NONPHARMACOLOGIC TREATMENTS FOR MENOPAUSE-ASSOCIATED VASOMOTOR SYMPTOMS

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Full-length report available on ESP website:
http://www.hsrdrresearch.va.gov/publications/esp/reports.cfm
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  Minneapolis, MN

- ESP Center
  Los Angeles, CA

- ESP Center
  Durham, NC

- HSR&D/QUERI, VACO
  Washington, DC
Please tell us how you spend the majority of your workweek?
a) Primary care clinic/CBOC
b) Women’s Health Clinic
c) Emergency room/in-patient setting
d) Research
e) Other

POLL QUESTION
Vasomotor Symptoms

- Hot flashes/Night sweats
- 80% women
- Median duration over 7 years
- Impact:
  - Physical
  - Psychological
  - Social
  - Healthcare utilization

Avis. 2015
Women Veterans are twice as likely as civilian women to be prescribed hormone therapy
• 10.3% in FY 2009
Nonhormonal Pharmacologic Treatment

Hormone Therapy

Nonhormonal Nonpharmacologic Treatments

No Treatment
- Most effective treatment
- Women with bothersome VMS, aged <60 and <10 years since menopause
- Balance risks/benefits

Stuenkel. 2015; ACOG 2014
CURE ALL!  →  Evil!!  →  Maybe ok?

Hormone Therapy
Nonhormonal Pharmacologic Treatment

Nonhormonal Nonpharmacologic Treatments

Stand-alone or adjunct treatments
• SSRI/SNRI
• Gabapentin
• Isoflavones
• Black Cohosh
• Ginseng

Grant et al. AHRQ. 2015
Nonhormonal Nonpharmacologic Treatments

- Mind/body practices
  - Yoga
  - Tai chi
- Meditation
- Structured exercise
- Acupuncture

Stand-alone or adjunct treatments
Perceptions of Providers and Administrators in the Veterans Health Administration Regarding Complementary and Alternative Medicine

Carol E. Fletcher, PhD, RN,* Allison R. Mitchinson, MPH, NCTMB,* Erika L. Trumble, MPH,*
Daniel B. Hinshaw, MD, FACS,* and Jeffery A. Dusek, PhD†

Med Care 2014; 52: S91-S96

A Factor Analysis and Exploration of Attitudes and Beliefs Toward Complementary and Conventional Medicine in Veterans

Lisa M. Betthauser, MA, MBA,* † Lisa A. Brenner, PhD,* † Jeri E. Forster, PhD,* §
Trisha A. Hostetter, MPH,* Alexandra L. Schneider, BA,* and Theresa D. Hernández, PhD* //

Med Care 2014; 52: S50-S56.
Key Question

In women with vasomotor symptoms (VMS) that are associated with perimenopause or postmenopause, what are the effects on VMS, health-related quality of life, and adverse events of the following nonpharmacologic, nonhormonal interventions:

Yoga, tai chi, and qigong
Acupuncture
Relaxation, hypnosis, meditation, and mindfulness
Structured exercise
Poll Question

• Which of the following treatments are available to Veterans at your local facility (choose all that apply)?
  – Acupuncture
  – Relaxation or meditation training
  – Yoga
  – Structured exercise
  – I don’t know
METHODS
Review of reviews

Recent Randomized Controlled Trials

Qualitative & Quantitative Summaries as appropriate
Primary Outcomes:
1) Vasomotor symptoms
2) Quality of life (QoL)
<table>
<thead>
<tr>
<th>Study characteristic</th>
<th>Eligibility Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population</strong></td>
<td>Peri/postmenopausal women with bothersome VMS</td>
</tr>
<tr>
<td><strong>Interventions</strong></td>
<td>Acupuncture</td>
</tr>
<tr>
<td></td>
<td>Yoga, tai chi, qigong</td>
</tr>
<tr>
<td></td>
<td>Structured exercise</td>
</tr>
<tr>
<td></td>
<td>Relaxation, hypnosis and meditation</td>
</tr>
<tr>
<td><strong>Comparators</strong></td>
<td>Any inactive or active control</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td>Frequency/severity of VMS</td>
</tr>
<tr>
<td></td>
<td>Overall Quality of Life (QOL), or</td>
</tr>
<tr>
<td></td>
<td>Menopause-specific QOL</td>
</tr>
<tr>
<td><strong>Timing</strong></td>
<td>SRs: as specified by authors</td>
</tr>
<tr>
<td></td>
<td>RCTs: outcomes assessed &gt;60 days after treatment assignment</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>Outpatient or community setting</td>
</tr>
</tbody>
</table>
Nonpharmacologic, nonherbal management of menopause-associated vasomotor symptoms: an umbrella systematic review (protocol)

