The Clinical Significance of Patient-Reported Outcomes:

Yoga for Cancer Survivors

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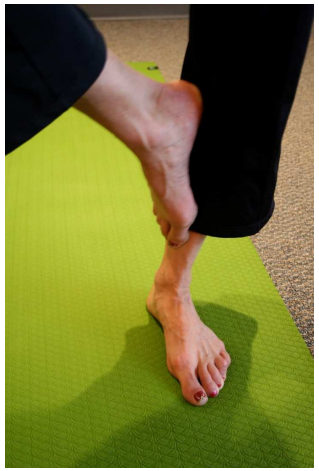
Overview

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)

Culos-Reed SN, Mackenzie MJ, Sohl SJ, Jesse MT, Ross A, Danhauer SC. (Accepted). Yoga and cancer interventions: a review of the clinical significance of patient-reported outcomes for cancer survivors. *Evidence-Based Complementary and Alternative Medicine.*

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

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Alberta Health Services
Cancer Care

- 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

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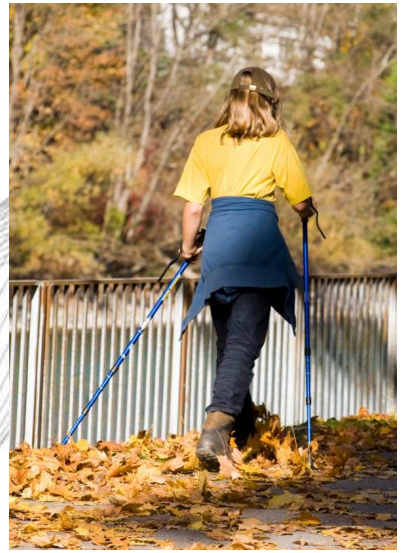
Alberta Health Services
Cancer Care

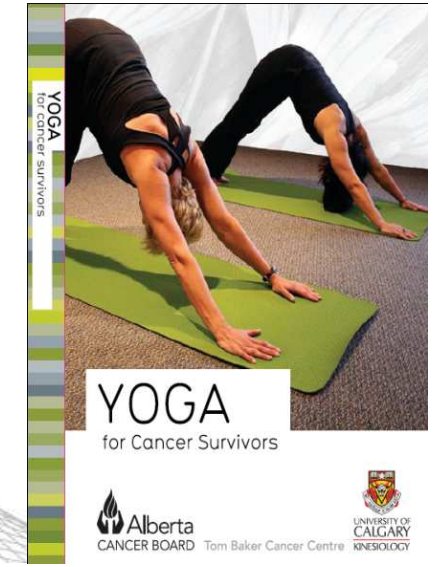
Building a Community Yoga Program for Cancer Survivors

