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Original Investigation

Validation of FACIT-fatigue in Spanish-speaking patients with rheumatoid arthritis

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ABSTRACT

Introduction: Fatigue is a frequent symptom in patients with rheumatoid arthritis (RA). The Functional Assessment of Chronic illnesses Therapy-Fatigue (FACIT-F) is an instrument that assesses self-reported fatigue and was validated for measuring fatigue in RA.
Objective: The aim of this study was to validate the FACIT-F for use in Spanish-speaking RA patients.
Materials and methods: Cross-sectional, multicentre study. We included patients (n = 192) with RA diagnosis from two hospitals. Exploratory and confirmatory analyses were conducted. Construct validity and internal consistency were evaluated.
Results: FACIT-F showed high internal consistency (Alpha = .87, Omega = .93). Analysis of the main components showed a single factor, which explained 62% of the variance. The confirmatory factor analysis showed a satisfactory fit of the model. We found a correlation between FACIT–F, VAS fatigue (−.72 p-value <,001), and BRAF-MDQ (−.81 p-value <.001).
Conclusion: FACIT-F is a valid instrument with a high internal consistency for measuring fatigue in clinical practice and research in Spanish-speaking patients with RA.

Validación de la escala FACIT-fatiga en una muestra de población hispanohablante con artritis reumatoide

Palabras clave:
Fatiga
Artritis reumatoide

RESUMEN

Introducción: La fatiga es un síntoma frecuente entre los pacientes con artritis reumatoide (AR). La Escala de Evaluación Funcional de Terapia de Enfermedades Crónicas-Fatiga (FACIT-F) es una herramienta usada para medir la fatiga.

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Validación de un instrumento
Escala de Evaluación Funcional de Terapia de Enfermedades Crónicas-Fatiga (FACIT-F)
Estudio de validación

Objetivo: El objetivo de este estudio fue la validación de FACIT-F en una población hispanohablante con AR.

Materiales y métodos: Diseño transversal multicéntrico. Se incluyeron pacientes con AR (n = 192). Se realizó un análisis factorial exploratorio y confirmatorio para la escala FACIT-F. Se evaluó la validez del constructo y la consistencia interna del cuestionario.

Resultados: FACIT-F presentó una alta consistencia interna (Alfa = 0,87, Omega = 0,93). El análisis de componentes principales mostró un solo factor, lo que explicó el 62% de la varianza total. El análisis factorial confirmatorio mostró un ajuste satisfactorio del modelo. Se observó una fuerte correlación significativamente estadística entre FACIT–F, EVA fatiga (-0,72 p-valor <0,001) y BRAF-MDQ (-0,81 p-valor <0,001).

Conclusión: FACIT-F es un instrumento válido y con alta consistencia interna para medir la fatiga en la práctica clínica y en la investigación dirigidas a la población hispanohablante con AR.

Introduction

Fatigue is a prevalent extra-articular symptom in rheumatoid arthritis (RA).[1–6] For the American College of Rheumatology (ACR)/European Alliance of Associations for Rheumatology (EULAR)[7] and for the Outcome Measures in Rheumatoid Arthritis Clinical Trials (OMERACT) group,[8] fatigue is an important aspect of study and an outcome measure to assess in all clinical trials related to RA. It is a symptom that affects multiple aspects of the patient's life and in some cases with greater relevance than pain.[9,10]

In recent years, the "results perceived by the patients" (Patient Reported Outcomes [PRO]), defined by the Food and Drug Administration (FDA) as "any measurement of some aspect of the patient's health status that is performed directly by himself"[11] has gained importance due to the repercussion that certain symptoms have on quality of life. The information from the PROs is collected using tools called Patient Reported Outcomes Measures (PROM).

There are currently multiple instruments to measure fatigue, but the cut-off point has not been determined,[12,13] and it has not been established whether specific instruments (designed only to measure fatigue in RA) or generic instruments (which can be applied to anyone) should be used.[12,13]

One of the instruments to measure fatigue is the Functional Assessment of Chronic Illnesses Therapy-Fatigue (FACIT-F) scale.[14]

The FACIT scale was created in 1987 with the purpose of measuring the quality of life of patients with chronic diseases; more than 40 FACIT scales have been described, including 3 general scales, 14 are specific for a certain disease, 5 for specific treatments, 8 for specific conditions and 10 for measurements in non-oncological patients.[15]

The FACIT-F scale, one of the multiple scales of the FACIT system, was developed in 1994 for the evaluation of fatigue associated with anemia in cancer patients.[16] Subsequently, it has been validated in patients with RA,[14] and has demonstrated sensitivity to change,[12,13] as well as good internal validity, like other instruments such as the Multidimensional Assessment of Fatigue (MAF) and the Short Form (SF) 36.[12,13]

Being a generic scale (i.e., it is not specific for patients with RA, but can be used in other diseases), it allows to compare fatigue in other rheumatic pathologies such as psoriatic arthritis, ankylosing spondylitis and osteoarthritis, among others.

