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-Fatigue) 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 Guidance and the International Society for Pharmaeconomics and Outcomes Research Clinical Outcome Assessment Emerging Good Practices Task Force. 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, 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

Participants

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

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 2

Cognitive debriefing

- The interviews were used to understand for 13 participants
- The response options were good and adequately captured experiences with fatigue for each item for most participants
- The item “I’m too tired to eat” in previous studies was spontaneously mentioned by participants during the interviews
- All FACIT-Fatigue items mapped directly onto concepts spontaneously mentioned by participants during the interviews
- The instructions were easy to understand for 13 participants
- Symptoms that varied in intensity over time were reported by 10 participants
- Attribution of symptoms to SLE rather than any other condition was reported by 10 participants
- The recall period was easy or very easy in terms of comprehension, relevance, and clarity for 11 participants
- Item mapping of the FACIT-Fatigue was used to identify correspondence between the concepts identified in the CE interviews and the FACIT-Fatigue instrument

Results

- SLE-related fatigue was the most debilitating symptom for the participants of this study, who conformed 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 reported concept saturation and clarity were high, with no new concept-relevant information identified upon the conduct of further interviews, 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
  - Findings from this report are consistent with a previous qualitative study examining the use of FACIT-Fatigue for SLE
  - This study supports the content validity of the FACIT-Fatigue instrument for use in this population

Conclusions

- SLE-related fatigue was the most debilitating symptom for the participants of this study, who conformed 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:
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References


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