

P206

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

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Disclosures

- Tiphaine Lévy-Heidmann and Valentin Morisseau are employees, and Marion Azoulai was a former employee, of Carenity, France.
- Lindsey Lair and Carol Jamieson are employees of the Janssen Pharmaceutical Companies and own(ed) stock in Johnson & Johnson.
- Leigh E. Charvet is a former employee of Johnson & Johnson and owns stock.
- Lauren B Krupp has received advisory board/consulting fees, travel and meal allowances, and/or research funding from Sanofi Aventis, Biogen, Novartis, Gerson Lehrman, EMD Serono, Allergan Inc., and Tesaro Inc. She is also a non-compensated consultant and/or advisory board member with Novartis and Celgene and receives royalties for use of the Fatigue Severity Scale by various biopharmaceutical entities.



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.
- 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

FSIQ-RMS, Fatigue Symptoms and Impacts Questionnaire - Relapsing Multiple Sclerosis; MS, multiple sclerosis; PRO, patient-reported outcome.

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>

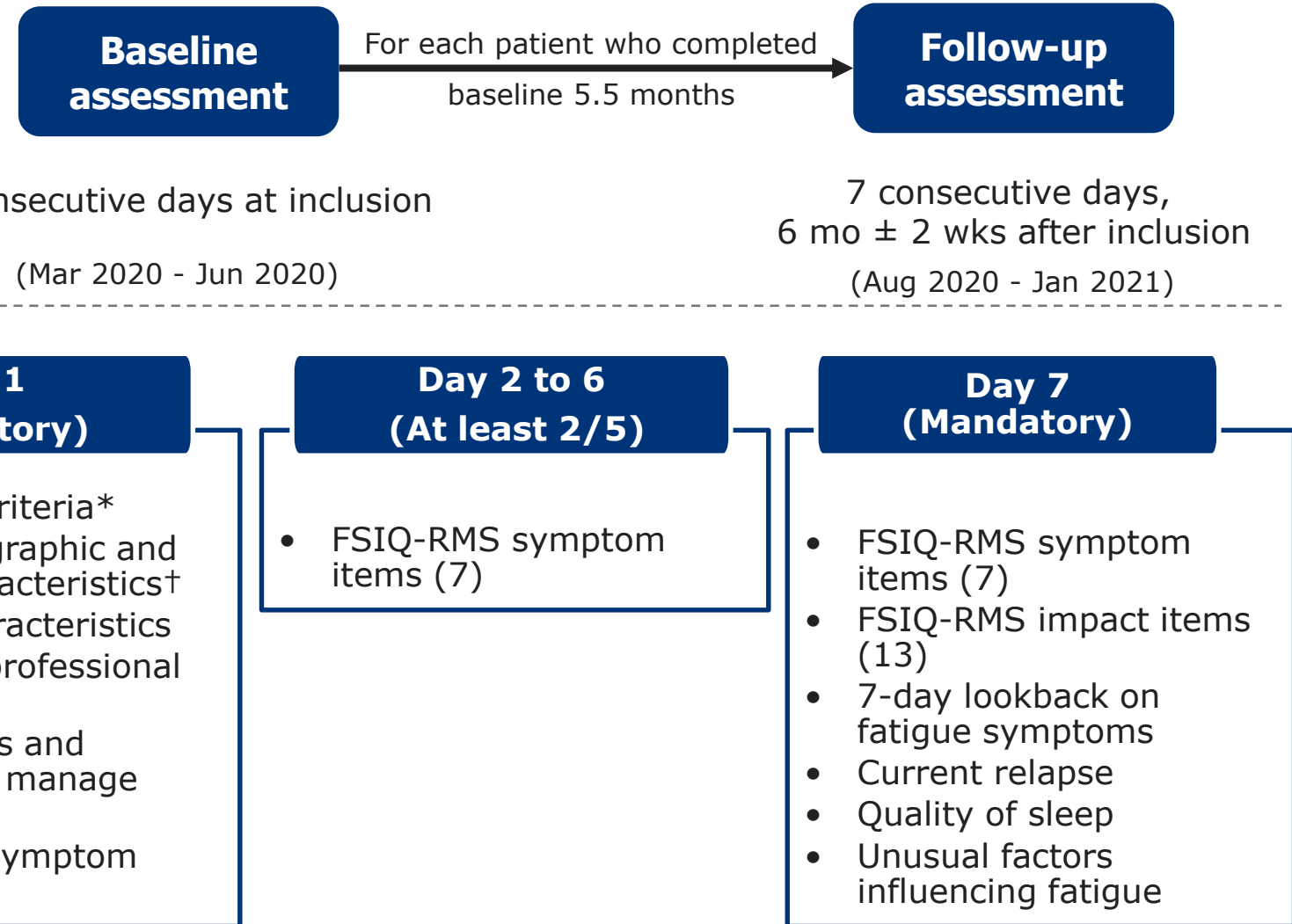


Methods

An ongoing, non-interventional, prospective, longitudinal study

- Adult (18–55 years), ambulatory (PDDS <6) RMS patients from the United States 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 indicates greater severity).
- Self-reported data were collected via an online patient platform (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.

FSIQ-RMS, Fatigue Symptoms and Impacts Questionnaire - Relapsing Multiple Sclerosis; MS, multiple sclerosis; PDDS, Patient Determined Disease Steps



Results

Patient and fatigue characteristics

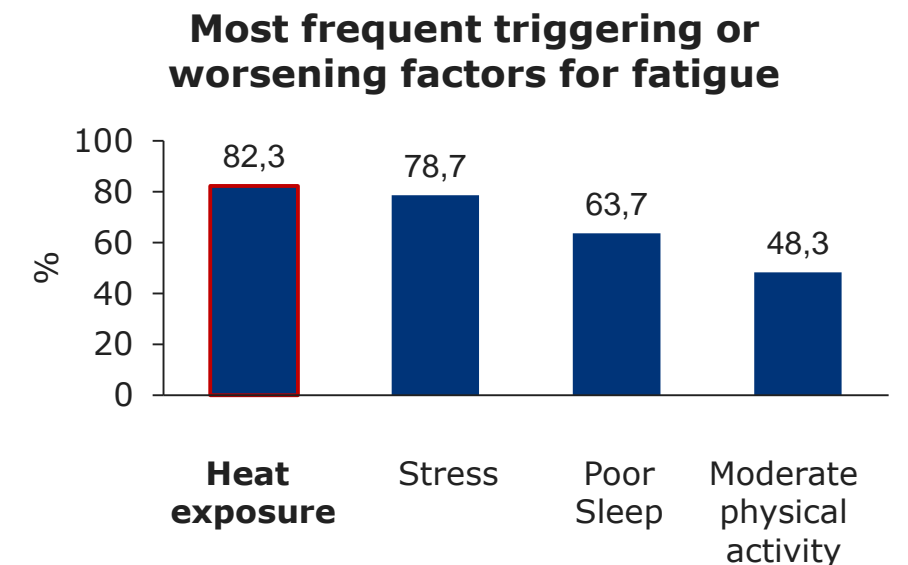
Characteristic	N=300
Female, n (%)	264 (88.0)
Age (years)	43.0 (7.6)
Age at diagnosis of MS (years)	32.0 (8.5)
RMS type, n (%)	
RRMS	290 (96.7)
SPMS	9 (3.0)

