

Dutch-Flemish PROMIS

Dr. Caroline Terwee

Dutch-Flemish PROMIS group
VU University Medical Center
Department of Epidemiology and Biostatistics

- Dutch-Flemish PROMIS experiences, challenges and lessons learned
- Validation results
- Different ways of using PROMIS in the Netherlands and Flanders

- Oct 2006 First conversation with Dave Cella
- Dec 2008 First meeting Dutch-Flemish PROMIS group
- Juli 2010 Grant for translation (Reumafonds)
- 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
- Feb 2014 Release of first short forms
- Sep 2017 First CATs implemented in clinical practice
- Q4 2017 Dutch-Flemish PROMIS foundation and Assessment Center

- Caroline B Terwee, VU University Medical Center, Department of Epidemiology and Biostatistics, Amsterdam, the Netherlands
- Leo D Roorda, Reade, Center for Rehabilitation and Rheumatology, Amsterdam, the Netherlands
- Henrica CW de Vet, VU University Medical Center, Department of Epidemiology and Biostatistics, Amsterdam, the Netherlands
- Joost Dekker, VU University Medical Center, Department of Rehabilitation Medicine and Department of Psychiatry, Amsterdam, the Netherlands
- Rene Westhovens, Catholic University Leuven, Department of Rheumatology, Leuven, Belgium
- Jaap van Leeuwen, CEO Leones Group bv, Amsterdam, the Netherlands
- Maarten Boers, VU University Medical Center, Department of Epidemiology and Biostatistics, Amsterdam, the Netherlands

- Lotte Haverman, Emma Children's Hospital, Academic Medical Center, Amsterdam, the Netherlands
- Martha Grootenhuis, Emma Children's Hospital, Academic Medical Center, Amsterdam, The Netherlands
- Hein Raat, Department of Public Health, Erasmus MC-University Medical Center Rotterdam, Rotterdam, The Netherlands
- Marion van Rossum, Emma Children's Hospital and Reade, Center for Rehabilitation and Rheumatology, Amsterdam, The Netherlands
- Eline van Dulmer-den Broeder, VU University Medical Center, Department of Paediatrics, Amsterdam, the Netherlands
- Karel Hoppenbrouwers, Youth Health Care, KU Leuven, Leuven, Belgium

Requirements:

- Grant for translation: difficult to find
€100.000 for translating 26 item banks (Dutch Arthritis Association)
- Permission from PHO to translate PROMIS using approved translation methodology
- Time: 1.5 years for translating 26 item banks, including cognitive debriefing
- One person should preferably participate in all translations as a reviewer

Dutch-Flemish PROMIS item banks

| Volwassenen | # items |
|---|----------------|
| Anger | 22 |
| Anxiety | 29 |
| Depression | 28 |
| Fatigue | 95 |
| Pain Behavior | 39 |
| Pain Interference | 40 |
| Physical Function | 121 |
| Sleep Disturbance | 27 |
| Sleep-Related Impairment | 16 |
| Ability to Participate in Social Roles and Activities | 35 |
| Satisfaction with Social Roles and Activities | 44 |
| Companionship | 6 |
| Emotional support | 16 |
| Informational support | 10 |
| Instrumental support | 11 |
| Social Isolation | 14 |
| Global health | 10 |
| Total | 563 |

| Kinderen | # items |
|--|----------------|
| Anger | 5 |
| Anxiety | 13 |
| Asthma Impact | 17 |
| Depressive Symptoms | 13 |
| Fatigue | 23 |
| Physical Function - Mobility | 23 |
| Physical Function – Upper extremity Function | 29 |
| Pain Interference | 13 |
| Peer Relationships | 15 |
| Total | 151 |

DUTCH-FLEMISH PROMIS



zoek

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[Zorgverleners](#)