The FACIT scale, originally in English, has been translated into more than 50 languages, including Spanish; however, a translation of the questionnaire does not always guarantee the preservation of its psychometric properties, which is why it is necessary to validate it in the language and in the target population.

In the literature review, despite having been previously used in a study in the Spanish population,[17] it was not found that it was previously validated for Spanish-speaking patients with RA. Therefore, the objective of this study was to validate the FACIT-F questionnaire in this specific population.

Materials and methods

A cross-sectional, multicenter study was conducted from May 2021 to May 2022. Patients were invited to participate according to their disposition in the outpatient clinics of the Rheumatology Services of the *Hospital Universitari de Tarragona Joan XXIII* and the *Hospital Universitari Sant Joan de Reus*. Sampling was by convenience.

Patients over 18 years of age who met the classification criteria for RA (ACR/EULAR 2010 criteria) and who attended controls in outpatient clinics at the two hospitals participating in the study were included.

Patients with cognitive deterioration that prevented them from answering the surveys or with severe visual or hearing impairment were excluded. Patients with a diagnosis of fibromyalgia or important comorbidities such as heart failure, active neoplasia, neurological degenerative diseases, and any other that the clinician considered could influence fatigue were also excluded.

Data collection was carried out through self-questionnaires that were delivered (in physical format) to patients at the time of a routine visit for their underlying pathology. The order of the questionnaires delivered was as follows: Visual Analogue

Scale (VAS) Fatigue; Bristol RA Fatigue Multi-Dimensional Questionnaire (BRAF-MDQ); Rheumatoid Arthritis Impact Disease (RAID); Hospital Anxiety and Depression Scale (HAD); Health Assessment Questionnaire (HAQ) and FACIT-F. Laboratory and clinical variables were collected at the time of the visit.

The variables studied were the following:

- Demographic: age (years) and sex (man/woman).
- Clinical outcome measures: Disease Activity Score 28, C-reactive protein (DAS28-CRP).
- Patient-reported outcome measures:
  - FACIT-F: is based on a 5-point Likert scale (0 = none; 1 = a little; 2 = somewhat; 3 = much and 4 = very much). The recovery period for each question is "for the last seven days". The possible score range is from 0 to 52, with 52 being the absence of fatigue. To obtain a score from 0 to 52, each answer for each item (except items 7 and 8) is recoded, so that 0 is a bad answer and 4 is a good answer. All answers are added with the same weight, divided by the number of questions answered and multiplied by 13. The questionnaire is discarded if more than 50% of the items are not answered.
  - Authorization to conduct this study was obtained from the FACIT.org organization. The version 4 of the FACIT-F in "universal Spanish" was used.
  - VAS fatigue: scale from 0 to 100 (0 is the absence of fatigue).
  - BRAF-MDQ[18]: a fatigue measurement scale designed specifically for RA. It consists of a 20-item questionnaire, with a score from 0 to 70 (70 is the worst state of fatigue). It is made up of 4 subscales that assess fatigue in various aspects (physical, cognitive, experiential and emotional).
  - RAID[19]: measures the global health status. Scale from 0 to10 (10 is the worst health status).
  - Pain scale (Brief Pain Inventory)[20]: scale from 1–10 (10 represents severe pain).
  - HAD[21]: consists of 2 subscales (HAD anxiety and HAD depression) of 7 items, each one with scores from 0 to 3. A score of 21 indicates the presence of major anxiety or depression.
  - HAQ[22]: A scale that measures functional capacity. It is scored from 0 to 3 (3 is the worst functional capacity).

Ethical considerations

Patients accepted to participate in the study and signed an informed consent. The research was approved by the *Comitè Ètic d'Investigació amb Medicaments de l'Institut d'Investigació Sanitària Pere Virgili* (Ethics Committee for Research on Medications of the Pere Virgili Health Research Institute).

