

Validation of the Danish Version of the Fibromyalgia Impact Questionnaire Revised

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Purpose: Increasing recognition of chronic pain diseases, including Fibromyalgia, warrants the need for tools to monitor the impact of the disease as well as the efficacy of interventions. The Revised Fibromyalgia Impact Questionnaire (FIQR) has previously proved to be a valuable tool in both clinical and research settings. The study objective was to translate and validate the FIQR in Danish.

Patients and Methods: A forward/backward translation, following the WHO-guidelines, was used to develop the Danish version of FIQR. The Danish translation of FIQR was answered by 101 patients suffering from fibromyalgia. The patients simultaneously answered the Hospital Anxiety and Depression Scale (HADS) and the 36-Item Short-Form Health Survey (SF-36) for validation.

Results: The Danish FIQR showed excellent internal consistency, and reliability with Interclass Correlation Coefficients above 0.9. The correlations to HADS and SF-36 ranged from fair to very good. All results were found to have a p-value <0.05.

Conclusion: The present version of the Danish FIQR presents a valid and reliable tool for monitoring the impact of fibromyalgia.

Keywords: fibromyalgia, questionnaire, chronic pain, evaluation, validation, translation

Introduction

Fibromyalgia (FM) is a debilitating chronic pain syndrome affecting 2–5% of the population.^{1,2} The etiology is unclear but presumably multifactorial and complex.^{3,4} The main symptoms are widespread pain and widespread mechanical hyperalgesia, accompanied by varying degrees of stiffness, fatigue, insomnia, cognitive disturbance and anxiety.⁵ The intensity of symptoms in FM varies in an unpredictable manner which can be undermining, pervasive and disabling for the patient. Furthermore, this fluctuating disease pattern makes it difficult for clinicians to monitor treatment results in daily care. Adequate tools to follow the development and severity of FM, as well as the efficacy of treatments, are therefore essential.

Burckhardt et al⁶ developed The Fibromyalgia Impact Questionnaire (FIQ) for this evaluation in 1991. Due to problems with a complicated scoring system and socioeconomic and cultural differences, the Fibromyalgia Impact Questionnaire-Revised (FIQR) was developed and validated by Bennett et al in 2009.⁷ The FIQR has proven to be a valuable tool in the clinical evaluation of functional limitations and disability in fibromyalgia, as well as in the evaluation of efficiency of treatment regimens. It is organized into three domains (function, overall impact, and symptoms) with a total of 21 questions. All questions are graded from 0 to 10, and the questionnaire can be completed by the patient in less than five minutes and the subsequent scoring by investigators can likewise be completed in less than five minutes.⁷

With the presentation of the 11th version of the International Classification of Diseases (ICD-11), the diagnosis chronic primary pain was introduced including both chronic widespread pain and FM as primary pain conditions.⁸ In these conditions, the pain cannot fully be explained by tissue damage, but is rather considered a result of pain hypersensitivity with amplification of nociceptive signals or poor inhibitory control of pain, also described as

nociplastic pain features.⁹ Whereas, eg chronic low back pain can be the result of a broad spectrum of neurophysiologic mechanisms, including nociplastic pain features, CWP and FM are considered to be driven almost exclusively by nociplastic pain mechanisms.¹⁰ Being a well-described disease entity with well-validated classification criteria, FM patients are often used in clinical trials to investigate pharmacological interventions' efficacy on chronic primary pain.¹¹ With the growing number of clinical pharmacological trials, the Outcome Measures in Rheumatology Clinical Trials (OMERACT) initiative agreed on a core set of domains to be assessed in FM trials in 2009.¹² According to the latest update in 2011, the FIQ/FIQR is now recommended as a measure of the global impact of FM, but also as subscales and single items ie, covering measures of physical function, pain, sleep quality, fatigue, anxiety, and depression. This highlights the need for cross-cultural validation of the questionnaire.

The FIQR has been translated and validated in several languages.^{13–16} To our knowledge, translation and validation have not previously been performed in Danish. The aim of this study was to translate and validate the English version of FIQR to Danish.

Materials and Methods

Translation

We conducted a forward/backward translation of the FIQR-questionnaire from English to Danish, following the WHO guidelines for translation.^{17,18} Permission for the usage and translation of FIQR was obtained from Dr. Robert M. Bennet.⁷ The translation process fell in three phases. In the first phase, three independent translators, amongst them a medical doctor, fluent in Danish and English, made independent translations of the English text to Danish. Subsequently, they agreed on a mutual Danish translation. In the second phase, a backward translation to English was conducted independently by three persons, equally fluent in both languages. None of the translators from this group had prior knowledge of the original questionnaire. In the third phase, a consensus translation in Danish was made by a panel of the six translators.