Welkom bij de Dutch-Flemish PROMIS groep

Het 'Patient Reported Outcomes Measurement Information System' (PROMIS) is een valide en betrouwbaar meetsysteem waarmee op zeer efficiënte wijze patiënt-gerapporteerde gezondheidsuitkomsten en welzijn gemeten kan worden, bij volwassenen en kinderen. PROMIS is ontwikkeld in Amerika, met financiering van de [NIH](#). PROMIS instrumenten kunnen als papieren vragenlijst afgenomen worden, maar ook door middel van Computer Adaptief Testen (CAT). In 2010 is de 'Dutch-Flemish PROMIS' groep opgericht met als doel om PROMIS in het Nederlands-Vlaams te vertalen en in Nederland en Vlaanderen te implementeren. Op deze website vindt u informatie over de beschikbare meetinstrumenten en het gebruik van PROMIS in Nederland.

NIEUW: Nederlands-Vlaamse PROMIS short forms zijn nu beschikbaar voor gebruik. Klik [hier](#) voor een overzicht van de beschikbare short forms.

Wij zijn op zoek naar onderzoeksgroepen die willen meewerken aan de validatie van PROMIS en interesse hebben om hierover gezamenlijk artikelen te publiceren. Kijk [hier](#)...

Dutch-Flemish PROMIS
is geregistreerd partner
van NIH PROMIS.

PROMIS

VUmc

PROMIS International group 2014: Minimum requirements for the release of PROMIS instruments after translation and recommendations for further psychometric evaluation

| Instrument | Minimum requirement BEFORE release |
|---------------|---|
| Short form | Availability of good validation data previous to the translation and a good quality translation |
| Item bank/CAT | An evaluation of Differential Item Functioning (DIF) between language groups and within relevant sub-groups |

Validation

| Instrument | Recommendations for further psychometric evaluation AFTER release | Sample size |
|------------------------|---|---|
| Item bank | Calibration of item banks in relevant patient groups and the general population; | Minimum 500 Optimal 1000-2000 |
| Short form / item bank | The collection of language- or country-specific reference scores in the general population; | At least 300-400 |
| Short form / item bank | An evaluation of the relevance and comprehensiveness of the items (content validity) of the item bank and cultural adaptation; | 4-6 focus groups or 12 interviews |
| Short form / CAT | Further psychometric evaluation (construct validity, internal consistency, test-retest reliability, measurement error, DIF among different patient groups) of PROMIS instruments in specific patient populations; | 200 subjects per group for DIF 50-100 for other measurement properties |
| Short form / CAT | Responsiveness and Minimal Important Change of PROMIS instruments in relevant patient populations. | 50-100 |

Dutch-Flemish Validation

- Each item bank should be calibrated in at least one relevant sample of about 1000 patients
- Collaborative effort
 - *15 validation studies*
 - Cross-sectional studies, including full item banks and legacy instruments
 - Patient recruitment through hospital records
- Reference scores for the Dutch general population for 11 item banks
- IRT expertise is required

Dutch-Flemish validation studies

| Item bank | items | Population | Sample size | CFI | RMSEA |
|--------------------------------|-------|--|-------------|-------|-------|
| Pain behavior | 39 | Chronic pain | 1042 | 0.960 | 0.099 |
| Pain behavior | 39 | SMT | 1631 | 0.814 | 0.094 |
| Pain behavior | 39 | General population | 1049 | 0.986 | 0.082 |
| Pain Interference | 40 | Chronic pain | 1085 | 0.986 | 0.159 |
| Pain Interference | 40 | RA (Dutch/Flemish) | 2020 | 0.997 | 0.128 |
| Pain Interference | 40 | OA | 390 | 0.966 | 0.107 |
| Pain Interference | 40 | SMT | 1631 | 0.901 | 0.145 |
| Pain Interference | 40 | General Population | 1049 | 0.992 | 0.146 |
| Physical Function | 121 | Chronic pain | 1247 | 0.976 | 0.122 |
| Physical Function | 121 | Physiotherapy | 753 | 0.982 | 0.091 |
| Physical Function | 121 | General Population | 1309 | 0.991 | 0.094 |
| Anxiety | 29 | Common mental disorders and general population | 2010 | 0.990 | 0.085 |
| Depression | 28 | Common mental disorders and general population | 2010 | 0.995 | 0.093 |
| Fatigue | 95 | RA (Dutch/Flemish) | 2020 | 0.994 | 0.116 |
| Fatigue | 95 | General population | 1007 | 0.98 | 0.09 |
| Ability .. Social Roles | 34 | General population | 1016 | 0.972 | 0.108 |
| Satisfaction with Social Roles | 44 | General population | 1016 | 0.959 | 0.109 |

