RESULTS FROM THE MINDSET STUDY

A Multi-site randomized controlled trial comparing Mindfulness-based Stress Reduction to Supportive-Expressive Therapy on psychological and biological variables

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presented by Joanne Stephen PhD (Co-Investigator, SET therapist) and Sarah Sample, MSW (Collaborator, MBSR therapist)
Research Questions answered today:

1) What are the comparative changes pre- to post-intervention among the three groups on psychological outcomes?

2) What are the comparative changes pre- to post-intervention on 1 of the biological outcomes (cortisol profiles)?

3) Do intervention preferences relate to improvement on outcomes?

4) Does personality relate to improvement on outcomes?
Study Design

Initial Contact and Eligibility Assessment

Consent and Pre-Intervention Assessment (n=30/cohort/site)
- questionnaires
- saliva samples

Randomization

MBSR (n=12)  SET (n=12)  control (n=6)

12 weeks

Post-Intervention Assessment (n=30/cohort/site)
- questionnaires
- saliva samples

Randomization

MBSR (n=3)  SET (n=3)

Post-Intervention Assessment (n=6/cohort/site)
- questionnaires
- saliva samples

6 and 12 month follow-up Assessment (n=30/cohort/site)
- questionnaires
- saliva samples
Baseline Measures

- Distress thermometer (DT)
- Demographics
- Disease Characteristics
- Health Behaviors
- Contamination (other therapies)

- Background (Moderators)
  - Emotional Repression:
    - Weinberger Adjustment Inventory (WAI)
  - Emotional Suppression
    - Courtauld Emotional Control Scale (CECS)
  - Personality:
    - NEO FFI
  - Patient Preferences
Psychological Outcome Measures

- **Mood**
  - Profile of Mood States (POMS)

- **Stress**
  - Calgary Symptoms of Stress Inventory (C-SOSI)

- **Quality of Life**
  - Functional Assessment of Cancer Treatment – breast (FACT-B)

- **Spirituality**
  - Functional Assessment of Chronic Illness Therapy – Spirituality (FACIT-Sp)

- **Social Support**
  - Medical outcomes survey social support scale (MOS-SSS)

- **Benefit-finding**
  - Post-traumatic growth inventory (PTGI)
Biological Outcome Measures

- **Salivary cortisol**
  - Measured 4 times/day for three days
- **Blood samples**
  - Frozen for later analyses
  - Telomere length, telomerase and cytokines
Preliminary Data Analysis

• Objectives 1 and 2: group comparisons of psychological and biological outcomes
• Baseline checks (one-way ANOVA; $\chi^2$): no group differences
• Linear Mixed-Models ITT sample: Missing data estimated
• Per-protocol completers analysis
• Planned contrasts: MBSR vs. Control; SET vs. Control; MBSR vs. SET
Research Results
Primary outcomes: Intent-to-treat

Main effect of Time. Interaction: MBSR> SET and control, p<.05
Main effect of time. Significant Interaction: MBSR>SET and control, p<.05
Main effect of time. Interaction: MBSR > Control, p < .05
Diurnal cortisol rhythms: Normal vs. dysregulated

Slide courtesy of Dr. David Spiegel and Dr. Sandra Sephton
Cortisol and survival: Metastatic Breast Cancer

Cortisol: Change in average slope

Interaction: MBSR, SET > decrease in slope than control, p<.05
Cortisol group difference at each timepoint

Bedtime cortisol (log)

Cortisol concentrations

Pre Post

MBSR
SET
SMS
Effect of personality on outcomes?

7 Personality traits investigated:
Suppression, repression, neuroticism, extraversion, openness to experience, agreeableness and conscientiousness

Multiple regression Analyses:
7 personality moderators X 4 outcomes (mood, stress, QL, social support) = 28 possible effects
Openness to experience – effects on SS

Moderator effects of Openness for Social support

Social support means

<table>
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<th>Low Openness</th>
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<tr>
<td>Social support means</td>
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<td>SMS</td>
<td>MBCR</td>
<td>SET</td>
<td>Pre</td>
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Pre
Post
What are program preferences and impact on outcomes?