- 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





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Alberta Health Services

Study	Outcome Measure	Internal Consistency (Cronbach α)	SEM (Baseline SD x √1-Cronbach α)		Baseline 0.5 SD		Baseline Mean (SD)		Within-Groups Mean Difference (95% CI)		Within-Groups Effect Size - Hedges' g (95% CI)		Between Groups Mean Difference (95% CI)	Between Groups Effect size - Hedges' g (95% CI)
			Yoga	Control	Yoga	Control	Yoga	Control	Yoga	Control	Yoga	Control		
~~Cwikiel~~ et al., 2010 [36]	SF36 PCS (Physical)	.80	2.60	3.40	4.00	5.00	41.80 (8.20)	41.8 (10.6)	1.60 [-1.34, 4.54]	-2.80 [-6.35, 0.75]	0.18 [-0.19,0.54]	-0.27 [-0.62,0.08]	4.40 [-0.52, 9.32]*	0.46 [-0.06,0.97]
	SF36 MCS (Mental)	.90	3.80	5.80	6.00	9.00	47.80 (12.00)	48.0 (11.1)	1.80 [-2.16, 5.96]	1.80 [-1.76, 5.36]	0.17 [-0.19, 0.54]	0.18 [-0.17, 0.52]	0.00 [-5.45,5.45]	0.00 [-0.51,0.51]
Cohen-Reed et. al, 2006 [28]	HRQL-Qol. (Overall)	.89	8.50	4.28	12.82	6.43	69.50 (25.63)	62.04(12.85)	15.68 [2.85, 24.47]*	0.45 [-6.36, 7.08]	0.56 [0.08,1.04]*	0.03 [-0.43,0.47]	13.20 [0.52,25.88]*	0.67 [0.01,1.32]*
	HRQL-Emo (Emotional)	.80	9.01	6.64	10.07	7.43	79.50 (20.34)	75.00(14.85)	4.22 [-4.05, 12.49]	-4.77 [-11.57, 3.25]	0.23 [-0.22,0.67]	-0.23 [-0.70,0.20]	8.34 [-2.71,19.40]*	0.48 [-0.16,1.13]
Barbaute et al., 2009 [27]	FACT-B (Overall)	.90	6.30	7.70	10.00	12.20	104.80(18.90)	101.1 (20.4)	9.90 [-0.73, 20.51]*	-2.70[-17.80,12.40]	0.48 [-0.06,1.02]	-0.09 [-0.58,0.41]	12.6[-0.12,31.32]*	0.49 [-0.25,1.24]
	FACT-SWB (Social)	.89	2.60	3.00	2.60	2.70	23.30 (4.70)	21.4 (3.4)	-0.20 [-2.84, 2.44]	-1.00 [-4.26, 2.26]	-0.04 [-0.55,0.47]	-0.35 [-0.88, 0.35]	0.80 [-3.43,5.03]	0.14 [-0.80,0.87]
	FACT-PWB (Functional)	.88	2.60	3.30	2.90	3.50	18.70 (5.70)	18.0 (6.9)	3.20 [0.33, 6.07]*	-0.80 [-4.38, 3.18]	0.57 [0.03,1.12]*	-0.08 [-0.57, 0.42]	3.80 [-1.00, 8.60]*	0.58 [-0.17,1.34]
	FACT-EWB (Emotional)	.89	2.00	2.70	2.00	2.80	18.30 (3.80)	18.5 (5.2)	2.70 [0.74, 4.66]*	-0.30 [-3.29,2.69]	0.70 [0.13,1.28]*	-0.05 [-0.54,0.44]	3.00 [-0.63,6.63]*	0.81 [-0.19,1.33]
	FACT-FWB (Physical)	.83	3.00	2.20	3.80	2.80	19.70 (7.00)	20.7 (5.1)	2.80 [-1.38, 6.78]	0.40 [-2.44,3.24]	0.36 [-0.17,0.89]	0.07 [-0.42,0.56]	2.40 [-2.44,7.24]*	0.36 [-0.38,1.10]
	SF-12 PCS (Physical)	.88	4.30	3.80	6.10	5.30	42.30 (12.30)	40.6 (10.1)	2.10 [-4.36, 8.76]	2.10 [-3.68,7.88]	0.16 [-0.33,0.67]	0.18 [-0.32, 0.68]	0.00 [-8.79,8.79]	0.00 [-0.73,0.73]
	SF-12 MCS (Mental)	.83	4.40	4.50	5.30	5.30	49.40 (10.30)	49.8 (10.2)	8.80 [3.87, 13.63]*	-2.40 [-8.80, 4.10]	0.85 [0.30,1.35]**	-0.18 [-0.68,0.31]	11.20[3.01,19.39]*	1.00 [0.22,1.78]**
Littman et al., 2011 [29]	FACT-B (Overall)	.90	2.97	4.49	4.20	7.30	89.00 (9.40)	87.8(14.2)	1.30 [-2.38,5.28]	-0.10 [-5.61,5.41]	0.12 [-0.24,0.49]	-0.03 [-0.37,0.28]	1.40 [-3.34,8.14]	0.13 [-0.42,0.64]
