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A Real World Study Characterizing Impact of Fatigue and Patient Symptom Recall in Adults with Relapsing Multiple Sclerosis

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INTRODUCTION

- Fatigue is among the most frequent and disabling symptoms in patients with relapsing multiple sclerosis (RMS).[1]
- Patient reported outcomes (PROs) are fundamental to studying fatigue.
- Questions remain regarding MS fatigue and their impacts, and determining the best time frame for data collection e.g., daily assessments versus recall of fatigue as experienced over a 1- or 2-week interval.[2,3]
- In an ongoing non-interventional prospective study of RMS patients recruited via an online survey, we addressed these questions by measuring responses on the validated RMS-specific Fatigue Symptoms and Impacts Questionnaire-Relapsing Multiple Sclerosis (FSIQ-RMS) and examining the relation between daily fatigue assessment and a 7-day recall assessment.
- Patients completed questionnaires including disease history, disease status, sleep, social and emotional functioning.

OBJECTIVES

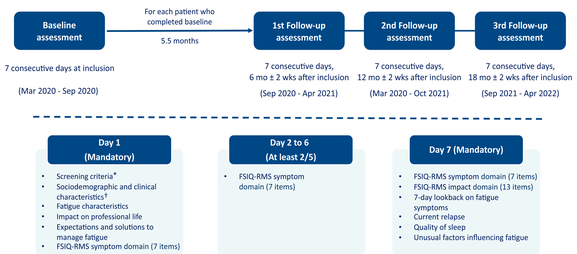
- To use the FSIQ-RMS to measure MS fatigue symptoms and their impact on daily life in a real-world population.
- To compare fatigue symptom data collected daily for 7 days versus a 7-day recall.

METHODS

- The FSIQ-RMS Symptom Diary was administered daily for 7 days [daily recall] and on Day 7 patients recalled their symptoms over the previous 7-day period [7-day recall].
- The FSIQ-RMS Impacts questionnaire was administered on Day 7, using a 7-day recall.
- We evaluated the results of FSIQ-RMS symptom score collected daily to that of the 7-day recall, using mean values to identify agreement between scores and possible sources of bias.
- Additionally, we analyzed the scores for symptom domain and physical, cognitive, and emotional, and coping impacts as well as socio-demographic and disease related data to validate the results of the 7-day recall questionnaire.

METHODS *(Contd.)*

Figure 1: Study Design



*Only during baseline assessment.
†Type of MS, year of diagnosis, mobility impairment through the PDDS, current treatments for MS, comorbidities, etc.
FSIQ-RMS, Fatigue Symptoms and Impacts Questionnaire - Relapsing Multiple Sclerosis; mo, months, MS, Multiple Sclerosis; PDDS, Patient Determined Disease Steps; wks, weeks

RESULTS

Relationship between 24-hr-recall and 7-day-recall of FSIQ-RMS symptoms domain

Individual differences:

- 25% of the patients show a smaller mean score Day 1-Day 7 compared to 7-day recall score of > 6.3 points and 10% of >10 points.
- 10% of the patients show a larger mean score Day 1-Day 7 compared to 7-day recall score of > 8.6 points.

Trend over time – adjusted daily scores:

- There is slight tendency of higher correlation of daily score closer to Day 7, but the increase in Spearman's coefficient is very small.
- There is a high internal consistency between the daily scores and the 7-day recall, Cronbach Alpha = 0.954.

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- There is slight tendency of higher correlation of daily symptom scores closer to Day 7, but the increase in Spearman's coefficient is very small.
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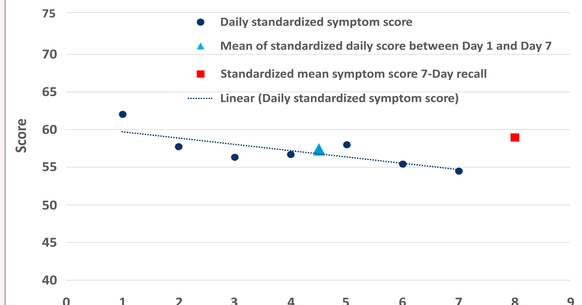
RESULTS *(Contd.)*

Figure 2: FSIQ-RMS symptom score collected daily over 7 days versus 7 day recall



The FSIQ RMS domain scores range from 0-100 (higher score indicates greater severity)

Figure 3: FSIQ-RMS symptom score collected daily over 7 days versus 7 day recall

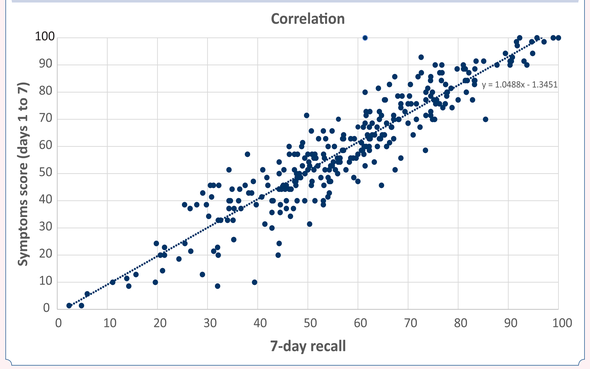
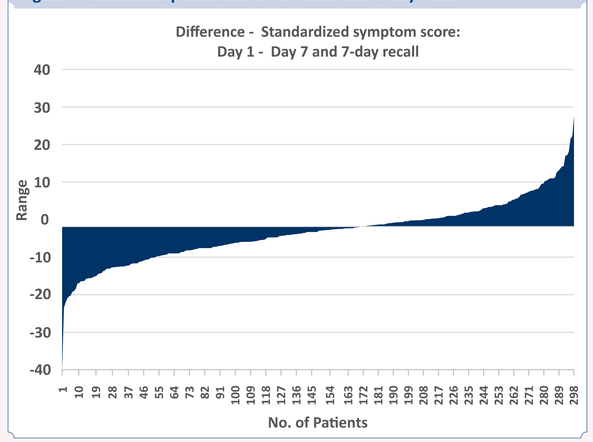


Figure 4: Relationship between 24-hr-recall and 7-day-recall



- Daily symptom scores were highly variable within patients between Day 1 to Day 7 (25% of the patients have differences between their daily scores of > 38 points on a scale of 0-100).
- However, there was high internal consistency between the daily recall and the 7-day recall (Cronbach Alpha > 0.954 for all daily scores).
- We found a tendency of higher correlation of the 7-day recall score and daily item scores as the data collected was closer to Day 7 (Pearson Correlation Coefficients increasing from 0.75 to 0.85).
- Sociodemographic and clinical characteristics show only a slight influence on 7-day recall.
- The magnitude of impact (no impact, mild-moderate impact, and severe-very severe impact) does not influence the correlation of the 7-day recall and the mean Day 1 to Day 7 symptom score.

CONCLUSIONS

- **The FSIQ-RMS is a novel and MS-specific patient reported outcome measure that can advance the understanding and management of fatigue.**
- **The 7-day recall was consistent with the daily symptom score of Day 1 to Day 7.**

References:

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Disclosures:

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T. Zwingers is a consultant for Cros-NT. **M. Ait-Tihyaty**, **G. Kanevsky**, **E. Katz** are employees of Janssen Pharmaceuticals and may hold stock or stock options in Johnson & Johnson.
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