Yoga for Low Back Pain, Depression, Insomnia, & Falls Prevention

Symposium on Yoga Research
Kripalu Center for Yoga & Health
September 30, 2015

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Objectives

- Summarize the evidence that pertains to the effectiveness and safety of yoga for low back pain, mental illness, insomnia, and the prevention of falls.

- Inform future research on yoga.
Outline

- Summarize the Evidence Map of Yoga for High-Impact Conditions Affecting Veterans
- Reflections
- Questions and discussion
Evidence Map of Yoga for High-Impact Conditions Affecting Veterans*

- Prepared for the Department of Veterans Affairs, Veterans Health Administration, Quality Enhancement Research Initiatives (QUERI), Health Services Research and Development Service, Washington, DC

- Prepared by the Evidence-based Synthesis Program (ESP) Center, Durham Veterans Affairs Healthcare System, Durham, NC

Courtesy of The Jealous Curator
www.jealouscurator.com
Topic Development

- Topic commissioned by the VA’s Evidence-based Synthesis Program
- Stakeholders and technical expert panel convened and consulted
- Key questions formulated
Stakeholders and TEP

**Key Stakeholders**
- Laura Krejci, Office of Patient Care Services
- Stephen Eziji-Okoye, Veterans Administration Central Office Field Advisory Committee on Complementary and Alternative Medicine

**Technical Expert Panel**
- Heidi Prather, F. Todd Wetzel, Shari Davidson, Justin Moore, Anne Reichertet, Matthew R. D’Uva, Serg Perrot
High-Impact Conditions Affecting Veterans

- Low back pain
- Mental illness (depressive disorders, anxiety disorders, PTSD)
- Insomnia
- Prevention of falls
Key Question 1

What are the extent, distribution, and methodological designs of intervention studies that evaluate yoga for the following conditions?

- Low back pain
- Mental illness (Depressive disorders, anxiety disorders, posttraumatic stress disorder)
- Insomnia
- Prevention of falls
Key Question 2

What are the extent, distribution, and designs of studies that assess the adverse effects of yoga?
Evidence Mapping

- An emerging approach to identifying and synthesizing information in the published literature
- Goals: Describe the breadth, depth, and methodology of the published literature and identifying gaps in that literature
- In contrast to a systematic review of the literature
Definitions

- Evidence map
- Systematic review
- Meta-analysis
- Pooled estimate
- Comparative effectiveness research
In consultation with a research librarian, we searched:

- PubMed
- Cochrane Databases of Systematic Reviews
- Embase
- Allied and Complementary Medicine Database (AMED)
- Clinicaltrial.gov
PICOTS

- **P**atients/Population/People: Adults with a clinical condition of interest
- **I**nterventions: Yoga
- **C**omparators: Any comparator
- **O**utcomes: Health outcomes
- **T**iming: Follow-up of 1 month or greater
- **S**ettings: Healthcare-related or community settings
Search Limits

- English-language publications

- Systematic reviews
  - Published January 2008 to July 2014

- Randomized clinical trials (RCTs)
  - Published January 2011 to July 2014
  - Sample size > 100 subjects
Yoga

- Collection of spiritual and physical practices originating in ancient India
- Different styles, with different focus (physical, lifestyle, breathing, relaxation, meditation, mindfulness)
- Recent introduction of fitness-oriented yoga regimens
Yoga

- Yoga has 3 components:
  - Physical exercise and bodily positions/postures
  - Breath control practices
  - Meditation

- Included studies that self-identified the intervention as “yoga”, including ones that only involved breath control

- Excluded interventions that may share features of yoga, and excluded studies in which yoga was one of several interventions
Quality Assessment

- Used key quality criteria adapted to categorize each systematic review as:
  - Good quality
  - Moderate quality
  - Poor quality
Data Synthesis

- Grouped systematic reviews (SRs) & RCTs by clinical topic
- Described the studies qualitatively
- Evaluated unique primary studies reported in SRs
- Reported treatment effects estimated by SRs using Standardized Mean Differences (SMD)
- Summarized and interpreted the findings
Standardized Mean Differences (SMD)

