

Patient Insights of Fatigue in Systemic Lupus Erythematosus and Content Validation of the FACIT-Fatigue

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Introduction

- In this qualitative study, interviews were conducted to understand fatigue in those diagnosed with SLE, and to evaluate the content validity of the Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue¹ patient-reported outcome (PRO) instrument in the SLE population

Methods

Study design

- This qualitative study (GSK study 209226) followed the methods for PRO content validation studies outlined in the United States Food and Drug Administration PRO Guidance² and the International Society for Pharmacoeconomics and Outcomes Research Clinical Outcome Assessment Emerging Good Practices Task Force³
- The study was composed of 90-minute semi-structured telephone interviews conducted in the USA during July 2018
 - Concept elicitation (CE) aimed to identify important concepts of experiences in SLE, specifically with fatigue
 - Cognitive debriefing (CD) aimed to assess content validity of the FACIT-Fatigue as a fit-for-purpose measure of fatigue in SLE. Each element of FACIT-Fatigue (items, instructions, recall period) was evaluated for ease of comprehension, relevance, and clarity
- A formal saturation analysis was conducted to confirm that saturation, a measure of validity defined as the point at which no new concept-relevant information is identified upon the conduct of further interviews,⁴ was achieved
- Item mapping of the FACIT-Fatigue was conducted to determine correspondence between the concepts identified in the CE interviews and the FACIT-Fatigue instrument

Study population

- 18+** ≥18 years
- Spoke and read US English
- Self-reported doctor diagnosis of SLE for ≥6 months
- Reported testing positive for antinuclear antibody or anti-double-stranded deoxyribonucleic acid
- Persistent symptoms for ≤6 months or ≥1 SLE flare in the previous 12 months despite treatment with steroids/immunosuppressants

Results

Participants

- Fifteen participants with SLE were interviewed, 87% (n=13) of whom were female (in line with the general SLE population)⁵

Concept elicitation

- Concept saturation was achieved at n=15 participants
- Twenty-seven signs and symptoms associated with SLE were reported; those reported in ≥5 participants are shown in **Figure 1**
- Symptoms that varied in intensity over time were reported by 60.0% of participants, and almost all (93.3%) reported that their symptoms could be brought on or intensified by triggers (**Figure 2**)
- Triggers reported to prompt or intensify symptoms and symptoms reported as the most bothersome are shown in **Figure 2**
 - Patient descriptions of fatigue further illustrate the day-to-day burden (**Figure 3**)
 - Figure 4** shows the words used to describe a typical day when fatigue is experienced
- The impacts of fatigue are shown in **Figure 5**

Cognitive debriefing

- The instructions were easy to understand for 13 participants
- The response options were good and adequately captured experiences with fatigue for each item for most participants (n=11)
- The recall period was easy or very easy in terms of remembering information relevant to responses for 11 participants
- The items or questions were not reported to have problems with comprehension or understanding.
 - The item "I'm too tired to eat" in previous studies was found to be less relevant to individuals with SLE than other items.⁶ However, deeper probing in the current study revealed that individuals with SLE are often too tired to eat
- Almost all participants (n=14) reported that a meaningful change in their fatigue would be to have the ability to be more active and have a more normal lifestyle

Item mapping

- All FACIT-Fatigue items mapped directly onto concepts spontaneously mentioned by participants during the interviews

Results (continued)

Table 1. Participant demographics and characteristics

	Total population (N=15)
Age, years, mean (SD)	52.1 (13.1)
Female, n (%)	13 (86.7)
Race, n (%)	
White/non-Hispanic	8 (53.3)
Black/African-American	6 (40.0)
Other White/African-American	1 (6.7)
Years since SLE diagnosis, mean (SD)	17.9 (11.2)
SLE severity, n (%)	
Moderate	7 (46.7)
Severe	4 (26.7)
Don't know/not sure	1 (6.7)
My doctor has not told me	3 (20.0)
Number of flares in the previous 12 months, n (%)	
1-3	6 (40.0)
4-6	4 (26.7)
7-10	2 (13.3)
≥11	3 (20.0)

Figure 1. Most commonly reported SLE symptoms (≥5 participants)