Dutch-Flemish validation studies

| Item bank | items | Pop | Sample size | CFI | RMSEA |
|--|-------|-------------|-------------|-------|-------|
| Anger | 5 | JIA | 196 | 0.999 | 0.072 |
| Anxiety | 13 | JIA | 195 | 0.991 | 0.082 |
| Depressive symptoms | 13 | JIA | 195 | 0.995 | 0.076 |
| Fatigue | 23 | JIA | 196 | 0.989 | 0.091 |
| Physical function – Mobility | 23 | JIA | 199 | 0.991 | 0.052 |
| Physical Function – Upper Extremity Function | 29 | JIA | 196 | 0.994 | 0.043 |
| Pain Interference | 13 | JIA | 196 | 0.982 | 0.120 |
| Peer Relationships (pediatric) | 15 | JIA | 195 | 0.944 | 0.141 |
| Sleep Disturbances | 27 | Adolescents | 1024 | 0.790 | 0.125 |
| Sleep-Related Impairment-3 | 16 | Adolescents | 1024 | 0.960 | 0.125 |

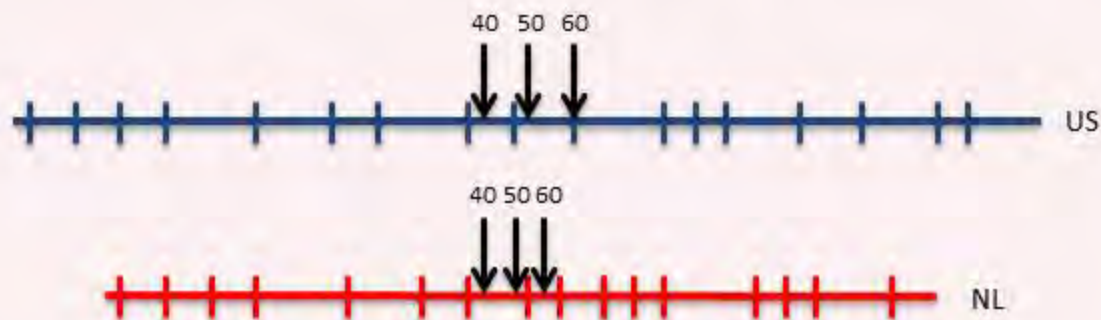
Dillema's for implementation

1. US item parameters or country-specific item parameters?
2. US average of 50 or country-specific average of 50?

US or country-specific item parameters?

The problem

IRT scales calibrated in different populations have different scales
T-scores are not comparable



Differential Item Functioning (DIF)

- The item parameters in the CAT software should be applicable to all patients
- Ideally, we should all use the same item parameters in our CAT software
- However, item parameters might be different across population. If so, we need population-specific CAT software
- In IRT people with the same level of the trait should have the same probability of giving a certain response to an item (similar item locations). If not, there is DIF.

