

# Evidence Map of Yoga for High-Impact Conditions Affecting Veterans

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# PREFACE

Quality Enhancement Research Initiative's (QUERI) Evidence-based Synthesis Program (ESP) was established to provide timely and accurate syntheses of targeted healthcare topics of particular importance to Veterans Affairs (VA) clinicians, managers and policymakers as they work to improve the health and healthcare of Veterans. The ESP disseminates these reports throughout the VA, and some evidence syntheses inform the clinical guidelines of large professional organizations.

QUERI provides funding for four ESP Centers and each Center has an active university affiliation. The ESP Centers generate evidence syntheses on important clinical practice topics, and these reports help:

- develop clinical policies informed by evidence;
- guide the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- set the direction for future research to address gaps in clinical knowledge.

In 2009, the ESP Coordinating Center was created to expand the capacity of HSR&D Central Office and the four ESP sites by developing and maintaining program processes. In addition, the Center established a Steering Committee comprised of QUERI field-based investigators, VA Patient Care Services, Office of Quality and Performance, and Veterans Integrated Service Networks (VISN) Clinical Management Officers. The Steering Committee provides program oversight, guides strategic planning, coordinates dissemination activities, and develops collaborations with VA leadership to identify new ESP topics of importance to Veterans and the VA healthcare system.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP Coordinating Center Program Manager, at Nicole.Floyd@va.gov.

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# **EXECUTIVE SUMMARY**

### **INTRODUCTION**

Patient-centered care supports the active involvement of patients and their families in the decision-making process between options for treatment. Part of this mission is to identify, develop, and implement new practices and approaches that are found to be effective in promoting the transformation to a patient-centered model and improved patient care. Complementary and alternative medicine (CAM) strategies such as yoga are widely available in the private sector, and some Veterans would like access to these strategies through the Veterans Affairs (VA) system. Determining the state of evidence on the benefits and harms of yoga and other CAM modalities is a priority for the Veterans Health Administration (VHA).

To fulfill the joint research needs of the Office of Patient Centered Care and the Field Advisory Committee on Complementary and Alternative Medicine, and to help VA leadership determine the most appropriate guidelines/policy for the implementation of CAM therapies within the VA, the Evidence-based Synthesis Program Coordinating Center proposed a CAM evidence mapping project to evaluate the existing evidence on yoga for common clinical conditions in Veterans.

#### **METHODS**

#### **Data Sources and Searches**

We searched PubMed, the Cochrane Database of Systematic Reviews, Embase, and the Allied and Complementary Medicine Database (AMED) for systematic reviews and recent randomized controlled trials (RCTs) of yoga for any of the conditions of interest. In addition, we mapped the evidence for the adverse effects of yoga and searched PROSPERO, the Cochrane Database of Systematic Reviews, and ClinicalTrials.gov for ongoing systematic reviews or trials. Searches were completed in July 2014.

#### **Study Selection**

Eligible studies had to meet the following inclusion criteria:

- Study designs: We included systematic reviews published from 2008 forward that evaluated yoga for one of the specified health conditions. Our goal was to identify current systematic reviews, as prior studies have shown that reviews can become out of date in 3 to 5 years. We also included RCTs (sample size ≥100 subjects) published since January 2011. The goal was to identify recent large RCTs that may not have been identified in published systematic reviews.
- Patients: Adults with low back pain (acute, chronic, or prevention of recurrence), at high risk of falls, or with depressive disorders, generalized anxiety disorder, panic disorder, posttraumatic stress disorder (PTSD), or insomnia. We used inclusive criteria for these conditions to include patients with substantial symptoms or meeting a criterion diagnosis.
- Interventions: We included studies that self-identified the intervention as yoga. We



excluded studies that reviewed therapies that did not have a specific focus on yoga, as well as reviews where yoga was only one of many interventions evaluated.

- Comparators: Any inactive control (waitlist, attention, or information control; or unenhanced usual care) or active comparator.
- Outcomes: Health outcomes including symptom severity, health-related quality of life, global measures of well-being, mortality, and adverse effects (including falls).
- Timing: For RCTs, studies that reported follow-up of one month or greater. For systematic reviews, we accepted the outcome timing specified in the review's eligibility criteria.

#### **Data Abstraction and Quality Assessment**

We abstracted the following data elements from published systematic reviews: study characteristics; synthesis methods; results; funding source; conflict of interest; and authors' conclusions. Data elements were abstracted by one investigator and verified by a second. Disagreements were resolved by consensus or a third investigator.

We categorized each systematic review as good, fair, or poor quality. We did not formally assess the quality of the primary literature; instead we relied on quality assessments as reported by the authors of the systematic reviews.

#### **Data Synthesis and Analysis**

We grouped the systematic reviews and RCTs by clinical topic and described them qualitatively. When there were multiple systematic reviews for a clinical topic, we created tables to describe the overlap in the primary studies. We then evaluated each unique primary study to determine if it evaluated yoga for a clinical condition of interest. We used systematic reviews, prioritizing the most recent good-quality review together with any other RCTs (sample size  $\geq 100$  subjects) identified, to describe the number of studies, study designs, patient populations, intervention characteristics, and treatment effects.