Statistical methods

The following analysis was performed:

- Descriptive analysis of the sample: mean and deviation for quantitative variables and absolute and relative frequencies for qualitative variables.
- For each item in the questionnaire the mean, range and floor ceiling effect, defined as the percentage of people with the lowest (floor) and highest (ceiling) score in each dimension have been calculated.
- The internal consistency of the questionnaire was measured using the Cronbach's alpha and the omega coefficient. It was considered that values higher than 0.7 were sufficient to guarantee the internal consistency of the questionnaire.
- The construct validity of the FACIT-F questionnaire was performed through an exploratory factor analysis (EFA) and a confirmatory factor analysis (CFA).
- A structural equation model was adjusted for the CFA. The goodness of fit was carried out using the following indices: Comparative Fit Index (CFI), Tucker-Lewis Index (LTI), Standardized Root Mean-Square (SRMR) and Root Mean Square Error of Approximation (RMSEA). The thresholds were the following:
  - CFI: the model was considered to fit the sample if the value was ≥ 0.95.
  - TLI: a value ≥ 0.90 was adequate and if it was ≥ 0.95 it was considered optimal, with the ideal score being 1.
  - SRMR: a cut-off point ≤ 0.08 was recommended.
  - RMSEA: if the value ≤ 0.05, it was considered that the model fit adequately to the sample.
- Adequacy of the sample size for the EFA, which was verified using the Kaiser-Meyer-Olkin (KMO) test and the Bartlett test of sphericity.
- Correlations between the items and the main factor.
- Concurrent criterion validity: bivariate analyses were performed between the FACIT-F scale and two other validated tools for the measurement of fatigue (VAS-fatigue and BRAF-MDQ). Pearson's correlation coefficient was calculated.
- Bivariate analyses between fatigue measured by FACIT-F and the other data of interest reported by the patient (HAQ, HAD, pain scale, RAID, general condition of the patient) and DAS28-CRP. A correlation between 0.30 and 0.50 was considered moderate, while a correlation between 0.50 and 1.00 was considered a strong correlation.

The statistical analysis was performed using the SAS v9.4 software (SAS Institute Inc., Cary, NC, USA). Statistical decisions were carried out taking the p value = 0.05 as the level of significance.

Results

Descriptive analysis

A total of 192 patients participated, 140 (72.9%) women and 52 (27.1%) men, with a mean age of 58.4 (standard deviation [SD] ± 11.6) years; 48.9% of them used a biological disease-modifying drug (DMARD), 35,9% methotrexate and 16,15% leflunomide.

The patients presented a mean DAS28-CRP of 2.4 (SD ± 1.0) and of 0.6 (SD ± 0.5); 3.8 (SD ± 3.0); 6.7 (SD ± 4.2); 5.1 (SD ± 4.0) and 5.2 (SD ± 4.8) of HAQ, RAID, HAD-anxiety, HAD-depression and pain scale, respectively.

The mean fatigue measured by FACIT-F was 36.5 (SD ± 12.1), by VAS-fatigue 4.0 (SD ± 2.8) and 19.6 (SD ± 16.6) by BRAF-MDQ.

Table 1 – Descriptive analysis of each item and floor-ceiling effect of the FACIT-F scale.

FACIT-F item	Mean (minimum–maximum)	Floor	Ceiling
1	1.4 (0–4)	25.5	3.1
2	1.2 (0–4)	37.5	2.1
3	1.1(0–4)	44.8	4.2
4	1.5 (0–4)	24.5	3.7
5	1.2 (0–4)	39.6	3.7
6	1.3 (0–4)	34.4	4.2
7	2.1 (0–4)	7.8	2.6
8	2.4 (0–4)	8.3	11.9
9	0.9 (0–4)	42.7	0.52
10	0.4 (0–4)	75.0	0.52
11	0.6 (0–4)	63.5	1.6
12	0.9 (0–4)	50.0	4.2
13	0.9 (0–4)	48.4	2.6

FACIT-F: Functional Assessment of Chronic Illnesses Therapy-Fatigue.

Table 2 – Percentage of variability explained for each item.

Variable	Communality
1. I feel exhausted	0.869
2. I feel weakness all over my body	0.881
3. I feel down	0.885
4. I feel tired	0.872
5. I have difficulty getting things started because I am tired	0.919
6. I have difficulty finishing things because I am tired	0.852
7. I have energy	−0.583
8. I am able to do my usual activities (work, go to school, shopping)	−0.486
9. I need to sleep during the day	0.462
10. I'm too tired to eat	0.593
11. I need help to do my usual activities	0.678
12. I am frustrated because I am too tired to do the things I want to do.	0.886
13. I have to limit my social activities due to tiredness	0.830

Ceiling and floor effects

The mean obtained in each item of the FACIT-F and the floor-ceiling values are found in Table 1. It was observed that items 10 and 11 are the least discriminatory (in item 11, 75% of participants scored 0, that is, the floor value or lower limit).