Pilot Study

The Danish paper version of the FIQR was tested by four patients diagnosed with FM. After completion, they commented on their experiences of the questionnaire.

Participants and Study Design

Participants were included if they were aged 18 years or older, presented sufficient skills in speaking, reading, and writing Danish to fulfil the questionnaires, and were diagnosed with FM by a rheumatologist or the participating pain specialist at the Middelfart Pain Center, Denmark. Participants with previous cerebral hemorrhage or ischemia were excluded. The study was surveyed by the Danish Data Protection Agency (18–22,684) and was conducted in accordance with the Declaration of Helsinki. Because the study was non-interventional, it was not due approval from an ethics committee due to Danish law but was evaluated by the ethics committee of Southern Denmark. Written informed consent was obtained from all subjects.

The first 15 patients included in the study were consecutive patients attending the Middelfart Pain Center. These patients participated in a test–retest design, where the FIQR were answered in paper copies twice with an intermediate period of 7–10 days, simultaneously to HADS and SF 36 questionnaires. After this phase of the trial, patients from a previous study (the Danish Pain Research Biobank, DANPAIN,¹⁹ located at the Pain Center of Southern Denmark, Odense University Hospital) were contacted by telephone and invited to participate in the study, completing an online questionnaire consisting of FIQR, HADS and SF36. We did not record data about medication or other treatment modalities.

Statistical Analysis

The demographic and clinical data were analyzed with descriptive statistics. Categorical data are presented as numbers and percentages. Continuous, normal distributed data are presented as mean and standard deviation (SD), and not-normal

distributed continuous data and ordinal data are presented as median and inter-quartile range (IQR). The sample was a convenience sample where the size was based on previous comparable validation studies of the FIQR.^{15,16,20} Test–retest reliability was analyzed using Intraclass Correlation Coefficient (ICC) one-way random-effects model with absolute agreement. Based on 95% confidence intervals (CI), values less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and greater than 0.90 indicate poor, moderate, good and excellent reliability, respectively. Cronbach’s alpha coefficient was used to test internal consistency with a value >0.7 deemed satisfactory. Spearman’s rho correlation coefficient was used to test correlation with HADS and SF-36 domains. Correlations were assessed as poor ($0.00 < r < 0.25$), fair ($0.25 \leq r < 0.50$), good ($0.50 \leq r < 0.75$) and very good ($r \geq 0.75$). A p-value below 0.05 was considered significant.

Results

Minor linguistic adjustments in both forward and backward translations were agreed upon by the two groups of translators. In the pilot group of patients, the understanding was excellent and there was no need for changes in the text. The general comments from patients in both pilot and test groups were positive, and several commented that they found the questions relevant and easy to relate to from their disease patterns.

A total of 101 patients out of 110 invited patients (92%) agreed to participate. Of these, 15 were from the Pain Clinic and were included in the test–retest assessment and 86 were from the DANPAIN-Biobank study. No patients fulfilled the exclusion criteria. Table 1 presents the demographic data of the study sample.

An overview of mean scores for each FIQR item in both the whole sample and the test–retest sample are presented in Table 2. Most of the items presented good or excellent reliability. Two items (“Energy rating” and “Sleep quality”) presented poor reliability, and one item (“Pain rating”) showed moderate reliability.

Test-Retest Reliability

The overall FIQR-score as well as the individual domain scores, all demonstrated excellent reliability between test and re-test, with the highest scores for FIQR total score and function (Table 3). Cronbach’s alpha was 0.95 for the whole sample, 0.95 for the test–retest sample, round one, and 0.94 for the test–retest sample, round 2, indicating excellent levels of internal consistency.

Table 1 Demographic Data of Fibromyalgia Patients

Gender (female) n=101 n(%)	99	(98)
Age in years n=101 mean (SD)	49.9	(10.3)
Education (highest level) n=86* n(%)		
< 11 year school	11	(13)
Sixth-form college	8	(9)
Shorter further education	35	(41)
University bachelor	24	(28)
University master	4	(5)
Other	4	(5)
Work status n=86* n(%)		
Working full time	11	(13)
Working part time	23	(27)
Student	4	(5)
Unemployed	2	(2)
Sick leave	3	(3)
Early retirement with benefit support	31	(36)
Retired	4	(5)
Other	8	(9)

Notes: *For the test-retest sample (n=15), no data on education and work status was obtained.

