Dutch-Flemish translation and validation of PROMIS

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1. PROMIS
   • Conceptual model
   • Item banks

2. Dutch-Flemish PROMIS
   • Translation
   • Validation
   • Implementation
Patient Reported Outcomes Measurement Information System

Initiative of 6 US research groups and the National Institutes of Health (NIH), funded by the NIH (2004)

PROMIS aims to provide clinicians and researchers access to efficient, precise, valid, and responsive adult– and child–reported measures of health and well–being.

www.nihpromis.org
1. PROMIS consists of a collection of item banks
   - Large series of questions (items)
   - All measuring the same concept (unidimensional domains)
   - The concepts are generic, i.e. applicable in all (patient) populations

2. All items have been calibrated on the same scale using Item Response Theory (IRT) methods

3. Items can be selected from an item bank for use in research or clinical practice
   - As questionnaire
   - As Computer Adaptive Test (CAT)
Item Response Theory (IRT)

- Characteristics of an IRT-based questionnaire:
  - Each item has its own ‘location’ on the scale
  - The items are ordered from ‘easy’ to ‘difficult’
  - The distances between the item locations are known
  - Scores are on interval level instead of ordinal level

- Persons are placed on the same scale as the items
How does IRT work?

Each item has an Item Characteristic Curve

Probability of a positive response ("yes")

Item response function: $P_i(\theta) = \frac{e^{a(\theta - b_i)}}{1 + e^{a(\theta - b_i)}}$

$\Theta$ (theta) = concept being measured

$a$ = discriminative ability

$b$ = item location (difficulty)
Example IRT item bank

Physical Functioning Item Bank

Are you able to get in and out of bed?
Are you able to stand without losing your balance for 1 minute?
Are you able to walk from one room to another?
Are you able to walk a block on flat ground?
Are you able to run or jog for two miles?
Are you able to run five miles?
How does CAT work?

- Questionnaires are administered by computer
- The computer selects items from an item bank
- The items are selected based on answers to previous items (adaptive)
- After each item theta (with confidence interval) is being estimated
- When the confidence interval becomes small enough the computer stops asking questions (average 3-7 items)

Demo: [www.assessmentcenter.net](http://www.assessmentcenter.net)
PROMIS domain framework
PROMIS experiences

2012:
• 502 active studies with 26,365 participants

2014:
• >285 publications

PROMIS is being used in
  ▪ DSM-5 field trials
  ▪ US Department of Defense management
  ▪ Population health monitoring
    ▪ National Health Interview Survey (since 1957)
    ▪ RAND American Life Panel
    ▪ Healthy People 2020
Dutch-Flemish PROMIS group

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## Dutch-Flemish PROMIS

<table>
<thead>
<tr>
<th>Volwassenen</th>
<th># items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boosheid</td>
<td>22</td>
</tr>
<tr>
<td>Angst</td>
<td>29</td>
</tr>
<tr>
<td>Depressie</td>
<td>28</td>
</tr>
<tr>
<td>Vermoeidheid</td>
<td>95</td>
</tr>
<tr>
<td>Reacties op pijn</td>
<td>39</td>
</tr>
<tr>
<td>Belemmeringen door pijn</td>
<td>40</td>
</tr>
<tr>
<td>Lichamelijk functioneren</td>
<td>121</td>
</tr>
<tr>
<td>Slaap stoornissen</td>
<td>27</td>
</tr>
<tr>
<td>Problemen door slaapstoornissen</td>
<td>16</td>
</tr>
<tr>
<td>Vermogen aandeel te hebben in sociale rollen en activiteiten</td>
<td>35</td>
</tr>
<tr>
<td>Tevredenheid met sociale rollen en activiteiten</td>
<td>44</td>
</tr>
<tr>
<td>Gezelschap</td>
<td>6</td>
</tr>
<tr>
<td>Emotionele steun</td>
<td>16</td>
</tr>
<tr>
<td>Steun bij het verkrijgen en begrijpen van informatie</td>
<td>10</td>
</tr>
<tr>
<td>Praktische steun</td>
<td>11</td>
</tr>
<tr>
<td>Sociale isolatie</td>
<td>14</td>
</tr>
<tr>
<td>Global</td>
<td>10</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>563</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Kinderen</th>
<th># items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boosheid</td>
<td>5</td>
</tr>
<tr>
<td>Angst</td>
<td>13</td>
</tr>
<tr>
<td>Asthma</td>
<td>17</td>
</tr>
<tr>
<td>Depressieve klachten</td>
<td>13</td>
</tr>
<tr>
<td>Vermoeidheid</td>
<td>23</td>
</tr>
<tr>
<td>Lichamelijk functioneren-Mobiliteit</td>
<td>23</td>
</tr>
<tr>
<td>Lichamelijk functioneren-bovenste Extremiteit</td>
<td>29</td>
</tr>
<tr>
<td>Belemmeringen door pijn</td>
<td>13</td>
</tr>
<tr>
<td>Relaties met peers</td>
<td>15</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>151</strong></td>
</tr>
</tbody>
</table>