Validation of internal consistency

The value of Cronbach's alpha coefficient was 0.877, that is, the internal consistency of the items was high.

Construct validity

Exploratory factor analysis. The Bartlett's test of sphericity ($p = 0.001$) and the KMO index, higher than 0.5 (0.935), showed that the structure of the correlation matrix was adequate to proceed with the factor analyses. A factor that explains 62% of the total variability is obtained from the factor analysis. Table 2 shows the correlation between the items and the factor. Items 8 and 9 ("I am able to do my usual activities: work, go to school, shopping" and "I need to sleep during the day") of the FACIT-F scale presented moderate communality (less than 0.5).

Confirmatory factor analysis. In order to confirm the structure obtained in the EFA, a CFA was performed (Fig. 1). The goodness-of-fit indices were: CFI = 0.91; TLI = 0.89; RMSEA = 0.12, 90% confidence interval (CI) [0.11–0.14]; and SRMR = 0.05. The Omega coefficient was 0.91.

Concurrent criterion validation

FACIT–F showed a significant strong correlation with other fatigue assessment measures (VAS fatigue −0.72 ($p < 0.001$) and BRAF-MDQ −0.81 ($p < 0.001$)) (Table 3).

Correlations between fatigue measured by FACIT-F and other variables

Likewise, a moderate significant correlation was found between FACIT-F and DAS28 ($r = 0.34$, $p < 0.001$), strong between FACIT and HAD (−0.70 $p < 0.001$), HAQ (−0.81 $p < 0.001$), pain scale (−0.67 $p < 0.001$) and the RAID (0.71 $p < 0.001$) (Table 3).

Discussion

The evaluation of fatigue is of special importance for the rheumatologist, because it is a prevalent symptom that affects all aspects of the life of the patient with RA.[2,4] It is necessary to have instruments validated in the field of health in the language of origin to be able to compare the results obtained with other studies that have used the same instrument.

FACIT-F is a scale with advantages over the others, because it has an intermediate number of items (13 items), compared with the 16 of the MAF, the 4 of the SF36 and the 21 of the BRAF-MDQ.[12,13]

It has been used in more than 150 studies published in more than 40,000 individuals. It is a scale designed for self-administration on one page, easy to administer, with an approximate filling time of 3 to 4 minutes.[12,13] As it is a generic scale for the measurement of fatigue, it could be of interest in comparative studies with other pathologies.

The mean of the FACIT-F scale in healthy adults is 43.6 (SD ± 9.4). In patients with RA, a mean of 29.17 (SD ± 11.06) has been documented in patients with RA, a figure lower (which represents greater fatigue) than that obtained in the present study (36.5 SD ± 12.1).[15] In the Spanish-speaking population, this scale has been used by Corominas et al.[17] in a prospective study in patients with moderate-severe RA with lack of response to anti-TNF or synthetic disease-modifying drug (DMARD). The baseline FACIT-F in this study population was 26.8 (SD ± 1.4). It should be noted that the higher FACIT-F value (less fatigue) found in our sample is possibly due to the fact that these are patients with controlled disease activity.

Our study showed that FACIT-F is an instrument with high internal consistency, as has been demonstrated in previous studies with alpha values of 0.86 to 0.87,[16] that is, there is a high homogeneity of the items of the instrument, which indicates that there is a relationship between them.

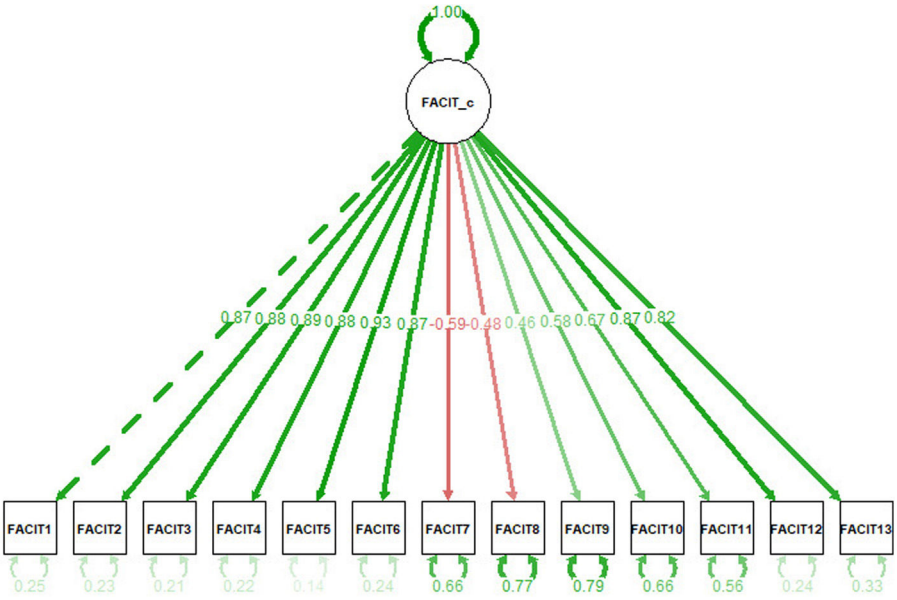

Fig. 1 – Results of the confirmatory factor analysis.

