

# The Dutch-Flemish PROMIS project

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## Dutch-Flemish PROMIS group

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## What is PROMIS?

Patient Reported Outcomes Measurement Information System (PROMIS), funded by the National Institutes of Health (NIH), is a system of highly reliable, valid, flexible, precise, and responsive assessment tools that measure patient-reported health status

[www.nihpromis.org](http://www.nihpromis.org)

## What is PROMIS?

PROMIS has constructed 22 item banks → collections of questions measuring the same concept

Generic item banks → applicable to all kinds of (patient) populations

Item banks contain 6-124 items

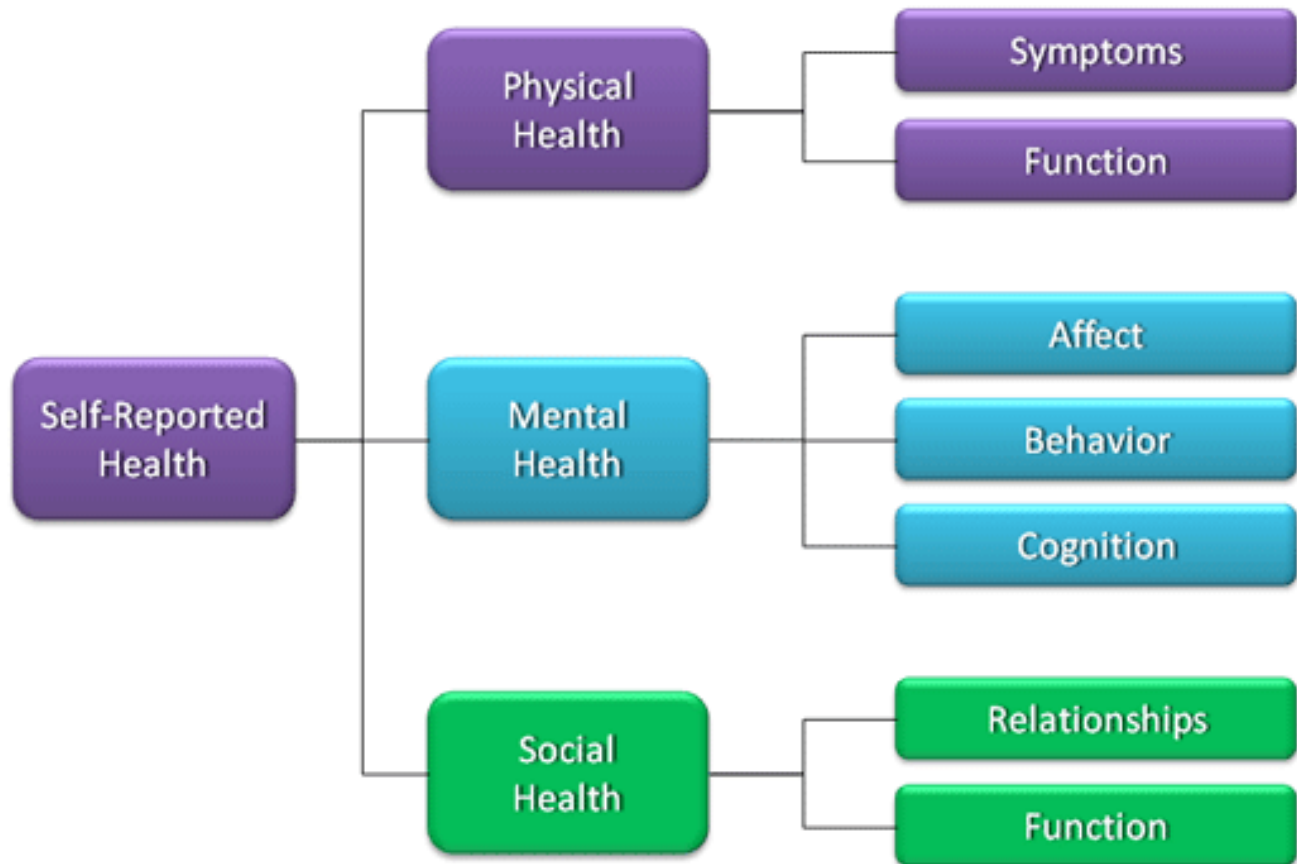
Items can be administered adaptively through computerized adaptive testing (CAT).

