Validity and reliability of a 36-item problem-related distress screening tool in a community sample of 319 cancer survivors

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Background

- There are a number of validated measures to screen for distress and identify areas of unmet need
- Screening program was chosen because:
  - Automated touchscreen interface
  - Ability to tailor referrals
  - Option to provide summary and print material in real time
  - Patient-friendly screening tool
- Screening tool had not been validated
- Presented a unique opportunity to test psychometric properties in a community sample
<table>
<thead>
<tr>
<th>How Much Of A Problem Is This For You?</th>
<th>Sleeping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not a Problem</td>
<td></td>
</tr>
<tr>
<td>Mild Problem</td>
<td></td>
</tr>
<tr>
<td>Moderate Problem</td>
<td></td>
</tr>
<tr>
<td>Severe Problem</td>
<td></td>
</tr>
<tr>
<td>Very Severe Problem</td>
<td></td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td></td>
</tr>
<tr>
<td>Do not know</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How Can We Best Work With You On This Problem?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide Written Information</td>
</tr>
<tr>
<td>Talk with a Member of the Team</td>
</tr>
<tr>
<td>Written Information and Talk with Team Member</td>
</tr>
<tr>
<td>Nothing Needed at This Time</td>
</tr>
</tbody>
</table>
Phase 1: Refined 53-item tool

- 350 cancer patients
- Process used statistical and theoretical criteria
- Reduced and refined City of Hope 53-item tool to meet community needs
  - 19 items dropped
  - 6 items revised
  - 2 items added
Phase 2: Validated 36-item tool

- Sample included 319 cancer survivors across 14 CSC affiliate sites
- Pen-and-paper survey
  - 36-item screening tool
  - FACT-G
  - CES-D
  - Distress thermometer
  - Socio-demographic and clinical questions
- Subsample of 101 completed the 36-items a second time
Statistical Methods

- **Internal reliability**
  - Cronbach’s alpha coefficient

- **Concurrent validity**
  - Pearson correlation coefficient ($R^2$ reported)
  - ROC curve analysis

- **Known groups validation**
  - Wilcoxin rank-sum and Kruskal-Wallis tests

- **Test-retest reliability**
  - Intraclass correlation coefficient
  - Percent agreement
Sample characteristics

- Median age: 61 years
- 84% female
- 83% white, 8% Hispanic/Latino
- 25% <$40K total annual income
- 45% breast cancer, 12% blood, 9% gynecologic, 5% lung, 5% prostate
- 20% <1 y from cancer dx, 33% 5 y+
- 70% active tx for cancer within 2 y
Top 5 items rated moderate to very severe problem

- Worry about the future: 50%
- Sleeping: 44%
- Fatigue: 44%
- Side-effects of treatments: 38%
- Managing my emotions: 34%
Top 5 items for which assistance was requested

- Worry about the future: 52%
- Feeling anxious or fearful: 49%
- Managing my emotions: 48%
- Feeling down or depressed: 47%
- Fatigue: 41%
Summary scores

- The median number of items rated moderate to very severe problem was 6

- Half (52%) did not rate any item as a severe or very severe problem

- 14% rated 1 item; 10% rated 2 items severe or very severe
Internal reliability

- A 6-item depression subscale was calculated as the sum of the following:
  - feeling down or depressed;
  - feeling anxious or fearful;
  - managing my emotions; worry about the future;
    - feeling isolated, alone or abandoned;
  - feeling irritable or angry.

- Cronbach’s alpha
  - 0.91 for 36 items
  - 0.88 for 6 depression items
## Concurrent validity

Correlations ($R^2$) between the screening tool and the FACT-G, the CES-D and the DT

<table>
<thead>
<tr>
<th>Summary Scores</th>
<th>Overall</th>
<th>Emotion</th>
<th>Physical</th>
<th>Function</th>
<th>Social</th>
<th>CES-D</th>
<th>Distress Therm.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary of problem ratings</td>
<td>0.58</td>
<td>0.34</td>
<td>0.42</td>
<td>0.34</td>
<td>0.23</td>
<td>0.48</td>
<td>0.35</td>
</tr>
<tr>
<td>Depression subscale</td>
<td>0.50</td>
<td>0.49</td>
<td>0.21</td>
<td>0.30</td>
<td>0.23</td>
<td>0.50</td>
<td>0.37</td>
</tr>
<tr>
<td>Count of items ≥ 3</td>
<td>0.50</td>
<td>0.32</td>
<td>0.41</td>
<td>0.28</td>
<td>0.18</td>
<td>0.44</td>
<td>0.34</td>
</tr>
<tr>
<td>Count of items ≥ 4</td>
<td>0.31</td>
<td>0.14</td>
<td>0.26</td>
<td>0.17</td>
<td>0.15</td>
<td>0.30</td>
<td>0.22</td>
</tr>
</tbody>
</table>

$R^2 ≥ 0.49$: strong

$0.49 > R^2 ≥ 0.16$: moderate
Receiver Operating Characteristic curve for the count of screening items rated moderate to very severe problem compared to the CES-D ($\geq 16$)

Area under ROC curve = 0.8289
## Known groups validation

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>CES-D&lt;16</th>
<th>n</th>
<th>CES-D≥16</th>
<th>Number of items severe or very severe (mean ± SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Depression</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CES-D&lt;16</td>
<td>192</td>
<td></td>
<td></td>
<td>0.8 ± 1.7</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>CES-D≥16</td>
<td>120</td>
<td></td>
<td></td>
<td>3.4 ± 4.0</td>
<td></td>
</tr>
<tr>
<td><strong>Distress</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DT&lt;4</td>
<td>151</td>
<td></td>
<td></td>
<td>0.6 ± 1.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>DT≥4</td>
<td>141</td>
<td></td>
<td></td>
<td>2.9 ± 3.5</td>
<td></td>
</tr>
<tr>
<td><strong>Active tx for cancer</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥2y</td>
<td>96</td>
<td></td>
<td></td>
<td>1.3 ± 2.9</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>&lt;2y</td>
<td>220</td>
<td></td>
<td></td>
<td>2.1 ± 3.1</td>
<td>0.002</td>
</tr>
<tr>
<td>&lt;5 mo</td>
<td>19</td>
<td></td>
<td></td>
<td>2.4 ± 3.4</td>
<td></td>
</tr>
<tr>
<td>5 mo-1 y</td>
<td>44</td>
<td></td>
<td></td>
<td>2.2 ± 3.3</td>
<td></td>
</tr>
<tr>
<td>1 – 2 y</td>
<td>57</td>
<td></td>
<td></td>
<td>1.9 ± 2.5</td>
<td></td>
</tr>
<tr>
<td>2 – 5 y</td>
<td>84</td>
<td></td>
<td></td>
<td>1.5 ± 2.5</td>
<td></td>
</tr>
<tr>
<td>≥ 5 y</td>
<td>101</td>
<td></td>
<td></td>
<td>1.9 ± 3.7</td>
<td>0.35</td>
</tr>
</tbody>
</table>
Test-Retest Reliability

- Percent agreement between test and retest responses was high for all 36 items ranging in value from 71-99%.
- The Intraclass Correlation Coefficient (ICC) was $\geq 0.75$ for all 36 screening items except ability to have children.
- There was 98% agreement for ability to have children with 86 of 89 (97%) participants rating the item as not a problem at both test and retest.
Conclusion

- Strong psychometric properties in a community sample of cancer survivors.
  - Strong internal reliability, discriminant validity and test-retest reliability
  - Moderate concurrent validity

- Study begins to demonstrate feasibility of systematic screening for distress in the community.