

Psychometric Properties Of A New PROMIS® Physical Function Short Form For Use In Relapsing And Progressive Multiple Sclerosis Types: The PROMIS PF_{MS} Short-Form

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INTRODUCTION

- Health authorities consider the assessment of symptoms and functional impacts including fatigue, activities of daily living, crucial to appropriately evaluate disability and patient-relevant benefit for therapies in MS [2,3].
- Existing MS PRO measures have showed various limitations vis-à-vis current regulatory evidentiary standards, especially with respect to physical function [4,5].
- A new physical function short form for use in MS, based on the NIH PROMIS physical function item bank, has recently been derived [6].

OBJECTIVES

- To determine the psychometric properties of the new PROMIS PF_{MS} short form for use in relapsing and progressive forms of multiple sclerosis (MS)

METHODS

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

Analysis

- Graded response model analysis. S-χ² Chi-square statistic.
- 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 Physical Function_{MS} short-form (23 items) derived from previous phases [6]
- Self-reported EDSS
- PROMIS Global Health Scale (GHS)
- MS Impact Scale (MSIS)-29
- MS walking Scale (MSWS)-12
- Other assessments

RESULTS

Table 1. Summary of issues identified during item level analysis: 23-item PROMIS Short Form

Attribute	Items
Inter-item correlations. rho > 0.8	64 item pairs
Floor/Ceiling effects. More than 30% on lowest/highest item response score	11 items; 6 items
Local dependency. Q3 residual correlations after graded response model, greater than 0.2 – 0.3	6 item pairs

- Study participants (n = 558) had a mean age of 49.9 (SD =9.7; range = 19 to 65) years and 76% were female. The time since MS diagnosis was 10.62 (8.9) years.
- The median self-reported EDSS score was 5 (range: 0 – 6.5); 42% of the sample had self-reported EDSS of 0 – 4. 9.8% (n = 54) had PPMS.

Item-level analysis

- Item-level analysis of the initial 23 items in the PROMIS PF_{MS} uncovered various issues (Table 1).
- A panel (including PHO investigators), weighed all evidence, including additional feedback from a council of MS patients, and agreed to delete 8 items; 15 items were retained in the final version.

Psychometric properties

- The sample had a mean PROMIS PF_{MS} T-score of 38.6 ± 10.44 (range: 12.8 to 63.6); 5.9% had T-scores of > 60 and < 65.
- Cronbach's α [0.97] and ICC of scores between baseline and 1-week follow-up in patients with unchanged physical health [n = 130, ICC 0.97] supported reliability.
- The PROMIS PF_{MS} showed moderate-strong correlations with related PRO measures (rho, range: ±0.56 to ± 0.86).
- Score differences across clinically-distinct patient groups were consistent with apriori expectations (Figures 1, Figure 2)

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

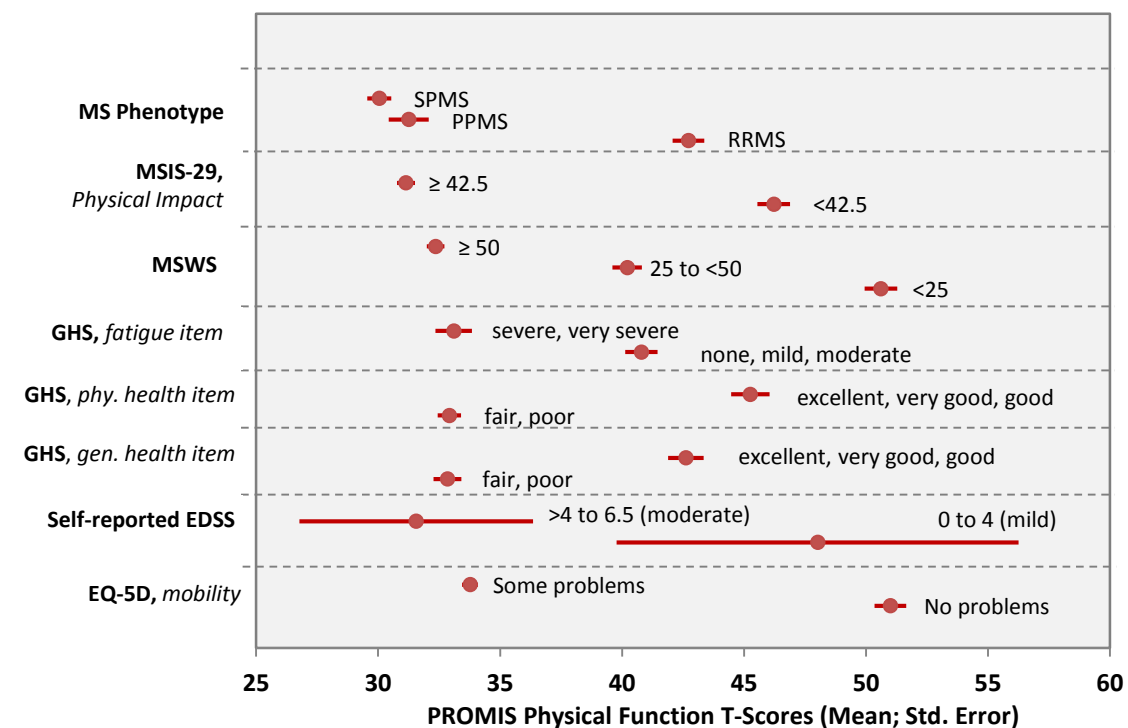
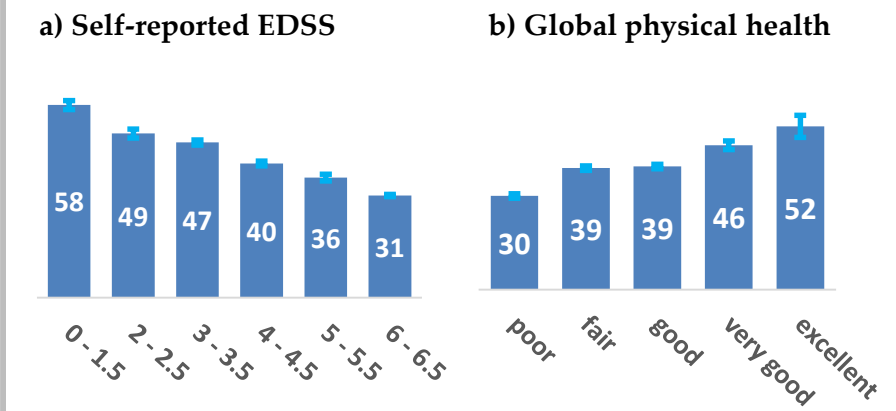


Figure 2. PROMIS PF_{MS} T-score trends across disability levels



CONCLUSIONS

- These results provide evidence supporting the reliability and validity of the PROMIS PF_{MS} short form in relapsing and progressive MS types.
- The PROMIS PF_{MS} offers an opportunity to improve measurement of physical function in MS, given its optimal targeting of PF ranges relevant in MS.
- Collection of longitudinal data for further psychometric evaluation is currently ongoing.

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