Introduction to the Patient-Reported Outcomes Measurement Information System (PROMIS)

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PROMIS

- Patient-reported outcomes measurement information system (PROMIS) project

  - Item banks measuring patient-reported outcomes
  - Computer-adaptive testing (CAT) system

- http://www.nihpromis.org/

PROMIS Banks (454 items)

http://www.assessmentcenter.net/ac1/

- Emotional Distress [86]
  - Depression (28)
  - Anxiety (29)
  - Anger (29)
- Physical Function [124]
- Pain [80]
  - Behavior (39)
  - Impact (41)
- Fatigue [95]
- Satisfaction with Participation in Discretionary Social Activities (12)
- Satisfaction with Participation in Social Roles (14)
- Sleep Disturbance (27)
- Wake Disturbance (16)

American Psychiatric A. DSM 5

"As part of a roadmap for clinical research, the NIH began an effort to produce a Patient-Reported Outcome Measurement Information System™ (PROMIS) that "aims to revolutionize the way patient-reported outcome tools are selected and employed . . . . PROMIS™ aims to develop ways to measure patient-reported symptoms . . . . across a wide variety of chronic diseases and conditions." www.nihpromis.org

PROMIS™ has developed assessments for a number of clinical domains that have been identified by the DSM-5 Task Force as areas on which quantitative ratings would be useful for this cross-cutting assessment. One advantage for using the scales developed by the PROMIS™ initiative is that they are short. Further, the initiative has developed Computerized adaptive testing methods that can be used to establish a patient's rating by comparison to national norms with as few questions as possible. For the DSM-5 field trials, a simpler approach, using the paper and pencil fixed-item "short forms" for each PROMIS™ domain, will be available although a computer assisted version may also be used. The short forms focus on a single domain, such as depressed mood, and use a set of questions identified using item response theory to place an individual's response along a unidimensional continuum based on population norms. Relevant short forms that could be included in DSM-5 include the scales for depressed mood, anxiety, anger, sleep problems, and perhaps fatigue and pain impact."

Reliability and SEM

- For z-scores (mean = 0 and SD = 1):
  - Reliability = $1 - SEM^2$

    = 0.91 (when SEM = 0.30)

    = 0.90 (when SEM = 0.32)

- With 0.90 reliability
  - 95% Confidence Interval
    - z-score: - 0.62 → 0.62

- T-score = (z-score * 10) + 50
    - T-score: 44 → 56

In the past 7 days

I was grouchy

- Never
- Rarely
- Sometimes
- Often
- Always

Previous | Next | Exit

Response	Theta	Score	SE
EDANG30=3	0.61	56.1	0.57

In the past 7 days

I felt like I was ready to explode

- ○ Never

- ○ Rarely

- ○ Sometimes

- ○ Often

- ○ Always

Response	Theta	Score	SE
EDANG30=3	0.61	56.1	0.57
EDANG15=1	0.19	51.9	0.48

In the past 7 days

I felt angry

○ Never

○ Rarely

○ Sometimes

○ Often

○ Always

https://www.assessmentcenter.net/ac1/Modules/ProofSheet.aspx?Module=13&NavIndex=1&Action=Next

Response	Theta	Score	SE
EDANG30=3	0.61	56.1	0.57
EDANG15=1	0.19	51.9	0.48
EDANG09=2	0.05	50.5	0.39

In the past 7 days

I felt angrier than I thought I should

○ Never

○ Rarely

○ Sometimes

○ Often

○ Always

Response	Theta	Score	SE
EDANG30=3	0.61	56.1	0.57
EDANG15=1	0.19	51.9	0.48
EDANG09=2	0.05	50.5	0.39
EDANG28=1	-0.12	48.8	0.36

In the past 7 days

I felt annoyed

○ Never

○ Rarely

○ Sometimes

○ Often

○ Always

Response	Theta	Score	SE
EDANG30=3	0.61	56.1	0.57
EDANG15=1	0.19	51.9	0.48
EDANG09=2	0.05	50.5	0.39
EDANG28=1	-0.12	48.8	0.36
EDANG35=3	0.01	50.1	0.32

In the past 7 days

I made myself angry about something just by thinking about it

○ Never

◉ Rarely

○ Sometimes

○ Often

○ Always

Response	Theta	Score	SE
EDANG30=3	0.61	56.1	0.57
EDANG15=1	0.19	51.9	0.48
EDANG09=2	0.05	50.5	0.39
EDANG28=1	-0.12	48.8	0.36
EDANG35=3	0.01	50.1	0.32
EDANG06=2	0.02	50.2	0.28

End of Form

Translational Tools for Clinical Studies of CAM Interventions

- "T1" Translation research: "apply discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans."

- "FOA is not to be used for randomized controlled trials of efficacy or effectiveness for CAM interventions, and applications that do propose such trials will be considered non-responsive."

RFA-AT-10-001

- National Center for Complementary and Alternative Medicine (NCCAM)
  - Dr. Partap S. Khalsa
  - Division of Extramural Research
  - Scientific/Research Contact
- Due date: 03-23-10; Start date: 12-01-10
- 8 grants, 6 million total per year
- 330k direct costs/year; 5-year duration

Example Research Topic

- Development and Early-stage Validation of CAM-relevant Patient-Reported Outcomes Measurement Information System (PROMIS) assessment tools for CAM mind-body interventions, manual therapies and/or yoga

Focus

- Item pool for evaluation of:
  - Spinal manipulation (osteopaths, physical therapists, chiropractors)
  - Massage (accupressure)
  - Acupuncture
  - Yoga
- NHIS indicates that1/3 of CAMS use for treatment of chronic pain disorders (back pain largest component)

Steps

- Review literature
- Focus groups
- Draft items
- Cognitive interviews
- Revise item pool
- Field test
- Finalize item pool for future studies

Example PROMIS Publications

- Arthritis Res Ther. 2009;11(6):R191. Epub 2009 Dec 16. **Better assessment of physical function: item improvement is neglected but essential.**

- Qual Life Res. 2010 Feb;19(1):125-36. Epub 2009 Nov 26. **Efficiency of static and computer adaptive short forms compared to full-length measures of depressive symptoms.**

- Pain. 2009 Nov;146(1-2):158-69. Epub 2009 Aug 15.**Development and psychometric analysis of the PROMIS pain behavior item bank.**

- Qual Life Res. 2009 Sep;18(7):873-80. Epub 2009 Jun 19. **Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items.**

Thank you!