

Measuring the symptoms and impacts of fatigue in relapsing multiple sclerosis using a novel disease specific scale

Ophélie Wilczynski¹, Eva Katz², Leigh E. Charvet³, Lauren B Krupp³, Maximilian Schuier⁴, Lindsey Lair^{5*}

¹ Carenity, Paris, France; ² Janssen Research & Development, LLC, Raritan, NJ, USA; ³ NYU Langone Health, Department of Neurology, New York, NY, USA;

⁴ Janssen Janssen-Cilag GmbH, Neuss, Germany; ⁵ Janssen Research & Development, LLC, Titusville, NJ, USA

BACKGROUND

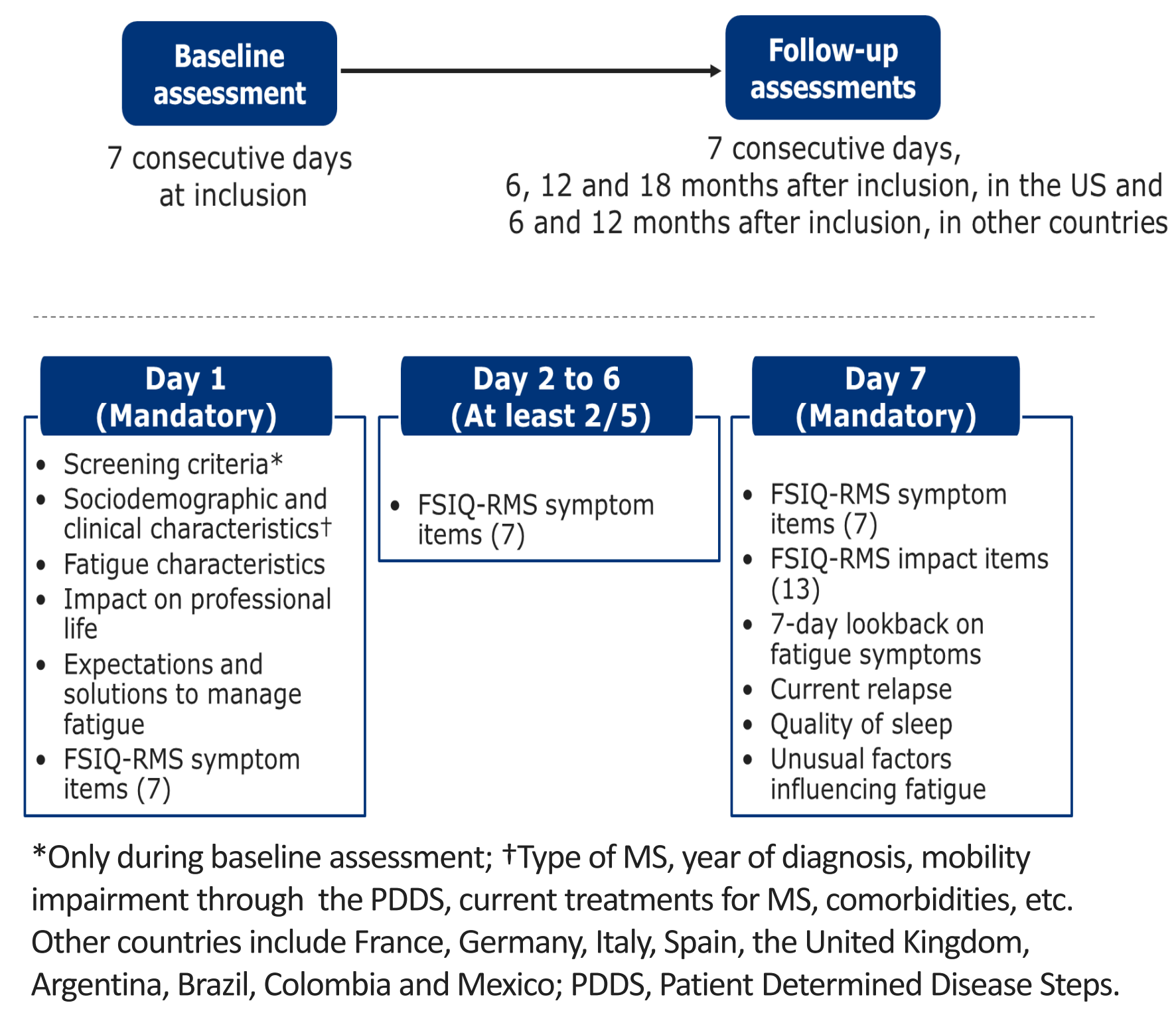
- Fatigue is among the most frequent and disabling symptoms in patients with relapsing multiple sclerosis (RMS) and a main cause of impaired health-related quality of life.¹
- Fatigue is defined by subjective experience and measured via patient reported outcome (PRO) instruments.²
- However, previously 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).



