PROMIS® Outcome Measures for Yoga Research

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Disclaimer: I have no conflicts of interest to report.
Objectives

At the conclusion of this presentation, participants will be able:

- To describe electronic PRO systems such as the Patient-Reported Outcome Measurement Information System (PROMIS)

- To discuss the incorporation of patient reported outcomes (PRO) in yoga therapy
Background

Yoga Therapy in the community

- Cross-sectional survey of 1,000+ IYNAUS teachers
- 100% (n = 471) report modifying poses for injuries, health conditions, or symptoms
- 57.3% do not keep any records/assessments except attendance
- 84% assess effectiveness by “asking students”
- <2% utilize a standardized/validated questionnaire to assess effectiveness
What is a standardized/validated Patient Reported Outcome (PRO) measure?

Validity and Reliability
Why is it important to assess PROs

• Providers underestimate symptoms and overestimate function & quality of life
• Quantify change - worse, getting better, or staying about the same?
• Patients want to know how others feel while taking a new therapy.

"I can't help you unless you're more specific.  
Now are you feeling 'yucky' or are you feeling 'icky'?"
Traditional Challenges Of Questionnaires

- Multiple measures of same health concept
- Quality varies
- Difficult to compare and combine data
  - across studies
  - across conditions
- Long and Complex
  - Collecting, Storing and Scoring
- Limited use for practitioners in the real world

In September 2004, the NIH initiated a multicenter cooperative group to develop a number of measurement initiatives including:

- NIH toolbox
- Neuro-QOL
- PROMIS

Goal: To develop psychometrically sound measures that:

- Are available at low or no cost.
- Utilized modern test development theory to develop measures
- Improved measurement quality and precision
Psycho-metric Testing

Item Bank
(Items reviewed, analyzed, and refined)

Short Form Instruments

CAT

Domain Framework: Adult

PROMIS Adult Self-Reported Health

Physical Health:
- Physical Function
- Pain Intensity
- Pain Interference
- Fatigue
- Sleep Disturbance

Mental Health:
- Depression
- Anxiety

Social Health:
- Ability to Participate in Social Roles & Activities

PROMIS Profile Domains
- Pain Behavior
- Pain Quality
- Sleep-related Impairment
- Sexual Function
- Gastro-Intestinal Symptoms
- Dyspnea

PROMIS Additional Domains
- Anger
- Cognitive Function
- Alcohol Use, Consequences, & Expectancies
- Psychosocial Illness Impact
- Self-efficacy
- Smoking

Satisfaction with Social Roles & Activities
- Social Support
- Social Isolation
- Companionship

03/28/2014
Value of PROMIS®: Comparability

PROMIS Fatigue Across Five Clinical Conditions

- N = 310: Cancer w/ benefit (2 mos) vs. Cancer Chemo (B)
- N = 229: Back Pain (3 mos) vs. Back Pain (1 mos) vs. Back Pain (B)
- N = 114: Depression (3 mos) vs. Depression (1 mos) vs. Depression (B)
- N = 64: HF Post-transplant vs. HF Pre-transplant
- N = 125: COPD Stable (B) vs. COPD Exacerbation (E)

Average for General Population
PROMIS®: Brief, flexible, inclusive & free

**Short Form: Emotional Distress – Depression**

<table>
<thead>
<tr>
<th>In the past 7 days...</th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 I felt worthless</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 I felt helpless</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 I felt depressed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 I felt hopeless</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 I felt like a failure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Short Form: Fatigue**

<table>
<thead>
<tr>
<th>During the past 7 days...</th>
<th>Not at all</th>
<th>A little bit</th>
<th>Somewhat</th>
<th>Quite a bit</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 I feel fatigued</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 I have trouble starting things because I am tired</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>In the past 7 days...</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 How run-down did you feel on average? ...</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 How fatigued were you on average? ...</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
http://www.nihpromis.org/
Software

PROMIS through the Assessment Center provides online research management tools supporting researchers' use of PROMIS measures.
WHAT IS ASSESSMENT CENTER™

Assessment Center™ is a free, online data collection tool that enables researchers to create study-specific websites for capturing participant data securely online.

