Research into Non-Opioid Therapies for Pain at Department of Veterans Affairs

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Chronic Pain and Opioid use among Service Members after Combat Deployment

Chronic pain (more than 3 months)
- General public estimates: 26%
- U.S. military after combat deployment: 44%

Opioid use (in the past month)
- General public estimates: 4%
- U.S. military after combat deployment: 15%
Unique Aspects of VA for Pain Research

• Serves 6 million Veterans at over 1000 sites of care
  – Focus on implementation, spread, fidelity
  – Emphasis on self-care, telehealth, caregiver issues

• Global budget
  – Need to assess value of new interventions
  – Demand for different approaches, virtual options

• Steady increase in provision of CIH in VA
  – 2015: 93% of medical centers offer 2+ CIH modalities

• Pain often overlaps with other co-morbidities
  – Need to address mental health, SUD, social support
Results: What CIH Did Veterans Use in Past Year

<table>
<thead>
<tr>
<th>CIH Approach</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Massage therapy</td>
<td>44%</td>
</tr>
<tr>
<td>Chiropractic</td>
<td>37%</td>
</tr>
<tr>
<td>Mindfulness</td>
<td>34%</td>
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<tr>
<td>Non-mindful/Mantram medit.</td>
<td>24%</td>
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<tr>
<td>Yoga</td>
<td>25%</td>
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<tr>
<td>Progressive relaxation</td>
<td>20%</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>17%</td>
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<tr>
<td>Movement therapy</td>
<td>17%</td>
</tr>
<tr>
<td>Animal assisted therapy</td>
<td>15%</td>
</tr>
<tr>
<td>Acupressure</td>
<td>14%</td>
</tr>
<tr>
<td>Reflexology</td>
<td>12%</td>
</tr>
<tr>
<td>Mantram meditation</td>
<td>11%</td>
</tr>
<tr>
<td>Tai Chi</td>
<td>10%</td>
</tr>
<tr>
<td>Guided imagery</td>
<td>9%</td>
</tr>
<tr>
<td>Healing/Therapeutic touch or reiki</td>
<td>9%</td>
</tr>
<tr>
<td>Creative art therapy</td>
<td>8%</td>
</tr>
<tr>
<td>Biofeedback</td>
<td>7%</td>
</tr>
<tr>
<td>Pilates</td>
<td>6%</td>
</tr>
<tr>
<td>Qi Gong</td>
<td>6%</td>
</tr>
<tr>
<td>Native American healing</td>
<td>5%</td>
</tr>
<tr>
<td>EMDR</td>
<td>4%</td>
</tr>
<tr>
<td>Using hypnotherapy/hypnosis</td>
<td>3%</td>
</tr>
</tbody>
</table>

52% used any type of CIH approach in the past year (n=1,230):
Office of Research and Development

- **Biomedical and Laboratory (BLR&D)** supports preclinical (cellular and animal) research to understand molecular, genomic, and physiological

- **Clinical Science (CSR&D):** Human subject research to identify causes of disease and to test the effectiveness of new drugs, therapy, or devices. *Cooperative Studies Program (CSP) – large, multi-site trials*

- **Health Services (HSR&D):** Studies issues of health care system and delivery, including access, quality and safety, costs and value, implementation, and patient experience.

- **Rehabilitation (RR&D):** Novel approaches to restore full and productive lives to Veterans with traumatic amputation, central nervous system injuries, loss of sight or hearing, or other physical and cognitive impairments.
Studies on CIH & pain

**Conditions**
- Chronic musculoskeletal pain
- Lower back pain
- Muscle pain
- Neck pain

**CIH Interventions**
- Acupuncture
- Biofeedback
- Exercise training
- Guided imagery
- Hypnosis
- Massage
- Meditation
- Spinal cord manipulation
- Tai Chi
- Yoga

**Outcomes**
- Cost of healthcare utilization
- Health-related QOL
- Mental health (anxiety, depression, stress)
- Opioid use
- Pain severity
Multiple therapies have sufficient evidence to support broad implementation

**Manual therapies**
- Acupuncture
- Manipulation
- Massage

**Exercise/movement therapies**
- Exercise (aerobic, resistance coordination/stabilization,)
- Tai Chi
- Yoga

**Behavioral/psychological therapies**
- Cognitive Behavioral Therapy (CBT)
- Acceptance & Commitment Therapy (ACT)
- Mindfulness-Based Stress Reduction (MBSR)