CAT require 3–7 items for precise scores.



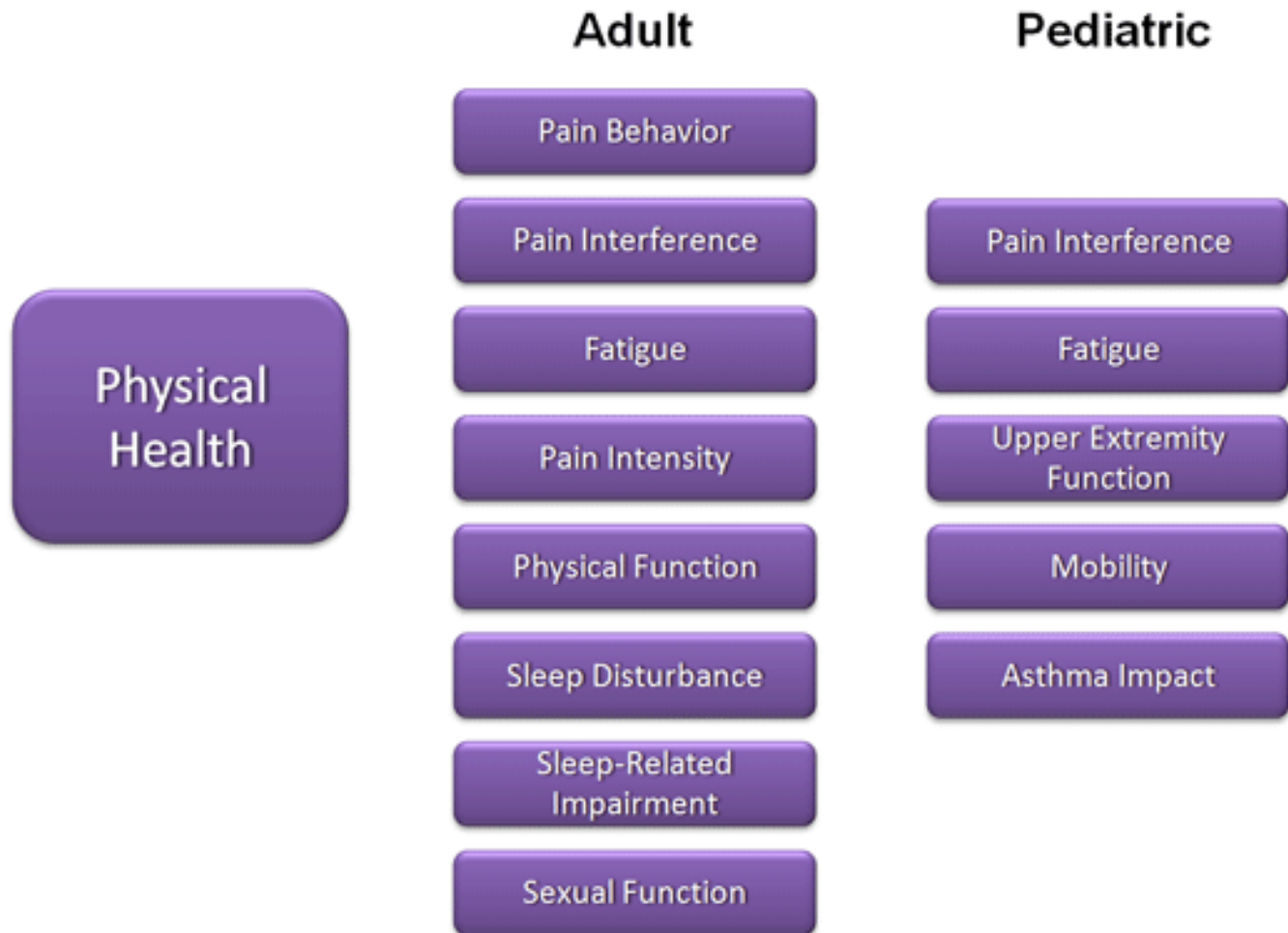
# PROMIS concepts

## PROMIS Domain Framework



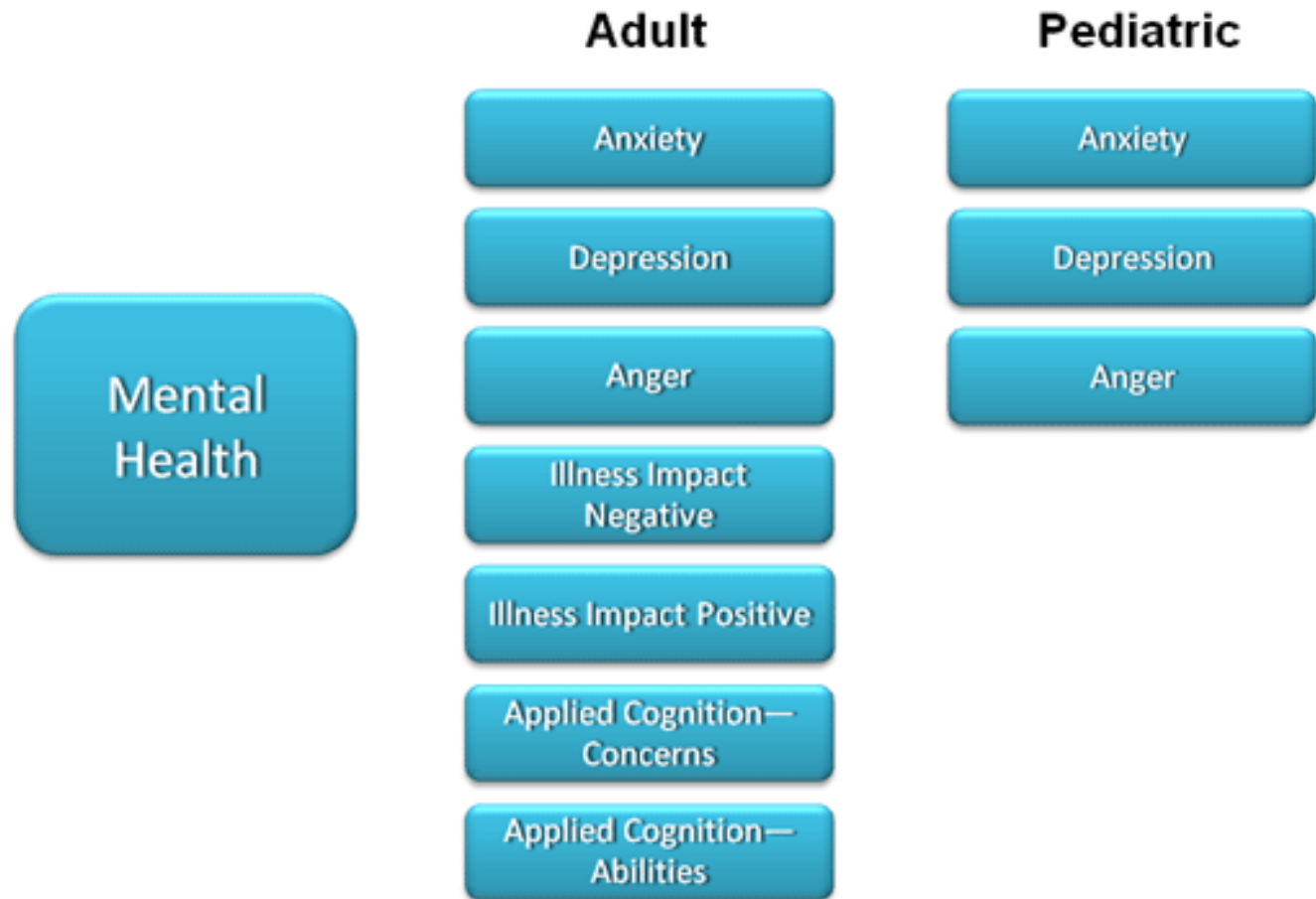
# PROMIS concepts

## PROMIS Current Physical Health Banks



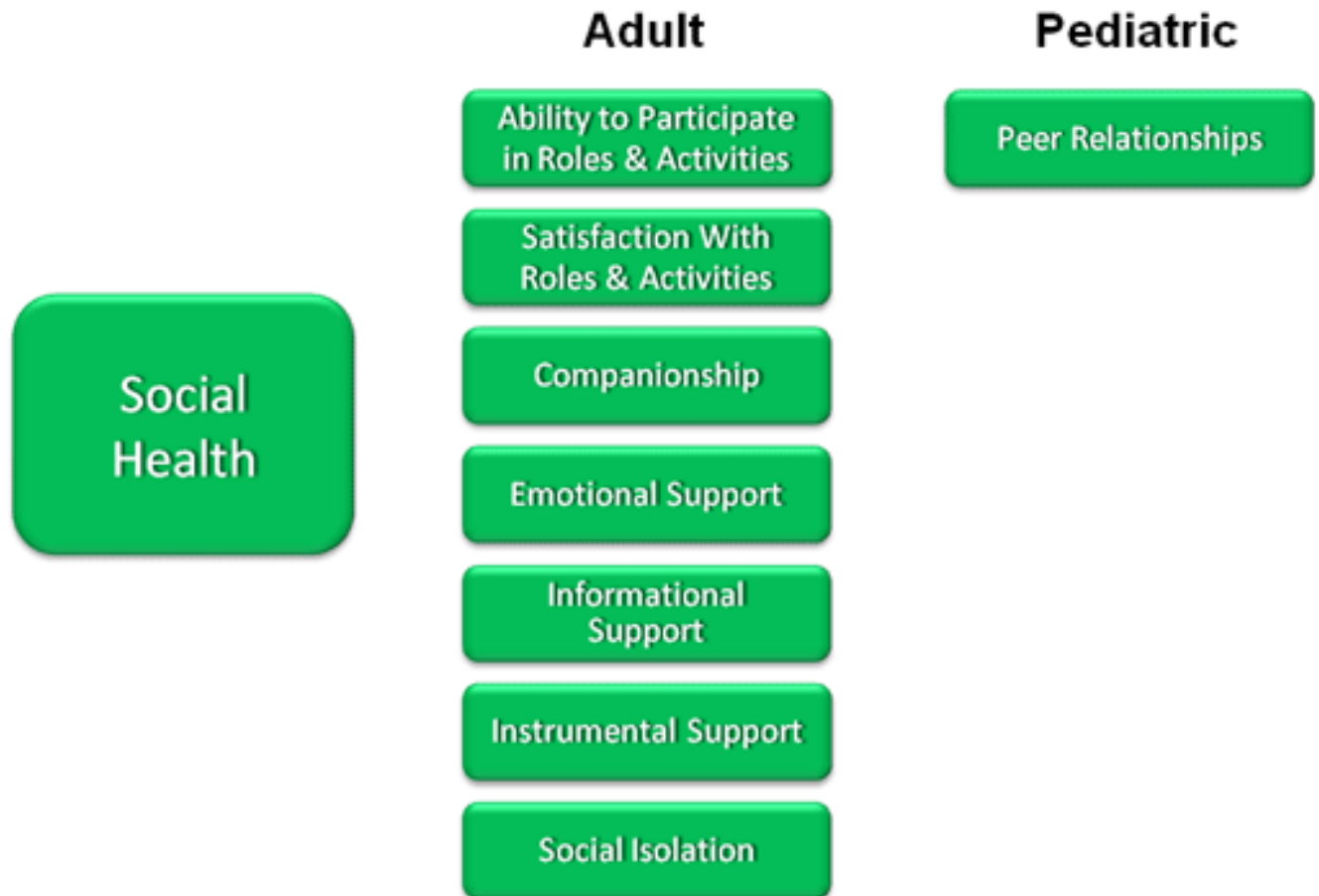
# PROMIS concepts

## PROMIS Current Mental Health Banks



# PROMIS concepts

## PROMIS Current Social Health Banks





# **Dutch-Flemish PROMIS cross-cultural validation**

Use of PROMIS in the Netherlands requires careful cross-cultural validation

Two steps

1. Qualitative – translation

2. Quantitative – calibration

# Translation

## translation



- Four forward translations (2 Dutch, 2 Flemish)
- Reconciliation of the forward translations
- Two back-translations of the reconciled version into English
- Comparison of source and back-translated versions
- Three independent reviews by bilingual, native Dutch/Flemish-speaking experts
- Harmonization of translations for consistency of meaning across languages
- Finalization
- Proofreading

## testing



- Cognitive debriefing in at least 75 members of the general population
- Refine translation

## Dutch-Flemish PROMIS

Sub-domain	Number of items Calibrated in English
Anger	29
Anxiety	29
Depression	28
Fatigue	95
Pain Behavior	39
Pain Interference	41
Physical Function	124
Sleep Disturbance	27
Sleep-Related Impairment	16
Social Satisfaction_DSA	12
Social Satisfaction_Roles	14
Global	10
<b>Total</b>	<b>464</b>