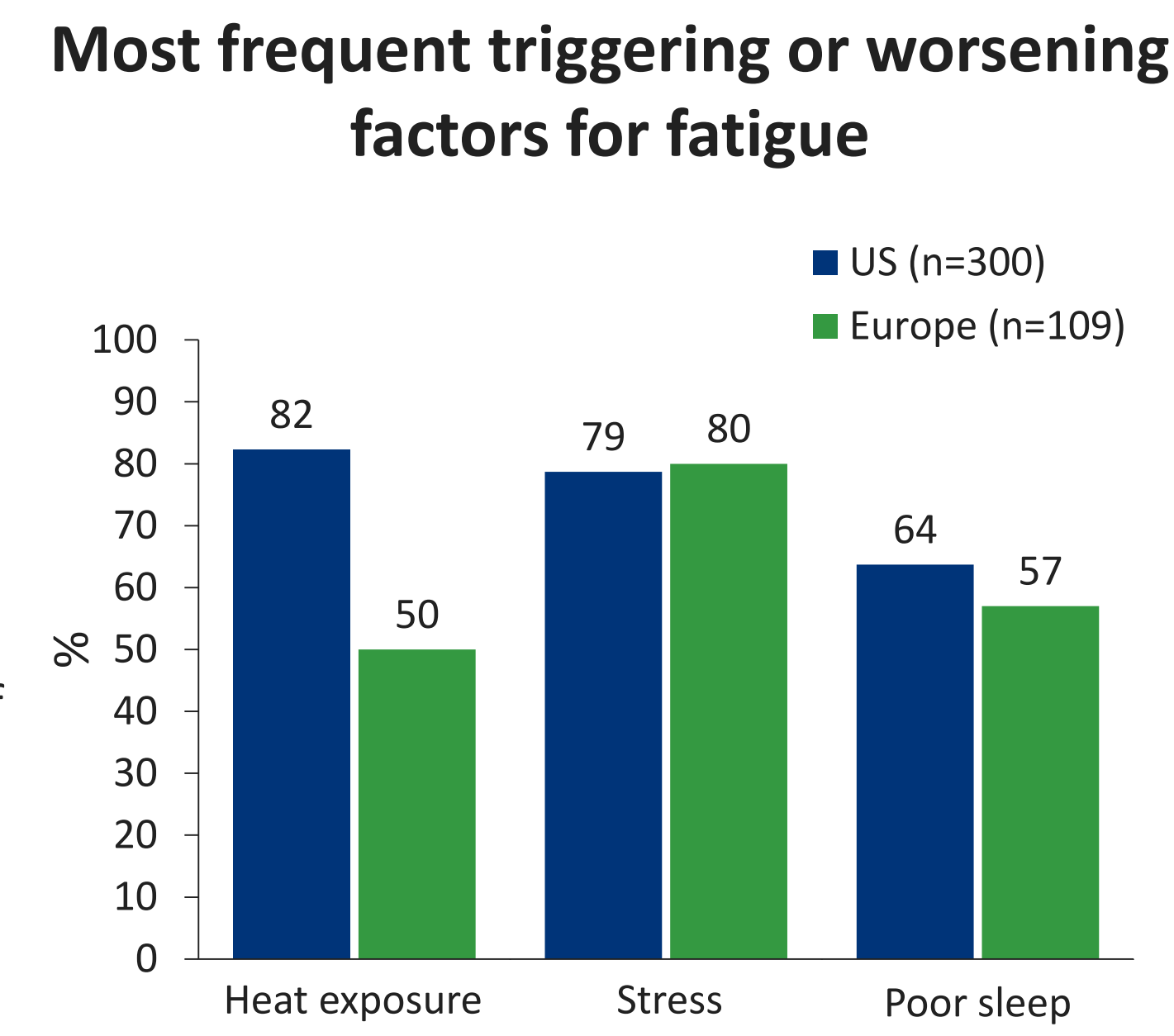
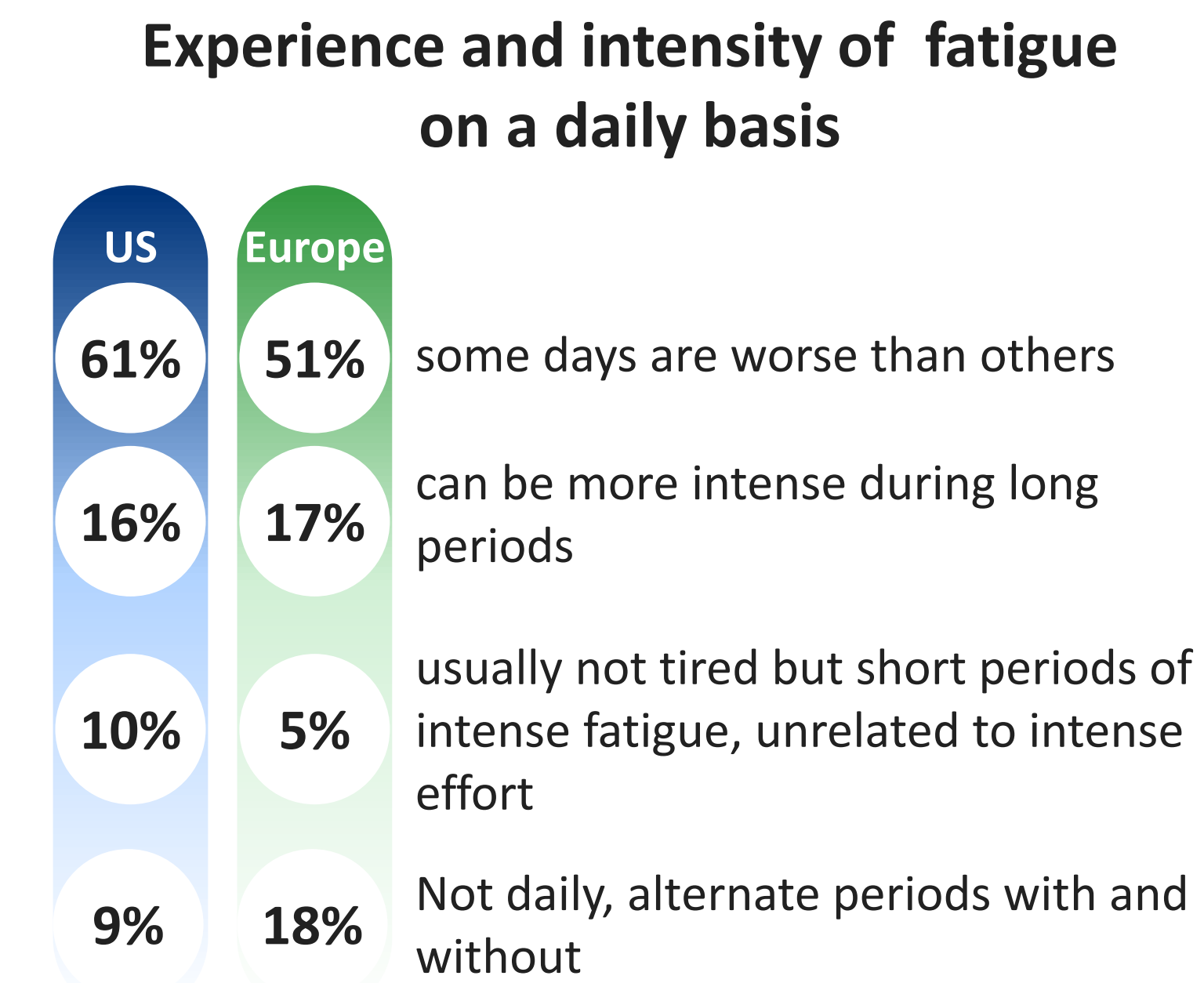
Baseline assessment data of RMS patients enrolled in the US (n=300) and Europe (UK and Italy; n=109) are presented.