Karen M. Goldstein¹² *, Jennifer R. McDuffie¹², Megan Shepherd-Banigan¹, Deanna Befus³, Remy R. Coeytaux⁴, Megan G. Van Noord⁵, Adam P. Goode⁴⁶, Varsha Masilamani¹, Soheir Adam⁷, Avishek Nagi¹ and John W. Williams Jr¹²
RESULTS
Yoga, tai chi, qigong

**Yoga**—a spiritual and ascetic Hindu discipline, including breath control, simple meditation, and specific bodily postures, that is practiced for health and relaxation

**Tai chi**—a Chinese martial art and form of stylized, meditative exercise characterized by slow circular and stretching movements and positions of bodily balance

**Qigong**—an ancient Chinese health care system that integrates physical postures, breathing techniques and focused intention
Yoga, tai chi, qigong

Yoga—a spiritual and ascetic Hindu discipline, including breath control, simple meditation, and specific bodily postures, that is practiced for health and relaxation

- Relieves conditions that may affect women in menopausal transition: QoL, anxiety, sleep disturbances
- More commonly used by women than men
- Used by older adults
Yoga, tai chi, qigong

1 Yoga (5 RCTs)
0 Tai chi
0 Qigong

N = 582
Yoga, tai chi, qigong

SR

1 Yoga (5 RCTs)
0 Tai chi
0 Qigong

New RCTs

2 Yoga
0 Tai chi
0 Qigong

N = 582

N = 686

15% increase in patients assessed
## Yoga

<table>
<thead>
<tr>
<th>Prior Systematic Review</th>
<th>Method</th>
<th>Comparator</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cramer 2012</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Meta-analysis 2 RCTs; n = 208</td>
<td>Active/inactive control</td>
<td>No difference</td>
</tr>
<tr>
<td></td>
<td>Meta-analysis 2 RCTs; n = 232</td>
<td>Active control (subgroup)</td>
<td>No difference</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>New RCTs</th>
<th>Study</th>
<th>Comparator</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Avis, 2014</td>
<td>Active/Inactive control</td>
<td>No effect</td>
</tr>
<tr>
<td></td>
<td>n = 54</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ngowsiri 2014</td>
<td>Wait list control</td>
<td>VMS Severity</td>
</tr>
<tr>
<td></td>
<td>n = 50</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Yoga versus Control on change in hot flash severity at end of treatment

<table>
<thead>
<tr>
<th>Study</th>
<th>Design Type</th>
<th>Yoga Mean</th>
<th>Yoga SD</th>
<th>Yoga N</th>
<th>Control Mean</th>
<th>Control SD</th>
<th>Control N</th>
<th>SMD [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elavsky 2007</td>
<td>Wait list control</td>
<td>-0.33</td>
<td>1.56</td>
<td>61</td>
<td>-0.08</td>
<td>1.25</td>
<td>39</td>
<td>-0.17 [-0.57, 0.23]</td>
</tr>
<tr>
<td>Avis 2014</td>
<td>Wait list control</td>
<td>-3.60</td>
<td>5.15</td>
<td>18</td>
<td>-1.25</td>
<td>6.73</td>
<td>36</td>
<td>-0.37 [-0.94, 0.20]</td>
</tr>
<tr>
<td>Ngowsiri 2014</td>
<td>Wait list control</td>
<td>-1.10</td>
<td>1.63</td>
<td>24</td>
<td>0.00</td>
<td>1.76</td>
<td>26</td>
<td>-0.64 [-1.21, -0.07]</td>
</tr>
<tr>
<td><strong>Summary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>-0.34 [-0.92, 0.25]</strong></td>
</tr>
<tr>
<td>Chattha 2008</td>
<td>Attention control</td>
<td>-0.84</td>
<td>1.71</td>
<td>54</td>
<td>-0.21</td>
<td>1.40</td>
<td>54</td>
<td>-0.40 [-0.78, -0.02]</td>
</tr>
<tr>
<td><strong>Overall Summary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>-0.36 [-0.65, -0.07]</strong></td>
</tr>
</tbody>
</table>