Table 2 Mean Values and Standard Deviation of Each Danish FIQR Item (Scale 0–10) for the Whole Sample (n=101), Test-Retest Sample (n=15), and Test-Retest Reliability

	Whole Sample		Test-retest Time 1		Test-retest Time 2			
	Mean	SD	Mean	SD	Mean	SD	ICC*	CI
Comb hair	2.97	2.76	2.93	3.33	2.80	3.12	0.98	(0.94;0.99)
Walk for 20 min.	5.54	3.30	6.80	2.96	6.13	3.38	0.92	(0.77;0.97)
Prepare a meal	5.46	2.78	6.13	2.33	6.00	2.45	0.96	(0.89;0.99)
Clean floors	7.21	2.57	7.87	2.07	7.73	2.40	0.94	(0.84;0.98)
Carry a bag of groceries	6.94	2.87	7.67	2.47	7.60	2.23	0.93	(0.78;0.97)
Climb a flight of stairs	5.28	3.20	5.80	2.83	6.27	2.58	0.81	(0.44;0.93)
Change bed sheets	6.19	3.07	7.33	2.35	6.73	2.79	0.75	(0.29;0.92)
Sit for 45 min.	5.88	3.26	7.00	2.51	7.13	2.92	0.94	(0.83;0.98)
Go shopping for groceries	5.50	2.78	6.47	2.39	5.87	2.45	0.90	(0.70;0.97)
Cannot achieve goals	6.58	2.62	7.00	2.54	6.60	2.56	0.83	(0.51;0.94)
Feel overwhelmed	5.47	2.98	5.64	3.00	5.87	3.00	0.88	(0.65;0.96)
Pain rating	6.10	2.33	6.40	2.47	6.80	1.93	0.73	(0.23;0.91)
Energy rating	6.77	1.94	7.00	1.73	7.93	1.10	0.00	(0.00;0.52)
Stiffness rating	6.31	2.35	6.93	2.46	7.13	2.26	0.91	(0.73;0.97)
Sleep quality	7.22	2.41	6.73	2.79	7.67	2.19	0.43	(0.02;0.85)
Depression level	3.74	2.80	4.33	3.37	4.27	3.28	0.78	(0.36;0.92)
Memory problems	6.41	2.62	6.93	2.99	6.40	2.72	0.88	(0.66;0.96)
Anxiety level	2.58	2.96	2.73	3.65	2.07	2.70	0.93	(0.80;0.98)
Tenderness level	5.79	3.10	6.07	3.15	6.27	3.03	0.95	(0.85;0.98)
Balance problems	4.87	2.69	5.07	2.81	4.73	2.69	0.88	(0.66;0.96)
Environmental sensitivity	6.97	2.73	7.67	2.66	7.53	2.47	0.96	(0.89;0.99)

Notes: Adapted from Bennett RM, Friend R, Jones KD, Ward R, Han BK, Ross RL. The Revised Fibromyalgia Impact Questionnaire (FIQR): validation and psychometric properties. *Arthritis Res Ther.* 2009;11(4):R120. Creative Commons.⁷ *Intraclass Correlation Coefficient.

Table 3 FIQR Scores for the Whole Sample (n=101) and for Test-Retest Samples (n=15)

	Whole Sample		Test-retest Time 1		Test-retest Time 2			
	Mean	SD	Mean	SD	Mean	SD	ICC*	CI
FIQR total score	57.4	19.5	61.5	20.0	61.6	17.3	0.96	(0.89;0.99)
FIQR function	51.0	20.3	58.0	17.6	56.3	19.0	0.96	(0.89;0.99)
FIQR impact	12.0	5.4	12.3	5.4	12.5	5.2	0.92	(0.77;0.97)
FIQR symptoms	56.8	18.0	59.9	20.0	60.7	15.6	0.91	(0.74;0.97)

Notes: *Intraclass Correlation Coefficient.

Correlation with HADS and SF-36

Comparable symptoms in FIQR, HADS, and SF-36 are correlated in [Table 4](#).

The correlations ranged from fair to very good, with a significance level of <0.01. The best correlation was found between FIQR physical function and SF-36 physical functioning ([Table 4](#)).