RESULTS

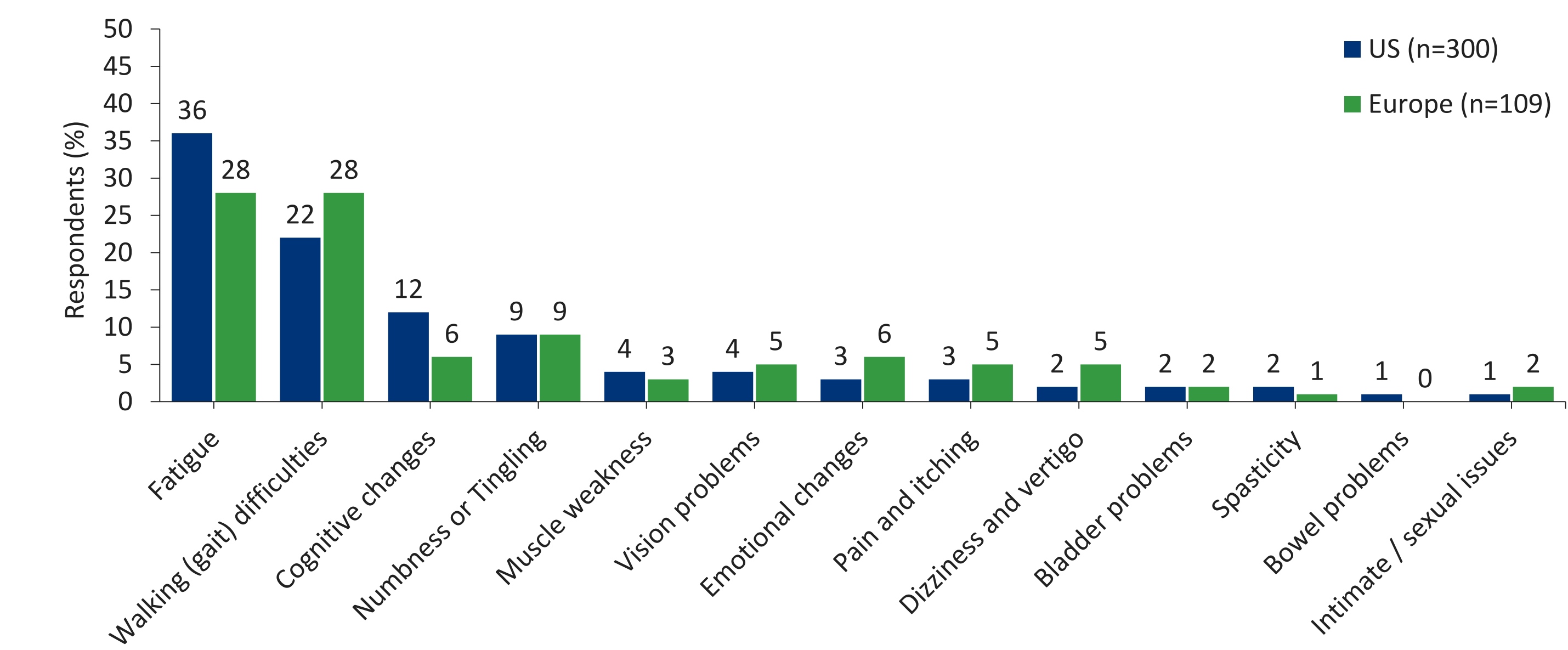
Patient and fatigue characteristics

Characteristic	US N=300	Europe N=109
Female, n (%)	264 (88.0)	93 (85.3)
Age, mean (SD), years	43.0 (7.6)	43.2 (7.1)
Age at diagnosis of MS, mean (SD), years	32.0 (8.5)	32.7 (8.7)
RMS type, n (%)		
RRMS	290 (96.7)	97 (89.0)
SPMS	9 (3.0)	12 (11.0)

