

Content Validation of the Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Scale in Moderately to Highly Active Rheumatoid Arthritis

Karen Kaiser^{1*}, Sara Shaunfield¹, Marla L. Clayman², Eric Ruderman³ and David Cella¹

¹Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, 625 North Michigan Avenue, Suite 2700, Chicago, IL, 60611, USA

²American Institutes for Research, Chicago, IL, USA

³Department of Medicine-Rheumatology, Northwestern University Feinberg School of Medicine, USA

*Corresponding author: Karen Kaiser, Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, 625 North Michigan Avenue, Suite 2700, Chicago, IL, 60611, USA, Tel: 312-503-3521; E-mail: k-kaiser@northwestern.edu

Received date: February 26, 2016; Accepted date: April 21, 2016; Published date: April 25, 2016

Copyright: © 2016 Kaiser K, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Abstract

Objective: Fatigue is one of the most burdensome symptoms of Rheumatoid Arthritis (RA), thus validated measures are needed to assess it in practice and research. Although performance and responsiveness of the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) has been demonstrated in moderately to highly active RA and several other conditions, the face and content validity of the instrument in this context has not been evaluated.

Methods: Semi-structured interviews were conducted with patients with moderately to highly active RA. Participant comments were analysed using a constant comparative approach, and findings were mapped to the FACIT-Fatigue to assess content validity.

Results: A total of 17 patients participated in the study; saturation was obtained after 16 interviews. Participants had been living with an RA diagnosis from 2 months to 36 years. Participants were primarily female (82%), white (59%), and mean age was 54. FACIT-Fatigue was found to have good face validity and strong content validity for RA. No significant gaps in content were identified. However, three items were found to be less relevant to RA fatigue: "I feel weak all over", "I feel listless ('washed out')", and "I am too tired to eat".

Conclusion: The FACIT-Fatigue has good face and content validity for patients with moderately to highly active RA. The instrument could be further tailored to RA patients by removing a few items deemed less relevant than others in this context; however, even those less-relevant items retained their relevance for a good number of patients.

Significance and Innovations

- Fatigue is one of the seven key clinical outcomes recommended by The European League against Rheumatism and the American College of Rheumatology for reporting disease activity in rheumatoid arthritis clinical trials.
- Our study assessed the content validity of the FACIT-Fatigue for moderately to highly active rheumatoid arthritis patients and highlights the most important dimensions of fatigue for these individuals.
- These patients described their fatigue experience as tiredness, energy loss, and, to a lesser extent, fatigue and exhaustion. Fatigue significantly impacts their ability to engage in day-to-day activities resulting in frustration.
- The FACIT-Fatigue was found to capture the majority of fatigue-related concepts reported by patients, and thus has strong content validity.

Rheumatoid arthritis (RA) is an autoimmune and inflammatory disease associated with premature mortality and disability affecting approximately 1.3 million Americans [1]. In addition to the well-established core outcomes associated with RA such as chronic pain and disease activity (i.e., swollen/tender joints, inflammation), patients

identify fatigue as one of the most intrusive and debilitating symptoms of RA [1-5]. Fatigue associated with RA can be present even in the absence of exertion and may affect patients' physical, cognitive, emotional, and social life quality [1,5-8]. Moreover, fatigue is one of the seven key clinical outcomes recommended by The European League against Rheumatism (EULAR) and the American College of Rheumatology (ACR) for reporting disease activity in RA clinical trials [5]. Consequently, the assessment, identification, and treatment of RA fatigue is increasingly prioritized by researchers and clinicians [2,3].

Given the recognized importance of fatigue, validated measures of fatigue would have value [2,8]. However, obtaining accurate fatigue assessments is challenging due to the multidimensional manifestation (e.g., physical, cognitive, emotional, social), and its interaction with other disease-related factors such as pain, sleep disturbance, and depression [9-11]. Given the inherent complexity of fatigue and the limited extant research regarding RA-specific fatigue [9,12], research is needed that investigates the complex nature of RA fatigue to establish the adequacy of tools used to assess RA-specific fatigue [8].