When examining single-item correlations, the following values using Spearman correlation were found: HADS depression correlated with FIQR “Depression level”: 0.58; HADS anxiety with FIQR “Anxiety level”: 0.72; SF-36 Bodily pain with FIQR “Pain rating”: -0.66; and SF-36 Vitality, energy with FIQR “Energy rating”: -0.45.

Discussion

In this study, we found the Danish translation of the FIQR to be a valid and reliable measure for monitoring disease severity and impact of disease in Danish patients with FM. The translation and validation were made in agreement with

Table 4 Spearman Correlations of the Danish FIQR Domains to/HADS and SF-36 Subscales

	Median	FIQR	FIQR Total*	FIQR Function*	FIQR Impact*	FIQR Symptoms*
HADS# anxiety	7	(5–10)	0.50	0.34	0.34	0.61
HADS depression	6	(4–9)	0.50	0.40	0.37	0.57
SF-36§ summary						
Physical component score	33	(22–46)	–0.73	–0.71	–0.62	–0.68
Mental component score	51	(33–63)	–0.62	–0.50	–0.46	–0.66
SF-36 health items						
Physical functioning	48	(33–63)	–0.72	–0.79	–0.63	–0.60
Role difficulties. Physical	0	(0–25)	–0.38	–0.35	–0.31	–0.34
Bodily pain	31	(22–41)	–0.70	–0.65	–0.62	–0.65
General health	35	(25–55)	–0.46	–0.38	–0.34	–0.51
Vitality, energy	25	(15–40)	–0.46	–0.45	–0.36	–0.47
Social functioning	50	(38–75)	–0.62	–0.54	–0.50	–0.62
Role difficulties. Emotional	33	(0–100)	–0.40	–0.28	–0.26	–0.46
Mental health	68	(56–80)	–0.54	–0.40	–0.38	–0.63

Notes: * All p-values < 0.01. # = Hospital anxiety and depression scale. § = Short Form Health Survey.

standardized guidelines.¹⁷ The process presented no substantial challenges and the questions were simple to answer for the relevant population.

The Danish version of the FIQR showed excellent internal consistency which is consistent with the previous findings in other similar studies.^{7,15,16} Likewise, the Danish FIQR overall score showed excellent reliability with an ICC OF 0.96. Comparable high ICC were found for the three domain scores; function, impact and symptoms. This is consistent with or somewhat higher than what was found in the Spanish and Arabic translations of the FIQR-questionnaire.^{15,16} Most of the single items showed good or excellent reliability, but the two items, “energy rating” and “sleep quality”, had poor reliability. The OMERACT initiative currently recommends these items as patient-reported outcome measures (PROM) in clinical trials covering the level of fatigue and the level of sleep disturbance.¹² The “pain rating” item, also recommended by OMERACT as a PROM covering the level of pain, showed moderate reliability.

Construct validity of the Danish FIQR was tested by comparing similar domains and single items of the FIQR and the Danish version of the HADS and RAND SF36 questionnaires. Here, we found a good correlation to both HADS and SF36, with significant Spearman’s rho correlation coefficients. The best correlation was found between the domains FIQR physical function and SF-36 physical functioning, supporting the OMERACT recommendations that these patient-reported outcome measures (PROMs) are equally suitable for use in clinical trials. The FIQR single items “depression”, “anxiety” showed good correlations to HADS “depression”, HADS “anxiety”, respectively, and the FIQR “pain rating” correlated well to SF-36 “pain” and only one FIQR item: “energy rating”, showed a fair correlation to SF-36 “vitality, energy”.

A limitation to the study is the relative absence of male participants. FM is diagnosed more frequently in females, with a male/female ratio of 1/3 in the general population,² but our validation was performed in an almost solely female population. Consequently, there is a possibility of flawed validity of the questionnaire in male FM patients. We share this problem with all former translations.^{13–16,20} However, performing chores and tasks of private life after work is generally shared fairly equally between the genders in Denmark.²¹ Consequently, we would expect the questions to be equally relevant in both Danish males and females.

Another limitation could be that the majority of our participants were recruited from a previous study. Whether this would introduce selection bias to the patient sample is uncertain and has also been reported in other translation studies.¹⁵

Conclusion

We found the Danish translation of FIQR to be a valid and reliable tool for assessing the impact of fibromyalgia in Danish patients. Thus, it can be adapted for use by Danish healthcare professionals involved in research and clinical care of Danish patients with fibromyalgia.

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Not applicable.

Disclosure

The authors report no conflicts of interest in this work.

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