

A real-world study characterizing symptoms and impacts of fatigue in US adults with relapsing multiple sclerosis using a novel disease specific scale

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BACKGROUND

- Fatigue is among the most frequent and disabling symptoms in patients with relapsing multiple sclerosis (RMS) and a main cause of impaired health-related quality of life.¹
- Fatigue is defined by subjective experience and measured via patient reported outcome (PRO) instruments.²
- However, previously available PROs that assess MS-related fatigue do not meet instrument development and psychometric property requirements based on current guidelines.³
- PRO tools that are MS-specific can improve understanding of MS fatigue and its impact, improving its clinical management.
- Fatigue Symptoms and Impacts Questionnaire - Relapsing Multiple Sclerosis (FSIQ-RMS), a novel MS-specific PRO instrument, was developed to assess both fatigue in patients with RMS and its impacts on physical activity, cognitive and emotional function and coping mechanisms.²

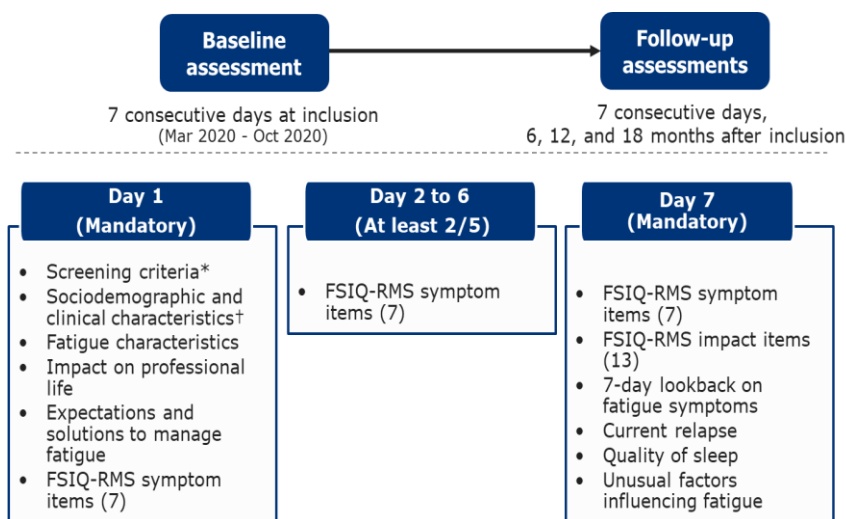
• The study was aimed at measuring MS fatigue symptoms and their impact on daily life in a real-world population using a self-administered online questionnaire including the RMS-specific FSIQ-RMS

METHODS

Design: An ongoing, non-interventional, prospective, longitudinal study

- Adult (18–55 years), ambulatory (PDDS <6) RMS patients from the US were recruited via an online questionnaire.
- The 20-item FSIQ-RMS addresses MS fatigue, rated for severity based on the mean daily ratings over 7 days, and the corresponding impacts of fatigue on 3 subdomains: physical, cognitive/emotional, and coping.
- The FSIQ-RMS domain scores range from 0-100 (higher score=greater severity).
- Self-reported data were collected via an online patient community (Carenity).

Baseline assessment data of 300 RMS patients are presented.



*Only during baseline assessment.

†Type of MS, year of diagnosis, mobility impairment through the PDDS, current treatments for MS, comorbidities, etc.

PDDS, Patient Determined Disease Steps

RESULTS

Patient and fatigue characteristics

Characteristic	N=300
Female, n (%)	264 (88.0)
Age (years)	43.0 (7.6)
Age at diagnosis of MS (years)	32.0 (8.5)
RMS type, n (%)	
RRMS	290 (96.7)
SPMS	9 (3.0)

Data are expressed as mean (SD), unless otherwise specified; RMS, relapsing MS; RRMS, relapsing – remitting MS; SD, standard deviation; SPMS, secondary progressive MS

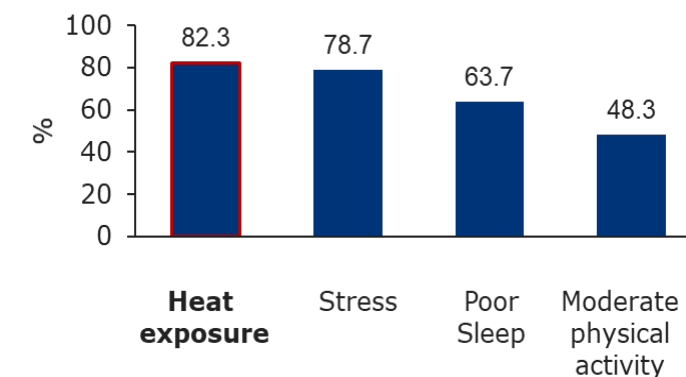
Time of onset of fatigue, n (%)	N=300
Before MS diagnosis	157 (52.3)
After MS diagnosis	70 (23.3)
Don't remember	25 (8.3)
Always experienced fatigue	23 (7.7)
After a relapse	18 (6.0)
After diagnosis of another condition	5 (1.7)
Other (no fatigue)	2 (0.7)