Studies can include measures within the Assessment Center library as well as custom instruments entered by the researcher. The instrument library includes self- and proxy-report short forms, computerized adaptive tests (CATs), and batteries or profiles from:

- Patient-Reported Outcomes Measurement Information System (PROMIS)
- Quality of Life in Neurological Diseases (Neuro-QOL)
- NIH Toolbox

Among other important features, Assessment Center also enables:

- Downloading library instruments for administration on paper
- Customization of items or instruments (e.g., format, randomization, skip patterns)
- Real-time scoring of CATs and short forms
- Storage of protected health information (PHI) in a separate, secure database
- Automated accrual reports
- Real-time data export
- Ability to capture endorsement of online consent forms

ANNOUNCEMENTS

Assessment Center Release 9.9

- Neuro-QOL v2.0 PDFs now available: Neuro-QOL version 2 instrument changes include the creation of a single Cognitive Function item bank comprised of items measuring executive function and general cognition as well as recalibrated pediatric fatigue and cognitive function item banks.
- Updated versions of select Toolbox Instruments within the Emotion Battery: some Toolbox Instruments have had minor modifications (typically removal of 1-2 items).
- Slides along with questions/answers from the June 2014 webinar on Person-Centered Outcomes remains available under Presentations.

http://www.assessmentcenter.net/
Instruments Available for Use in Assessment
July 15, 2013

The Assessment Center Instrument Library includes instruments from PROMIS, Neuro-QOL, and others, and instruments are available for use in data collection through Assessment Center. Most instruments are available as PDFs that can be used for paper/pencil data collection or to facilitate data collection in other applications.

1. Register in Assessment Center (www.assessmentcenter.net)
2. Login
3. Click on the PDF hyperlink in the upper right corner of the application
4. Agree to the Terms and Conditions of Use and download the instruments of interest

PROMIS

PROMIS has many assessment options available to measure self-reported health for clinical research. PROMIS assessment instruments are drawn primarily from calibrated item banks (sets of well-developed items) measuring concepts such as pain, fatigue, physical function, depression, and social function. Item banks can be used to derive short forms (typically requiring 4-10 items per concept), or complex tests (CAT; typically requiring 4-7 items per concept for more precise measurement). PROMIS allows for the creation of item pools, child self-report, child proxy report, and parent proxy report for his/her child.

Table 1 through 4 list the calibrated PROMIS item banks or scales, item pools, short forms, and calibrated items from which a summary score can be obtained from a subset of items (i.e. via CAT), whereas scales are calibrated items from which a summary score should be obtained. Item pools are collections of related items that are not intended to produce scores unless used as single items. Short forms are static subsets of item banks, and profiles measuring multiple concepts. Table 6 lists PROMIS instruments currently under development.

Table 1: PROMIS Instruments Available in Assessment Center (www.assessmentcenter.net)

<table>
<thead>
<tr>
<th>Domain</th>
<th>Adult # Items</th>
<th>Pediatric # Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional Distress – Anger</td>
<td>22</td>
<td>8</td>
</tr>
<tr>
<td>Emotional Distress – Anxiety</td>
<td>29</td>
<td>4, 6, 7, 8, 13</td>
</tr>
<tr>
<td>PROMIS-Cancer – Anxiety</td>
<td>22</td>
<td>8</td>
</tr>
<tr>
<td>Emotional Distress – Depression</td>
<td>26</td>
<td>4, 6, 8, 8b, 13</td>
</tr>
<tr>
<td>PROMIS-Cancer – Depression</td>
<td>30</td>
<td>13</td>
</tr>
<tr>
<td>Applied Cognition – Abilities</td>
<td>33</td>
<td>4, 6, 8</td>
</tr>
<tr>
<td>Applied Cognition – General Concerns</td>
<td>34</td>
<td>4, 6, 8</td>
</tr>
<tr>
<td>Psychosocial Illness Impact – Positive</td>
<td>39</td>
<td>4, 6</td>
</tr>
<tr>
<td>Psychosocial Illness Impact – Negative</td>
<td>32</td>
<td>4, 6</td>
</tr>
<tr>
<td>Alcohol – Alcohol Use</td>
<td>37</td>
<td>7</td>
</tr>
<tr>
<td>Alcohol – Positive Consequences</td>
<td>20</td>
<td>7</td>
</tr>
</tbody>
</table>

Neuro-QOL

Neuro-QOL is a set of self-report measures that assesses the health-related quality of life (HRQOL) of adults and children with neurological disorders. Neuro-QOL is comprised of item banks and scales that evaluate symptoms, concerns, and issues that are relevant across disorders (generic measures) along with instruments that assess areas most relevant for specific patient populations (targeted). Both self- and proxy-report versions are available. The Neuro-QOL instruments enable within-disease as well as cross-disease comparisons and are intended for use in both neurology clinical trials and clinical practice.