Of the 23 scales previously used to measure RA fatigue, only six illustrated evidence of adequate validity, one of which was the Functional Assessment of Chronic Illness-Fatigue scale (FACIT-Fatigue) [9]. Although the FACIT-Fatigue has been validated and

found to be appropriate with respect to reliability, psychometric performance, and minimally important difference in patients with severe to moderate RA [6,9], a formal study investigating the face and content validity of the instrument in RA patients has not yet been reported. Such work would confirm whether the FACIT-Fatigue captures the multidimensional nature of fatigue specific to RA and address recommendations by The Federal Drug Administration (FDA) that patient reported outcomes (PROs) used in clinical trials be validated for content in the population of interest [13,14]. Thus, the goal of the current study was to evaluate the face and content validity of the FACIT-Fatigue in adults with moderately to highly active RA.

Patients and Methods

Patients with a physician-confirmed diagnosis of moderately or highly active RA as defined by the Clinical Disease Activity Index (CDAI) or the 28 Joint Disease Activity Score Calculator for Rheumatoid Arthritis (DAS28) [15-17], with morning joint stiffness lasting at least 30 minutes, and aged 18 or older were eligible. Individuals not fluent in English, with cognitive impairment, and those with a rheumatologic diagnosis other than RA or a documented history of fibromyalgia were ineligible. Patients were recruited in 2013-2014 from the Northwestern Medical Group Rheumatology Clinic. A study coordinator approached eligible patients attending clinic appointments and obtained written consent from willing participants. Face-to-face interviews occurred in a private location outside of the clinic setting. All study procedures were approved by the Northwestern University Institutional Review Board.

An experienced interviewer conducted all interviews using a semi-structured interview guide modelled after guides used in prior work to develop or validate PRO instruments [18,19]. Patients were asked a series of questions regarding fatigue: “Has fatigue been an important concern for you?” “Could you please describe the fatigue you experience because of your RA?” “How does your fatigue affect your day to day life?”

Next, patients completed the FACIT-Fatigue. The 13-item FACIT-Fatigue assesses the impact of fatigue on physical, functional, emotional, and social functioning over the past seven days [20]. Items are measured on a four-point Likert scale from 0 (Not at all) to 4 (Very much). Face validity was assessed with the following question: “Please take a moment to look over the (FACIT-Fatigue) questions again. Do these questions, in your opinion, capture your fatigue experience?” Patients also assessed the appropriateness of the FACIT-Fatigue response options, the length of the questionnaire, the clarity of the instructions, and the period of time they considered when responding (results available by request). Lastly, the interviewer guided each participant through a cognitive interview to assess comprehension and relevance of each item [21]. Interviews last, on average, 45 minutes. Interviews were audiotaped, transcribed, and de-identified. Relevant disease information was obtained from the patient medical record.

Two independent coders generated a list of fatigue-related concerns (i.e., “codes”) from the data using a constant comparative approach [22]. Coding categories were continually refined by collapsing redundant categories and removing irrelevant categories. Saturation—the extent to which no new relevant information is obtained—was assessed beginning with the 12th interview. Saturation was achieved when three consecutive interviews occurred without producing a new, relevant concept. Cognitive interview data was summarized and tabulated.

The mapping process identified key themes from the qualitative interview (i.e., “universe of content”) and overlap with FACIT-Fatigue content [23] by considering, 1) dimensions of fatigue reported by patients and covered by FACIT-Fatigue; 2) FACIT-Fatigue content that does not align with RA patients’ fatigue experiences; and 3) patient fatigue experiences not represented by FACIT-Fatigue content. This process is illustrated in Figure 1.