Data are expressed as mean (SD), unless otherwise specified

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

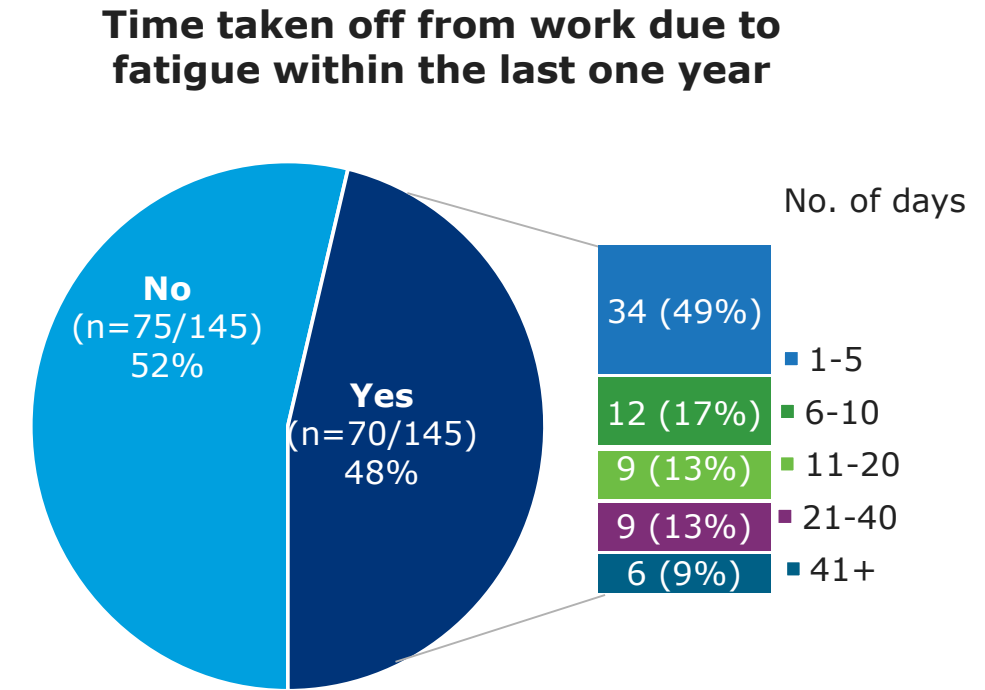
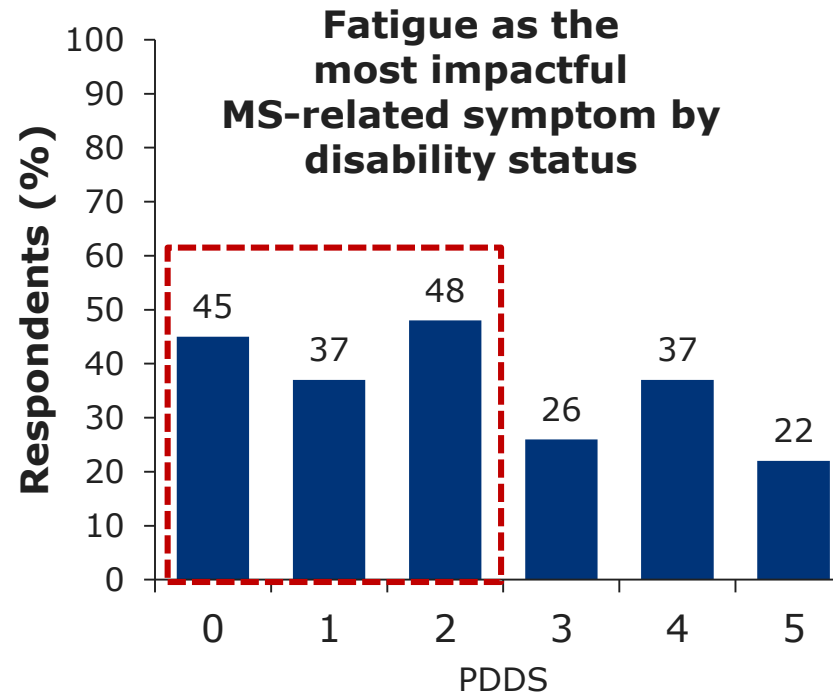
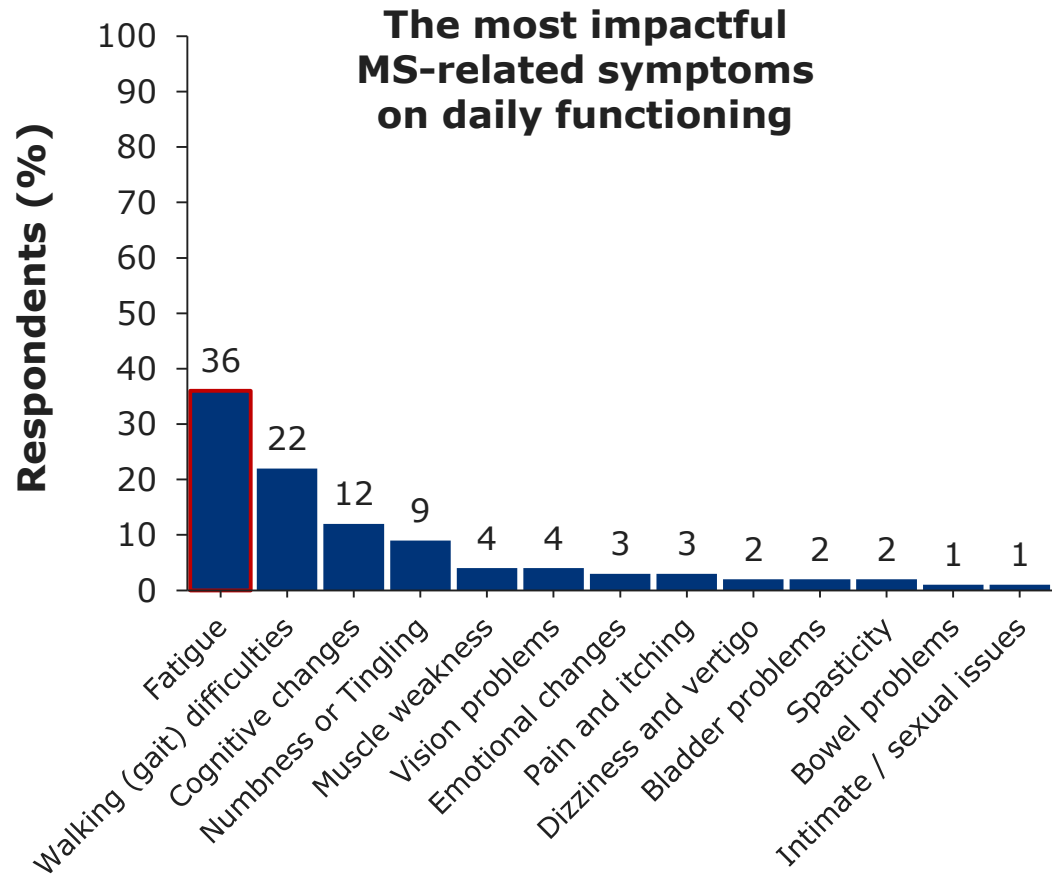


