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# Correlations Between Patient-Reported and Clinical Outcomes in Patients With Multiple Sclerosis in the MS-LINK Outcomes Study Cohort

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## CONCLUSIONS

- The MS-LINK Outcomes Study uses a unique, decentralized approach for gathering data about the real-life experiences of people with MS
- This baseline analysis found correlations of varying strengths between PROs and clinical measures
  - Low correlation strengths demonstrate a disconnect between clinical measures and patients' lived experiences
- These findings are a valuable starting point in understanding the magnitude and significance of correlations between PROs and clinical measures in MS
- The longitudinal nature of the Outcomes Study will facilitate future investigations into the changes in these values over time and allow providers to assess the clinical impact of incorporating PROs into their standard of care

## BACKGROUND

- PROs can provide valuable insights into MS disease progression and treatment by capturing the patient's perspective
- PROs can also be assessed frequently and outside of regular clinic visits, providing distinct advantages over traditional clinical measures, which are generally administered annually
- However, these measures are currently underutilized, which has led to an incomplete understanding of patients' true experience of MS
- The overall goals of the MS-LINK Outcomes Study are to:
  - Create a comprehensive registry of MS patient data
  - Examine PROs in diverse subpopulations of people with MS
  - Correlate PROs with functional and clinical outcomes
  - Gather data to guide future substudy design

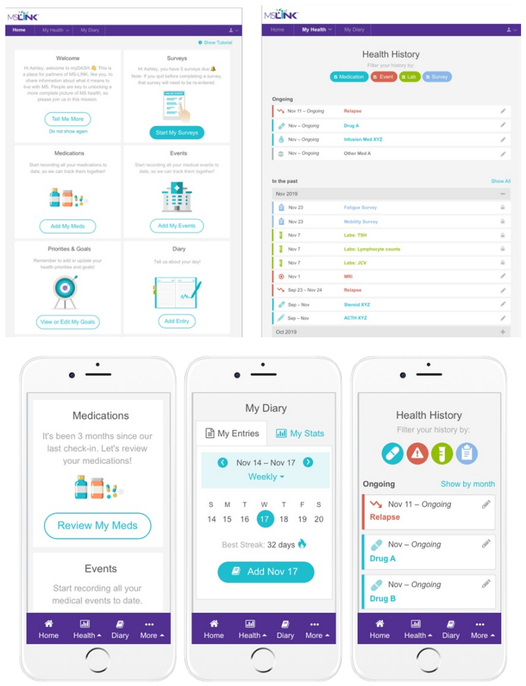
## OBJECTIVES

- To examine relationships between PROs and clinical measures in order to facilitate their interpretation and utility in the context of provider-reported outcomes and healthcare resource utilization

## METHODS

- The MS-LINK Outcomes Study is a prospective, longitudinal, multicenter observational study that digitally collects the PROs, clinical outcomes, demographics, and medical histories of patients with MS (**Figure 1**)
  - Digital, decentralized data collection is intended to build comprehensive data on different aspects of patient experiences both at, and outside of, specific points of care
- The overall study aims to enroll ≥2000 patients from 8 to 10 sites in North America
  - Study sites are encouraged to recruit and enroll all eligible and interested patients in their practice
- Participants will be followed for 3 years
- The following PROs will be collected at study entry (baseline) and periodically during follow-up:
  - PROMIS Fatigue MS
  - PROMIS Physical Function MS
  - PROMIS Anxiety
  - PROMIS Cognitive Function
  - PDDS
  - PHQ9
  - Wasson Health Confidence Scale
  - HRQoL
  - WPAI-MS
  - MSTAQ
- Information about MS relapses and healthcare resource utilization (e.g., hospitalizations, emergency room visits) will also be collected

**Figure 1. The digital data collection portal**




- This investigation examines potential correlations between baseline values for four of the PROs and four common clinical measures

**PROs**

- PROMIS Fatigue
- PROMIS Physical Function
- PROMIS Anxiety
- PROMIS Cognitive Function

