Behavioral Interventions for Hot Flashes.

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Overview

Behavioral Interventions for Hot Flashes.

Review of clinical trials

Next Steps

Behavioral interventions for hot flashes

- Paced Respiration
- Mindfulness-Based Stress Reduction
- Cognitive-Behavioral Therapy
- Yoga
- Clinical Hypnosis

Conflict of Interest Statement

The author of this presentation has no financial or commercial conflicts of interest pertinent to this presentation within the last 12 months.

Behavioral interventions for hot flashes

- There is a need for a safe and effective treatment alternatives for women suffer from hot flashes and insomnia.
- Hormone therapy may be contraindicated for some women.
- Many women seek options for the treatment of hot flashes due to concerns over risks and potential side-effects of pharmaceutical therapies.

Advantages of Behavioral Treatments

- Generally considered safe
- Many are skill-based
- No side effects
- May have side benefits (stress)
- But are they effective in reducing hot flashes...?
The Placebo Effect & Hot Flash Clinical Trials

- Placebo effect can be quite remarkable in hot flash trials (>30%-40%).
- The reason for the size of this placebo effect is not fully understood.
- Establishing clinical significance (>50%)

Paced Respiration

- Slow measured breathing intervention, often paired with progressive muscle relaxation or relaxation response training.
- Paced Respiration “protocol”:
  - 8 hours, biweekly, laboratory-based, one-on-one instruction
  - Practice, 15 min, 2X day
  - Application at each HF (slow deep breathing at each HF onset)

Paced Respiration

- Initially combined with progressive muscle relaxation in a study of 14 healthy midlife women (Germaine & Freedman, 1984)
  - Reduced diary-recorded HF after 6 weeks & 6 months.
- Follow-up comparative study of paced respiration (n=11), progressive muscle relaxation (n=11), and attention control (n=11).
  - Only paced respiration showed significant reductions in objectively measured hot flashes after 8 weeks.
  - 50% reduction in hot flash frequency by diary and objective measure.

Paced Respiration...Further Study...

- A 16-week, 3 group, partially blinded, controlled trial (2:2:1 randomization and stratification: breast cancer/no cancer), 218 women received either paced respiration, a breathing control group, or usual care. (Carpenter et al., 2013)
  - Results of this study showed no significant group differences for HF frequency, severity, and bother at 8 or 16 weeks post-randomization.
  - The authors concluded the paced respiration is unlikely to provide clinical benefit for menopausal symptoms in breast cancer survivors or menopausal women without cancer. Small benefits in mood and sleep disturbance.

Mindfulness-Based Stress Reduction

- Learning to recognize and discriminate more accurately between the components of experience such as thoughts, feelings, and sensations, and developing a non-reactive awareness of these.
Mindfulness-Based Stress Reduction

- MBSR training teaches mindfulness through breathing, body awareness exercises, sitting and walking meditation as well as gentle yoga.
- Shifting emphasis from focus (inward thinking) to awareness (outward, "seeing the scenery").

Mindfulness-Based Stress Reduction

- A randomized controlled study of mindfulness training for coping with hot flashes was published in 2011. 110 women were randomized to MBSR or wait list control. (Carmody, Crawford, Aldinsego-Blotcher, Long, Churchill & Orlandi, 2011)
- Primary outcome was degree of bother from hot flashes. Secondary outcomes were hot flash intensity, quality of life, insomnia, anxiety & perceived stress.
- Results showed within-woman changes in bother from hot flashes differed significantly by treatment arm. HF bother decreased by 14.7% in MBSR vs. 6.8% in WLC. At 20 weeks, total reduction in bother was 21.6% in MBSR vs 10.5% in WLC. There were no differences in HF intensity.

Mindfulness-Based Stress Reduction

- 15 symptomatic women completed an 8-week MBSR program, keeping daily diaries of hot flashes and completing hot flash related quality of life instruments at baseline and follow-up.
- Significant improvements on quality of life measures and hot flash severity decreased by 40%.
- HF frequency reduced 39%.