- A majority of patients experienced fatigue daily and before MS diagnosis
- Heat exposure (82%) was the most common triggering factor for fatigue



Results

Impact of MS-related symptoms on daily functioning



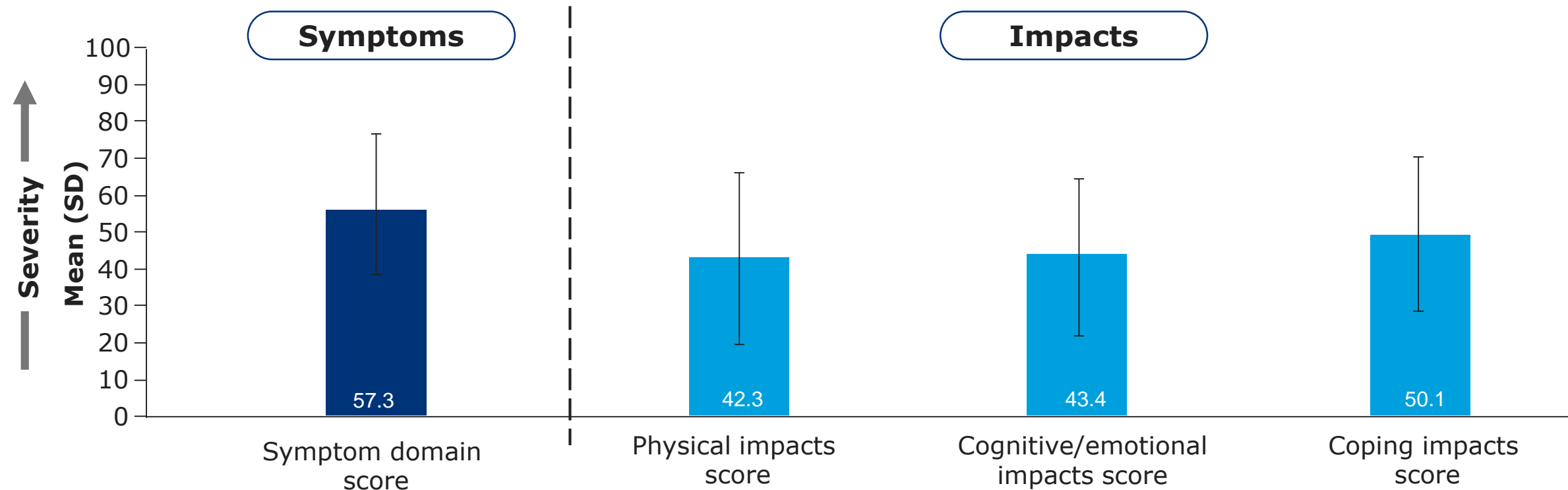
- Fatigue was rated as the most impactful symptom on daily functioning, followed by walking difficulties
- Patients with lower disability (PDDS 0-2) tended to rate fatigue as the most impactful symptom on daily functioning
- Fatigue led to work absence in nearly half of all patients (mean loss 1 to 5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

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).