- A way of reporting treatment effects associated with a given intervention, relative to another intervention
- Appropriate when primary studies use different scales to assess conceptually similar outcomes
- SMDs of about 0.2 = small treatment effects
- SMDs of about 0.5 = moderate effects
- SMDs larger than 0.8 = large effects
Results: Systematic Review

1112 Total references
105 Full-text review
9 Included (9 SRs,

3 Low back pain
1 Prevention of falls
4 Mental illness
1 Insomnia
1 Adverse effects
Results: RCTs

No eligible RCTs with $\geq 100$ subjects
Evidence Map

Number of RCTs/number of patients for the various other conditions represented were: 1/8 for PTSD; 10/956 for LBP; and 12/619 for depression.
Key Question 1

What are the extent, distribution, and methodological designs of intervention studies that evaluate yoga for the following conditions?

- Low back pain
- Mental illness (Depressive disorders, anxiety disorders, PTSD)
- Insomnia
- Prevention of falls
Low Back Pain

- 3 good quality SRs
- Exclusive focus on chronic low back pain
- ClinicalTrials.gov: 1 large (n=320) and 1 small (n=10) RCT
Low back pain: Cramer et al., 2013

- 10 RCTs, 956 patients
- 8 RCTs included in a meta-analysis
- Consistent evidence for short-term benefit on pain (SMD= -0.48, 95% CI: -0.65 to -0.31).
- Long-term reduction reduction in pain (SMD= -0.33, 95% CI: -0.59 to -0.07) and back-specific disability (SMD= -0.35; 95% CI: -0.55 to -0.15).
- No effect found for health-related quality of life
Limitations: Low Back Pain

- Subgroup analyses were conducted on small groups of studies
- Unclear or high dropout or noncompliance rates
- Exclusive focus on chronic low back pain, with no studies of acute back pain
- No veterans or military populations
- Etiology of back pain not specified
Conclusions: Low Back Pain

- Evidence suggests potential benefit of yoga in midlife adults with nonspecific low back pain
- Uncertain effects on health-related quality of life
- Uncertain effects of yoga for acute or subacute low back pain, or prevention
- Given multidimensional nature of chronic low back pain, yoga as monotherapy may not be sufficient
- Without additional RCTs, further SRs are not needed
Results: Depressive Disorders

4 Systematic Reviews

- 1 good, 1 moderate, and 2 low quality
- 3 evaluated RCTs only. 1 included nonrandomized studies
- ClinicalTrials.gov: 1 ongoing RCT (N=150)
- 1 focused on depressive disorders. Others on multiple mental illnesses
- 2 included meta-analyses
### Results: Depressive Disorders

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<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>Condition(s)</strong></td>
<td>Depressive disorders</td>
<td>Multiple mental illnesses</td>
<td>Multiple mental illnesses</td>
<td>Mood and anxiety disorders</td>
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<td>June 2011</td>
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<td>July 2008</td>
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<td>PubMed Scopus Cochrane Library PsyCINFO IndMED Gray literature</td>
<td>MEDLINE Cochrane Central Register of Controlled Trials Embase PsyCINFO</td>
<td>PubMed Cochrane Central Register of Controlled Trials Google Scholar EBSCO</td>
<td>PubMed PsyCINFO</td>
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<td>RCTs</td>
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<td>All disorders 12 12</td>
<td>Depressive disorders 16 4</td>
<td>10 5</td>
<td>34 16</td>
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<tr>
<td><strong>Meta-analysis performed?</strong></td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td><strong>Systematic review quality</strong></td>
<td>Good</td>
<td>Moderate</td>
<td>Low</td>
<td>Low</td>
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</tbody>
</table>
Depressive Disorders: Cramer, 2013

- 12 RCTs (619 patients)
- Depressive disorders meeting DSM-IV or ICD-10 criteria
- Yoga interventions classified as nonphysical vs. exercise-based vs. complex (postures plus meditation or breathing or both)
- Median number of hours planned for yoga was 11 (4-18)
- 8 week median for program length (3 days to 12 weeks)
- Outcomes assessed at median of 10 weeks (3 days-9 months)
- SR authors judged 3 RCTs to be at low risk and 9 to be at high risk of bias
Compared with usual care, yoga improved short-term depressive symptoms (SMD= -0.69; 95% CI: -0.99 to -0.39), but effects varied substantially across studies.