I² = 0.0%, Q = 1.7, P=0.42

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VETERANS HEALTH ADMINISTRATION
Yoga versus Control on change in hot flash severity at end of treatment

<table>
<thead>
<tr>
<th>Estimate source</th>
<th>#studies</th>
<th>#patients</th>
<th>SMD [95%CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous SR (Cramer, 2012)</td>
<td>2</td>
<td>208</td>
<td>-0.04 [-0.68, 0.60]</td>
</tr>
<tr>
<td>Our new MA</td>
<td>4</td>
<td>312</td>
<td>-0.36 [-0.65, -0.07]</td>
</tr>
</tbody>
</table>

Favors Yoga  Favors Control
Yoga - conclusions

• Yoga associated with reduction in hot flash severity
  – Results contradict those from past SRs
• Yoga might be an acceptable therapy for women in the menopausal transition
• Updated results should be taken into consideration when revising clinical or policy recommendations
Acupuncture

• Acupuncture is a therapeutic modality that involves inserting small, metal needle into the skin
• Acupuncture has been an integral part of clinical medicine in Asia for several thousand years
• Acupuncture has increased in popularity and use in the U.S. in the past 40 years
• Vasomotor symptoms are a common indication for acupuncture
Acupuncture

**Acupuncture Visits per 1000 People in the U.S.**

- 1997: 20
- 2007: 100

**Patients (in Thousands) Who Received Acupuncture in the U.S.**

- 2002: 1000
- 2007: 3000
- 2012: 4000
Acupuncture

1. Good quality (15 RCTS)
2. Fair quality

N = 1127
Acupuncture

1 Good quality (15 RCTS)

2 Fair quality

4 new RCTs

N = 1127

38% increase in patients assessed

N = 1823
<table>
<thead>
<tr>
<th>Prior Systematic Review</th>
<th>Method</th>
<th>Comparator</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dodin 2013</td>
<td>Meta-analysis 3 RCTs; n = 463</td>
<td>No Acupuncture</td>
<td>VMS frequency/severity</td>
</tr>
<tr>
<td></td>
<td>Meta-analysis 8 RCTs; n = 414</td>
<td>Sham Acupuncture</td>
<td>VMS severity only</td>
</tr>
<tr>
<td>New RCTs</td>
<td>Study</td>
<td>Comparator</td>
<td>Finding</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ee 2016</td>
<td></td>
<td>Sham acupuncture</td>
<td>VMS composite score</td>
</tr>
<tr>
<td>n = 327</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avis 2016</td>
<td></td>
<td>Waitlist control</td>
<td>VMS frequency/severity</td>
</tr>
<tr>
<td>n = 209</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mao 2015</td>
<td></td>
<td>Placebo, Gabapentin, Sham acupuncture</td>
<td>VMS composite score</td>
</tr>
<tr>
<td>n = 120</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nedeljkovic</td>
<td></td>
<td>Sham acupuncture, Placebo</td>
<td>VMS frequency/severity</td>
</tr>
<tr>
<td>n = 40</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
### Acupuncture vs. No Acupuncture: Change in VMS Frequency