Minimal standards for release

Short forms:

- Availability of good validation data previous to the translation and a **good quality translation**

Item banks/CATs

- Preliminary release: Availability of good validation data previous to the translation and a good quality translation
- Full release: an evaluation of **Differential Item Functioning (DIF)** between language groups and within relevant sub-groups
Validation

Aims

- Calibration of IRT model (model fit, item quality)
- Differential Item Functioning language (EN/NL)

Design

- Cross-sectional studies
- Relevant patient populations
- Sample size: > 1000 for calibration
- IRT analyses: assumptions of unidimensionality, local independence, monotonicity; GRM fit, item parameters, DIF
Validation studies

1. Reade: physical functioning, pain behavior, pain interference, global health in >1000 chronic pain patients
2. Twente: physical functioning in 690 RA patients
3. Dutch Society orthomanual physicians: pain behavior, pain interference in >1000 chronic pain patients
4. Stichting Benchmark GGZ: anxiety, depression in >1000 patients treated in GGZ
5. Hoensbroek: ability to participate in social roles and activities, satisfaction with social roles and activities in 500-1000 patient receiving rehabilitation:
6. KNGF: physical functioning in 1000 patients receiving physiotherapy
7. Vumc, pediatrics: sleep disturbances, sleep-related impairment in >1000 adolescents
Validation studies

8. Reade, CHECK: physical functioning in early OA
9. Reade, Leuven: pain behaviour, pain interference, fatigue, global health in RA patients
10. AMC, pediatrics: Juvenile arthritis
11. Twente: COPD patients
12. WKZ-UMC Utrecht: fatigue in children with SMA
First results

- Reade: 1046 chronic pain patients
- PROMIS pain behavior (39) and PROMIS pain interference (40) item banks
- Good fit to a one-dimensional model:
  - *Pain behavior*: $\text{CFI}=0.963$, $\text{TLI}=0.961$, 42% of the variance explained by the first factor
  - *Pain interference*: $\text{CFI}=0.961$, $\text{TLI}=0.987$, 66% of the variance explained by the first factor
Acceptable information (SE<0.3) for theta between -1.9 and 3.6 for pain behavior and between -3.3 and 2.8 for pain interference
First results

- 23 out of 741 (3%) pain behavior item pairs and 62 out of 820 (7.6%) pain interference item pairs marked as possibly locally dependent
- No DIF with respect to age, gender, and survey version
- DIF with respect to language: 6 DF-PROMIS-PB items and 2 DF-PROMIS-PI items
- The impact of DIF on the total item scores is minimal

Relation of total item score (TCC) and Theta, for all items and the items with DIF
Left: pain behavior  Right: pain interference
Conclusions

- The item banks pain behavior and pain interference fit a GRM and demonstrate good coverage across the range of the pain behavior and pain interference domain.

- Nearly all Dutch item parameters match the American item parameters and likely Dutch-specific item calibrations are not needed.

- The item banks can be used to develop a CAT.
BIG ISSUE

- >35 CATs, many users

Need

- CAT software (CAT generating software)
- Central web-based management tool
  - Server
  - Database
  - Participant interface for completing CATs
  - Administration
  - Feedback, reports
  - Security, privacy, link to EPD
- Expertise
- Money
Developing functional design

Exploring possibilities

- www.assessmentcenter.net
- Cooperate with commercial companies
- Open-source software

Pilot test June 2014 (SBG)

Sustainability
Timeline

- Oct 2006  First conversation with Dave Cella
- Dec 2008  First meeting Dutch-Flemish PROMIS group
- Juli 2010  Grant for translation (Reumafonds)
- April 2011 Signed contract with FACITtrans and PROMIS
- May 2011  Letter of permission to translate PROMIS
- June 2012 Translation of first item bank ready
- Sep 2012  Start first validation study
- Nov 2012  Translation of 26th item bank ready
- March 2013 Launch www.dutchflemishpromis.nl
- Jan 2014  First publication (Terwee et al QLR 2014)
- Feb 2014  Release of first short forms
- June 2014 First 2 CATs running