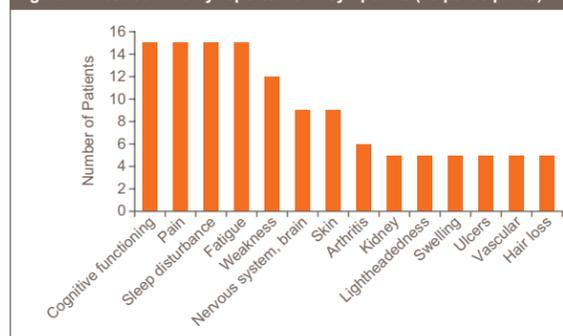
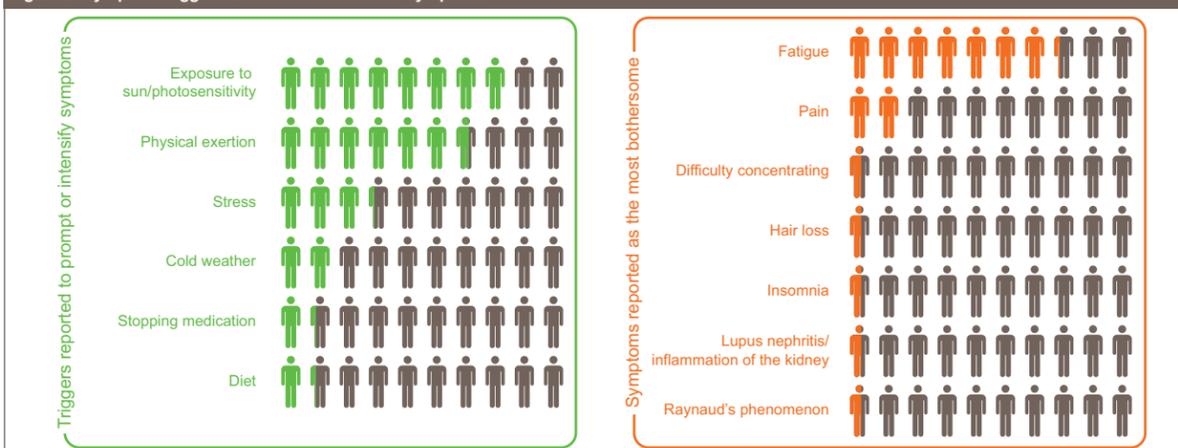


Figure 2. Symptom triggers and most bothersome symptoms*



*Percentages in each category may not total 100% because participants may have reported more than one symptom, trigger, or impact

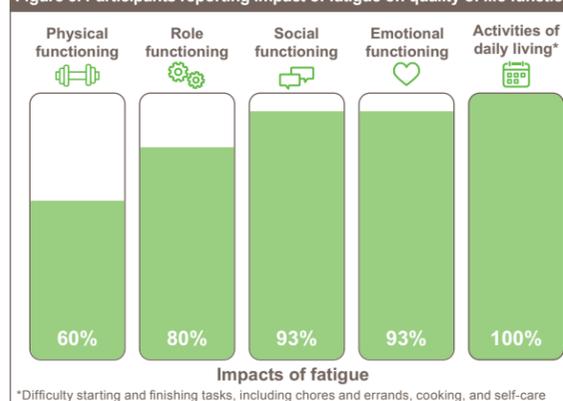
Figure 3. Representative quotes from participants' descriptions of fatigue

Figure 4. A typical day with fatigue*



*Size of words reflects the frequency with which participants mentioned them

Figure 5. Participants reporting impact of fatigue on quality of life function



*Difficulty starting and finishing tasks, including chores and errands, cooking, and self-care

Conclusions

- SLE-related fatigue was the most debilitating symptom for the participants of this study, who conveyed numerous impacts of fatigue on their lives, both daily and during flares
- Findings from this qualitative study support the importance of the concept of fatigue in SLE
- Limitations of the current research include:
 - A US sample with limited gender diversity
 - Participants self-reported diagnosis and severity due to restrictions associated with protected health information
 - Attribution of symptoms to SLE rather than any other diagnosis was also based on patients' own reports
- Despite these limitations, our findings provide valuable information about SLE-related fatigue and associated impacts from the patient perspective
- Findings from this report are consistent with a previous qualitative study examining the use of FACIT-Fatigue for SLE⁶
- This study supports the content validity of the FACIT-Fatigue instrument for use in this population

References

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Disclosures

- JP and AVJ are employees of GSK and hold shares in the company. KR and MW are employees of Optum, which received funding from GSK to conduct this study.