<table>
<thead>
<tr>
<th>Study</th>
<th>Acupuncture Mean</th>
<th>Acupuncture SD</th>
<th>Acupuncture N</th>
<th>Waitlist Mean</th>
<th>Waitlist SD</th>
<th>Waitlist N</th>
<th>SMD [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avis 2008</td>
<td>-3.50</td>
<td>3.82</td>
<td>19</td>
<td>-2.00</td>
<td>3.49</td>
<td>19</td>
<td>-0.40 [-1.04, 0.24]</td>
</tr>
<tr>
<td>Borud 2009</td>
<td>-5.80</td>
<td>4.60</td>
<td>134</td>
<td>-3.70</td>
<td>3.70</td>
<td>133</td>
<td>-0.50 [-0.75, -0.26]</td>
</tr>
<tr>
<td>Kim 2011</td>
<td>-6.67</td>
<td>7.34</td>
<td>116</td>
<td>-3.39</td>
<td>6.27</td>
<td>59</td>
<td>-0.47 [-0.78, -0.15]</td>
</tr>
<tr>
<td>Painovich 2012</td>
<td>-3.50</td>
<td>3.00</td>
<td>12</td>
<td>-1.20</td>
<td>2.14</td>
<td>9</td>
<td>-0.83 [-1.73, 0.07]</td>
</tr>
<tr>
<td>Avis 2016</td>
<td>-3.70</td>
<td>3.91</td>
<td>170</td>
<td>0.90</td>
<td>4.37</td>
<td>39</td>
<td>-1.15 [-1.51, -0.78]</td>
</tr>
</tbody>
</table>

Summary (I² = 61.7%, Q = 10.4, P=0.034) -0.66 [-1.06, -0.26]
## Acupuncture vs. No Acupuncture: Change in VMS frequency

<table>
<thead>
<tr>
<th>Comparator</th>
<th>Source estimate</th>
<th># Pts</th>
<th>Outcome</th>
<th>SMD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Acupuncture</td>
<td>Dodin 2013</td>
<td>463</td>
<td>Frequency</td>
<td>-0.50 [0.69, -0.31]</td>
</tr>
<tr>
<td>No Acupuncture</td>
<td>New MA</td>
<td>710</td>
<td>Frequency</td>
<td>-0.66 [-1.06, -0.26]</td>
</tr>
</tbody>
</table>
### Acupuncture vs. No Acupuncture: Change in VMS severity

<table>
<thead>
<tr>
<th>Comparator</th>
<th>Source estimate</th>
<th># Pts</th>
<th>Outcome</th>
<th>SMD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Acupuncture</td>
<td>Dodin 2013</td>
<td>463</td>
<td>Frequency</td>
<td>-0.50 [0.69, -0.31]</td>
</tr>
<tr>
<td></td>
<td>New MA</td>
<td>710</td>
<td>Frequency</td>
<td>-0.66 [-1.06, -0.26]</td>
</tr>
<tr>
<td>No Acupuncture</td>
<td>Dodin 2013</td>
<td>463</td>
<td>Severity</td>
<td>-0.54 [-0.73, -0.35]</td>
</tr>
<tr>
<td></td>
<td>New MA</td>
<td>501</td>
<td>Severity</td>
<td>-0.49 [-0.85, -0.13]</td>
</tr>
</tbody>
</table>
Acupuncture vs. Sham Acupuncture: Change in VMS frequency

<table>
<thead>
<tr>
<th>Comparator</th>
<th>Source estimate</th>
<th># Pts</th>
<th>Outcome</th>
<th>SMD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Acupuncture</td>
<td>Dodin 2013</td>
<td>463</td>
<td>Frequency</td>
<td>-0.50 [0.69, -0.31]</td>
</tr>
<tr>
<td></td>
<td>New MA</td>
<td>710</td>
<td>Frequency</td>
<td>-0.66 [-1.06, -0.26]</td>
</tr>
<tr>
<td></td>
<td>Dodin 2013</td>
<td>363</td>
<td>Severity</td>
<td>-0.54 [-0.73, -0.35]</td>
</tr>
<tr>
<td></td>
<td>New MA</td>
<td>501</td>
<td>Severity</td>
<td>-0.49 [-0.85, -0.13]</td>
</tr>
<tr>
<td>Sham Acupuncture</td>
<td>Dodin 2013</td>
<td>414</td>
<td>Frequency</td>
<td>-1.13 [-2.55, 0.29]</td>
</tr>
<tr>
<td></td>
<td>New MA</td>
<td>761</td>
<td>Frequency</td>
<td>-0.21 [-0.49, 0.07]</td>
</tr>
</tbody>
</table>
### Acupuncture vs. Sham Acupuncture: Change in VMS severity