Yoga was more effective than relaxation (SMD= -0.59; 95% CI: -1.03 to -0.22) and aerobic exercise (SMD= -0.59; 95% CI: -0.99 to -0.18).

Remission rates infrequently reported.

Authors’ conclusion: “Despite methodological drawbacks of the included studies, yoga could be considered an ancillary treatment option for patients with depressive disorders and individuals with elevated levels of depression.”
Conclusions: Depressive Disorders

- “We reached a different conclusion than the review authors. We think these studies suggest potential benefits for yoga in midlife adults with depression, but our confidence in the treatment effect is low...Larger, higher quality RCTs with longer term outcomes that include depression severity, functional status, and adverse effects would be needed to more fully evaluate the effects of yoga.”

- “For subsyndromal depression, yoga may be a reasonable option as monotherapy”

- “For major depressive disorder, yoga could be an alternative to other active treatments or used as add-on therapy for patients treated with antidepressants.”
Yoga for Anxiety Disorders

- 2 poor quality SRs

- Included patients with anxiety symptoms outside of the generalized anxiety disorder or panic disorder spectrum

- ClinicalTrials.gov: 1 large (N=230) ongoing 3-arm RCT comparing yoga to mindfulness-based stress reduction and cognitive behavioral therapy in patients with generalized anxiety disorder
# Yoga for Anxiety

## Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>da Silva, 2009</th>
<th>Cabral, 2011</th>
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</thead>
<tbody>
<tr>
<td><strong>Conditions</strong></td>
<td>Mood and anxiety disorders</td>
<td>Multiple mental illnesses</td>
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<td><strong>Search date</strong></td>
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<td><strong>Databases searched</strong></td>
<td>PubMed, PsycINFO</td>
<td>PubMed, Cochrane Central Register of Controlled Trials, Google Scholar, EBSCO</td>
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<tr>
<td><strong>Study designs included</strong></td>
<td>RCTs and nonrandomized studies</td>
<td>RCTs</td>
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<tr>
<td><strong>Studies included</strong></td>
<td>34 8</td>
<td>10 4</td>
</tr>
<tr>
<td><strong>Meta-analysis performed?</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Systematic review quality</strong></td>
<td>Poor</td>
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</table>
Conclusions: Anxiety

- Evidence in support of potential effectiveness of yoga for anxiety disorders is preliminary.

- Evidence suggests that yogic exercises, including meditation, breathing, and postures may have a positive, short-term effect on symptoms and severity of anxiety in those diagnosed with an anxiety disorder.
Results: Yoga for PTSD

- 2 poor quality SRs
  - 1 small RCT (8 patients)
  - 2 nonrandomized studies (total of 22 patients)
- ClinicalTrials.gov: Completed but as-yet unpublished trial with 108 patients.
- Too few studies to estimate potential benefits (if any) of yoga for PTSD or PTSD symptoms
Results: Insomnia

- 1 fair quality SR
- Included 3 poor-quality RCTs that evaluated yoga for individuals at increased risk for insomnia
- Did not include any primary studies with clinical diagnosis of insomnia as a subject eligibility criterion
- The review reported improved sleep associated with yoga in all 3 RCTs
- Authors concluded that there is “Grade C evidence (low-grade data) supporting a potential benefit for yoga for sleep complaints”
Results: Prevention of Falls

- Single SR of yoga for falls prevention
- Includes 15 studies (687 patients, with ages 10-93)
- Healthy populations—not on high-risk populations, which was the focus of our Evidence Map
- Outcomes included a variety of measures of balance, rather than frequency of falls
- Inconclusive results. Further research needed.
Results: Adverse Effects

- 1 good quality SR that specifically addressed adverse effects associated with yoga
- 37 case reports or case series
- 76 individual adverse effects occurring in patients engaged in yoga
- Musculoskeletal injuries, orbital involvement (9 cases, including new and worsening glaucoma and optic vascular events), and headache were the most common adverse effects
Limitations of the Evidence Map

- English-language publications only
- Only recently published SRs and large RCTs
- We relied on the information provided by authors of the SRs (with some verification by us)
- Possible misclassification of “yoga”
- High “heterogeneity” of individual studies
Applicability

