Validity of the Healing Encounters and Attitudes Lists (HEAL) in persons with ongoing pain

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No Conflicts of Interest to Disclose

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PCORI METHODS PROJECT (ME-1402-10114)
Measuring the Context of Healing: Using PROMIS in Chronic Pain Treatment

The Healing Context in CAM: Instrument Development and Initial Validation (NIH NCCIH R01 AT 006453)

CTSI: NIH UL1TR000005
The Challenge

Similar patients + Similar conditions = Different outcomes

- People can respond to the same treatment differently.
- Even placebos can have a positive effect at times.

Why does this happen?
Can we identify what makes the difference?
How can we measure and begin to use what we learn to improve treatment outcomes?
Our Assumptions

- **Mind** and **body** work together in healing.
- A person’s experience of **healthcare** includes a lot more than a drug or procedure.
- Measuring **patients’ characteristics** and **perceptions of care** may **explain** different responses to treatment and can be **useful** to researchers, clinicians, and patients.
The HEAL Study

Healing Encounters and Attitudes Lists (HEAL)

- Questionnaires developed and validated to measure subjective factors such as patients’ characteristics and perceptions of care which could influence treatment outcomes.
Measuring Nonspecific Factors in Treatment: Healing Encounters and Attitudes Lists (HEAL)

Develop Questionnaires for topics such as treatment expectations, Patient-provider relationships, and other nonspecific factors. “Item banks” are needed.

- **Item banks** = sets of questions that are the building blocks of Computerized Adaptive Tests (CATs)
- **CATs** = questionnaires that adapt to the test-taker’s answers, so that very few items are needed
- Items can be made into **Short Form** tests (6-7 items)

**Question:** to what extent do nonspecific factors contribute to treatment improvement?

- Measuring such factors may help to dismantle ‘placebo’
PROMIS Methodology

- Development of item banks
  - Patient focus groups for relevant concepts
  - Interviews with clinicians
  - Comprehensive literature searches for existing questionnaires
  - Writing, revising, removing questions, with help from patients

- From over 16,000 potential questions, a set of ~300 were considered for further testing
Choosing the Final Item Banks

Pilot Testing on 296 retained items

- Internet Sample N = 1400
- Pittsburgh Sample N = 257

Classical Test Theory Analysis: 250 items retained

Item Response Theory Analysis: 168 items retained

HEAL Final Item Banks and Short Form

- Patient-Provider Connection 57 items
- Healthcare Environment 25 items
- Treatment Expectancy 27 items
- Positive Outlook 27 items
- Spirituality 26 items
- Attitudes toward CAM Short Form 6 items
Healing Encounters and Attitudes Lists (HEAL)

- **Treatment Expectancy**
  - Your expectations about whether the treatment will be helpful

- **Patient-Provider Connection**
  - Your views of your relationship with your healthcare provider

- **Healthcare Environment**
  - Your views about the healthcare provider’s office and staff

- **Positive Outlook**
  - Your level of confidence and optimism, in general

- **Spirituality**
  - Your spiritual beliefs and experience of spiritual support

- **Attitudes toward CAM**
  - Your views about integrative medicine or CAM
## Sample Items

<table>
<thead>
<tr>
<th>Item Bank/domain</th>
<th>Example Item</th>
<th>Response scale (5 point)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient-provider connection</td>
<td>I trust my healthcare provider</td>
<td>Not at all…very much</td>
</tr>
<tr>
<td>Healthcare Environment</td>
<td>The staff was respectful</td>
<td>Not at all…very much</td>
</tr>
<tr>
<td>Treatment Expectancy</td>
<td>I am confident in this treatment</td>
<td>Not at all…very much</td>
</tr>
<tr>
<td>Positive Outlook</td>
<td>I am hopeful about my future</td>
<td>Not at all…very much</td>
</tr>
<tr>
<td>Spirituality</td>
<td>I find comfort in my faith</td>
<td>Not at all…very much</td>
</tr>
<tr>
<td>Attitudes toward CAM</td>
<td>I prefer natural remedies</td>
<td>Not at all…very much</td>
</tr>
</tbody>
</table>
PCORI Project
Measuring the Context of Healing
Using HEAL and PROMIS in Chronic Pain Treatment

• Predictive validity?
• Useful in treatment settings?
  – To Patients? To Treatment Providers?

BraveNet sites Collaboration:
Venice Clinic (CA) and Allina Health (MN)
PCORI Project

Participants:
- 209 adults with chronic pain, starting new CAM (n=109) or Conventional (n=100) treatment

Procedures:
- HEAL and PROMIS measures Online
- Baseline, 2 months, 4 months

Cognitive ‘think aloud’ Interviews
- 44 patients, 13 clinicians
# Description of Sample

<table>
<thead>
<tr>
<th>Sociodemographic</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age $\bar{X} = 47.5$ (SD=14.9)</td>
<td>---</td>
</tr>
<tr>
<td>Gender (% female)</td>
<td>75.1</td>
</tr>
<tr>
<td>Race (% non-White/multi-racial)</td>
<td>23.0</td>
</tr>
<tr>
<td>Education level (&lt; 4yr college degree)</td>
<td>48.3</td>
</tr>
</tbody>
</table>

## Top three types of pain

<table>
<thead>
<tr>
<th>Type of pain</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back pain</td>
<td>45.9</td>
</tr>
<tr>
<td>Arthritis or joint pain</td>
<td>12.0</td>
</tr>
<tr>
<td>Neck pain</td>
<td>7.7</td>
</tr>
</tbody>
</table>