Time of onset of fatigue, n (%)	US N=300	Europe N=109
Before MS diagnosis	157 (52.3)	40 (36.7)
After MS diagnosis	70 (23.3)	32 (29.4)
Don't remember	25 (8.3)	13 (11.9)
Always experienced fatigue	23 (7.7)	7 (6.4)
After a relapse	18 (6.0)	13 (11.9)
After diagnosis of another condition	5 (1.7)	2 (1.8)
Other (no fatigue)	2 (0.7)	2 (1.8)

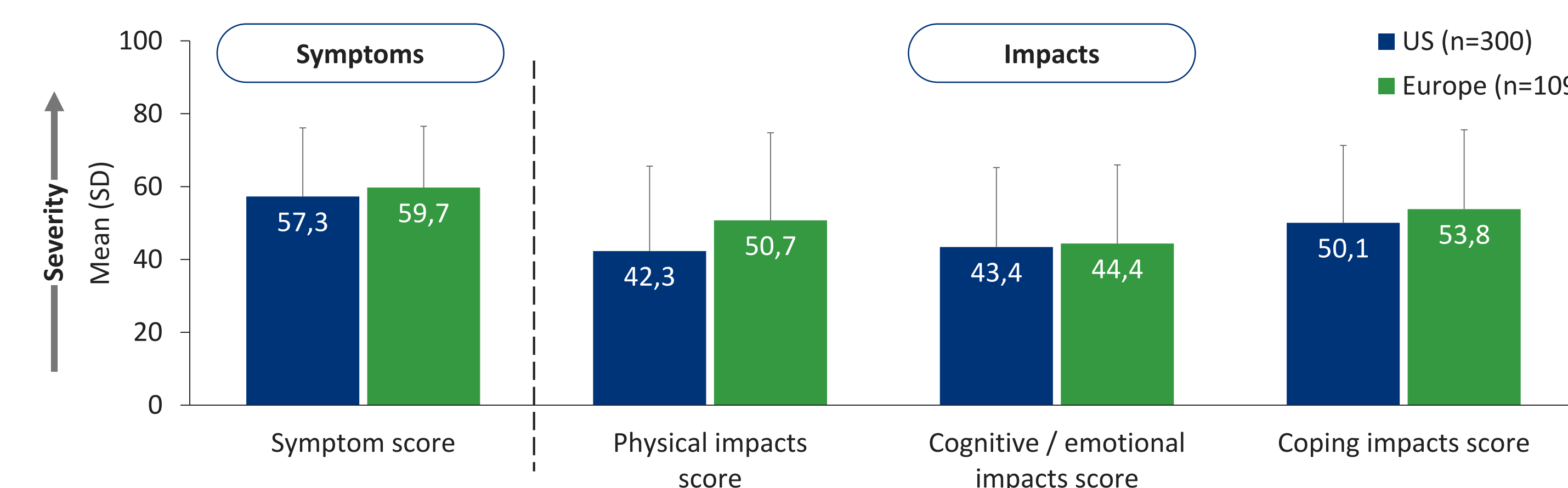


The most impactful MS-related symptoms on daily functioning



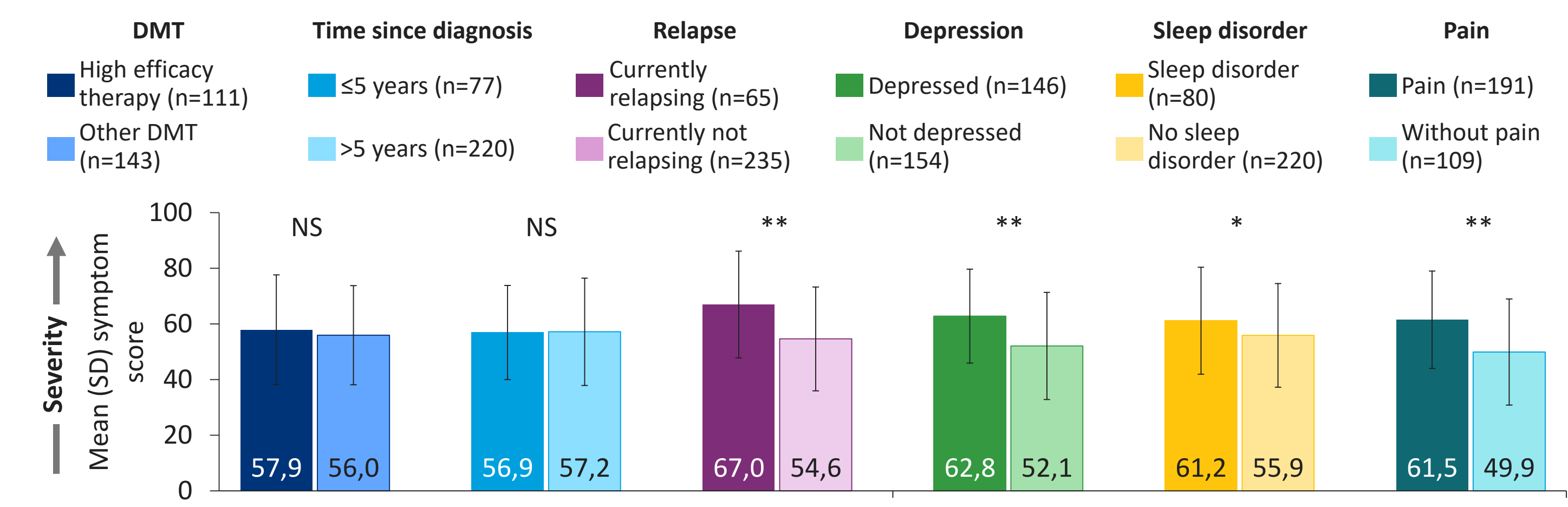
- In both US and Europe, most patients experienced fatigue daily and maximum percentage of patients experienced fatigue before MS diagnosis