Results

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

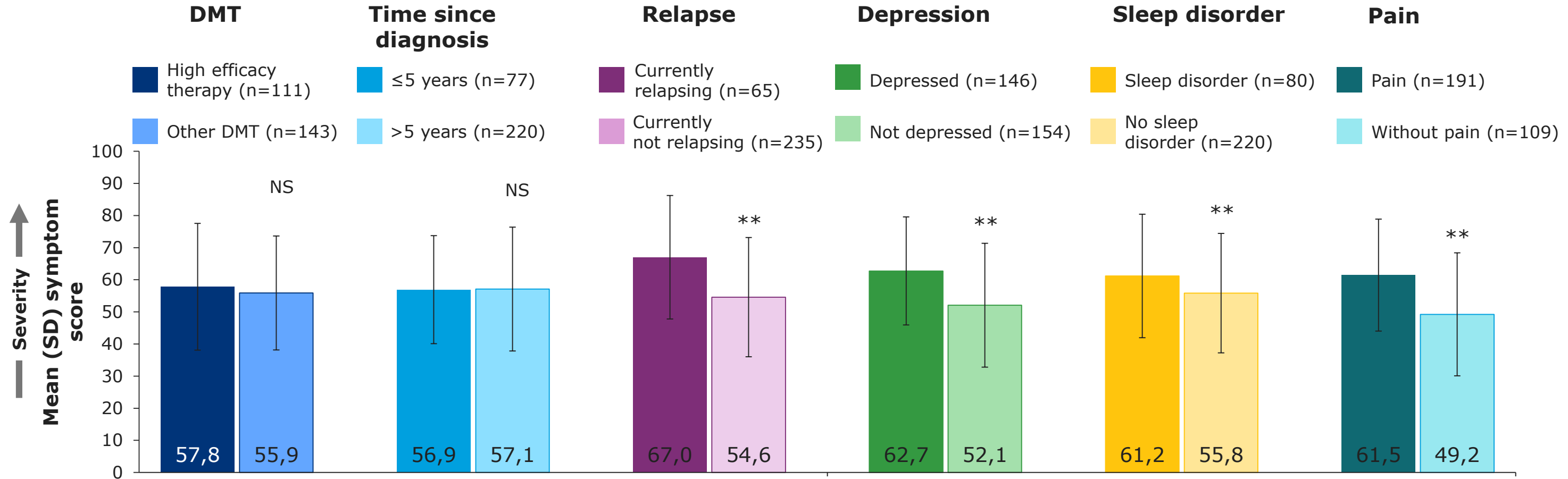


- The FSIQ-RMS captured high levels of fatigue and associated impacts at baseline across subdomains (physical, cognitive/emotional, and coping)



Results

FSIQ-RMS – Symptoms scores by subgroups



- 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

NS; not significant; ** P<0.001

DMT, disease modifying therapy; FSIQ-RMS, Fatigue Symptoms and Impacts Questionnaire – Relapsing Multiple Sclerosis

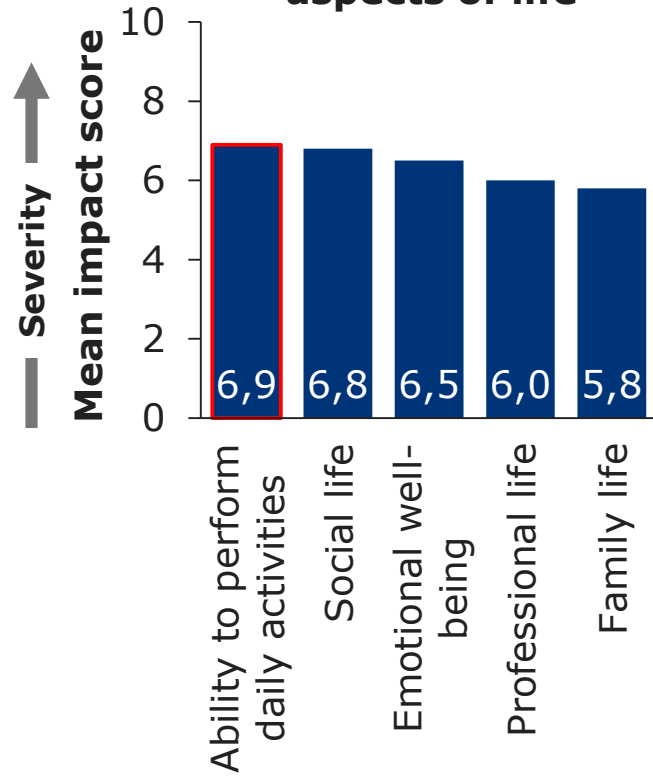
Sleep disorder: narcolepsy, restless leg syndrome or sleep apnea; High efficacy therapy: Ocrelizumab, rituximab, and natalizumab

Statistical comparisons were performed by Student's t-test. P<0.05 was considered as statistically significant.