<table>
<thead>
<tr>
<th>Comparator</th>
<th>Source estimate</th>
<th># Pts</th>
<th>Outcome</th>
<th>SMD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Acupuncture</td>
<td>Dodin 2013</td>
<td>463</td>
<td>Frequency</td>
<td>-0.50 [0.69, -0.31]</td>
</tr>
<tr>
<td></td>
<td>New MA</td>
<td>710</td>
<td>Frequency</td>
<td>-0.66 [-1.06, -0.26]</td>
</tr>
<tr>
<td></td>
<td>Dodin 2013</td>
<td>463</td>
<td>Severity</td>
<td>-0.54 [-0.73, -0.35]</td>
</tr>
<tr>
<td></td>
<td>New MA</td>
<td>501</td>
<td>Severity</td>
<td>-0.49 [-0.85, -0.13]</td>
</tr>
<tr>
<td>Sham Acupuncture</td>
<td>Dodin 2013</td>
<td>414</td>
<td>Frequency</td>
<td>-1.13 [-2.55, 0.29]</td>
</tr>
<tr>
<td></td>
<td>New MA</td>
<td>761</td>
<td>Frequency</td>
<td>-0.21 [-0.49, 0.07]</td>
</tr>
<tr>
<td></td>
<td>Dodin 2013</td>
<td>297</td>
<td>Severity</td>
<td>-0.45 [-0.84, -0.05]</td>
</tr>
<tr>
<td></td>
<td>New MA</td>
<td>644</td>
<td>Severity</td>
<td>-0.35 [-0.70, 0.01]</td>
</tr>
</tbody>
</table>

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*Favors Acupuncture: -2.00 to 0.00; Favors Comparator: 0.00 to 1.00*
Acupuncture conclusions

- Acupuncture is associated with significant improvement in VMS frequency and severity as well as quality of life measures compared with no acupuncture.

- There are mixed findings regarding acupuncture’s effectiveness compared with sham acupuncture.

- These findings suggest that acupuncture may be effective as an adjunctive treatment for VMS.

- The extent to which nonspecific or placebo effects contribute acupuncture’s effectiveness is unclear.
Relaxation, hypnosis, meditation, and mindfulness

- **Relaxation** – collection of behavioral techniques related to somatic and/or cognitive relaxation
  - Example: paced respiration, progressive muscle relaxation

- **Hypnosis** – use of suggestions to change perception, sensation, emotion, thought or behavior

- **Meditation** – action or practice of meditating

- **Mindfulness** – self-regulation on attention and an orientation to the present
  - Example: Mindfulness Based Stress Reduction

Hempel 2014; Saensak 2014; Cramer 2015
Relaxation, hypnosis, meditation and mindfulness

- Good
  - 1 Relaxation (4 RCTs)
  - 1 Hypnosis (3 RCTs)
  - 3 Multiple Intervention
  - 0 Meditation

- Fair
  - 1 Relaxation
  - 1 Mindfulness-based stress reduction

N = 681
Relaxation, hypnosis, meditation and mindfulness

1 Relaxation (4 RCTs)
1 Hypnosis (3 RCTs)
3 Multiple Intervention
0 Meditation

3 Paced respiration
3 Applied relaxation
0 Meditation/Hypnosis

1 Relaxation
1 Mindfulness-based stress reduction

N = 681

48% increase in patients assessed

N = 1,304
### Hypnosis

#### Prior Systematic Review

<table>
<thead>
<tr>
<th>Method</th>
<th>Comparator</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 RCTs (n = 247)</td>
<td>Active/inactive control</td>
<td>VMS frequency/severity</td>
</tr>
<tr>
<td>1 RCT (n = 27)</td>
<td>Gabapentin</td>
<td>No difference</td>
</tr>
</tbody>
</table>