- The most common triggering factor for fatigue in RMS patients in the US was heat exposure (82%) and in Europe was stress (80%)
- Fatigue was rated as the most impactful symptom on daily functioning along with gait difficulties in patients in Europe

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

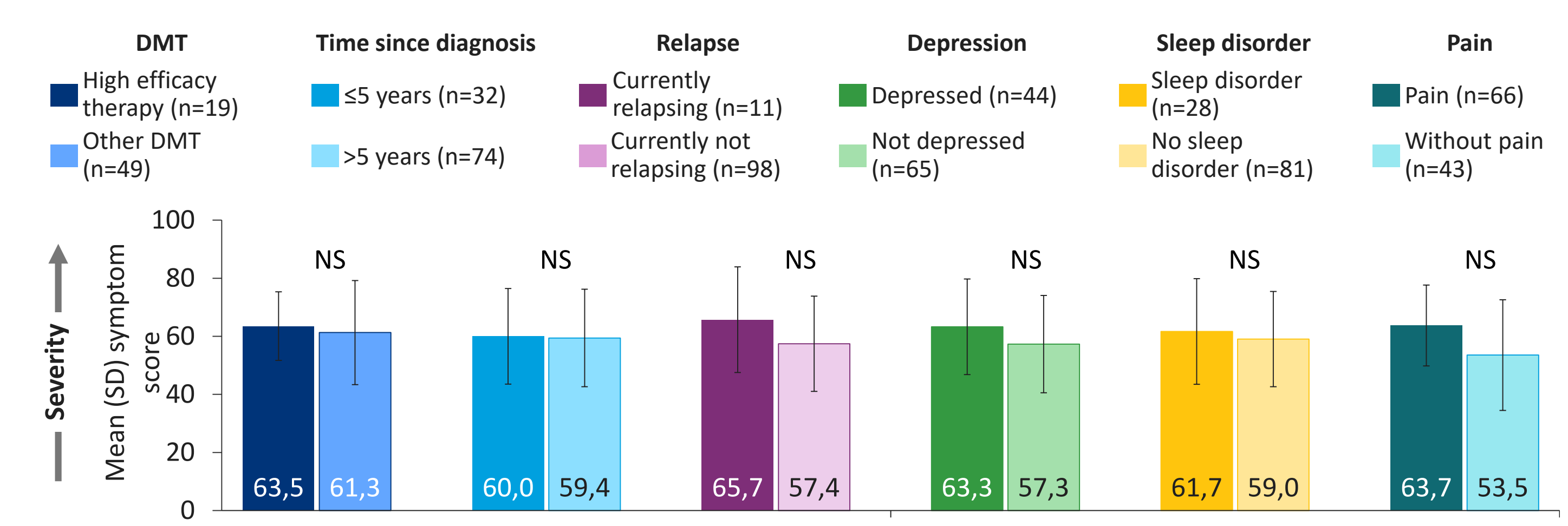


- The FSIQ-RMS captured high levels of fatigue and associated impacts at baseline across subdomains (physical, cognitive/emotional, and coping)