We used these data and a structured approach to make judgments about possible next steps for evaluating yoga for the clinical conditions of interest.

# RESULTS

#### **Results of Literature Search**

A combined search of PubMed, the Cochrane Database of Systematic Reviews, Embase, and AMED on the 7 conditions of interest yielded 1015 unique citations, of which 105 full-text articles were retrieved. Of these, 95 were excluded, leaving 10 articles consisting of 9 systematic reviews, one review of reviews, and no recent RCTs with n≥100. A search of PROSPERO, the Cochrane Database of Systematic Reviews, and CinicalTrials.gov identified one relevant systematic review protocol, 6 ongoing studies, and 9 completed but unpublished studies that addressed yoga for one of the eligible conditions.

#### Summary of Results for Key Questions

#### Key Question 1 (Effectiveness)

We identified 9 systematic reviews that pertained to Key Question 1. Three of these focused on chronic low back pain; one focused on yoga for prevention of falls but did not identify any primary studies that reported falls as an outcome; 4 focused on mental illness (2 on depression and 2 on depressive disorders, anxiety disorders, and PTSD); and one focused on insomnia but did not identify any primary studies that included patients with a clinical diagnosis of insomnia. RCTs identified in the eligible systematic reviews included 10 RCTs representing 956 patients with chronic low back pain, 12 RCTs representing 619 patients with depressive disorders, and one RCT representing 8 patients with PTSD (Figure ES-1). The eligible systematic reviews did not include any RCTs of yoga for prevention of falls, generalized anxiety disorder, panic disorder, or insomnia. High-quality systematic reviews were identified for low back pain, depressive disorders, and adverse effects. Generalized anxiety disorder, panic disorder, PTSD, and insomnia were reviewed in moderate- to low-quality systematic reviews. We did not identify any RCTs with n $\geq$ 100 published since 2011 that met our criteria and had not been included in one of the eligible systematic reviews. We identified 10 RCTs with n<100 not captured by the included systematic reviews.



#### Figure ES-1. RCTs Evaluating Yoga

Notes to Figure ES-1:

\*Represents prevention of falls, GAD, PD, and insomnia (no RCTs identified for any of these conditions). 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.

Abbreviations: GAD=generalized anxiety disorder; LBP=low back pain; PD=panic disorder; PTSD=posttraumatic stress disorder; RCT(s)=randomized controlled trial(s)

Overall, the included reviews identified 23 unique RCTs evaluating yoga for one of our eligible conditions (Table ES-1). These RCTs were conducted in North America (n=12), Asia (n=8), and Europe (n=3). Typical enrollment was 25 to 50 patients. The median of the mean ages was 44 years (range 21.5 to 66.5). Median sex was 75% female (range 37% to 100%). Interventions



typically provided a total of 10 to 20 hours of yoga instruction and assessed outcomes over a range of 3 days to 24 weeks, with a median of 8 weeks. Yoga was most commonly compared to attention controls (*eg*, education), usual care, or exercise. In 9 of the 10 RCTs for low back pain, the authors specified that certified or experienced teachers served as instructors, but this was the case for only 5 of the 12 RCTs of yoga for depression. A total of 15 studies reported the experience or certification of the yoga instructors.

Yoga has been studied most extensively for low back pain and depressive disorders. Only the trials evaluating yoga for these 2 conditions were assessed for risk of bias by the systematic review authors. They judged the majority of the low back pain studies to be at low risk of bias, and the majority of studies in patients with depressive disorders to be at high risk of bias.

Systematic review authors conducted meta-analyses for 2 conditions, low back pain and depressive disorders. Meta-analyses showed consistent short-term benefits of yoga on pain (n=6; standardized mean difference [SMD] -0.48; 95% confidence interval [CI], -0.65 to -0.31; I2=0%) and more variable benefits for back-specific disability (n=8; SMD -0.59; 95% CI, -0.87 to -0.30; I2=59%). A smaller set of studies (n=5) reported long-term effects, and these also showed benefit for pain and back-specific disability. No short-term (n=4) or long-term effect (n=2) was found for health-related quality of life.

Compared with usual care, yoga improved short-term depressive symptoms (n=5; SMD -0.69; 95% CI, -0.99 to -0.39), but effects varied substantially across studies (I2=86%). Yoga was also more effective than relaxation (n=3; SMD -0.59; 95% CI, -1.03 to -0.22; I2=0%) and aerobic exercise (n=2; SMD -0.59; 95% CI, -0.99 to -0.18) for this outcome. Long-term effects on depressive symptoms were reported infrequently, as were other outcomes such as remission rates and health-related quality of life.

For the other conditions, the lack of RCTs precluded estimates of treatment effects.

