (72%)	0.826
<b>Extra items</b>				
Decrease in quality (satisfaction)	3.03 ± 3.33	2.41 ± 3.08	3.26 ± 3.41	0.015***
Decrease in quality (satisfaction) <sup>a</sup>	2 (0; 5)	1 (0; 5)	2 (0; 6)	0.179
Sex life deterioration due to sadness/depression	2.88 ± 3.34	2.21 ± 3.00	3.13 ± 3.44	0.007*
Sex life deterioration due to sadness/depression <sup>a</sup>	2 (0; 5)	0 (0; 4.25)	2 (0; 6)	0.153

<sup>a</sup>Data show the median (*P*<sub>25</sub>; *P*<sub>75</sub>)

<sup>b</sup>Calculations obtained without including patients not answering or having a “not applicable” situation for two or more items

\**p* value obtained with Poisson loglinear model (applied due to the high variability in the scores; the global score was calculated as the sum of the different items)

**Table 4** Corrected item-total correlation and Cronbach Alpha Coefficient when the item was eliminated from Qualisex\_MA

QUALISEX_MA	Mean ± SD	Corrected item-total correlation	Cronbach alpha if item is eliminated
Item 1 (sex life)	3.22 ± 3.38	0.928	0.967
Item 2 (treatment)	2.69 ± 3.15	0.880	0.968
Item 3 (sex drive)	3.45 ± 3.54	0.911	0.967
Item 4 (sexual performance)	3.46 ± 3.51	0.930	0.967
Item 5 (relationship with your partner)	1.97 ± 2.92	0.715	0.972
Item 6 (loss of self-esteem)	2.36 ± 3.11	0.787	0.970
Item 7 (feel less sexually attractive)	2.66 ± 3.06	0.813	0.970
Item 8 (pain)	2.86 ± 3.20	0.839	0.969
Item 9 (tiredness)	3.18 ± 3.28	0.844	0.969
Item 10 (overall satisfaction) <sup>a</sup> modified	4.34 ± 3.08	0.666	0.973
Extra item 1 (quality/satisfaction)	3.14 ± 3.38	0.890	0.968
Extra item 2 (sex life due to depression)	2.96 ± 3.38	0.935	0.966

<sup>a</sup>Opposite scale



**Table 5** Spearman's correlations between Qualisex\_MA scores and other questionnaires and measures

	$r_s$	$p$ value
Patient global assessment	0.378	<0.001
Physician global assessment of disease activity	0.337	<0.001
DAS28-ESR	0.302	0.001
RAID	0.516	<0.001
HAQ	0.489	<0.001
HADS		
Anxiety	0.436	<0.001
Depression	0.024	0.796
SF-12		
Physical component	−0.458	<0.001
Mental component	−0.468	<0.001
MGH_SFQ	−0.665	<0.001

In the final version of Qualisex adopted by the present study, two extra items were included, in addition to the ten items in the original version, in accordance with proposals made during the pilot study. The changes resulting from these additions were examined.

Item 10 was the only item for which low values indicated worse sexual function. Although the wording is correct, normally items with an inverse response or simple negation carry a higher cognitive burden, which may lead to misinterpretation. We noted those replies to this item that were not coherent with answers to other items (including the extra items). The three versions of this questionnaire, i.e., Qualisex, Qualisex\_M (with item 10 modified) and Qualisex\_MA (two extra items added to the Qualisex\_M version), were all analyzed. The validity and reliability analyses of the Qualisex and Qualisex\_M questionnaires are shown in Supplementary data S2.

The present study found that RA patients experienced worse conditions compared to the general Spanish population (i.e., scores below 50;  $p < 0.001$ ) in the physical component of the SF-12 questionnaire [18]. As for the grip section in HAQ, 60% of women reported severe disability or were unable to do it, compared to 29% of men. Some studies observed that muscle strength and physical functioning may play a role in RA patient sexuality [5, 6, 20]. The study by Dorner et al. observed that grip strength was associated with desire, frequency and sexual pleasure [20].

In the study sample, there was a slightly lower disease impact (mean RAID score was 0.8 lower) than in the study by Gossec et al. [12]. Fatigue is another aspect of particular interest, with considerable impact on RA patient sexuality [5, 20, 21]. The highest score (worst condition) on the RAID questionnaire corresponded with the fatigue/tiredness

domain, with a mean of 4.4, which was 0.6 points lower than in the study by Gossec et al. [12].

The impact of RA on patient sexuality is well known [2–4, 7, 22–25] and worsens during high disease activity due to chronic pain, fatigue and stiffness [5, 6, 20, 22, 23, 25]. RA activity, as measured with DAS28-ESR, was slightly lower than that reported in the study by Gossec et al. (mean values of 2.5 and 3.5, respectively) [12]. Only 2% of patients exhibited high activity, 23% moderate activity and 75% remained in remission or presented low disease activity.

