

Further Evidence On The Validity Of The Multiple Sclerosis-Specific PROMIS® Fatigue Short Form: UK MS Register Population

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INTRODUCTION

- Health authorities (such as the US FDA) consider the assessment of symptoms and functional impacts including fatigue, activities of daily living, crucial to the assessment of disability and therapeutic benefit related to therapies in multiple sclerosis (MS) [1,2].
- Several PRO measures of fatigue are currently in use in MS; there remains a lack of consensus in the field on a publicly available instrument for use in research and clinical practice that fulfils health authority evidentiary requirements [3,4].
- The PROMIS Fatigue_{MS} [5] was identified as a potential candidate for future standardization for fatigue assessment in MS.

OBJECTIVES

- To generate further evidence on the measurement properties of the PROMIS Fatigue_{MS} short form in relapsing and progressive MS types

METHODS

- This is an ongoing longitudinal observational study based on the UK MS Register population, with a 96-week follow-up. Only the baseline and week 1 follow-up results are reported in the current poster.
- Key eligibility criteria:** clinician confirmed MS diagnosis, self-reported EDSS < 7, and age of 18 – 65 years.

Analysis

- Confirmatory factor analysis (CFA). Goodness of fit statistics.
- Score distribution. Floor and ceiling effects.
- Reliability. Internal consistency; test-retest at 1 week
- Known-groups validity. Expected differences across clinically distinct groups.
- Convergence validity. Correlations with related PRO measures

Assessment instruments

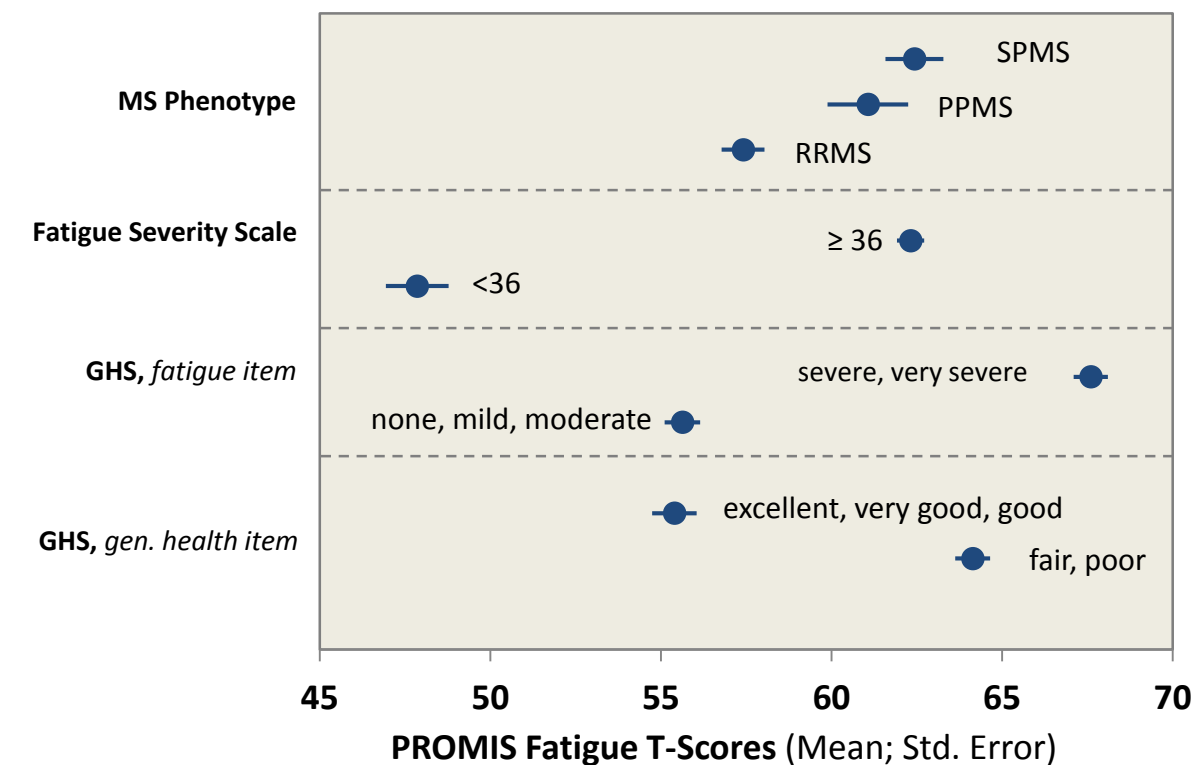
- PROMIS Fatigue_{MS} short form
- Self-reported EDSS
- PROMIS Global Health Scale (GHS)
- Fatigue Severity Scale (FSS)
- Other PRO assessments