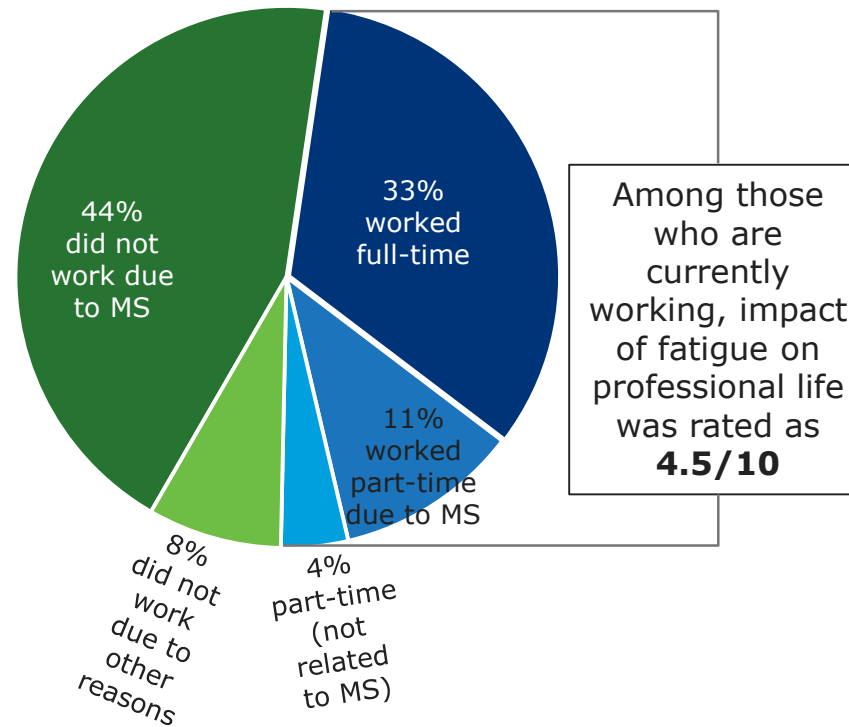


Results

Impact of fatigue on different aspects of life



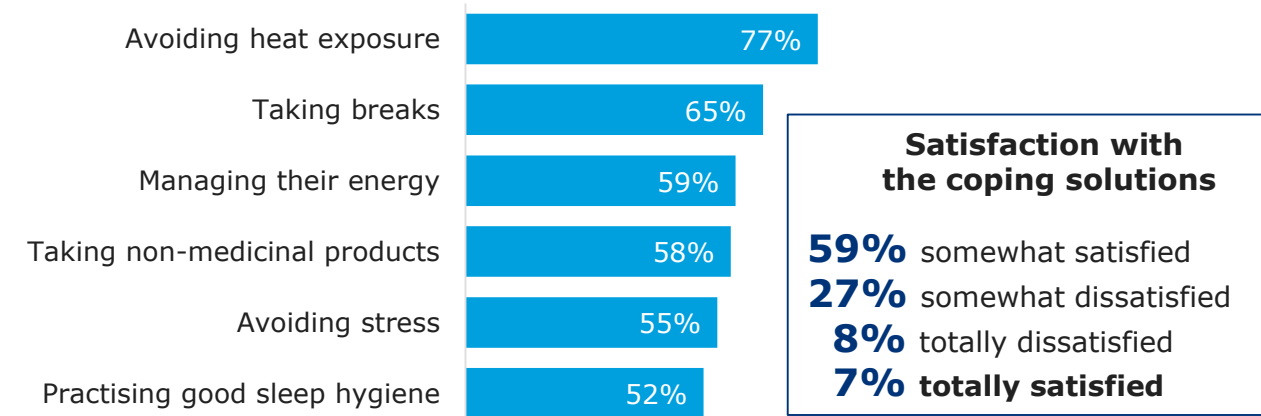
Impact of fatigue on professional life



Frequency of discussion on fatigue with neurologist



Most common solutions tried to cope with fatigue



- Fatigue had an impact on participant's ability to perform daily activities, and on professional life in general among participants who were working.
- Most participants had adaptive solutions to cope with fatigue; however, only few were totally satisfied.

QoL, quality of life

The impact of fatigue on several aspects of patient's life was rated from 0 (no impact) to 10 (very high impact).



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.