Program preference at baseline

55% preferred MBSR, 13% SET, 16% SMS, 16% no preference

Baseline preference and actual randomization to treatment

50 patients (31%) were randomized into their preferred program
Effects of preference on stress symptoms

CSOSI: Stress symptoms

- In preferred program
- In non-preferred program

Pre-CSOSI | Post-C-SOSI
--- | ---
\[\text{Mean} \] | \[\text{Mean} \]

BC Cancer Agency CARE + RESEARCH
An agency of the Provincial Health Services Authority

Alberta Health Services

Division of Psychosocial Oncology
Helping You Live Well with Cancer
Effect of preference on quality of life

FACT b: Quality of life

- In preferred program
- In non-preferred program

Mean

Pre-FACITb | Post-FACITb
MINDSET Conclusion

- The **MBSR** group improved more on **mood** and **stress** relative to both **SM** and **SET** groups.
- The **MBCR** group improved more in **quality of life** pre-post relative to **SM** but not **SET** group.
- Both **MBSR** and **SET** groups significantly improved **diurnal cortisol rhythms** and **bedtime cortisol** from Pre to Post relative to **SM**.
- Personality was not a strong moderator of outcomes, except for **openness to experience** which improved social support in **SET**.
- Women who got their preferred treatment improved more on **stress symptoms** and **quality of life**.
Mindfulness-Based Stress Reduction (MBSR)

- Developed by Jon Kabat-Zinn and colleagues at UMass Medical Centre in 1979
- 8-week secular training in mindfulness meditation combined with gentle Hatha yoga (2.5 hr classes, 45 min homework, 8hr Saturday retreat)
- First applied to chronic pain and anxiety patients
- Hundreds of scientific studies of its effects across many psychiatric and medical disorders
Vancouver Cancer Centre

- MBSR program developed in 2000 by Sarah Sample
- Based Jon Kabat-Zinn curriculum
- 8 weeks; 2 hr. classes

- Open to cancer patients
- 600 participants
- Core clinical program
Study Program Design

• MBCR 8-week intervention
  – 1.5 hour weekly meetings with 2 instructors
  – Discussion followed by mindful yoga and meditation (body scan, sitting, walking)
  – Follow booklet which outlines the program/ includes a bibliography
  – Daily meditation practice encouraged and monitored - formal and informal (CD provided)
  – Homework log of time spent in meditation
  – 6-hour silent “retreat” between weeks 6 and 7
What is mindfulness?

• Simple definition:
  – Purposely paying attention to present-moment experience with an open and accepting attitude
  
  – Components of Intention, Attention and Attitude (Shapiro, Carlson, 2009)

• Contrast this with typical past- or future-focused thinking
Mindful Attitudes

- Non-judging
- Patience
- Acceptance

- Letting go
- Non-striving
- Trust
- Beginners Mind
Weekly Themes

1. Introduction to Mindfulness
2. Mindfulness Attitudes
3. Mindbody Wisdom and Healing (stress responding vs. reacting)
4. Balance (breathing)
5. Mindful Coping
6. Cultivating Beneficial States of Heart and Mind (Imagery)
7. Deepening and Expanding
8. Moving into the World
Book: The Art and Science of Mindfulness

- Shapiro and Carlson 2009
- Clinician training manual
- Includes chapters on theories of mindfulness, the mindful therapist, mindfulness-influenced therapy and mindfulness-based therapies
Book: Mindfulness-Based Cancer Recovery

- Carlson & Speca
- Published Feb 2011
- Patient-centered
- Covers full MBCR curriculum with detailed exercises
In conclusion

- The MBSR program at BCCA has demonstrated superiority in distress reduction, and should be supported as a core PFC provincial program.

- Although SET groups are less popular, they appear to be equal in efficacy to MBSR with regard to Q of L and stress biomarker(s).

- This trial lends support to the claim that psychosocial intervention impacts medically-relevant as well as psychologically relevant outcomes.

- Future analyses and research is needed to clarify the clinical significance of changes in biomarkers, including salivary cortisol and telomeres.

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