The mean score of Qualisex was 3.04 (SD 2.61). Women's scores were slightly higher than men's, which indicates a greater impact on sexual functioning. These results are similar to those obtained by Gossec et al. [12]. The two extra items revealed the same behaviors. Similarly, scores from the MGH-SFQ questionnaire showed values significantly lower for women than for men, as was observed in the MGH-SFQ validation in the Spanish general population [11]. There are differences between male and female RA patients in terms of sexual activity, and some studies have observed that women have fewer sexual thoughts and fantasies [3, 7, 24]. During intercourse, the key problems are pain and limited joint movement [3, 4, 24–26].

For all items in the Qualisex\_MA questionnaire, discrimination was satisfactory, with  $p$ -values equal to or lower than 0.001. Internal consistency, with a Cronbach alpha coefficient of 0.971, was slightly higher than that obtained by Gossec et al. [12]. Although the grade of incoherence was addressed by modifying item 10 when the answer was clearly incoherent compared to responses for the remaining items, there is still a chance that some other patients had interpreted item 10 incorrectly. In any case, the consistency of Qualisex\_M improved compared to Qualisex with the original data. For this reason, we propose modifying the wording of the scale used for item 10 in the following way: “Not satisfactory at all” (score 0) and “Highly satisfactory” (score 10).

Qualisex\_MA has shown an adequate convergent validity (Table 5). There were significant correlations with scores obtained from other questionnaires, except for depression as measured by HADS, which is similar to the results obtained by Gossec et al. [12]. As mentioned by the authors, the absence of correlation suggests that the questionnaire measures sexual aspects more often associated with the disease itself rather than with psychological issues [12]. The questionnaire's reliability was excellent (0.88); indeed, slightly higher than the result obtained by Gossec et al. [12].

In adapting the Qualisex questionnaire, differences were noted between the original version and the Spanish version. This has occurred with adaptations of other questionnaires addressing quality of life and reflects sociocultural differences between countries [10, 11]. The inclusion of the two

extra items and the modification of item 10 did not have a negative bearing on the questionnaire's validity, and certain improvements were observed for some parameters.

Patients were invited to participate during their visits to the Rheumatology department. A limitation of the present study is that data on patients who were unwilling to partake in the study are not available. Nevertheless, the study sample is representative of the RA patient population in Spain in terms of both age and sex [14].

In conclusion, the present study shows that the Spanish version of the Qualisex questionnaire boasts high reliability and consistency. All of the parameters used to assess it showed highly acceptable values. Qualisex provides a global score for RA patients' sexual function and can be self-administered.

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**Author contributions** MRB was responsible for the study conception and coordination, contributed to the acquisition and interpretation of data, and drafted the work. DS-M was responsible for the methodology and coordination, contributed to the interpretation of data, and drafted the work. JJA-S, LL, MACR and JC-A contributed to the design of the study and the acquisition of data. BF contributed to the design of the study. CS, VN-M, DF-N and ROC contributed to the acquisition of data. All authors revised the work and approved the final version.

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**Availability of data and material** The data underlying this article will be shared on reasonable request to the corresponding author or proyectos@ser.es.

**Code availability** Not applicable.

## Declarations

**Conflict of interest** The authors declare that they have no conflict of interest related to this work.

**Ethics approval** The Declaration of Helsinki and Good Clinical Practice Standards were followed. The study protocol and materials were approved by the Research Ethics Committee (REC) of Hospital Uni-

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**Consent to participate** Written informed consent was obtained from all participants. Patient data entered in the CRF were codified, and only researchers from each center, as well as the study monitor, could link these data with the corresponding medical history.