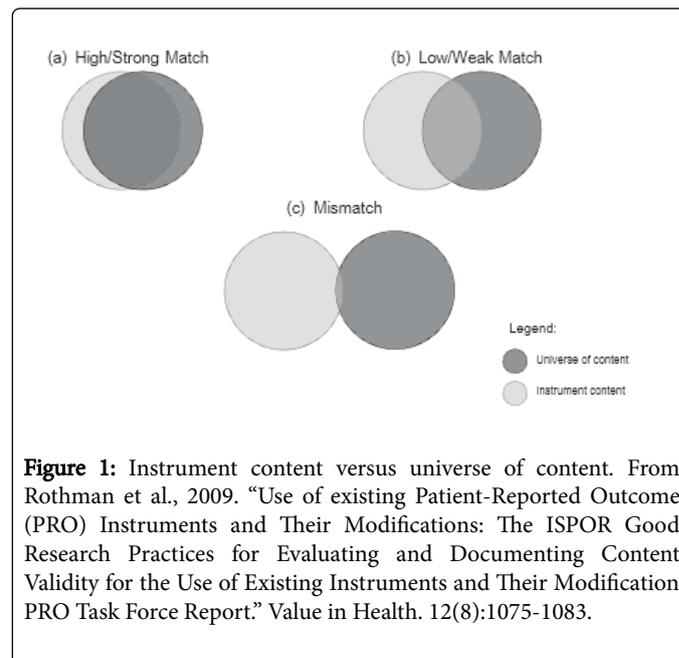


Figure 1: Instrument content versus universe of content. From Rothman et al., 2009. “Use of existing Patient-Reported Outcome (PRO) Instruments and Their Modifications: The ISPOR Good Research Practices for Evaluating and Documenting Content Validity for the Use of Existing Instruments and Their Modification PRO Task Force Report.” *Value in Health*. 12(8):1075-1083.

RESULTS

Seventeen participants were interviewed. Saturation was obtained by interview 16. The majority of participants were female and White (Table 1). Time since diagnosis varied from a few months to several decades. Over half of the sample had at least a college degree; 41 percent had a high school degree or some college.

Patient Characteristic	Frequency or Mean (Range)
Age, Mean (range)	53.76 (31-66)
Gender	
Male	3 (17.65%)
Female	14 (82.35%)
Race	
White	10 (58.82%)
American Indian/ Native Alaskan	1 (5.88%)
African American	2 (11.76%)
Mixed	3 (17.65%)
Other	1 (5.88%)
Ethnicity	
Non- Hispanic	13 (76.47%)
Hispanic	4 (23.53%)

Time since diagnosis (months), Mean (range)	137.88 (2 months to over 36 years)
Education	
High school graduate/GED	2 (11.76%)
Some college/Technical degree	5 (29.41%)
College degree	6 (35.29%)
Advanced degree	4 (23.53%)
FACIT-Fatigue, Mean (range)	22.94 (7-25)
CDAI Score, Mean (range)*	22.68 (11.5-45)
ESR, Mean (range)**	19.76 (3-56)

than 2.8 indicate remission; 2.9 to 10.0 = low disease activity; 10.1 to 22.0 = moderate disease activity; 22.1 to 76 = high disease activity; **ESR = Erythrocyte Sedimentation Rate, a measure of inflammation. Normal ESR rates for adults vary by age and gender but are approximately less than 20.

Mapping of patient fatigue descriptions to the FACIT-Fatigue

The qualitative data provide strong support for validity of 10 of the 13 scale items (Table 2). Respondents spontaneously described their fatigue in ways that were consistent with each of these items. Moreover, at least 15 of the 17 respondents said that these items applied to them. Below we provide examples of relevant patient comments for each item and discuss interpretation of the data for items with nuanced data or weak support.

Table 1: Patient Demographics and Disease Characteristics (N=17); *CDAI = Clinical Disease Activity Index, range 0 to 76. Scores less

Item ID	Item	Support for Item Validity	Notes	Does this question apply to you?
HI7	I feel fatigued.	High	Retain item	No= 1
				Yes= 16
HI12	I feel weak all over.	Low to moderate	Retain item. Only 1 patient spoke spontaneously of weakness in qualitative interview; however, 15 of 17 patients said item was relevant in cognitive interview.	No=2
				Yes=15
An1	I feel listless ("washed out").	Low to moderate	Consider dropping item. No patients spoke spontaneously of listlessness in qualitative interview. Fifteen of 17 patients said item was relevant in cognitive interview; however, patients said "listless" was not a term they would use.	No= 2
				Yes= 15
An2	I feel tired.	High	Retain item	No= 1
				Yes= 16
An3	I have trouble starting things because I am tired.	High	Retain item	No= 2
				Yes= 15
An4	I have trouble finishing things because I am tired.	High	Retain item	No= 2
				Yes= 15
An5	I have energy.	High	Retain item	No= 1
				Yes= 16
An7	I am able to do my usual activities.	High	Retain item	No= 0
				Yes= 17
An8	I need to sleep during the day.	High	Retain item	No= 2
				Yes= 15
An12	I am too tired to eat.	Low	Consider dropping item. Not mentioned spontaneously in qualitative interviews. Most (9 of 17) patients indicated that this item did not apply to them in cognitive interview.	No= 9
				Yes= 8
An14	I need help doing my usual activities.	High	Retain item	No= 1
				Yes= 15