**Cramer 2015**

No new RCTS
## Applied Relaxation

<table>
<thead>
<tr>
<th>Prior Systematic Review</th>
<th>Method</th>
<th>Comparator</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Meta-analysis</td>
<td>Acupuncture</td>
<td>No difference</td>
</tr>
<tr>
<td></td>
<td>2 RCTs; n = 72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saensak 2014</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 RCTs; n = 183</td>
<td>Inactive/active control</td>
<td>No effect</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>New RCTs</th>
<th>Study</th>
<th>Comparator</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lindh-Astrad 2013</td>
<td></td>
<td>Inactive control</td>
<td>VMS at 12 weeks</td>
</tr>
<tr>
<td>n = 327</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saensak 2013</td>
<td></td>
<td>Modified-training</td>
<td>No difference</td>
</tr>
<tr>
<td>n = 71</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lindh-Astrad 2015</td>
<td></td>
<td>Inactive control</td>
<td>Stopped early</td>
</tr>
<tr>
<td>n = 46</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Paced Respiration on change in VMS at end-of-treatment

<table>
<thead>
<tr>
<th>Comparator</th>
<th>Source estimate</th>
<th># Pts</th>
<th>Outcome</th>
<th>SMD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New MA</td>
<td>316</td>
<td>Frequency</td>
<td>0.04 [-0.73, 0.82]</td>
<td></td>
</tr>
<tr>
<td>New MA</td>
<td>389</td>
<td>Severity</td>
<td>0.06 [-0.69, 0.80]</td>
<td></td>
</tr>
</tbody>
</table>
Structured exercise

Regular physical activity:
• Done with the intention of improving or maintaining physical fitness or health
• Or, performed as a part of a class
• Or, with support from a health professional
Structured exercise

1 Exercise (5 RCTs)

1 Exercise/Relaxation (3 RCTs)

Vs Yoga (2 RCTs)

Vs control (4 RCTs)

N = 762
Structured exercise

1 Exercise (5 RCTs)

1 Exercise/Relaxation (3 RCTs)

Vs control (4 RCTs)

Vs Yoga (2 RCTs)

N = 762

43% increase in patients assessed

N = 1,336

New RCTs

2 RCTs exercise vs control
## Structured exercise

### Prior Systematic Review

<table>
<thead>
<tr>
<th>Study</th>
<th>Method</th>
<th>Comparator</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daley 2014</td>
<td>Meta-analysis</td>
<td>Inactive Control</td>
<td>No effect</td>
</tr>
<tr>
<td></td>
<td>3 RCTs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Meta-analysis</td>
<td>Yoga</td>
<td>No difference</td>
</tr>
<tr>
<td></td>
<td>2 RCTs</td>
<td></td>
<td></td>
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</tbody>
</table>

### New RCTs

<table>
<thead>
<tr>
<th>Study</th>
<th>Comparator</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dujits 2012</td>
<td>Inactive control</td>
<td>No effect</td>
</tr>
<tr>
<td>n = 313</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daley 2015</td>
<td>Inactive control</td>
<td>No effect</td>
</tr>
<tr>
<td>n = 261</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Structured exercise on change in VMS at end-of-treatment

<table>
<thead>
<tr>
<th>Comparator</th>
<th>Source estimate</th>
<th># Pts</th>
<th>Outcome</th>
<th>SMD (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New MA</td>
<td>673</td>
<td>Frequency</td>
<td>-0.08 [-0.33, 0.16]</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New MA</td>
<td>878</td>
<td>Severity</td>
<td>-0.06 [-0.21, 0.10]</td>
<td></td>
</tr>
<tr>
<td>Intervention Type</td>
<td>Adverse events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-----------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acupuncture</td>
<td>Mild reactions when reported</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yoga</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured Exercise</td>
<td>No serious adverse reactions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Similar to placebo</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relaxation, Hypnosis &amp; Meditation</td>
<td>Mild</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Quality of Life

- **Acupuncture**
  - Insufficient data for acupuncture vs. no acupuncture
  - No improvement in quality of life vs. sham acupuncture:
    New MA: SMD -0.23, 95% CI -1.40, 0.95, 5 trials

- **Yoga**
  - Insufficient data for new MA
  - One small trial found non-statistically significant improvement

- **Structured exercise**
  - Insufficient data

- **Relaxation, hypnosis, and meditation**
  - Insufficient data
Limitations

• Of the Review of Reviews
  – Reliance on authors assessment of risk of bias, search strategy and synthesis