Table 3 – Correlation and 95% confidence interval between FACIT-F: VAS-F, BRAF-MDQ and other variables of interest.

Variable	Correlation
VAS-F	−0.72 (−0.64; −0.78)*
BRAF-MDQ	−0.81 (−0.75; −0.85)*
Physical	−0.73 (−0.66; −0.79)*
Social	−0.77 (−0.71; −0.83)*
Cognitive	−0.60 (−0.50; −0.69)*
Emotional	−0.74 (−0.67; −0.80)*
DAS28	−0.34 (−0.20; −0.46)*
HAD-anxiety	−0.70 (−0.61; −0.76)*
HAD-depression	−0.80 (−0.74; −0.84)*
HAQ	−0.81 (−0.76; −0.86)*
Pain scale	−0.67 (−0.58; −0.74)*
RAID	−0.70 (0.62; 0.76)*

FACIT-F: Functional Assessment of Chronic Illnesses Therapy Scale - Fatigue; VAS-F: Visual Analogue Scale- Fatigue; BRAF-MDQ: Bristol RA Fatigue Multi-Dimensional Questionnaire; DAS28: Disease Activity Score 28; HAD: Hospital Anxiety and Depression Scale; HAQ: Health Assessment Questionnaire; RAID: Rheumatoid Arthritis Impact Disease.

* $p < 0.001$.

In our sample of patients, it was corroborated that FACIT-F correlates significantly with two other instruments studied and validated in patients with RA (the VAS-fatigue and the BRAF-MDQ),[12,13] which demonstrates good concurrent criterion validity. It was decided to use these two scales, since they are practically opposite to each other: the VAS-fatigue is a generic, single-item tool, while the BRAF-MDQ is a multi-item tool, specifically designed to measure fatigue in patients with RA.[13]

In previous publications, the FACIT-F scale also showed a strong correlation with the vitality subscale of the SF36 ($r = 0.73$ to 0.84) and the MAF ($r = -0.84$ to -0.88),[12] which supports the construct validity. It has been described that FACIT-F presents a good correlation with measures of inflammatory activity (DAS28) and disability (HAQ),[13] results also found in our study.

The principal component analysis showed a single factor, which explains 62% of the total variance. In addition, it has been found that the items with the lowest communality (less than 50%) are items 8 and 9, which make reference to the ability to carry out usual activities and the need to sleep during the day. This last data has not been previously reported.

The confirmatory factor analysis presented values very close to those suggested to adjust the instrument, except for the RMSEA; however, it has been reported that in samples of less than 200 patients, the SRMR is more efficient than the RMSEA in rejecting models that do not fit closely.[23] In our study, the SRMR value was adjusted to the suggested values.

This study had limitations. Its cross-sectional design did not allow the assessment of the temporal stability of the FACIT-F scale in this population. The study was conducted during a post-pandemic period that could influence the symptoms reported by the patient. There are questions within the questionnaire that are applicable for cancer patients but could be irrelevant in patients with RA,[4,19] such as for example, the question "I am too tired to eat". In our study, it was confirmed that this item is the one that presented the highest percentage of answers with a zero score, that is, the greatest floor effect (up to 75% of the patients), so it could be considered in subsequent studies to make a modified version for patients with AR that omits this item.

Based on what was previously stated, this study demonstrated that FACIT-F is a valid tool with high internal consistency that could be used to measure fatigue in the Spanish-speaking population with RA. It is recommended that future studies evaluate the stability of the instrument over time.

Conclusions

FACIT-F is a valid instrument for use in clinical practice and in research aimed at the Spanish-speaking population with RA.

It is expected that the FACIT-F scale will be used as a tool for the study of fatigue in this specific population.

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Authors' contribution

All authors have participated in the data collection and writing of the article. Statistical analysis was performed by Dr. S. Rodríguez Muguruza and O. Valero.

Conflict of interest

The authors declare that they have no conflict of interest.

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