**Consent for publication** Not applicable.

## References

1. World Health Organization, Department of Reproductive Health and Research (2002) Defining sexual health: report of a technical consultation on sexual health. WHO, Geneva
2. Zhao S, Li E, Wang J, Luo L, Luo J, Zhao Z (2018) Rheumatoid arthritis and risk of sexual dysfunction: a systematic review and metaanalysis. *J Rheumatol* 45:1375–1382
3. Abdel-Nasser AM, Ali EI (2006) Determinants of sexual disability and dissatisfaction in female patients with rheumatoid arthritis. *Clin Rheumatol* 25:822–830
4. Josefsson KA, Gard G (2010) Women's experiences of sexual health when living with Rheumatoid Arthritis—an explorative qualitative study. *BMC Musculoskelet Disord* 11:240
5. Hill J, Bird H, Thorpe R (2003) Effects of rheumatoid arthritis on sexual activity and relationships. *Rheumatology (Oxford)* 42:280–286
6. Josefsson KA, Gard G (2012) Sexual health in patients with rheumatoid arthritis: experiences, needs and communication with health care professionals. *Musculoskeletal Care* 10:76–89
7. Van Berlo WTM, van de Wiel HBM, Taal E, Rasker JJ, Weijmar Schultz WCM, van Rijswijk M (2007) Sexual functioning of people with rheumatoid arthritis: a multicenter study. *Clin Rheumatol* 26:30–38
8. Romera-Baures M (2018) Sexuality and rheumatic diseases. *Reumatol Clin* 14:125–126
9. Gossec L, Paternotte S, Aanerud GJ, Balanescu A, Boumpas DT, Carmona L et al (2011) Finalisation and validation of the rheumatoid arthritis impact of disease score, a patient-derived composite measure of impact of rheumatoid arthritis: a EULAR initiative. *Ann Rheum Dis* 70:935–942
10. Esteve-Vives J, Batlle-Gualda E, Reig A, Grupo para la Adaptación del HAQ a la Población Española, (1993) Spanish version of the Health Assessment Questionnaire (HAQ): reliability, validity and transcultural equivalency. *J Rheumatol* 20:2116–2122
11. Sierra JC, Vallejo-Medina P, Santos-Iglesias P, Lameiras M (2012) Validation of Massachusetts General Hospital-Sexual Functioning Questionnaire (MGH-SFQ) in a Spanish population. *Aten Primaria* 44:516–526
12. Gossec L, Solano C, Paternotte S, Beauvais C, Guadin P, von Krause G et al (2012) Elaboration and validation of a questionnaire (Qualisex) to assess the impact of rheumatoid arthritis on sexuality with patient involvement. *Clin Exp Rheumatol* 30:505–513
13. Ortiz-Gutiérrez S, Cruz-Avelar A (2018) Translation and cross-cultural adaptation of health assessment tools. *Actas Dermosifiliogr* 109:202–206
14. Maese J, García De Yébenes MJ, Carmona L, Hernández-García C (2012) Management of rheumatoid arthritis in Spain (emAR II). Clinical characteristics of the patients. *Reumatol Clin* 8:236–242
15. Mokkink LB, Terwee CB, Knol DL, Stratford PW, Alonso J, Patrick DL et al (2010) The COSMIN checklist for evaluating the

- methodological quality of studies on measurement properties: a clarification of its content. *BMC Med Res Methodol* 10:22
16. Balsa A, Carmona L, Gonzalez Alvaro I, Belmonte Serrano MA, Tena X, Sanmartí R (2004) Value of Disease Activity Score 28 (DAS28) and DAS28-3 compared to American College of Rheumatology-defined remission in rheumatoid arthritis. *J Rheumatol* 31:40–46
  17. Quintana JM, Padierna A, Esteban C, Arostegui I, Bilbao A, Ruiz I (2003) Evaluation of the psychometric characteristics of the Spanish version of the hospital anxiety and depression scale. *Acta Psychiatr Scand* 107:216–221
  18. Vilagut G, Valderas JM, Ferrer M, Garin O, López-García E, Alonso J (2008) Interpretation of SF-36 and SF-12 questionnaires in Spain: physical and mental components. *Med Clin (Barc)* 130:726–735
  19. Sommerfleck FA, Schneeberger EE, Orozco MC, Zamora N, Landi M, Citera G (2018) Validation and cultural adaptation of the qualisex questionnaire in patients with axial spondyloarthritis in Argentina. *Rheumatol Int* 38:2103–2109
  20. Dorner TE, Berner C, Haider S, Grabovac I, Lamprecht T, Fenzl KH et al (2018) Sexual health in patients with rheumatoid arthritis and the association between physical fitness and sexual function: a cross-sectional study. *Rheumatol Int* 38:1103–1114
  21. Helland Y, Kjekken I, Steen E, Kvien TK, Hauge MI, Dagfinrud H (2011) Rheumatic diseases and sexuality: disease impact and self-management strategies. *Arthritis Care Res (Hoboken)* 63:743–750
  22. Kobelt G, Texier-Richard B, Mimoun S, Woronoff AS, Bertholow DR, Perdriger A et al (2012) Rheumatoid arthritis and sexuality: a patient survey in France. *BMC Musculoskelet Disord* 13:170
  23. Chancay MG, Guendeschadze SN, Blanco I (2019) Types of pain and their psychosocial impact in women with rheumatoid arthritis. *Womens Midlife Health* 5:3
  24. Tristano AG (2014) Impact of rheumatoid arthritis on sexual function. *World J Orthop* 5:107–111
  25. Alia F, Rim BS, Miladi S, Quenniche K, Kassab S, Chekili S et al (2019) Comparison of sexual function in Tunisian women with rheumatoid arthritis and healthy controls. *Clin Rheumatol* 38:3361–3365
  26. Bourg M, Ruysen-Witrand A, Bettiol C, Parinaud J (2020) Fertility and sexuality of women with inflammatory arthritis. *Eur J Obstet Gynecol Reprod Biol* 251:199–205

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