FSIQ-RMS – Symptoms scores by subgroups (US, n=300)



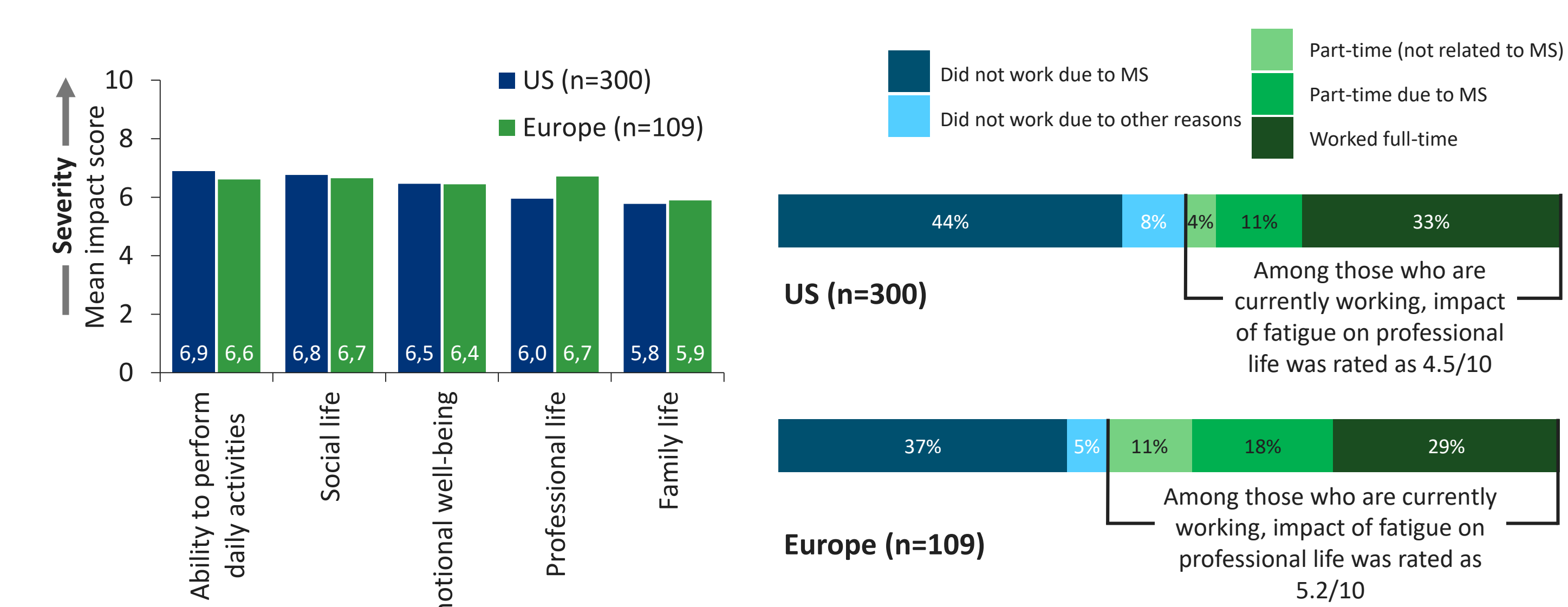
FSIQ-RMS – Symptoms scores by subgroups (Europe, n=109)



NS; not significant; ** P<0.001; *P<0.05; 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.

- Overall, fatigue severity did not vary across disease duration or DMT category
- Fatigue levels were significantly higher in the US patients, but not significant in patients in Europe, with self-reported relapse, depression, sleep disorder, and/or pain than those without

Impact of fatigue on different aspects of life



- Fatigue had an impact on participant's ability to perform daily activities, and on professional life in general among participants who were working.

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 patients with RMS across US and Europe.
- 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>