Evidence gaps relate to dose, delivery, and strategies to enhance participation

• For most therapies, need further study of...
  – Delivery approaches (e.g., in-person vs. on-line, group vs. individual)
  – Dose (e.g., frequency, intensity, duration)
  – Strategies for engaging patients, improving adherence, and maintaining benefits

• For care delivery models, need further study of multi-site implementation

Ongoing Non-Opioid Research at VA

- PMC Trial (Taylor and Zeliadt): 1) practitioner-delivered care (acupuncture & chiropractic); 2) self-care therapies (yoga, meditation and Tai Chi) vs 3) combination
- VOICE Trial – Krebs (PCORI) – low-intensity (Telecare pharmacist CM) to high-intensity (integrated pain team) strategy for cost effectiveness of CIH for chronic pain
- Caregiver-assisted vs. therapist massage for chronic pain
- Yoga vs. structured exercise
- Pain management in patients with co-occurring substance use
Conclusions

• Growing evidence base for the effectiveness of non-opioid therapies, stepped-care and integrated pain therapy.
• Remaining challenges involve how to make patient-centered approaches scalable, affordable and accountable across a diverse system.
• Extra Slides
Veterans’ Pain Care Organizational Improvement Comparative Effectiveness (VOICE) Trial

- Randomized trial of 2 care delivery strategies for Veterans with chronic pain on long-term opioids
  - Telecare Collaborative Management (pharmacist care manager) = \textit{low intensity arm}
  - Integrated Pain Team = \textit{high intensity arm}

- Objective: To improve effectiveness and safety of pain management by increasing use of non-opioid therapies & supporting opioid dose reduction

Funded by PCORI OPD-1511-33052 and supported by VA resources and facilities
Two VA studies highlighted as having most promising approach to multi-modal stepped care

Clinically significant improvement (≥30%) in pain and pain-related function for models vs usual care

<table>
<thead>
<tr>
<th>Models of Care</th>
<th>Best Evidence</th>
<th>RB (95% CI)</th>
<th>NNT (95% CI)</th>
<th>Response Rate†</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESCAPE⁴</td>
<td>One good-quality, 9-month RCT, N=241</td>
<td>1.52 (1.22, 1.99)</td>
<td>6 (4, 294)</td>
<td>39% vs 27%*</td>
</tr>
<tr>
<td>SEACAP²⁷</td>
<td>One good-quality, 12-month RCT, N=401</td>
<td>1.56 (1.02, 2.39)</td>
<td>13 (7, 271)</td>
<td>22% vs 14%*</td>
</tr>
<tr>
<td>SCAMP²⁵</td>
<td>One good-quality, 12-month RCT, N=250</td>
<td>2.40 (1.60, 3.20)</td>
<td>4 (3, 7)</td>
<td>42% vs 17%†</td>
</tr>
<tr>
<td>SCOPE²⁶</td>
<td>One good-quality, 12-month RCT, N=250</td>
<td>1.90 (1.40, 2.70)</td>
<td>4 (3, 6)</td>
<td>52% vs 27%†</td>
</tr>
<tr>
<td>StarT Back⁶⁰</td>
<td>One fair-quality, 12-month RCT, N=651</td>
<td>1.14 (1.01, 1.29)</td>
<td>11 (6, 206)</td>
<td>65% vs 57%*</td>
</tr>
</tbody>
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The **Evidence Synthesis Program** produces summaries of existing evidence based on careful review of individual research studies.

**Evidence Maps** are a convenient way to summarize a large body of research using published reviews.

**Evidence map topics:**

- Evidence Map of Acupuncture (2013)
- Evidence Map of Yoga for High-Impact Conditions Affecting Veterans (2014)
- Evidence Map of Mindfulness (2014)
- Evidence Map of Tai Chi (2014)
- Massage for Pain: An Evidence Map (2016)
- Evidence Map on Guided Imagery, Biofeedback, & Hypnosis (*in progress*)
Evidence Map: Acupuncture & Pain

Other ESP reviews

- CAM & PTSD (2011)
- Computerized CBT (2013)
- Repetitive TMS for Treatment-Resistant Depression (2014)
- CIH Use for Preventing or Reducing Opioid Use (2016)
- Cannabis & Chronic Pain/PTSD (2017)
- Stellate Ganglion Block for PTSD (2017)
- HBOT for TBI &/or PTSD (2018)
- Cranial Electrical Stimulation (2018)