## Dutch-Flemish PROMIS

<b>PROMIS sub-domains - Pediatric</b>	<b>Number of items Calibrated in English</b>
Anxiety	15
Anger	6
Asthma	17
Depressive Symptoms	14
Fatigue	23
PF - Mobility	23
PF - Upper Extremity	29
Pain Interference	13
Peer Relationships	15
<b>Total</b>	<b>155</b>

## Calibration

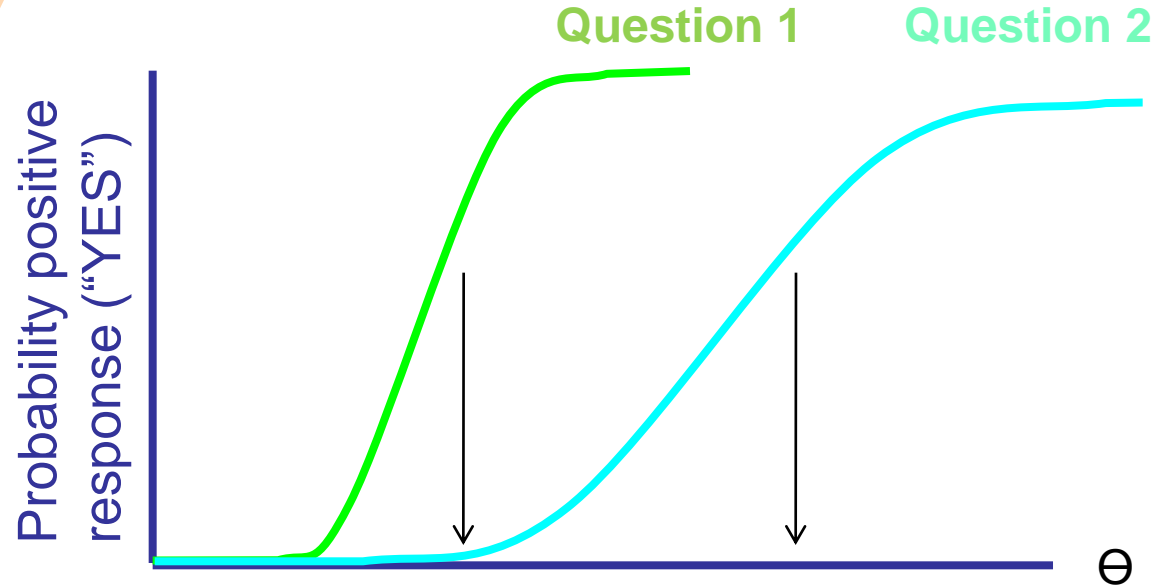
Do the translated item banks meet the same measurement assumptions as the original English item banks?

- Are the item banks unidimensional?
- Do the items fit the same IRT model?
- Are the item parameters of the IRT model comparable?

Are the item parameters similar in different (clinical) populations?