- Chronic pain (Dutch versus English): Pain Behavior (6), Pain Interference (2), Physical Function (10)
- General population (Dutch versus English): Anxiety (2), Depression (4), Fatigue (14), Pain Behavior (8), Pain Interference (0), Physical Function (4), Ability to Participate (), Satisfaction with Social roles (1)
- Rheumatoid Arthritis (Dutch versus Flemish): Pain Behavior (0), Pain Interference (0)

Study ongoing: assess the impact of DIF on individual CAT scores

DIF across populations

| Pain Behavior | Pain Interference | Physical Function |
|-------------------------------|-------------------------------|--|
| Chronic pain (n=2452) | Chronic pain (n=2623) | Chronic pain (n=921) |
| Rheumatoid arthritis (n=1456) | Rheumatoid arthritis (n=1917) | |
| | Osteoarthritis (n=408) | |
| | | Patients who received physical therapy (n=753) |
| General population (n=783) | General population (n=1049) | General population (n=1309) |

3 comparisons

6 comparisons

3 comparisons

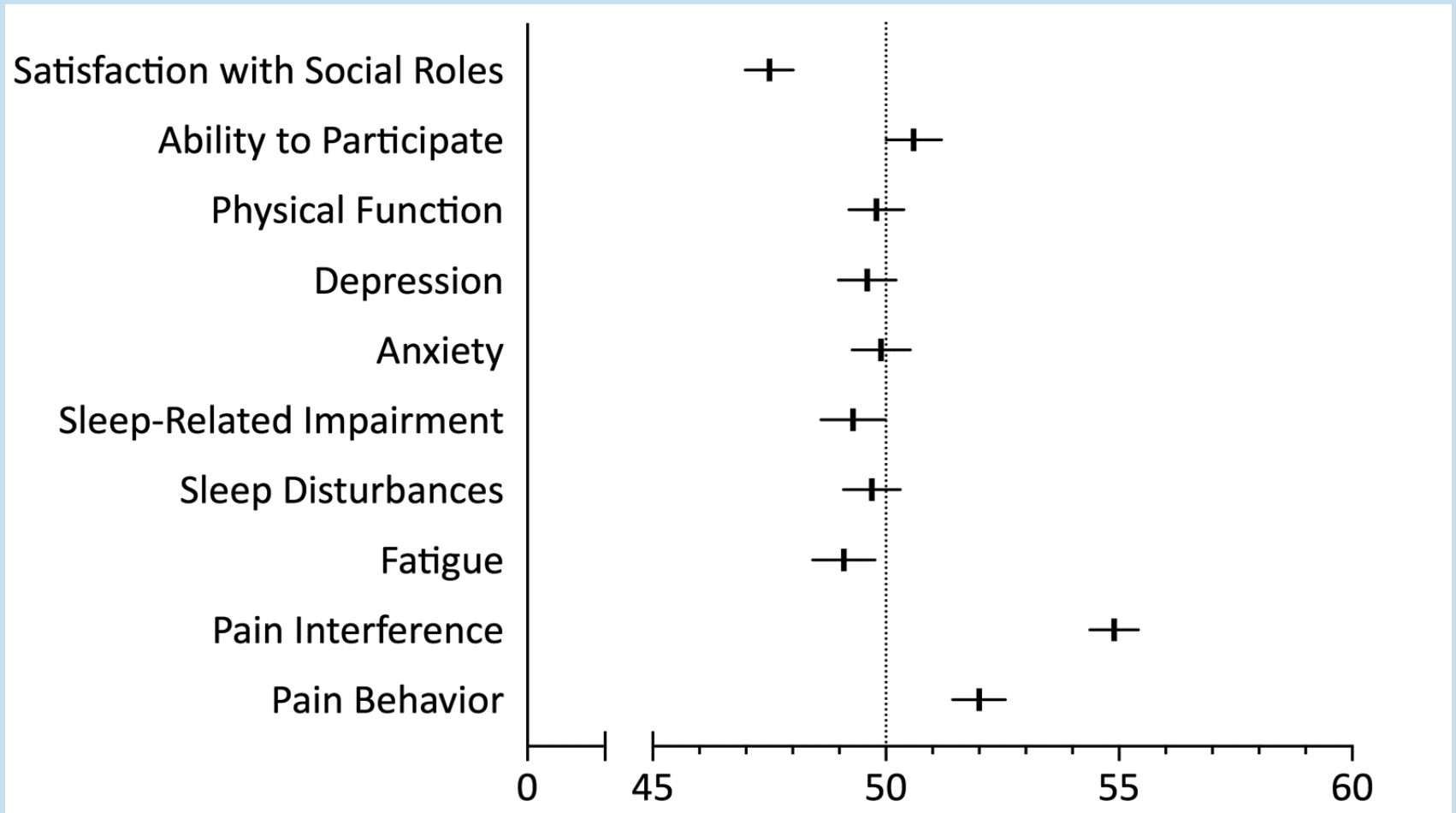
Only a limited number of items were flagged for DIF:

- Pain Behavior: 3 items flagged for DIF (out of 39)
- Pain Interference: 2 items flagged for DIF (out of 40)
- Physical Functioning: 7 items flagged for DIF (out of 121) (3 items were flagged for DIF twice)

However, some meaningful DIF was found (e.g. moving stiffly, calling for help, feeling pain as a burden)

It could be considered to implement population-specific item locations in CAT software. This would increase validity without losing comparability of scores.

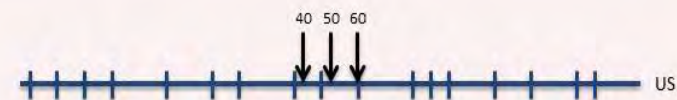
T-scores of Dutch general population



US or country-specific item parameters?

Possible solutions

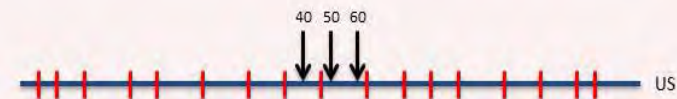
Scenario 1: use US item parameters



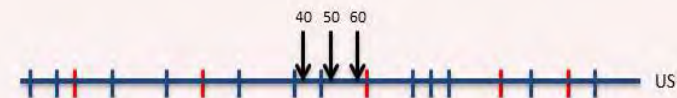
Scenario 2: use NL item parameters



Scenario 3: Rescale NL item parameters on US metric



Scenario 4: Use NL item parameters for DIF items and US item parameters for the other items



Implementation

PHO recommends to set up one PROMIS National Center (PNC) in each country

PHO board has defined the roles and responsibilities of the PNC

A PROMIS National Center will ...

- .. have the exclusive rights to distribute PROMIS materials in its country (PHO also retains the right)
- .. be responsible for coordinating all translation efforts performed in its country to ensure one unique translation per language
- .. be responsible that the most up to date versions of the PROMIS materials are distributed and synchronized with a central PHO library
- .. encourage widespread use of PROMIS and educate people about the value of IRT, CATs and PROMIS, e.g. through workshops and symposia
- .. set up a sustainable model to make PROMIS instruments available now and in the future at low costs (not only for profit)

Requirements

- Structure of the organization (advice)
- Business model / sustainability model
- Approval of model by PHO board
- CAT software
- Multiple translated and validated PROMIS item banks
- Scoring service
- Help desk
- Education

Dutch-Flemish PROMIS Foundation

MISSION: to improve the quality of health care and research by developing, translating, validating, improving, and stimulating the use of Dutch-Flemish PROMIS instruments and other innovative, top quality, measurement instruments in research and clinical practice

All PROMIS materials will be made available for use in the Netherlands and Flanders through a private not only for profit company: Dutch-Flemish Assessment Center (part of the Dutch-Flemish PROMIS foundation)

- Dutch-Flemish Assessment Center
 - *Instrument library (PROMIS and other instruments)*
 - *CAT engine– developed in R → will be tested against the US CAT software*
 - *Connections of CAT engine to other PRO data collection systems (e.g. Vital Health)*
 - *Patient website for self-monitoring*



cb.terwee@vumc.nl

leo.d.roorda.research@gmail.com