- None of the primary studies specifically involved veteran populations.
- For the most part, the populations studied represent generally healthy, middle-aged adults, most of whom were women.
- Applicability to older populations or patients with multiple medical problems is limited.
- Limited applicability to conditions for which few or no studies were identified (e.g., acute low back pain, prevention of falls, general anxiety disorder, or insomnia).
## Research Gaps and Future Research

<table>
<thead>
<tr>
<th>Condition</th>
<th>Gap</th>
<th>Recommended Study Designs</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low back pain</td>
<td>Acute back pain Subgroups (eg, young adults, or specific back pain etiologies)</td>
<td>Large RCTs</td>
<td>Long-term functional status</td>
</tr>
<tr>
<td>Prevention of falls</td>
<td>No good-quality SR No RCTs</td>
<td>Pilot trials</td>
<td>Falls</td>
</tr>
<tr>
<td>Depressive disorders</td>
<td>Existing trials poor quality</td>
<td>Large RCTs</td>
<td>Long-term functional status</td>
</tr>
<tr>
<td>Anxiety disorders (GAD/PD)</td>
<td>No good-quality SR No RCTs</td>
<td>Pilot trials</td>
<td>Standardized outcome measures</td>
</tr>
<tr>
<td>PTSD</td>
<td>No good-quality SR 1 small RCT</td>
<td>Pilot trials</td>
<td>Standardized outcome measures</td>
</tr>
<tr>
<td>Insomnia</td>
<td>No good-quality SR RCTs only in those at risk for sleep disorders</td>
<td>Pilot trials</td>
<td>Sleep quality</td>
</tr>
</tbody>
</table>
Our Conclusions

- Evidence from good quality SRs suggests that yoga can improve functional outcomes in patients with nonspecific low back pain.
- Existing evidence is less clear for other conditions.
- Potential benefit for yoga in adults with depressive disorders or elevated depressive symptoms.
- Limited evidence that suggests yoga may be beneficial for patients with anxiety or sleep disorder symptoms.
- Few trials of yoga for prevention of falls, PTSD, or insomnia.
- Quality of SRs generally high, but quality of primary studies generally low.
Just a Little Bit More...

- My reflections and recommendations re: yoga research
- Funding opportunities
- Invitation for you to update us on studies that were not included in our Evidence Map
- Questions and discussion
Reflections

- Yoga may be a powerful practice/intervention that has great potential
- Your trajectory is fast and steep (in a positive way)
- There is excitement in the air, as well as focus and intention
- You have the beginnings of a critical mass of researchers and high-quality evidence of effectiveness (but you may not be there just ye
Recommendations

- Support the International Journal of Yoga Therapy
- Publish your work in a timely manner
- Think: “PICOTS”
- Design, conduct, and report your research in such a way as to earn “Good Quality” ratings by people like me who conduct systematic reviews
- Consider adapting CONSORT to yoga research, as we have done for acupuncture research with the STRICTA guidelines
CONSORT

CONSOLiated Standards Of Reporting Trials

“The main product of CONSORT is the CONSORT Statement, which is an evidence-based, minimum set of recommendations for reporting randomized trials.”

http://www.consort-statement.org
STRICTA

STandards for Reporting Interventions in Clinical Trials of Acupuncture

http://www.stricta.info/

1. Acupuncture rationale
2. Details of needling
3. Treatment regimen
4. Other components of treatment
5. Practitioner background
6. Control or comparator interventions

http://www.stricta.info
Funding Sources

- Philanthropic organizations or individuals
- Department of Defense
  - Congressionally Directed Medical Research Program (CDMRP) ([http://cdmrp.army.mil/](http://cdmrp.army.mil/)).
  - Peer Reviewed Medical Research Program (PRMRP) ([http://cdmrp.army.mil/funding/primrp.shtml](http://cdmrp.army.mil/funding/primrp.shtml))
- Patient Centered Outcomes Research Institute (PCORI) ([www.pcori.org](http://www.pcori.org))
- Nonsurgical treatments for neck pain
Questions and Discussion

- Thank you for your time and attention!

- Your turn, now...