Experience and intensity of fatigue on a daily basis

- 61% some days are worse than others
- 16% can be more intense during long periods
- 10% usually not tired but short periods of intense fatigue, unrelated to intense effort

- A majority of patients experienced fatigue daily and before MS diagnosis
- Heat exposure (82%) was the most common triggering factor for fatigue

Most frequent triggering or worsening factors for fatigue



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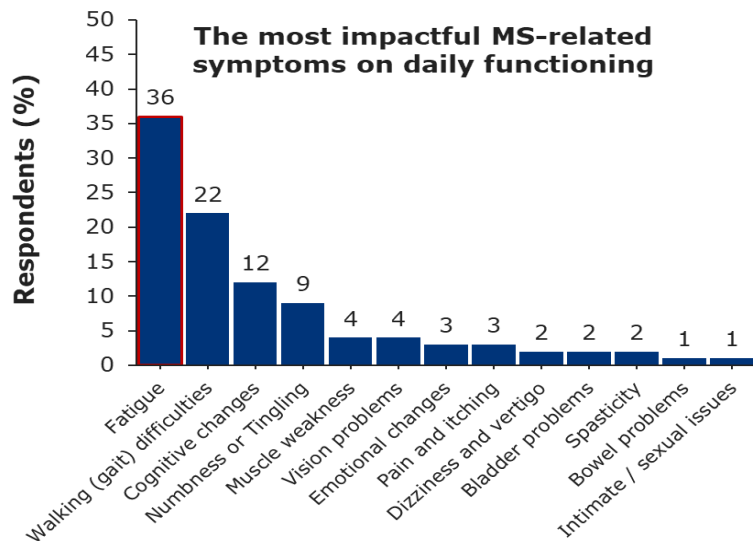
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RESULTS (Continued)

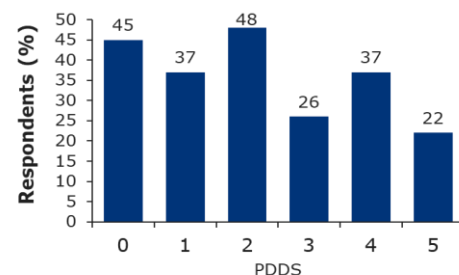
Impact of MS-related symptoms on daily functioning



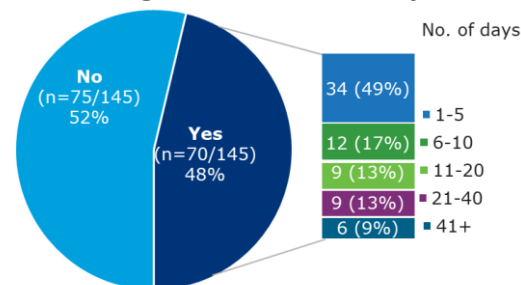
MS, multiple sclerosis; PDDS, Patient Determined Disease Steps. The PDDS is an ambulatory scale and has nine ordinal levels ranging between 0 (normal) and 8 (bedridden).

- Fatigue was rated as the most impactful symptom on daily functioning, followed by walking difficulties
- Patients with lower disability (PDDS 0-2) tended to rate fatigue as the most impactful symptom on daily functioning
- Fatigue led to work absence in nearly half of all patients (mean loss 1 to 5 days)