**Clinical measures**

- EDSS
- 9-HPT
- T25-FW
- SDMT

- PROs are collected through the digital data collection portal on a staggered schedule
  - PROMIS Fatigue – baseline and months 7, 13, 19, 25, and 31
  - PROMIS Physical Function – baseline and months 7, 13, 19, 25, and 31
  - PROMIS Anxiety – baseline and months 8, 14, 20, 26, and 32
  - PROMIS Cognitive Function – baseline and months 6, 12, 18, 24, 30, and 36
- Clinical measures are collected and updated from electronic medical records or reported by providers
- Spearman rank-order correlation coefficient (Spearman's rho) was used to assess correlations
  - Values of 0.1–0.3 are generally considered to indicate a weak correlation; 0.4–0.6 indicate a moderate correlation; and 0.7–0.9 indicate a strong correlation
  - No adjustments were made for multiplicity

## RESULTS

- As of July 2023, we report on baseline data from 1622 participants (**Table 1**)
- The mean age of the cohort is 50.8 years and 80.3% are female
- The study population is diverse with regard to race and ethnicity, with approximately 21% of patients self-reporting as *non-white* and 16% self-reporting as *Hispanic* or *other ethnicity*
- Approximately 47% of the sample were employed for wages or self-employed

**Table 1. Key sociodemographic characteristics of MS Outcomes Study participants (n = 1622)**

| Characteristic | |
|---|---|
| **Age, years** | |
| Mean (SD) | 50.8 (11.9) |
| **Sex at birth, n (%)** | |
| Female | 1302 (80.3) |
| Male | 320 (19.7) |
| **Race, n (%)** | |
| White or Caucasian | 1076 (66.3) |
| Black or African American | 268 (16.5) |
| Asian | 11 (0.7) |
| American Indian or Alaska Native | 12 (0.7) |
| Native Hawaiian or Other Pacific Islander | 2 (0.1) |
| Two or more races | 50 (3.1) |
| *No response* | *203 (12.5)* |
| **Ethnicity, n (%)** | |
| Not Hispanic | 1124 (69.3) |
| Hispanic | 56 (3.5) |
| Other | 204 (12.6) |
| Do not wish to disclose | 34 (2.1) |
| *No response* | *204 (12.6)* |
| **Employment status, n (%)** | |
| Employed for wages | 675 (41.6) |
| Self-employed | 102 (6.3) |
| Homemaker | 89 (5.5) |
| Military | 2 (0.1) |
| Student | 9 (0.6) |
| Out of work and looking for work | 33 (2.0) |
| Out of work but not currently looking for work | 36 (2.2) |
| Retired | 221 (13.6) |
| Unable to work | 249 (15.4) |
| *No response* | *206 (12.7)* |

- Using Spearman's rho, significant correlations were identified between most PROs and clinical measures (**Table 2**)
- EDSS scores were not correlated with either PROMIS anxiety or PROMIS cognitive function scores, but were correlated with PROMIS fatigue and PROMIS physical function