• Of the studies
  – Most were small, short-term trials
  – Mostly unmasked, self-report assessments
  – Varying outcome measures
  – Unexplained heterogeneity

• None of trials specifically involved Veterans
Nonpharmacologic, nonhormonal treatments for VMS

- Acupuncture vs control
- Yoga vs control
- +/- Hypnosis

- Acupuncture vs Sham Acupuncture
- Paced respiration
- Structured exercise

- Mindfulness
- Applied Relaxation
- Qigong
- Tai Chi
- Meditation
If you have further questions, please feel free to contact:

**Karen Goldstein, MD MSPH**

919.286.0411 ext. 7764
karen.goldstein@va.gov

Full-length report and cyberseminar available on ESP website:

http://www.hsrdr.research.va.gov/publications/esp/
Discussants

Dr. Alicia Christy
Deputy Director of Reproductive Health
Women’s Health Services

Dr. Jodie Katon
former Sr. Reproductive Epidemiology
Consultant for Women’s Health Services
Prevalence and severity of VMS among women Veterans

1Adjusted for age, race, education, time since menopause, obesity, pack years of smoking, depression, diabetes, hypertension and physical activity

VMS and Quality of Life

GH = general health, PF = physical function, EW = emotional well-being, SF = social function
*** p<0.001, ** p<0.01, * p<0.05

1 Adjusted for age, race, education, overall QOL at baseline, obesity, pack years of smoking, depression, diabetes, hypertension and physical activity

## Frequency of Menopausal Disorders

<table>
<thead>
<tr>
<th>Age Group</th>
<th>18-44 years old</th>
<th>45-64 years old</th>
<th>≥65 years old</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Menstrual disorders and endometriosis</td>
<td><strong>Menopausal disorders</strong></td>
<td>Osteoporosis</td>
</tr>
<tr>
<td>2</td>
<td>Other female reproductive organ conditions</td>
<td>Urinary conditions</td>
<td>Urinary conditions</td>
</tr>
<tr>
<td>3</td>
<td>STI and vaginitis</td>
<td>Other female reproductive organ conditions</td>
<td><strong>Menopausal disorders</strong></td>
</tr>
<tr>
<td>4</td>
<td>Urinary conditions</td>
<td>Benign breast conditions</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>5</td>
<td>Pregnancy-related</td>
<td>STI and vaginitis</td>
<td>Benign breast conditions <em>and</em> other female reproductive organ conditions</td>
</tr>
</tbody>
</table>

Partners with Veterans to discover their sense of meaning, aspiration, and purpose, and begins to create an overarching personal health plan.
**DEFINITIONS**

**Whole Health (WH):** is an approach to health care that empowers AND equips people to take charge of their health and well-being, and live their life to the fullest.

**Complementary and Integrative Health (CIH):**
- **Complementary health** is a group of diverse medical and health care systems, practices, and products that are not considered to be part of conventional or allopathic medicine. Most of these practices are used together with conventional therapies. *(NCCIH Strategic Plan 2016).*
- **Integrative medicine and health** reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic and lifestyle approaches, healthcare professionals and disciplines to achieve optimal health and healing. *(Academic Consortium for Integrative Medicine and Health 2016)*
WH/CIH Highlights 2016

- OPCC&CT launches 11 new Whole Health Design sites for FY 17, now working with a total of 18 WH sites
- VISN Directors commit to 18 full-scale implementation WH demonstration sites in FY 18
- IHCC Advisory Group approves acupuncture, massage, tai chi, yoga, meditation>>>more to come!
- OSI/Pain memo released for VISN CIH POC
The IHCC is charged with developing and implementing complementary and integrative health (CIH) strategies in clinical activities, education, and research across the system.