	FACT-SWB (Social)	.89	2.84	3.03	2.60	2.20	21.30 (5.10)	21.7 (3.4)	0.40 [-1.93,2.21]	-0.80 [-2.96,1.40]	0.08 [-0.29,0.44]	-0.34 [-0.80,0.23]	1.20 [-1.68,4.08]	0.22[-0.31,0.75]
	FACT-PWB (Functional)	.88	1.23	1.46	1.30	2.60	22.30 (3.30)	21.6 (5.1)	-0.10 [-1.47,1.27]	0.10 [-1.75,1.95]	-0.03 [-0.39,0.34]	0.02 [-0.39,0.39]	0.20 [-2.31,2.31]	0.05 [-0.50,0.57]
	FACT-EWB (Emotional)	.89	1.56	1.45	1.40	1.30	19.80 (2.80)	20.3 (2.6)	0.50 [-0.84,1.84]	0.50 [-0.59,1.59]	0.34 [-0.23,0.91]	0.37 [-0.20,0.94]	0.00 [-1.73,1.73]	0.00 [-0.53,-0.53]
	FACT-FWB (Physical)	.83	1.03	1.70	1.20	2.00	24.70 (2.30)	24.2 (3.9)	0.70 [-0.08,1.48]	0.30 [-1.47,1.87]	0.33 [-0.05,0.71]	0.02 [-0.34,0.39]	0.60 [-1.36,2.36]	0.38 [-0.39,0.71]
Mourtzi et al., 2007 [26]	FACT-G (Overall)	.89	5.96	8.31	8.99	12.23	76.33 (17.98)	77.54(24.45)	1.54 [-3.02,6.68]	-7.38 [-16.25,1.33]	0.09 [-0.20,0.37]	-0.30 [-0.68,0.09]	8.30 [-0.06,18.36]*	0.43 [-0.05,0.91]
	FACT-SWB (Social)	.89	3.47	3.46	3.52	3.31	20.96 (6.23)	22.32 (6.22)	-0.30 [-1.99,1.39]	-3.93[-6.41,-1.49]**	-0.09 [-0.34,0.24]	-0.80[-1.00,-0.19]***	3.65 [0.75,6.58]*	0.60 [0.11,1.09]*
	FACT-PWB (Functional)	.80	2.85	3.45	3.59	3.86	18.33 (6.38)	18.39 (7.72)	-0.36 [-2.08,1.36]	-1.38 [-4.08,0.82]	-0.02 [-0.31,0.28]	-0.26 [-0.63,0.12]	1.02 [-1.51,3.37]	0.28 [-0.22,0.74]
	FACT-EWB (Emotional)	.74	2.43	3.03	2.39	2.97	16.36 (4.77)	16.50 (5.94)	1.83 [0.51,3.14]**	-0.43 [-2.65,1.81]	0.40 [0.10,0.70]**	-0.07 [0.44,0.31]	2.24 [-0.39,4.87]	0.44 [-0.09,0.92]
	FACT-PWB (Physical)	.82	2.24	2.88	2.64	3.52	20.87 (5.28)	20.73 (7.03)	0.16 [-1.55,1.85]	-0.82 [-3.39,1.75]	0.03 [-0.26,0.32]	-0.12 [-0.49,0.26]	0.98 [-1.96,3.93]	0.26 [-0.32,0.84]
Vadiraja et al., 2009 [24]	HRQL-Phys (Physical)	.71	12.49	16.68	11.60	15.49	73.20 (23.20)	62.72 (30.98)	0.06 [-7.30,7.42]	6.24 [-4.39,16.86]	0.00 [-0.29,0.30]	0.20 [-0.14,0.54]	6.18 [-6.24,18.80]	0.23 [-0.23,0.68]
	HRQL-Role (Role)	.52	26.35	25.22	17.43	18.20	72.72 (34.86)	71.59 (36.40)	7.16 [-3.32,17.64]	1.26 [-11.80,14.33]	0.21 [-0.30,0.80]	0.03 [-0.30,0.37]	5.90 [-10.84, 22.64]	0.16 [-0.29,0.61]
	HRQL-Emo (Emotional)	.80	8.84	7.80	9.89	8.72	59.45 (19.77)	51.38 (17.44)	18.67 [12.47,24.87]*	7.65 [0.48,14.82]	0.89 [0.54,1.25]***	0.36 [-0.01,0.70]*	11.02 [1.57,20.47]*	0.53 [0.07,0.99]*
	HRQL-Cog (Cognitive)	.71	9.39	10.87	9.00	10.56	89.29 (18.00)	82.87 (21.32)	5.28 [0.33,10.43]	-1.90 [-9.66,5.86]	0.30 [0.00,0.61]*	-0.08 [-0.42,0.25]	7.18 [-1.83,16.19]	0.38 [-0.30,0.82]
	HRQL-Soc (Social)	.77	12.73	11.72	13.28	12.22	92.82 (26.55)	92.41 (26.43)	2.34 [-5.33,9.81]	-2.48 [-10.78, 5.82]	0.08 [-0.22,0.38]	-0.10 [-0.43,0.23]	4.82 [-6.74,15.98]	0.28 [-0.27,0.84]