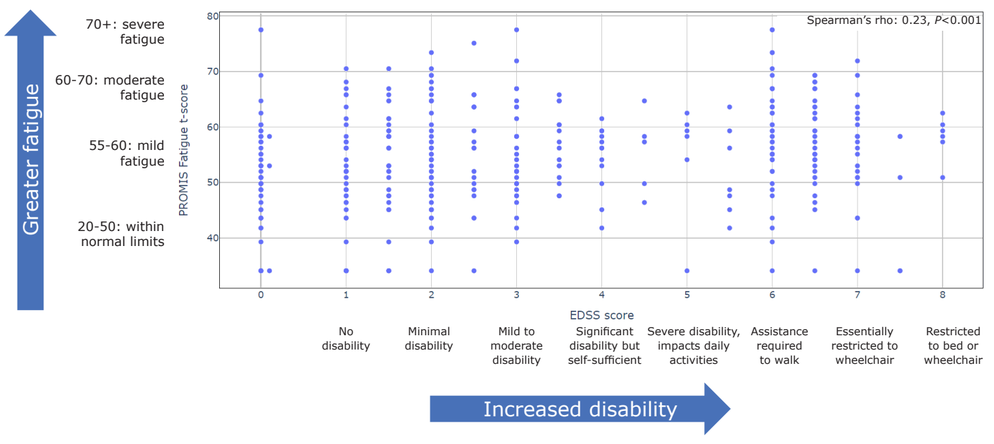
## RESULTS

**Table 2. Correlations between PROs and clinical measures**

| PRO and clinical measure | n | Spearman's rho | *P* value |
|---|---|---|---|
| **PROMIS fatigue and** | | | |
| EDSS | 397 | 0.23 | <0.001* |
| 9-HPT – left | 811 | 0.33 | <0.001* |
| 9-HPT – right | 814 | 0.28 | <0.001* |
| T25-FW | 1057 | 0.35 | <0.001* |
| SDMT | 876 | -0.28 | <0.001* |
| **PROMIS physical function and** | | | |
| EDSS | 394 | -0.74 | <0.001* |
| 9-HPT – left | 811 | -0.54 | <0.001* |
| 9-HPT – right | 814 | -0.50 | <0.001* |
| T25-FW | 1044 | -0.61 | <0.001* |
| SDMT | 864 | 0.42 | <0.001* |
| **PROMIS anxiety and** | | | |
| EDSS | 394 | -0.056 | 0.27 |
| 9-HPT – left | 809 | 0.12 | <0.001* |
| 9-HPT – right | 812 | 0.13 | <0.001* |
| T25-FW | 1059 | 0.11 | <0.001* |
| SDMT | 882 | -0.12 | <0.001* |
| **PROMIS cognitive function and** | | | |
| EDSS | 395 | -0.065 | 0.2 |
| 9-HPT – left | 812 | -0.20 | <0.001* |
| 9-HPT – right | 815 | -0.18 | <0.001* |
| T25-FW | 1050 | -0.25 | <0.001* |
| SDMT | 870 | 0.27 | <0.001* |

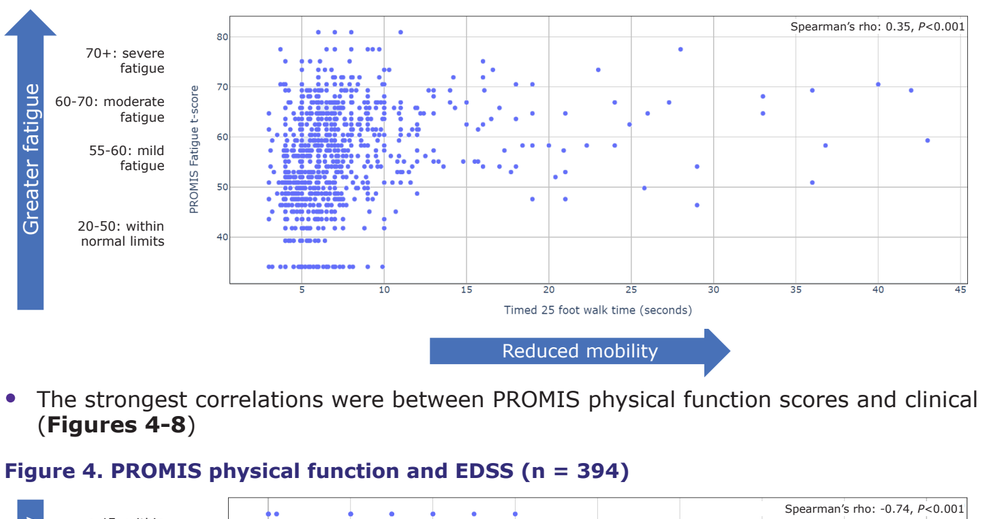
- The strongest correlations were observed between PROMIS physical function and clinical measures; overall, the strongest correlation observed (Spearman's rho 0.23) was between PROMIS physical function and EDSS scores
  - Strong correlations between patient- and clinician-reported outcomes further support and validate these measures. Long-term follow up will provide more insight into the relationship between physical function as reported by patients and as measured by clinicians
- EDSS was only weakly correlated with patient-reported fatigue (**Figure 2**)

**Figure 2. PROMIS fatigue and EDSS (n = 397)**




- The relationship between patient-reported fatigue and the T25-FW was similar (**Figure 3**)