				Missing= 1
An15	I am frustrated by being too tired to do the things I want to do.	High	Retain item	No= 1
				Yes= 16
An16	I have to limit my social activity because I am tired.	High	Retain item	No= 1
				Yes= 16

Table 2: Mapping of the Qualitative Patient Data to FACIT-Fatigue Items.

Item 1: I feel fatigued. Several participants described fatigue as the most burdensome aspect of RA. "...the fatigue in having rheumatoid arthritis is unbelievable" (Pt 14). "Besides pain, fatigue is the other main factor that holds me back from doing anything, even normal activities..." (Pt 11).

Item 2: I feel weak all over. One participant mentioned weakness during the open concept elicitation interviews. "Sometimes...I feel like (my joints) are tired and weak and so I look at that as fatigue as well. Like I sometimes have a hard time opening jars, and because it's like the lack of strength, which is for me weakness and, like weakness and fatigue, like my body's fatigued..." (Pt 13). Although her comments relate to joint weakness, she connected those feelings of weakness to fatigue. During the cognitive interviews, almost all of the participants interpreted this item as related to fatigue (e.g., "energy zapped of you", "head to toe fatigue", "totally depleted"); a few participants thought of the item as relating to a lack of strength.

Item 3: I feel listless ("washed out"). No participants spontaneously spoke of feeling listless or washed out. While about half of the participants liked the wording of the item, several indicated that they would not use the term 'listless'. For example, when asked to phrase the item in her own words, patient 01 said, "I would say wiped out or washed out and probably wouldn't use the term 'listless'". Others noted they would replace washed out with "worn out", "wiped out", or "drained".

Item 4: I feel tired. Participants frequently used the word "tired". "I'm always tired" (Pt 02). "You get up and you start walking around doing laundry and stuff, and all of a sudden you're tired and you wonder, you know, why am I tired" (Pt 05)? "I do find myself pretty tired all the time and just kind of like, 'Ugh. Why am I so tired?'"

Item 5: I have trouble starting things because I am tired. The majority of participants noted that fatigue affected their activities, especially activities such as housework or other daily tasks. "Besides pain, fatigue is the other main factor that holds me back from doing anything, even normal activities, even just as simple as cleaning the house." (Pt 11). "I'm just tired. I just feel that I'm not going to be able to do maybe what I had planned to do for that day" (Pt 01). Other participants mentioned delaying activities due to fatigue; "You know, I might delay a day in going for groceries or something like that, you know, but I'm still doing things more or less."

Item 6: I have trouble finishing things because I am tired. Rather than explicitly stating they had trouble finishing things, many participants spoke of being less productive or failing to do what they planned. For example, participant 17 cut walks short because of her fatigue; "I like to walk, and yet I'm so tired after I walk two blocks that I turn around to go back home." "Throughout the day I think I function well, but I don't feel that I can give it a full 100% just because I

am fatigued. By the end of the day the drive home is very tiring and I find most days I have no energy to do much of anything throughout the evening..." (Pt 10).

Item 7: I have energy. In addition to "tired", energy was the term used most frequently by participants to describe their fatigue. Many participants spoke of changes to their level of energy, or having a lack of energy. "I just feel like I've lost all the energy I used to have" (Pt 10). "I find myself being very intentional about using my energy wisely... I'm not as spontaneous with my activity... I don't have as much energy as I'm used to having" (Pt 12). "It's just that lack of energy and that worn down feeling" (Pt 13). "I just have no energy" (Pt 17).