Cognitive-Behavioral Therapy

- Cognitive behavior therapy (CBT) is a type of psychotherapeutic treatment that helps patients understand the relationship between thoughts and feelings and develop coping behaviors.
- Initial case reports showed substantial improvements in hot flash frequency, quality of life, depression and anxiety with improvements maintained 6 months post-treatment . (Allen, Dobkia, Boobur & Woolfolk, 2006)

Cognitive-Behavioral Therapy

- MENOS 2: Randomized, no-treatment control study of group cognitive behavioral therapy and guided self-help CBT in 140 symptomatic women. (Ayres, Smith, Hollier, Mann & Hunter, 2012)
- Group and self-help CBT reduced hot flashes and night sweat frequency at 6 and 26 weeks.
  - Combined HF/NS reductions at 26 weeks: 40% for group CBT, 30% for self-help CBT, 23% for control.
- Mood, indices of quality of life, indices of emotional functioning, and physical functioning showed significant improvements for group CBT at 26 weeks.

Mindfulness-Based Stress Reduction

- Prospective within-group design. Participants were 22 peri- and post-menopausal women experiencing at least 4 menopausal hot flashes per day, at least 4 days per week. Assessments were administered before and after completion of a 10-week yoga program.
- The authors found significant pre- to post-treatment improvements in the severity of questionnaire-rated total menopausal symptoms, hot-flash daily interference, and sleep efficiency, disturbances, and quality.
- Neither 24-h physiological monitoring nor accompanying diaries yielded significant changes in hot flashes.
Yoga

- 3-arm RCT (walking, yoga, control) was also published in 2007. (Elavsky & McAuley, 2007)
  - Four-month randomized controlled exercise trial with three arms: walking, yoga, and control. (n = 184; M age = 49.0)
  - Structured and supervised walking program meeting three times per week for 1 hour and supervised yoga program meeting twice per week for 90 minutes.
  - Results indicated that walking and yoga were effective in enhancing positive affect and menopause-related QOL and reducing negative affect.

Yoga

- MSFLASH 3x3 factorial, yoga, aerobic exercise and omega-3 fish oil supplementation:
  - The study involved 385 women who had >2 HF/day. Participants in the yoga group took group classes once a week for 12 weeks and practiced yoga at home in between classes. Study participants in the exercise group followed a specific exercise routine, 3 times per week, for 12 weeks at a study exercise center. All participants will be asked to take 3 study pills (Omega-3 or placebo) each day for 12 weeks.
  - Null results in HF reductions
  - Secondary endpoints of sleep, depressive symptoms and anxiety symptoms showed significant improvements with yoga or exercise.
  - Omega-3 fish oil results were null.

Clinical Hypnosis for the treatment of hot flashes.

- Hypnosis is a mind-body therapy in which a patient is provided suggestions for relaxation, mental imagery, an altered state of consciousness, and improvement in symptoms.
- Pilot in breast cancer survivors in 2008
  - 60 women randomized to clinical hypnosis or no treatment
  - Hot Flash Score (frequency x severity) reduced 68%.
  - Significant improvements in self-reported anxiety, depression, interference of hot flashes on daily activities, and sleep were observed for patients who received the hypnosis intervention.

Hypnosis

- RCT of clinical hypnosis versus structured attention. (Elkins, Fisher, Johnson, Carpenter, & Keith, 2013)
  - 187 post-menopausal women randomized to clinical hypnosis or structured attention control.
  - Self-report & physiological measurement of HF
  - At 12 weeks HF frequency reduced 74.16%
  - At 12 weeks HF score reduced 80.32%
  - Secondary outcomes significant for hot flash related daily interference, sleep, and treatment satisfaction.

Hypnosis for hot flashes: Elkins et al., 2013
Behavioral Interventions: Next steps

- Behavioral interventions have shown generally positive results.
- Hypnosis intervention shows clinically significant reduction in hot flashes (daily diaries and physiological measurement) and improve sleep quality and mood.
- It is unknown how hypnosis intervention works. Deconstruction is the critical next step.
- Identifying the effective components could lead to broader dissemination and reduce patient burden.