**Figure 3. PROMIS fatigue and Timed 25-foot walk (n = 1057)**




- The strongest correlations were between PROMIS physical function scores and clinical measures (**Figures 4-8**)

**Figure 4. PROMIS physical function and EDSS (n = 394)**

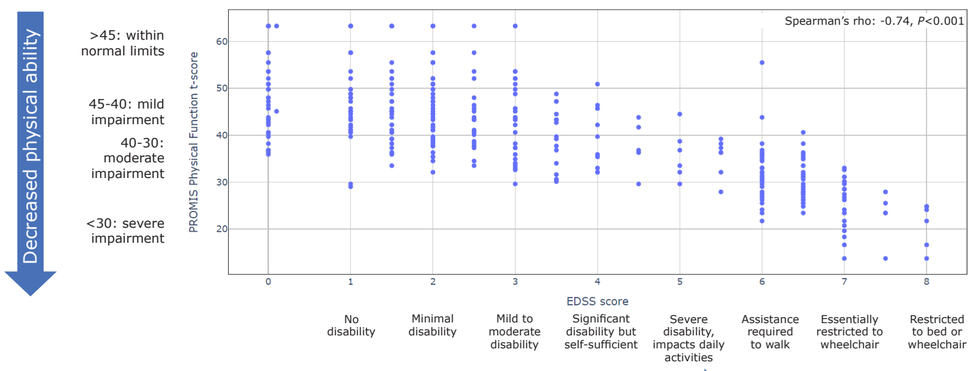



**Figure 5. PROMIS physical function and 9-Hole Pegboard Dexterity Test, left hand (n = 811)**

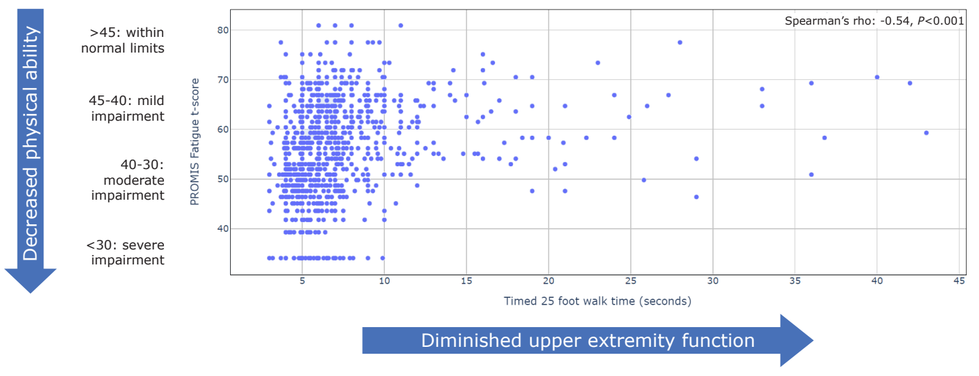



**Figure 6. PROMIS physical function and 9-Hole Pegboard Dexterity Test, right hand (n = 814)**

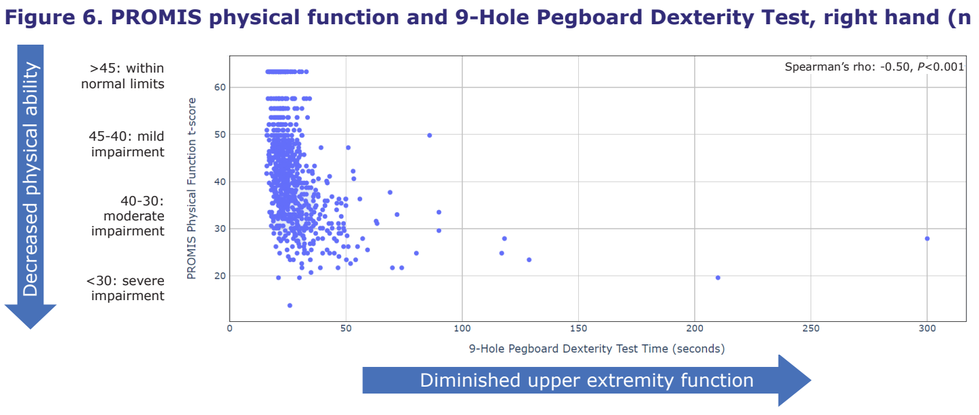



**Figure 7. PROMIS physical function and Timed 25-foot walk (n = 1044)**

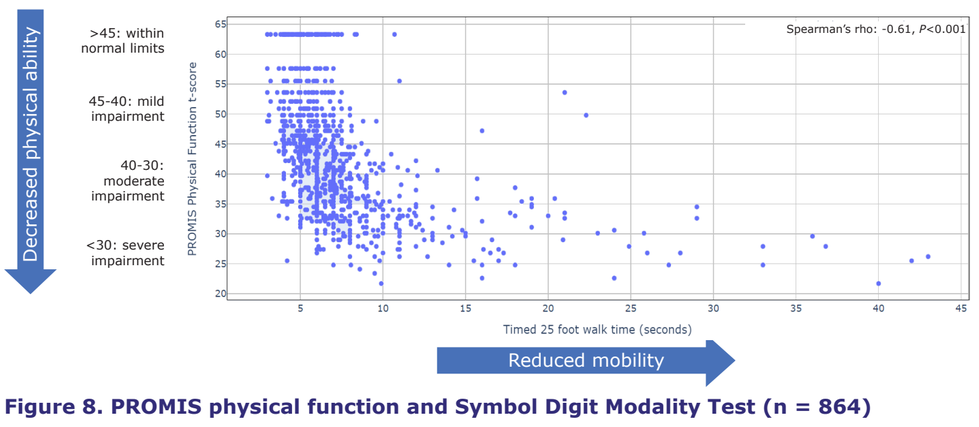
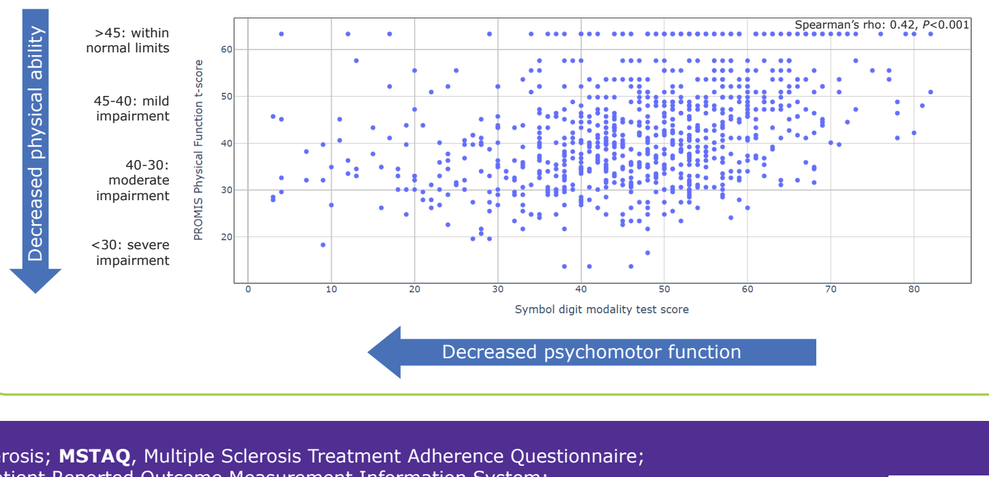



**Figure 8. PROMIS physical function and Symbol Digit Modality Test (n = 864)**




**Abbreviations: 9-HPT**, 9-hole peg test; **EDSS**, Expanded Disability Status Scale; **HRQoL**, health-related quality of life; **MS**, multiple sclerosis; **MSTAQ**, Multiple Sclerosis Treatment Adherence Questionnaire; **PDDS**, Patient Determined Disease Steps; **PHQ9**, Patient Health Questionnaire, Question 9; **PRO**, patient-reported outcome; **PROMIS**, Patient Reported Outcome Measurement Information System; **SDMT**, Symbol Digit Modalities Test; **T25-FW**, Timed 25-Foot Walk; **WPAI-MS**, Work Productivity and Activity Impairment Questionnaire.

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