The Clinical Significance of Patient-Reported Outcomes: Yoga for Cancer Survivors

Dr. Nicole Culos-Reed, PhD
Faculty of Kinesiology, University of Calgary
Department of Psychosocial Resources, Tom Baker Cancer Centre

Dr. Suzanne Danhauer, PhD
Department of Social Sciences and Health Policy,
Wake Forest School of Medicine

Michael Mackenzie, MSc, PhD Candidate
Faculty of Kinesiology, University of Calgary

Dr. Stephanie Sohl, PhD
Department of Social Sciences and Healthy Policy,
Wake Forest School of Medicine
Overview

1. Overview – role of yoga for cancer survivors
2. Clinical significance markers
3. Patient-reported outcomes
4. Results of recent review
5. Implications for building a community-based program
Yoga & Cancer

- Emerging research suggests yoga is a promising complementary exercise choice for cancer survivors
  - Positive effects reported on health-related quality of life, psychosocial and symptom measures
Yoga Reviews

• Ross & Thomas, 2010
  – Yoga a gentle form of physical activity
  – Many of the same health-related benefits

• Smith & Pukall, 2009
  – Positive psychological outcomes (ES)

• Lin et al., 2011
  – Meta-analysis
  – Yoga: improvements in psychological health
Clinical Significance Review

• Large number of newly published studies
• Necessary to examine clinical significance
  – Effect sizes
  – Narrative summary, trends (p value)

Clinical Significance

• Marker of the effectiveness of an intervention, taking into account *practical importance* of treatment effects

• Gives meaning to observed changes, in terms of implications for patient care

• Comparative metric of treatment effectiveness between studies
Clinical Significance Markers

• Distribution-based methods
  – 1 Standard Error of the Measurement (1 SEM)
  – 0.5 Standard Deviation (0.5 SD)
  – Effect Sizes (ES)
  – Confidence Intervals (CI)

• Do not use these markers in same way as p-values
  – Use concurrently to describe range of findings, relative magnitude of effect & generalizability
Purpose

• Review of the yoga and cancer literature, implementing multiple methods for calculating the clinical significance of patient-reported outcomes
Measures

• Patient reported outcomes (PROs)
  – Quality of life
  – Psychosocial
  – Symptoms
Studies

• Twenty-five published yoga studies
• 13 had necessary data to be included in the review
• Heterogeneity in:
  – Yoga interventions (type, duration)
  – Cancer types
  – Assessments (timing, measures)
• 7 RCTs; 6 single-group pre-post design
Results

• 18 PRO instruments
  – 6 HRQL
    • Overall, Physical, Mental, Emotional, Social, Functional
  – 8 Psychosocial
    • Depression, Anxiety, Positive Affect, Negative Affect, Spiritual well-being
  – 4 Symptom
    • Fatigue, Sleep
HRQL Results

• Beneficial effects of Yoga on:
  – Overall HRQL
    • Danhauer et al. (2009) and Culos-Reed et al. (2006) met the 1 SEM and 0.5 SD criteria for both pre-post and between yoga intervention and waitlist control
    • Medium between-group ES, ranged from 0.49 [95% CI - 0.25, 1.24; p=NS] [27] to 0.67 [95% CI 0.01, 1.32; p<.05] [28]
  – Mental
  – Emotional
  – Very limited impact on physical HRQL
Psychosocial Results

• Beneficial effects of yoga on:
  – Anxiety
    • Chandwani et al. (2010) moderate clinically significant differences within the yoga group, -0.63 ES [95% CI -1.04, -0.23; p<.01] and small clinically significant differences in the waitlist control group, ES -0.20 [95% CI -0.55, 0.15; p=NS]
    • Small clinically significant differences between yoga and waitlist control, ES of -0.46 [95% CI -0.98, 0.05; p=NS], meeting 1 SEM and 0.5 SD criteria
  – Depression
  – Negative Affect
  – Spiritual well-being
Symptom Results

• Beneficial effects of yoga on:
  – Fatigue
  • Clinically significant differences between the yoga intervention and control groups ranged from small ES, -0.17 ES [95% CI -0.68, 0.34; p=NS], meeting the 1 SEM criteria to medium ES, 0.71 ES [95% CI -0.04, 1.47; p=NS], meeting both the 1 SEM and 0.5 SD criteria
What does it all mean?

• Multiple criteria – met for quality of life and psychosocial outcomes (e.g., anxiety, depression, positive and negative affect, spiritual well-being), and for some limited symptom outcomes (e.g., fatigue, sleep)

• Indices vary in their sensitivity / conservatism for reporting clinical significance
• Role of yoga in physical, functional and social domains of HRQL remain far more inconclusive
  – Role of yoga in positive affect and sleep indices for cancer survivors??

• Considering clinical significance indicates stronger support for the preliminary efficacy of yoga for improving overall HRQL and its mental and emotional domains, in addition to psychosocial outcomes
Building a Community Yoga Program for Cancer Survivors

- Yoga Thrive, Calgary AB
- Yoga as an intervention to enhance PROs
  - Promote benefits of yoga – HRQL, anxiety, fatigue
- Understanding individual needs
  - Baseline scores, areas for improvement
- Promotion within clinical settings
Clinical – Community

• Evidence!

• Future research:
  – Symptom PROs
  – Comparison studies
    • Physical activity or psychosocial interventions
  – Consistency in measurement
    • Disease-specific measures
  – Mechanisms
    • Psychophysiological
Acknowledgements

Collaborators: Current and previous graduate students, colleagues, clinicians and partners, including Fitter First, All the Yoga Instructors and the Cancer Survivor Participants!
<table>
<thead>
<tr>
<th>Study</th>
<th>Outcome Measure</th>
<th>Initial Consistency (Cronbach’s α)</th>
<th>Mean (BasiLine SD x 1-Cronbach’s α)</th>
<th>Baseline 0.5 SD</th>
<th>Baseline Mean (SD)</th>
<th>Between-Groups Mean Difference (95% CI)</th>
<th>Within-Groups Effect Size - Hedge’s g (95% CI)</th>
<th>Between Groups Effect Size - Hedge’s g (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Yoga</td>
<td>Control</td>
<td>Yoga</td>
<td>Control</td>
<td>Yoga</td>
<td>Control</td>
<td>Yoga</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.91</td>
<td>2.92</td>
<td>2.82</td>
<td>2.82</td>
<td>2.77</td>
<td>2.82</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
<td>2.77</td>
</tr>
</tbody>
</table>