RESULTS

Table 1. Spearman's Correlation of the PROMIS Fatigue_{MS} with related PRO measures

Measure	Spearman's rho
Self-reported EDSS	0.533**
GHS, general health	0.573**
GHS, fatigue item	0.819**
Fatigue Severity Scale	0.782**

Figure 1. PROMIS Fatigue_{MS} T-score differences across clinically-relevant subgroups



- Study participants (n = 384) had a mean age of 49.9 (SD =9.7; range = 22 to 65) years and 76% were female. The time since MS diagnosis was 10 (SD= 9) years.
- The median self-reported EDSS score was 5 (range: 0 – 6.5); 44% of the sample had self-reported EDSS of 0 – 4, and 10% had PPMS.

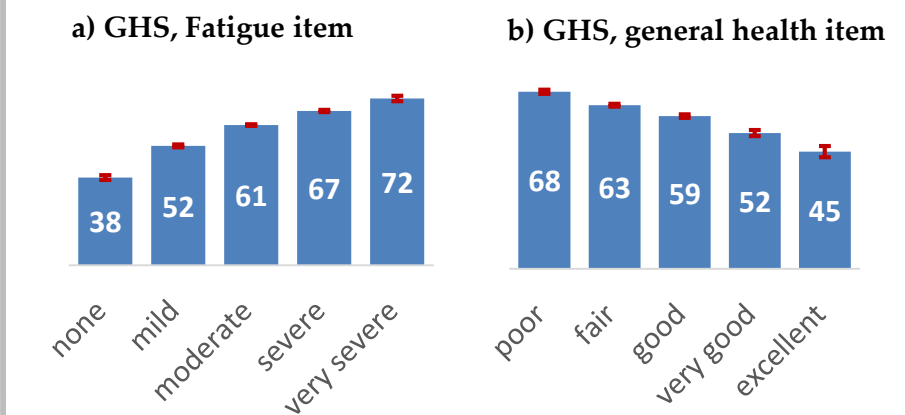
Item-level analysis

- Results of a 1-factor CFA showed optimal fit to the short form, supporting a unidimensional structure [CFI=0.99, SRMR=0.017, RMSEA=0.12; 90% CI=0.103-0.133]
- All 8-items of the short-form showed favorable properties and contributed to measurement.

Psychometric properties

- The sample had a mean PROMIS Fatigue_{MS} T-score of 58.9 ± 9.4 (range: 34.1 to 80.7); 3.4% had T-scores of ≥ 30 and < 35.
- Cronbach's α [0.96] and ICC of scores between baseline and 1-week follow-up in patients with unchanged fatigue [n = 135, ICC 0.91] showed strong reliability.
- The short form showed moderate-strong correlations with related PRO measures (Table 1).
- Score differences across clinically-distinct patient groups were consistent with a priori expectations (Figure 1, Figure 2)

Figure 2. PROMIS Fatigue_{MS} T-score across fatigue and general health states



CONCLUSIONS

- These results add to the cumulating evidence supporting the appropriateness of the PROMIS Fatigue_{MS} as a reliable and valid measure of fatigue in relapsing and progressive MS types.
- The short form offers an opportunity to improve measurement of fatigue in MS, given its optimal targeting and public availability.
- Collection of longitudinal data for further psychometric evaluation is currently ongoing.

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