## Item Characteristic Curve

# Item parameters



Item response function

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

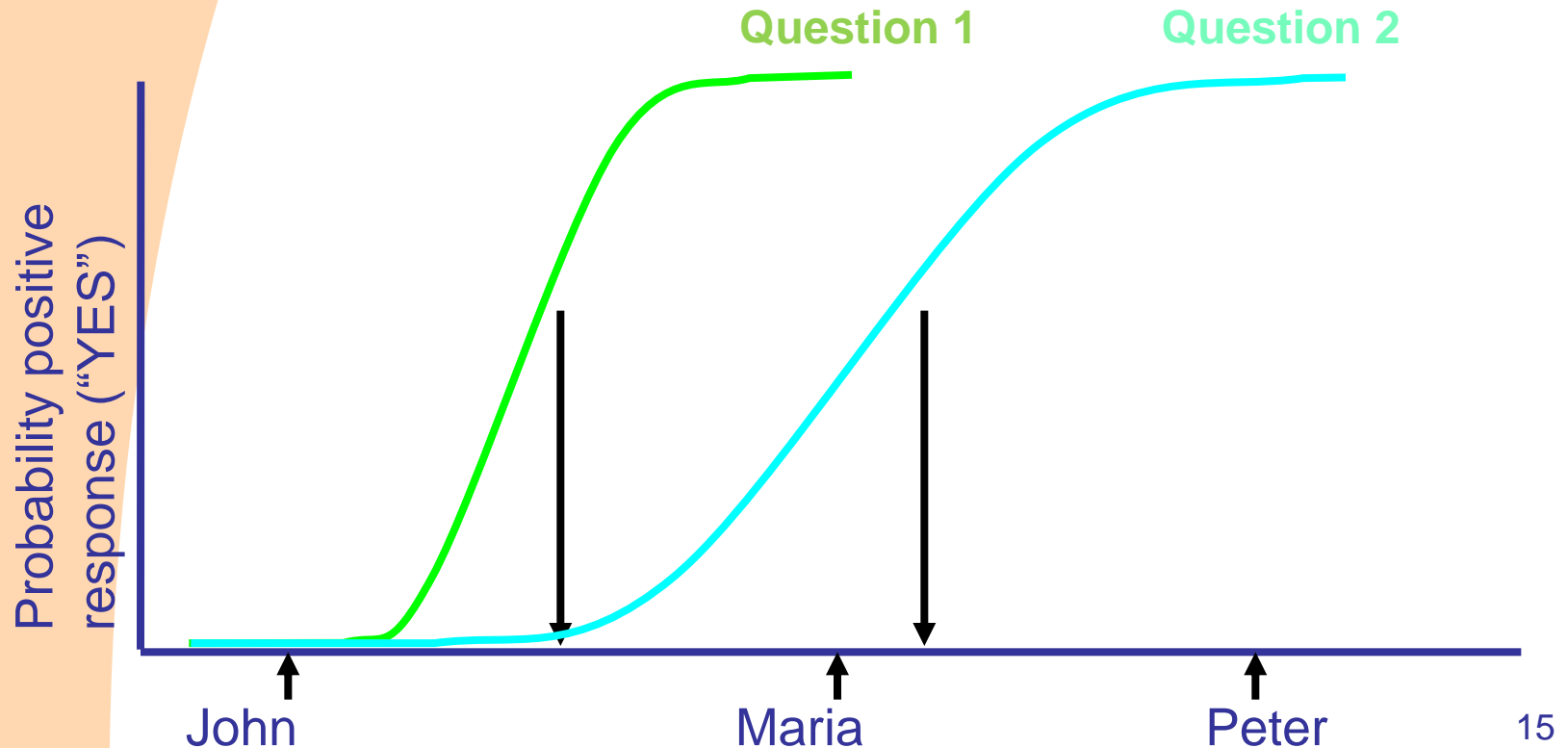
θ (theta) = the concept being measured (standardized with mean=0 and SD=1)

a = discriminating ability

b = item location (difficulty)

# CAT

When applying CAT, for each person a value of theta is estimated based on the answers to the questions, given the item parameters (a and b)



## Calibration - 1

People from the US and the Netherlands with the same level of the concept being measured (e.g. equally depressed) should get the same  $\Theta$  (theta) value.

Thus the item parameters for the US and Dutch population should be the same

If not, we have Differential Item Functioning (DIF) → different item locations per group



## Calibration - 2

People from different disease groups with the same level on the concept being measured (e.g. equal pain) should get the same  $\Theta$  (theta) value.

Thus the item parameters for different disease groups should be the same

## What needs to be done?

The Dutch-Flemish PROMIS item banks need to be calibrated before they can be used in research or clinical practice

### **Collaboration is needed**

To collect data for calibration we need the help of many Dutch research groups. Collaboration exists in analysis and publication of the results.

In this way we need to validate all items banks in several populations.

## Calibration – what do we need?

1. Data from a representative sample from the general Dutch population →  $n > 10.000$ ? (US  $n=21,133$ )

Design:

12 item banks (464 items)

- Some people will complete all items from 2 item banks (full-bank design)
- Some people will complete a random set of 7 items from all item banks (block design)

# Calibration – what do we need?

2. Data from representative clinical patient samples

→  $n > 1000$

Design:

- Full item banks
- Parts of banks.

# Collaboration

Register at the website [www.kmin-vumc.nl](http://www.kmin-vumc.nl)

- Name, affiliation
- Application (study design, (patient) population)
- Item banks

## Collaboration

- Help with statistical analysis
- Joint publications

## Time line

- Translation finished end of 2011
- Start data collection 2012

## Which item bank in which project?

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