Item 8: I am able to do my usual activities. Many participants described having to limit their normal activities due to fatigue. "Prior to the last, I'm going to say five years of having this disease, I still was pretty energetic. I was always on the go. I love to travel, for instance, take my son when he was younger to Disneyworld. I could never do that [now]. I could not walk that park if you paid me. So it has affected my activities" (Pt 17). Patients often specified that RA impacted their ability to do household chores. "Even if I plan on doing something at home on a given day, there's no guarantee that I can. When my RA is quiet and not real active I can plan on Saturdays to be my cleaning day and get my old routine done. When it [RA] is impacting me I struggle to do even the minimal amount of things that I wanted to do around the house" (Pt 11).

Item 9: I need to sleep during the day. About half of the participants noted that they needed to nap or rest during the day because of their RA. For example, "I've never been someone to sit around unless I'm reading or watching a movie, so when I'm suddenly hit with the fact that I guess, I wouldn't use the word lazy, but it is inactivity...you better sit down or lie down for a few hours and watch TV or try to take a nap" (Pt001). Patients noted needing to sleep during the day despite getting many hours of sleep at night. "You feel that you need to take a nap at like two, three o'clock in the afternoon even though you've gotten eight to ten hours of sleep the night before" (Pt 6). Notably, a subset of patients mentioned feeling tired during the day because RA-related pain or discomfort prevented them from sleeping well at night. These comments were not attributed to fatigue and are therefore not included here.

Item 10: I am too tired to eat. RA patients in our sample did not spontaneously discuss being too tired to eat. During the cognitive interview, participants interpreted the item as being either too tired to eat or too tired to prepare food. Participants who interpreted the item to mean unable to eat commonly stated they have never been too tired to eat, and the item did not apply to them. For example, participant 03 said, "I'm never too tired to eat. I thought about it, I was like, no, that doesn't apply to me." Other participants interpreted the item to mean being too tired to prepare a meal: "I took that to mean I was too tired

to physically do whatever it took to prepare a meal or order a meal” (Pt 16). Patients who interpreted the item as meaning too tired to prepare food were more likely to say the item applied to them.

Item 11: I need help doing my usual activities. A small portion of our sample spontaneously mentioned needing or using help for daily activities. “I hire out (household chores) as much as I can. I lean on other people to help me out” (Pt 08). “My husband drives me to work so I have a lot of people that are helpful to me in that respect” (Pt 09).

Item 12: I am frustrated by being too tired to do the things I want to do. Participants mentioned several emotional consequences of RA, including feeling overwhelmed, impatient, or depressed, but patients spoke most about frustration. For example, patient 008 said, “It just takes longer (to do simple tasks), you get more frustrated, you know, it has to do with fatigue as much as it has to do with your own physical limitations that come with the disease.” She continued, “For people like me who are driven, who have very busy careers and all that, that’s the hard part. I can ask somebody to open that bottle. It doesn’t bother me to do that anymore or I can ask them to help me do this or that, but... it’s so frustrating to be exhausted all the time.” Another participant described the frustration of living with a body that moves too slowly: “I always feel like when I want to (sic) do something my mind is going 100 miles an hour, my body’s like, ‘Okay, go ahead. We’ll catch up with you.’ So my mind is probably 100 miles an hour and my body is maybe 5 miles an hour, which you know, is a vast difference, so I definitely would use words like mmm, frustration...” (Pt 04).

Item 13: I have to limit my social activity because I am tired. Social activities were among the many activities impacted by fatigue. For example, one participant noted that her weekends involved less social activity: “...by the time the weekend comes you’re tired. So you know, staying home is totally fine. I used to love to run around and go out and do all kinds of things. But it’s tiring” (Pt 09). Similarly, another patient described how she would not follow through on social plans: “I like to travel. I travel for pleasure, I travel for business. But there have been times when I’ve gotten to my destination and been all happy and had plans...and I think I’d really rather just stay in—I’d really just rather stay quiet and not complete the social plans that I have” (Pt 16).

Additional aspects of fatigue mentioned by participants

Work: Participants often spoke of paid work when discussing the impact of RA-related fatigue on usual activities. Some said fatigue caused them to shorten their work day or diminish the effort they were able to put forth at work. In addition, a few patients noted that fatigue affected their ability to focus while on the job.

