Reducing survey burden: Feasibility and validity of PROMIS for multiple sclerosis

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The authors have nothing to disclose.
Overview

- Patient-reported outcomes
  - Benefits
  - Challenges

- PROMIS
  - What is it

- Feasibility and Validity of PROMIS for use with MS
Patient-reported Outcomes

- **Patient-Reported Outcome (PRO):** any report coming directly from a patient about how they function or feel in relation to their health, without interpretation by a clinician, or anyone else.
Why include PROs in Clinical Research?

- PROs measure treatment benefit according to patient perspective.

**Traditional clinical outcomes:**
- Biomarkers
- Disease status
- Events
- Survival

**Patient-reported outcomes:**
- Symptoms
- Functional capacity
- Adherence to/satisfaction with tx
- Quality of life
- Quality of care
- Utility
Challenges

- Time to administer and score
- Managing missing data
- Time to complete: participant survey burden
- Many different measures for the same construct
- Validation – variable quality of measures in use
- Comparability difficult across studies and across patient populations
What is PROMIS?

Patient Reported Outcome Measurement Information System

Revised PROMIS Domain Frameworks
The PROMIS domain framework has been revised to group domains by Adult Self-Reported Health and Pediatric Self-/Proxy-Reported Health.

More...

Researchers
Provides efficient, reliable, and valid assessments of adult and child (pediatric) self-reported health

- Common Questions About PROMIS and Its Instruments
- PROMIS Instruments, Selected References
- PROMIS In Research

Clinicians
Provides data about the effect of therapy that cannot be found in traditional clinical measures

- Common Questions About PROMIS and Its Instruments
- PROMIS for Clinicians
- Select Publications
- Computer Adaptive Test (CAT)

Patients
Measures what you are able to do and how you feel

- More on PROMIS
- What Patient Reported Outcomes (PROs) Are
- PROMIS Measures
PROMIS Conceptual Framework

**Global Health**

- **Mental Health**
  - Anxiety
  - Depression
  - Anger
  - Positive Affect

- **Physical Health**
  - Pain
  - Fatigue
  - Physical function
  - Sexual function

- **Social Health**
  - Social roles
  - Illness impact
  - Alcohol use
  - Support
Types of PROMIS Assessments

- Different types of PROMIS Assessments:
  - Static short forms (4, 6, or 8 questions)
  - Computerized adaptive tests (CAT)
  - Customizable forms

- All pull from the same item bank so each produces a standardized score on the same scale.
Scoring

- CAT scores are automatically converted to a T score
  - Referenced to the general US Population (mean 50, SD 10)
- Scores can be compared to age/gender specific categories
Exploratory Aim

- To evaluate the correlation of PROMIS CAT surveys and Legacy scales commonly used in MS research for Depression, Anxiety, Fatigue, Pain, and Physical Function.
Methods: Study Design: Cross-sectional

- **Participants:** 150 MS subjects between 18-90 years old
- **Recruitment:** OHSU and greater Portland metropolitan area.
- **Inclusion criteria:** 18 – 90 years old, read and write in English, diagnosis of MS by 2011 McDonald criteria.
- **Exclusion criteria:** Relapse within the previous 3 months.
Outcomes

- **Legacy Scales:**
  - Beck Depression Inventory I
  - State Trait Anxiety Inventory
  - Modified Fatigue Impact Scale
  - Pain Effects Scale
  - SF-36 Physical Function Subscale

- **PROMIS CAT v1.0 Scales:**
  - Depression
  - Anxiety
  - Fatigue
  - Pain Interference
  - Physical function
Study Flow

Assessed for eligibility (n=214)

Excluded (n=64)
- Declined participation (n=23)
- Did not meet inclusion criteria (n=20)
- Scheduling conflicts (n=13)
- No shows (n=7)
- Consented but died prior to study visit (n=1)

Completed study visit (n=150)

Excluded from analyses (n=4)
- Unable to confirm MS diagnosis (n=3)
- Protocol deviation, relapse within 3 months (n=1)

Included in final analysis (n=146)
<table>
<thead>
<tr>
<th></th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years, std)</strong></td>
<td>51.16 ± 12.76</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>113 (77)</td>
</tr>
<tr>
<td><strong>Using Disease Modifying Therapy</strong>*</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>99 (68)</td>
</tr>
<tr>
<td>No</td>
<td>47 (32)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>HS Diploma</td>
<td>55 (38)</td>
</tr>
<tr>
<td>College Grad</td>
<td>91 (62)</td>
</tr>
<tr>
<td><strong>Type of MS</strong></td>
<td></td>
</tr>
<tr>
<td>Relapsing Remitting</td>
<td>104 (71)</td>
</tr>
<tr>
<td>Secondary Progressive</td>
<td>27 (19)</td>
</tr>
<tr>
<td>Primary Progressive</td>
<td>15 (10)</td>
</tr>
<tr>
<td><strong>Disability</strong></td>
<td></td>
</tr>
<tr>
<td>None - Mild</td>
<td>67 (46)</td>
</tr>
<tr>
<td>Moderate</td>
<td>35 (24)</td>
</tr>
<tr>
<td>Support needed</td>
<td>37 (25)</td>
</tr>
<tr>
<td>Unable to walk</td>
<td>7 (5)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>133 (91)</td>
</tr>
<tr>
<td>Other</td>
<td>13 (9)</td>
</tr>
</tbody>
</table>

*DMTs used by participants included: glatiramer acetate, interferon-1b, interferon-1a, natalizumab, and fingolimod.
Feasibility

Mode of Administration

Missing data

Data management

Administration Time
<table>
<thead>
<tr>
<th>Trait</th>
<th>No. of Questions Avg</th>
<th>Time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>143</td>
<td>21</td>
</tr>
<tr>
<td>Anxiety</td>
<td>144</td>
<td>35</td>
</tr>
<tr>
<td>Fatigue</td>
<td>152</td>
<td>42</td>
</tr>
<tr>
<td>Pain</td>
<td>81</td>
<td>67</td>
</tr>
<tr>
<td>Physical</td>
<td>102</td>
<td>39</td>
</tr>
</tbody>
</table>

*Average time to complete legacy scales is estimated at a rate of 4 questions per minute.*
Feasibility: (Average) Time to Complete Surveys

- Dep: 250 seconds
- Anx: 200 seconds
- Fat: 300 seconds
- Pain: 150 seconds
- Phys: 100 seconds

Legend:
- Legacy
- PROMIS
1. Strong correlations between PROMIS CATs and corresponding legacy scales are evidence of **convergent validity**.
2. Bolded coefficients are higher than correlations in their row and column 87.5% of the time ($p<.05$), evidence of **discriminant validity**.
3. Confirmatory factor analysis verified results of the multitrait-multimethod analysis and returned a chi-squared statistic of $\chi^2(25)=43.22$, $p=0.013$; with a Goodness-of-fit index of 0.940 and RMSEA index of 0.074.
We found generally strong evidence for construct validity of PROMIS and found it feasible and easy to use in MS.

Several aspects of PROMIS CATs outweighed the use of legacy scales, including:

- Free, easy access for researchers and clinicians
- Fewer questions asked of participants and less time to complete
- Prompt, automatic scoring
- Dramatically reduced missing data
- Comparable across studies and populations
Acknowledgments

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• OHSU MS Center of Oregon
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References


Resources

- nihpromis.org
- assessmentcenter.net