Most Neuro-QOL instruments are calibrated item banks that can be administered as a computerized adaptive test (CAT) or as fixed-length short forms. T-scores are produced from the item-level calibrations. The remaining instruments are uncalibrated unidimensional scales. Some or all items can be administered with the sum or the total raw score used in analyses. The following instruments are included in Assessment Center.

Table 6: Neuro-QOL Instruments Available in Assessment Center (www.assessmentcenter.net)

<table>
<thead>
<tr>
<th>Domain</th>
<th>Format</th>
<th>Adult # Items</th>
<th>Pediatric (ages 10-17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>Bank/Bank</td>
<td>21 (8)</td>
<td>19 (8)</td>
</tr>
<tr>
<td>Depression</td>
<td>Bank/Bank</td>
<td>24 (8)</td>
<td>16 (8)</td>
</tr>
</tbody>
</table>

The NIH Toolbox for Assessment of Neurological and Behavioral Function

The NIH Toolbox is a multidimensional set of royalty-free, performance-based and self-report measures that assess cognitive, motor, sensory, and emotional function in people ages 3-85. Available in both English and Spanish, the NIH Toolbox can be used across diverse study designs and settings. The NIH Toolbox can be administered within two hours and divides tests into four domain batteries: Cognition, Motor, Sensation, and Emotion (self- and parent-report). In addition, within some domains, there are supplemental measures. The measures have been normed and validated in a broad sample of the U.S. population.

Table 7: NIH Toolbox Instruments Available on Assessment Center (www.assessmentcenter.net)

<table>
<thead>
<tr>
<th>Domain</th>
<th>Subdomain</th>
<th>Measure Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognition</td>
<td>Attention/Executive Function</td>
<td>NIH Toolbox Flanker Inhibitory Control and Attention Test</td>
</tr>
<tr>
<td>Cognition</td>
<td>Episodic Memory</td>
<td>NIH Toolbox Picture Sequence Memory Test</td>
</tr>
<tr>
<td>Cognition</td>
<td>Executive Function</td>
<td>NIH Toolbox Dimensional Change Card Sort Test</td>
</tr>
<tr>
<td>Cognition</td>
<td>Language</td>
<td>NIH Toolbox Oral Reading Recognition Test</td>
</tr>
</tbody>
</table>

Your scores for the CATs you completed are shown below.

The diamond ♦ is placed where we think your score lies. This diamond is placed on your T-Score, which is a standardized score that is based on an average score of 50, based on responses to the same questions in the United States general population. The T-score also has a standard deviation of 10 points, so a score of 40 or 60 represents a score that is one standard deviation away from the average score of the general US population.

The Standard Error (SE) is a statistical measure of variance and represents the possible range of your score. The lines on either side of the diamond in your profile report show the possible range of your actual score around this estimated score. It is very likely that your score is in the range of these lines.

<table>
<thead>
<tr>
<th>Your Score</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anger</td>
<td>48</td>
</tr>
<tr>
<td>Anxiety</td>
<td>64</td>
</tr>
<tr>
<td>Depression</td>
<td>62</td>
</tr>
<tr>
<td>Fatigue</td>
<td>34</td>
</tr>
<tr>
<td>Pain Behavior</td>
<td>43</td>
</tr>
<tr>
<td>Pain Impact</td>
<td>56</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Your Score</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Function</td>
<td>38</td>
</tr>
<tr>
<td>Social Activity</td>
<td>48</td>
</tr>
<tr>
<td>Social Role</td>
<td>45</td>
</tr>
</tbody>
</table>

The NIH Clinical Center
Questions?

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