Coping: Participants described a number a ways in which they cope with fatigue. For example, some patients tried to exercise whenever they had the energy because it made them feel better. Others drank caffeine to help them make it through the workday. One participant spoke of ignoring her fatigue and pushing herself until she had time to “crash.”

Exhaustion: Several participants described their fatigue with the word “exhaustion.” For example, “You’re always exhausted. And so like today it would have been very easy for me to just, you know, stay home and not do anything” (Pt 09).

Sleeping longer: In addition to needing to sleep during the day, participants spoke of sleeping longer. “I fall asleep easy now. When I get home, bang. So, I sleep longer when I have the chance. I used to not do that...I don’t want to put that on the fact that I am getting older.

You know, I’ll put it on the fatigue of the disease” (Pt 03). “Well, like today, from the time I got up my focus was, ‘When can I get back to bed?’ Even though I have a lot of things on my plate today, I’m just so sleepy and tired and I was advised to you know, sleep 10 to 12 hours a day... so it’s very difficult to sometimes get the rest that I need and still be productive, so my life has changed drastically” (Pt 04).

Patient evaluations of the FACIT-F

Face validity: The majority of respondents (N=14) indicated that the FACIT-Fatigue captured their fatigue experience. Of the three participants who did not endorse the scale’s face validity, one doubted the ability of any scale to capture her experience. Another participant (Pt 12) said the scale could be improved by clarifying what it means to have trouble finishing versus starting an activity and specifying mental versus physical fatigue. The third participant (Pt 16) thought the questions should further specify sleep (e.g., how long or how often).

Discussion

Fatigue is recognized as an important symptom of RA disease activity by the EULAR and the ACR [5] and can have significant impacts on patient quality of life [1,5-8]. We aimed to assess the face and content validity of the FACIT-Fatigue for patients with moderately to highly active RA. Following recommended methods for assessing content validity [23], we gathered data from patients via open-ended interview questions about fatigue experiences.

A strong content validity match need not be inclusive of all patient-provided concepts, but should represent the vast majority of patient input [23]. The FACIT-Fatigue was shown to have good face validity among patients with moderately to highly active RA. The instrument covers common patient descriptors of fatigue (fatigue, energy, tired) and addresses the impact of fatigue on activity, sleep, and emotion. Nonetheless, a few concepts mentioned by patients are not covered by the instrument. First, the FACIT-Fatigue does not contain an item related to work. However, work for pay represents an opportunity concept; not everyone is currently working for pay. Thus, it is preferable to assess fatigue’s impact on activities in general rather than on work specifically. Second, several participants noted ways they attempt to cope with their fatigue. However, as it refers to behaviours mounted to manage fatigue, rather than the experience or impact of fatigue upon function, coping is a different concept than what is intended to be measured by a fatigue questionnaire. Third, some patients described their fatigue as exhaustion. While the FACIT-Fatigue does not address exhaustion, the most common patient descriptors of fatigue in the qualitative interviews, tired and energy/energy loss, are included, as is fatigue. Thus, although the FACIT-Fatigue is not inclusive of all patient fatigue concepts, it covers three of the four most common ways patients spoke of fatigue. Finally, several participants described sleeping longer, which differed from needing to nap or sleep during the day. Future work should consider the utility of adding an item related to sleeping for longer amounts of time.

Three of the 13 FACIT-Fatigue items were not reflected in the qualitative patient data. Only one patient mentioned weakness during the concept elicitation interviews. However, during the cognitive interviews, almost all (N=15) of participants said the item, “I feel weak all over”, was relevant. Most participants interpreted the item to refer to fatigue, although some considered lack of strength. Thus, there is moderate evidence that weakness is relevant to patients, even if they do not spontaneously discuss weakness. Listlessness did not emerge as a

theme in the patient interviews. The patient cognitive data on the item, "I feel listless ('washed out')", is mixed. Eighty-eight percent (N=15) of participants indicated the item was relevant to their fatigue experience, yet several patients explained that they would not use the term "listless" to describe their fatigue. Thus, it may be prudent to remove this item when scoring the FACIT-Fatigue for assessments of RA fatigue. A third item, "I am too tired to eat" was not supported by the qualitative data. Although a minority of participants thought the item was applicable to their experiences, most of those participants interpreted the item to mean being too tired to prepare food. This item could function a floor item which characterizes the extreme end of fatigue. However, given that patients had differing interpretations of the item (i.e., too tired to eat versus too tired to prepare food), assessments of RA fatigue should consider excluding this item from fatigue scores.