Characteristic	Low Back Pain	Prevention of Falls	Depressive Disorders	Anxiety Disorders	PTSD	Insomnia
Number of systematic reviews (number of good- quality reviews)	3 (3)	1 (0)	4* (1)	2* (0)	2* (0)	1 (0)
Number of RCTs (number of patients)	10 (956)	0 (0)	12 (639)	0 (0)	1 (11)	0 (0)
Meta-analysis performed?	Yes	No	Yes	Yes	No	No

Table ES-1. Summary of Systematic Reviews and Primary RCTs for All Eligible Conditions

\*We identified a total of 4 systematic reviews of yoga for mental illness; 2 of these reported findings for depressive disorders, anxiety disorders, and PTSD.

Abbreviations: PTSD=posttraumatic stress disorder; RCTs=randomized controlled trials

#### Key Question 2 (Adverse Effects)

We identified a single good-quality systematic review of adverse effects associated with yoga (for any clinical condition). This review identified 37 case reports or case series, representing 76 individual adverse effects occurring in patients engaged in yoga. The headstand was associated most commonly with adverse outcomes (10 cases), and 3 reports involved the shoulder stand,

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but most reports of adverse effects did not have clear descriptions of the postures involved. Musculoskeletal injuries were reported in 27 cases, while orbital involvement (9 cases, including new and worsening glaucoma and optic vascular events) and headache (7 cases) were the next most common adverse effects. In the systematic reviews we identified for clinical conditions of interest for this report (low back pain, prevention of falls, depressive disorders, anxiety disorders, PTSD, and insomnia), only the studies of yoga for low back pain reported adverse effects. With most of the systematic reviews, it is unclear if adverse effects were truly not detected, or if this outcome was not addressed by the original study protocols and thus not captured. Given the small sample sizes of most RCTs included in the systematic reviews, it is possible that infrequent adverse effects may have been missed.

## DISCUSSION

#### **Key Findings**

#### Key Question 1 (Effectiveness)

Yoga has been studied most extensively for low back pain and depressive disorders. The majority of the low back pain studies were judged by systematic review authors to be at low risk of bias, while the majority of studies in patients with depressive disorder were judged to be at high risk of bias. For low back pain, yoga was associated with improvement in pain scores and back-specific disability. For depressive disorders, yoga was associated with improvement in depressive symptomatology.

#### Key Question 2 (Safety/Adverse Effects)

Very few adverse effects potentially associated with yoga were reported in the studies included in this report, but it is unclear if adverse effects were truly not detected, or if this outcome was not addressed by the original study protocols and thus not captured.

#### Applicability

None of the primary studies eligible for inclusion in this report specifically involved Veteran populations. For the most part, the populations studied represent generally healthy, middle-aged adults, most of whom were women. The applicability of the effectiveness and safety findings for older populations or populations characterized by multiple comorbidities is limited. There is also limited applicability of the findings to the many conditions for which few or no studies were identified, such as acute (as opposed to chronic) low back pain, prevention of falls, general anxiety disorder, or insomnia.

#### **Research Gaps/Future Research**

In this report, we summarize key gaps in the literature and the types of studies that might address those gaps. We conclude that for low back pain and depression, where there are already RCTs, new or more in-depth evidence syntheses are not currently needed, but additional trials with active comparators may be helpful. For conditions examined by small or poor-quality trials *(eg,* depressive disorders), larger, more rigorous trials would be informative. Trials in certain subgroups, such as specific etiologies of back pain, could help target yoga to those who would



benefit most. For all of the conditions for which yoga may be effective, longer term, validated, patient-reported outcomes should be assessed, and stakeholders, including patients, should be involved in prioritizing outcomes to be measured for future studies. Feasibility and acceptability studies could also be conducted to identify potential barriers and facilitators for learning and practicing yoga among various Veteran populations. Finally, enhancement of the applicability of findings to Veterans could be achieved by including Veterans or patients with similar demographic characteristics to achieve better representation of men and older adults. There are currently several relatively large, ongoing clinical trials of yoga, the results of which may provide important information about the effectiveness and safety of yoga.

#### Conclusions

We conclude that the evidence from good-quality systematic reviews suggests that yoga can improve functional outcomes in patients with nonspecific chronic low back pain. Existing evidence is less clear about the effectiveness and safety of yoga for the other conditions of interest. There is potential benefit for yoga in young to midlife adults with depressive disorders or elevated depressive symptoms. We found a limited amount of evidence that suggests that yoga may be beneficial for patients with symptoms of anxiety or insomnia. We found few or no trials that evaluated the effectiveness and safety of yoga for prevention of falls, PTSD, or insomnia. These findings and conclusions are generally consistent with those of a recent (2013) published review of systematic reviews of yoga for acute and chronic health conditions which concluded that yoga appears most effective for reducing symptoms in anxiety, depression, and pain. The authors of that review of reviews concluded, as we do, that the quality of existing systematic reviews is generally good, whereas the quality of the primary studies is generally poor.

AMED	Allied and Complementary Medicine Database
САМ	Complementary and alternative medicine
СІ	Confidence interval
PTSD	Posttraumatic stress disorder
RCTs	Randomized controlled trials
SMD	Standardized mean difference
VA	Veterans Affairs
VHA	Veterans Health Administration

# ABBREVIATIONS TABLE