**Two major functions:**
- Identify and address barriers to providing CIH across the VHA system.
- Serve as a resource for clinical practices and education for Veterans and VA staff.
Core IHCC Staff

- **Core IHCC Staff:**
  - **National Director,** Benjamin Kligler (MD, MPH)
  - **Program Manager:** Alison Whitehead, MPH, RYT, PMP
  - **Project Manager:** Belinda Collingbourne, MBA, PMP
  - **Lead Clinical Champion:** Kavitha Reddy MD FACEPABoIM

- In addition to core staff, IHCC works closely with other OPCC&CT staff, Clinical Champions and other partners across the VA and in the community.
Current IHCC Focus Areas

- Policy and Guidance Development
  - Planned release of CIH instruction manual FY 17 Q2
  - IHCC Advisory Committee
  - Workgroups (yoga, tai chi, nutraceuticals, acupuncture)
- Coding, Tracking, Billing
- New Occupations
  - Acupuncturists
  - Massage Therapists
- Access/Community Care
- Strategic Partnerships
- Metrics/Outcome evaluation
- Comprehensive Addiction and Recover Act 2016
S.524 - Comprehensive Addiction and Recovery Act of 2016 - Subtitle C—Complementary and Integrative Health (CIH)

- Sec. 931 & 932. Expansion of research and education on and delivery of CIH to veterans.
  - Establishment of “Creating Options for Veterans’ Expedited Recovery” Commission
  - Development of plan to expand research, education, and delivery of CIH to Veterans (within 180 days)

- Sec. 933. Pilot program on integration of CIH and related issues for Veterans and family members of Veterans.

Evidence Map of Acupuncture: Click [here](#)

Evidence Map of Tai Chi: Click [here](#)

Evidence Map of Yoga: Click [here](#)

Intranet Only: Massage for Pain: An Evidence Map

Evidence Map of Mindfulness: Click [here](#)
Resources

• **Whole Health Library:**
  http://projects.hsl.wisc.edu/SERVICE/curriculum/index.html
  – Module 25: Women’s Health

• **Clinical Tools**
  – Menopause
  – Hormone Replacement Therapy
  – Endometriosis
  – Fibroids
  – Phytoestrogens
  – Dysmenorrhea, Menstrual Cramping
  – Estrogen Dominance
  – Polycystic Ovarian Syndrome

• **OPCC&CT SharePoint:**
  http://vaww.infoshare.va.gov/sites/OPCC/default.aspx

• **IHCC SharePoint:**
  http://vaww.infoshare.va.gov/sites/OPCC/sitePages/IHCC-home.aspx
Healthy Aging in Women’s Health Services

Healthy aging priorities

– Develop capacity and improve care coordination (e.g. menopausal symptom management, pelvic floor disorders)
– Improve access
– Build partnerships around specialty specific reproductive health care needs
– Ensure adequate resources for providers
– Develop models of Best Practices for healthy aging
– Develop strategies to reach high risk subgroups
Healthy Aging in Women’s Health

• Evidence –based clinical management
  – Optimize medication management
  – Prioritize the impact of mental health and postmenopausal management

• Develop resources for providers and patients through the North American Menopause Society and ACOG
  – Patient Education
  – MenoPro Mobile App
  – Position statements (NAMS)
  – Practice bulletins (ACOG)
Healthy Aging in Women’s Health

- Incorporation of research to ensure access to current evidence-based treatment
- Recognition of unique characteristics of menopausal age Veterans and medical care within VHA (Katon 2015)
- Systematic reviews to evaluate non-pharmacologic and non-traditional therapies
  - SSRIs
  - Complimentary and alternative medications
  - Mind/body practices
References


References continued...


• References for included Systematic Reviews and Randomized Controlled Trials mentioned in this report can be found in the full report:
  http://www.hsrd.research.va.gov/publications/esp/reports.cfm
Additional Funding

Karen M. Goldstein is supported by VA HSR&D Career Development Award #13-263

Megan Shepherd-Banigan is supported by a VA OAA HSR&D PhD Fellowship TTP 21-027
Please include the following correction:

In response to the question about effect size for estrogen-based hormone therapies on vasomotor symptoms: according to the recent AHRQ systematic review by Grant and colleagues (see link below), the effect size for estrogen based hormone therapy on VMS is -0.50 for high dose estrogen compared to placebo, -0.64 for standard dose estrogen compared to placebo, and -0.55 for low dose estrogen compared to placebo.


In response to the question about the role of estrogen based hormone therapy for the treatment of osteoporosis: While it is a treatment option, it is generally not first-line therapy for prevention or treatment of osteoporosis due to associated risks.