## Type of medical care

<table>
<thead>
<tr>
<th>Type</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional</td>
<td>47.8</td>
</tr>
<tr>
<td>Complementary/Alternative Med (CAM)</td>
<td>52.2</td>
</tr>
</tbody>
</table>

## Top four treatments

<table>
<thead>
<tr>
<th>Treatment</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Therapy</td>
<td>26.8</td>
</tr>
<tr>
<td>Rx Medication</td>
<td>19.6</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>17.7</td>
</tr>
<tr>
<td>Chiropractic</td>
<td>13.9</td>
</tr>
</tbody>
</table>
Chronic Pain Reduced: Pain Intensity was significantly reduced from baseline to the 2 month assessment \[t_{(191)} = 7.5, p<0.001\]. Pain Interference was also significantly reduced \[t_{(191)} = 5.0, p<0.001\].
Clinical Global Impression of Improvement (CGI)

2 MONTHS
- Somewhat better: 45.9%
- Much better: 12%

4 MONTHS
- Somewhat better: 44%
- Much better: 15.3%
HEAL non-specific factors association with outcomes in chronic pain patients

<table>
<thead>
<tr>
<th></th>
<th>PROMIS Pain Interference 2 mo</th>
<th>PROMIS Pain Intensity 2 mo</th>
<th>4 mo</th>
<th>Clinical Global Improvement 2 mo</th>
<th>4 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Expectancy (TEX)</td>
<td>-.230**</td>
<td>-.191**</td>
<td></td>
<td>.182*</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.227**</td>
<td></td>
</tr>
<tr>
<td>Positive Outlook (POS)</td>
<td>-.311**</td>
<td>-.181*</td>
<td></td>
<td>.226**</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-.246**</td>
<td></td>
<td>.252**</td>
<td></td>
</tr>
<tr>
<td>Spirituality (SPT)</td>
<td>.155*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attitudes toward CAM (CAM)</td>
<td>-.144**</td>
<td>-.151**</td>
<td></td>
<td>.224**</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.245**</td>
<td></td>
</tr>
<tr>
<td>Patient-Provider Connection (PPC)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.257**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.202**</td>
</tr>
<tr>
<td>Healthcare Environment (HCE)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.232**</td>
</tr>
</tbody>
</table>

Spearmans rho, * p<.05, **p<.01
Results – predictive validity of HEAL

- HEAL scores at Baseline were Predictive of Patient-Reported Improvement:
  
  Positive Outlook and Spirituality
  • accounted for 18% of variance in PROMIS Pain Interference and 7.6% of variance in Pain Intensity at 2mo (unadjusted regression model).

Patient-Provider Connection and Attitudes towards CAM
• accounted for 9.4% of variance in 2 mo. CGI (unadjusted model).

Treatment Expectancy and baseline PROMIS Pain Intensity
• accounted for 47.5% of variance in 2 mo. Pain Int, and 41% of variance in 4 mo. Pain Int. (1-2% was due to HEAL TEX).
Treatment Expectations? PROMIS Pain and Function outcomes

Observed Mean by Low TEX vs. High TEX
Low TEX=Blue Dashed line & High TEX=Red Solid line

Av ePain

Health

PHYS

PI

PINT
Cognitive Interviews
44 patients, 13 clinicians

- Patients and clinicians rated:
  - Were items clear and easy to understand?
  - Were items relevant and useful?

- Clarity – very high

- Relevance and utility – higher for pain-related items
Example Graphic Display

PROMIS Measure Scores for 22864
Assessment 1: 12/3/2015

- Treatment Expectancy: 70.7
- Patient-Provider Connection: 72.8
- Healthcare Environment: 65

Your Scores
Examples – patient feedback

Graph:
• Brings to light everything on a scale for everything I’m dealing with and how I’m feeling.
• Clear, easy to read
• Prefer to have colors and Don’t like colors

Items:
• People-friendly – told me specifically what I answered
• Prefer to see words rather than numbers
General Feedback

Patients:
• Gives the provider as much info as he needs to help me and understand my experience of pain.
• Some domains are more helpful than others.
• Would not necessarily want provider to see responses (e.g., patient provider connection).

Providers:
• Questionnaires could be completed on iPad at sign-in.
• Important areas should be highlighted to be discussed with patient.
General Feedback

Treatment expectancy: “Shows them are you [going to] be a good patient? [This is] helpful, it might predict if you’ll show up for your appointments, if you’ll be compliant with your treatment.”
– Conventional patient

CAM provider on HEAL measures: “[They] are important for influencing the placebo effect. [You] know what you need to foster or bolster to improve treatment.”

CAM patient on HEAL measures: “My experience is separate pain and mental health. Integration between mental and physical is best”
Summary

HEAL questionnaires measure nonspecific factors that are part of many treatments.

HEAL scores predict improvement:

- **Treatment Expectancy**
- **Patient Provider Connection**
- **Healthcare Environment perceptions**
- **Positive Outlook**
- **Attitudes toward CAM**
- **Spirituality**

HEAL and PROMIS may be useful in treatment settings.
Are HEAL Questionnaires Useful?

Patients
Important to consider and track during treatment

Providers
Help improve the care they provide to patients

Health Systems
Important to measure in clinics
Next Steps

PCORI proposal: Dissemination & Implementation

HEAL Short Forms and scoring are available: greco@pitt.edu
Co-Authors

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Thank You

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