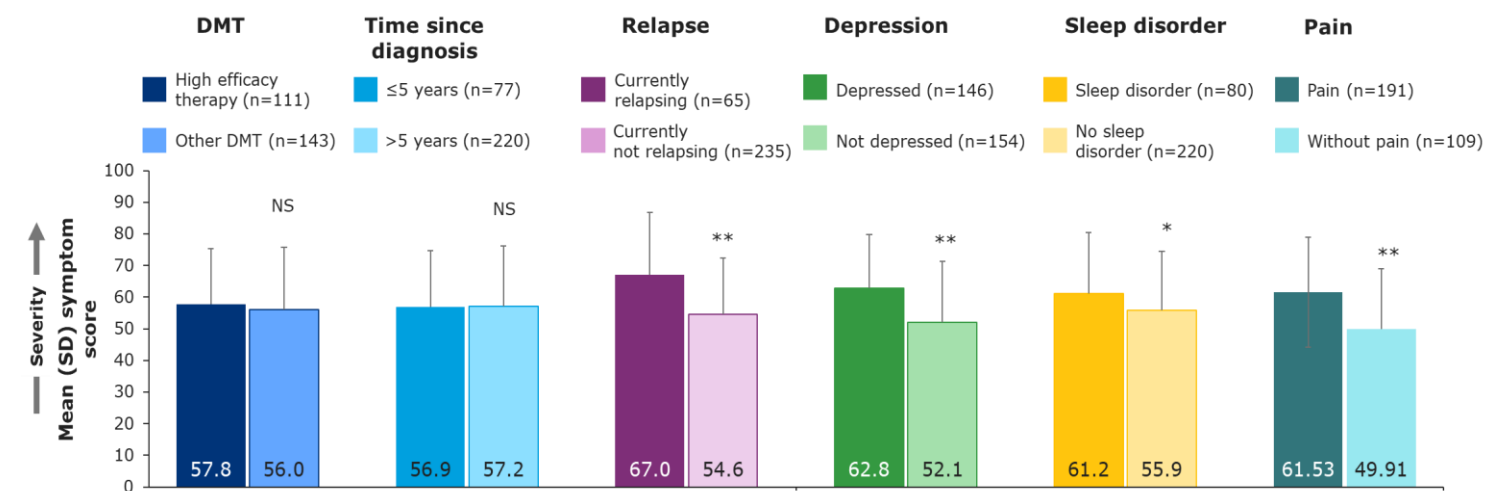
Fatigue as the most impactful MS-related symptom by disability status



Time taken off from work due to fatigue within the last one year



FSIQ-RMS – Symptoms scores by subgroups



NS; not significant; ** P<0.001; *P<0.01

DMT, disease modifying therapy; FSIQ-RMS, Fatigue Symptoms and Impacts Questionnaire – Relapsing Multiple Sclerosis
Sleep disorder: narcolepsy, restless leg syndrome or sleep apnea; High efficacy therapy: Ocrelizumab, rituximab, and natalizumab
Statistical comparisons were performed by Student's t-test. P<0.05 was considered as statistically significant.

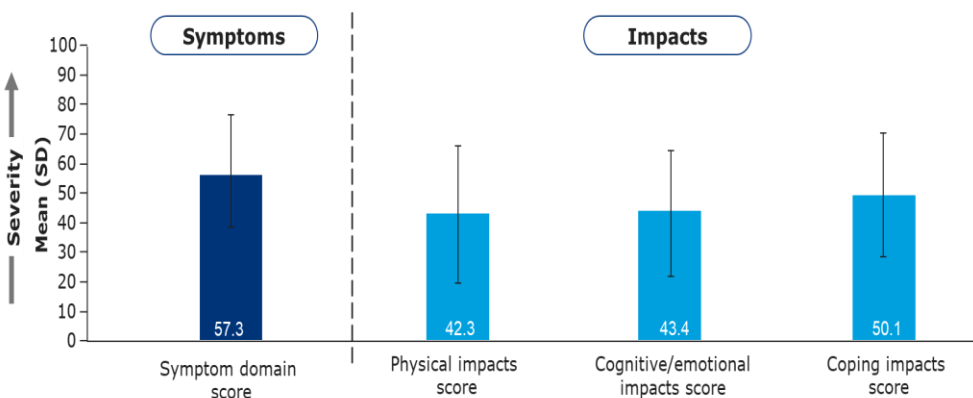
- Fatigue severity did not vary across disease duration or DMT category
- Fatigue levels were significantly higher in patients with relapse, depression, sleep disorder, and/or pain

CONCLUSIONS

- The FSIQ-RMS is a novel and MS-specific patient reported outcome measure that can advance the understanding and management of fatigue.
- The FSIQ-RMS was used to characterize the real-world impact of MS fatigue.
- Fatigue influences daily functioning for most with RMS.
- Symptom exacerbation, depression, sleep disorders and pain worsen the experience of fatigue.

References: 1. Flensner G, BMC Public Health. 2013;13:224; 2. Hudgens S. Value Health. 2019;22(4):453-466; 3. Food and Drug Administration. Guidance for Industry. Patient-reported outcome measures: use in medical product development to support labeling claims. <http://www.fda.gov/downloads/Drugs/Guidances/UCM193282.pdf>

Baseline FSIQ-RMS symptom and impact domain scores (Days 1-7)



The FSIQ-RMS captured high levels of fatigue and associated impacts at baseline across subdomains (physical, cognitive/emotional, and coping)