There are several shortcomings of this study. First, participants were recruited from a single institution. Although we have no reason to believe that patients from other institutions or regions would experience RA-related fatigue differently, we are unable to confirm that assumption with these data. Second, the perspectives of men with RA are underrepresented in our sample. Finally, although this study involved a small sample, our sample size was driven by established qualitative research practices whereby sample size is based on the number of participants needed to reach saturation. Past research indicates that saturation often occurs within the first 12 interviews [24]. Thus, our sample of 17 interviews, with saturation obtained at 16 interviews, is consistent with expectations.

Our study highlights the most important dimensions of fatigue for individuals with moderately to highly active RA. These patients described their fatigue experience as tiredness, energy loss, and, to a lesser extent, fatigue and exhaustion. Fatigue significantly impacts their ability to engage in day-to-day activities resulting in frustration. Patients experienced a need to sleep more during the day. The FACIT-Fatigue was found to capture the majority of fatigue-related concepts reported by patients, and thus has strong content validity. The instrument could be further tailored to RA patients by removing two of the thirteen items that were found to be less relevant to RA when scoring the instrument for RA patients. The FACIT-Fatigue provides a method for assessing and monitoring RA patients' subjective experiences with fatigue; clinical awareness of patients' fatigue experiences may in turn aid in managing their disease [25]. Given the significant impact of fatigue for RA patients, the varying significance of fatigue for patients, and the difficulty in controlling RA, it is helpful to measure and address fatigue as an important component of treatment evaluation, disease management, and patient quality of life.

