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Performance of PROMIS and Legacy Measures Among Advanced Breast Cancer Patients and Their Caregivers

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Background

- A symptom management trial tested reflexology delivered by friend or family caregivers to patients with advanced breast cancer
- Two samples:
  - clinical sample of women with advanced breast cancer
  - general population sample of their caregivers
- The PROMIS Profile-29 was compared to legacy measures of the same or similar conceptual content

Legacy measures

- Medical Outcomes Study Short Form 36 (SF-36)
- Center for Epidemiologic Studies-Depression (CES-D)
- State Anxiety
- Pittsburgh Sleep Symptom Questionnaire-Insomnia (PSSQ_I)
- M. D. Anderson Symptom Inventory (MDASI)
- Completed by both patient and caregiver, with few exceptions

Correspondence of measures

Domain	PROMIS	Legacy
Physical function	• Physical function Profile 1.0, 4 items	• SF-36 physical function, 10 items
Pain	• Pain interference Profile 1.0, 4 items • Pain severity Profile 1.0, 1 item	• SF-36 bodily pain, 2 items • MDASI (patient), 1 item
Fatigue	• Fatigue Profile 1.0, 4 items	• SF-36 vitality, 4 items • MDASI (patient), 1 item

Correspondence of measures

Domain	PROMIS	Legacy
Sleep	• Sleep disturbance Profile. 1.0 (caregiver), 4 items	• PSSQ_I sleep quality (caregiver), 5 items, PSSQ_I sleep interference (caregiver), 8 items • MDASI (patient), 1 item, range 0-10
Depressive symptoms	• Depression Profile 1.0, 4 items	• CES-D, 20 items • SF-36 mental health, 5 items • MDASI (patient), 1 item

Correspondence of measures

Domain	PROMIS	Legacy
Anxiety	• Anxiety Profile 1.0 (patient and caregiver), 4 items	• State Anxiety, 20 items • MDASI (patient), 1 item
Social role functioning	• Satisfaction with participation in social roles. Profile 1.0, 4 items • Ability to participate in social roles and activities. Short form 2.0 (caregiver), 4 items	• SF-36 social functioning, 2 items

Objective

To compare measures for both members of the patient-caregiver dyads with respect to:

- Length
- Distributions in patient and caregiver samples
- Correlations between pairs of measures of the same or similar construct (concurrent or convergent validity)
- Ability to discriminate patient and caregiver subgroups (known groups validity)
- Ability to discriminate groups with respect to interventions received (responsiveness)

Sample

N=256 dyads were recruited from 2 comprehensive cancer centers and 5 community-based oncology settings in the Midwest.

Patients:

- age 21 or older (actual mean=56, SD=11)
- treated with chemotherapy, targeted or hormonal therapy for advanced breast cancer
- had a friend or family caregiver participating with them

Caregivers:

- age 18 or older (actual mean=55, SD=15)
- identified as a caregiver by the patient (55% spouses)
- able and willing to provide the 30-minute reflexology protocol for 4 consecutive weeks

Study procedures

- Baseline telephone interview for patients and caregivers
- Randomization to attention control versus 4 weeks of reflexology delivered to patient by the caregiver
- For intervention dyads, caregivers were trained in standardized 30-minute protocol of stimulating 9 reflexes
- Week 5 (post-intervention) telephone interview, follow up at week 11
- For this report, data from baseline and week 5 interviews were used

Data analyses

- Distributions, % at floor (worst), % at ceiling (best), correlations
- Known groups validity: comparisons of subgroups according patient's cancer recurrence and metastasis, treatment type, comorbidity
- Responsiveness: intervention effect using two sets of measures. General linear models for outcomes at week 5; trial arm and baseline value were covariates.
- Focus on consistency of conclusions and magnitude of the effect sizes for PROMIS and legacy measures
- Effect size (Cohen's d): difference between subgroup means expressed in the standard deviation units

Results: length

- The SF-36 physical functioning and mental health, legacy measures of sleep, anxiety and depression are longer than the corresponding PROMIS short forms.
- In contrast, legacy measures of the cancer-related symptoms (MDASI) are single items, while PROMIS short forms have 4 items for each symptom.
- The 2-item SF-36 social role functioning is shorter than the PROMIS “Ability to participate in social roles” and “Satisfaction with participation in social roles.”
- The 4-item SF-36 vitality is the same length as the corresponding PROMIS fatigue short form.

Distributions, floor and ceiling effects

- Floor effects were not substantial; ceiling effects were pronounced and greater for caregivers than patients
- Shorter length was associated with greater percentage of observations at the ceiling
- Best PROMIS physical function for caregivers 74% v. 43% with the SF-36
- Lowest depression with PROMIS 34% for patients, 67% with caregivers versus CES-D 3% for patients,13% with caregivers

Concurrent and convergent validity

- The majority of the correlations were strong (r=0.6+) or very strong (r=0.8+), with only a few exceptions
- Moderate correlations: PROMIS satisfaction with participation in social roles with the SF-36 social functioning (r=0.57 for patients; r=0.44 for caregivers)
- PROMIS depression and severity of distress from MDASI: r=0.58 for patients

Known groups validity

- Similar effect sizes were observed for the differences between known groups, e.g. those with 2+ comorbid conditions v. <2, according to cancer recurrence and treatment type (patients)
- Patients with metastatic v. loco-regional disease:

  -differences in pain with the MDASI single item pain severity rating (d=0.30, p=0.02);

  -SF-36 bodily pain subscale produced smaller effect size (d=.19, p=0.15);

  -even smaller effect sizes were observed using the PROMIS pain interference and severity measures

Responsiveness

- Similar medium effect sizes were seen for reflexology versus attention control groups for pain, fatigue, and anxiety using PROMIS and legacy
- Post-intervention differences in patient depression were sizable (~ 1/3 of the SD) when assessed by the CES-D and the SF-36 mental health subscale, but not with PROMIS (d=.09). For the MDASI single item distress severity d=0.31.
- The same pattern with similar effect sizes was also seen with caregiver depression
- Content differences in PROMIS depression item banks and the CES-D have been previously noted

Conclusions

- Evidence of validity and reduced respondent burden support the use of shorter assessments for symptoms (MDASI, PROMIS) and functioning (PROMIS) in clinical and general populations
- The use of longer instruments such as the CES-D or the SF-36 mental health may have advantages in measuring depression over PROMIS SF-4
- Publicly available transparent scoring for PROMIS Profile-29 and the CES-D