References

- Helmick CG, Felson DT, Lawrence RC, Gabriel S, Hirsch R, et al. (2008) Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. *Arthritis and Rheumatism* 58: 15-25.
- Aletaha D, Landewe R, Karonitsch T, Bathon J, Boers M, et al. (2008) Reporting disease activity in clinical trials of patients with rheumatoid arthritis: EULAR/ACR collaborative recommendations. *Arthritis Care & Research* 59: 1371-1377.
- Yount S, List M, Du H, Yost K, Bode R, et al. (2007) A randomized validation study comparing embedded versus extracted FACT Head and Neck Symptom Index scores. *Quality of Life Research* 16: 1615-1626.
- Kulke MH, Benson AB, Bergsland E, Berlin JD, Blaszkowsky LS, et al. (2012) Neuroendocrine Tumors. *Journal of the National Comprehensive Cancer Network* 10: 724-764.
- Kirwan JR, Hewlett S (2007) Patient perspective: reasons and methods for measuring fatigue in rheumatoid arthritis. *The Journal of Rheumatology* 34: 1171-1173.
- Hewlett S, Hehir M, Kirwan JR (2007) Measuring fatigue in rheumatoid arthritis: A systematic review of scales in use. *Arthritis Care & Research* 57: 429-439.
- Whalley D, McKenna SP, de Jong Z, van der Heijde D (1997) Quality of life in rheumatoid arthritis. *Rheumatology* 36: 884-888.
- Kulke MH, Siu LL, Tepper JE, Fisher G, Jaffe D, et al. (2011) Future Directions in the Treatment of Neuroendocrine Tumors: Consensus Report of the National Cancer Institute Neuroendocrine Tumor Clinical Trials Planning Meeting. *Journal of Clinical Oncology* 29: 934-943.
- Cella D, Yount S, Sorensen M, Chartash E, Sengupta N, et al. (2005) Validation of the Functional Assessment of Chronic Illness Therapy Fatigue Scale relative to other instrumentation in patients with rheumatoid arthritis. *J Rheumatol* 32: 811-819.
- Denburg SD, Carbotte RM, Denburg RA (1997) Psychological aspects of systemic lupus erythematosus: cognitive function, mood, and self-report. *The Journal of Rheumatology* 24: 998-1003.
- Huyser BA, Parker JC, Thoreson R, Smarr KL, Johnson JC, et al. (1998) Predictors of subjective fatigue among individuals with rheumatoid arthritis. *Arthritis & Rheum* 41: 2230-2237.
- Rupp I, Boshuizen HC, Jacobi CE, Dinant HJ, van den Bos GAM (2004) Impact of fatigue on health-related quality of life in rheumatoid arthritis. *Arthritis Care & Research* 51: 578-585.
- U.S. Department of Health and Human Services Food and Drug Administration (2009) Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims.
- Patrick DL, Burke LB, Gwaltney CJ, Leidy NK, Martin ML, et al. (2011) Content Validity—Establishing and Reporting the Evidence in Newly Developed Patient-Reported Outcomes (PRO) Instruments for Medical Product Evaluation: ISPOR PRO Good Research Practices Task Force Report: Part 1—Eliciting Concepts for a New PRO Instrument. *Value in Health* 14: 967-977.
- van der Heijde DM, van 't Hof MA, van Riel PL, Theunisse LA, Lubberts EW, et al. (1990) Judging disease activity in clinical practice in rheumatoid arthritis: first step in the development of a disease activity score. *Annals of the Rheumatic Diseases* 49: 916-920.
- Prevo MLL, Van't Hof MA, Kuper HH, Van Leeuwen MA, Van De Putte LBA, et al. (1995) Modified disease activity scores that include twenty-eight-joint counts development and validation in a prospective longitudinal study of patients with rheumatoid arthritis. *Arthritis & Rheumatism* 38: 44-48.
- Aletaha D, Nell VPK, Stamm T, Uffmann M, Pflugbeil S, et al. (2005) Acute phase reactants add little to composite disease activity indices for rheumatoid arthritis: validation of a clinical activity score. *Arthritis Research & Therapy* 7: R796-R806.
- Magasi S, Mallick R, Kaiser K, Patel JD, Lad T, et al. (2013) Importance and Relevance of Pulmonary Symptoms Among Patients Receiving Second- and Third-Line Treatment for Advanced Non-Small-Cell Lung Cancer: Support for the Content Validity of the 4-Item Pulmonary Symptom Index. *Clinical lung cancer* 14: 245-253.
- Victorson DE, Anton S, Hamilton A, Yount S, Cella D (2009) A conceptual model of the experience of dyspnea and functional limitations in chronic obstructive pulmonary disease. *Value Health* 12: 1018-1025.
- Yellen SB, Cella DF, Webster K, Blendowski C, Kaplan E (1997) Measuring fatigue and other anemia-related symptoms with the Functional Assessment of Cancer Therapy (FACT) measurement system. *Journal of Pain and Symptom Management* 13: 63-74.
- Willis GB (2005) *Cognitive interviewing: A tool for improving questionnaire design*. Thousand Oaks.
- Glaser BG, Strauss AL (1965) The constant comparative method of qualitative analysis. *Social Problems* 12: 436-445.
- Rothman M, Burke L, Erickson P, Leidy NK, Patrick DL, et al. (2009) Use of Existing Patient-Reported Outcome (PRO) Instruments and Their

Citation: Kaiser k, Shaunfield S, Clayman ML, Ruderman E, Cella D (2016) Content Validation of the Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Scale in Moderately to Highly Active Rheumatoid Arthritis. *Rheumatology (Sunnyvale)* 6: 193. doi: [10.4172/2161-1149.1000193](https://doi.org/10.4172/2161-1149.1000193)

-
- Modification: The ISPOR Good Research Practices for Evaluating and Documenting Content Validity for the Use of Existing Instruments and Their Modification PRO Task Force Report. *Value in Health* 12: 1075-1083.
24. Guest G, Bunce A, Johnson L (2006) How Many Interviews Are Enough? *Field Methods* 18: 59-82.
25. Cipolletta S, Consolaro F, Horvath P (2014) When Health Is an Attitudinal Matter: A Qualitative Research. *Journal of Humanistic Psychology* 54: 391-413.