

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

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# Prepared by:

Evidence-based Synthesis Program (ESP) Center Durham Veterans Affairs Healthcare System Durham, NC John W. Williams, Jr., M.D., M.H.Sc., Director

# **Investigators:**

Principal Investigator: Remy R. Coeytaux, M.D., Ph.D.

#### Co-Investigators:

Jennifer McDuffie, Ph.D.
Adam Goode, D.P.T., Ph.D.
Sarah Cassel, B.A.
Wei Duan Porter, M.D.
Poonam Sharma, Ph.D.
Sreelatha Meleth, Ph.D.
Hilary Minnella, B.A.
John W. Williams, Jr., M.D., M.H.Sc.

Research Associates: Avishek Nagi, M.S.







#### **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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## **EVIDENCE REPORT**

#### INTRODUCTION

Patient-centered care as practiced by the Veterans Health Administration (VHA) 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 have requested that the VHA make them available in the VA system. Determining the state of evidence on the benefits and harms of yoga and other CAM modalities is a priority for the VHA.

Yoga is a term used to describe a collection of spiritual and physical practices originating in ancient India and used to cultivate deep meditative states in order to achieve greater union with the divine or true self. Sometime around the second or third century CE, the 8-limbed path of yoga (Ashtanga yoga) was first documented, which includes the following practices: 1) Yama, or ethical restraints; 2) Niyama, or personal observances; 3) Asana, or physical exercises; 4) Pranayama, or mastery of breath; 5) Pratyahara, or sense withdrawal; 6) Dharana, or concentration; 7) Dhyana, or meditation; and 8) Samadhi, translated as ecstasy or nondualistic consciousness. 1-3 By the 15th century, teachings describing the physical and mental aspects of yoga as purification practices in the context of Hinduism were compiled into a series of texts which include the Hatha Yoga Pradipika, Shiva Samhita, and Gherenda Samhita. 4 The modern conception of Hatha yoga, which is most broadly associated with yoga in the west, derives from these texts.

There are numerous styles or lineages of yoga that were drawn from the traditions of the yoga sutras or Hatha yoga, and many of these have emerged in the past century. Styles such as Sivananda, Kripalu, Iyengar, Ashtanga, and Vinyasa provide a greater emphasis on physical and lifestyle practices, while styles such as Kundalini, Sahaj, and Siddha emphasize more esoteric aspects of yoga philosophy. In recent decades, numerous fitness-oriented yoga regimens, such as Power yoga, Yogafit, and Bikram yoga, have also gained popularity, particularly in the United States.<sup>5</sup> As interest in the therapeutic applications of yoga expands, many of the interventions studied in the literature actually refer to particular techniques drawn from these various traditions. Examples of this include Sudarshan Kriya Yoga (SKY), which centers on rhythmic breathing practices; Kirtan Kriya, a meditative chanting exercise from Kundalini yoga; or yoga Nidra, a state of deep relaxation achieved through prescribed meditative techniques.<sup>6-8</sup> A glossary of yoga terms is provided in Appendix A.

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. Evidence mapping is an emerging approach used to characterize evidence for a broad area of medicine. 9-11 Evidence mapping can be defined as "the systematic organization and illustration







of a broad field of research evidence,"<sup>10</sup> with the goals of describing the breadth, depth, and methodology of published literature and identifying gaps in that literature. Evidence mapping differs from systematic reviews of the literature by covering broader topics and reporting on descriptive epidemiology of the literature rather than synthesizing evidence for a narrowly focused clinical question. It outlines the type and number of studies available in the literature and describes the basic features of the studies—location, design, population, intervention, and outcomes examined—but less commonly attempts to draw quantitative conclusions about treatment effects.

Through discussions with the key stakeholders, we prioritized an evidence map for: low back pain, prevention of falls, depressive disorders, anxiety disorders (generalized anxiety disorder and panic disorder), posttraumatic stress disorder (PTSD), and insomnia. In addition, we mapped the evidence for the adverse effects of yoga.





#### **METHODS**

Our protocol-directed approach was to begin by identifying recent relevant systematic reviews for each condition of interest, and to supplement these reviews by identifying any large (n≥100) randomized controlled trials (RCTs) not identified by the published reviews. We evaluated this literature to describe the breadth of studies assessing yoga for the health conditions of interest. In addition, where estimates of treatment effects were available from good-quality systematic reviews, we report these. The overall approach includes methods used in "overviews of reviews" <sup>12,13</sup> and evidence mapping. <sup>9-11</sup>

#### TOPIC DEVELOPMENT

This review was commissioned by the VA's Evidence-based Synthesis Program. The topic was nominated after a process that included a preliminary review of published peer-reviewed literature and consultation with investigators, VA and non-VA experts, and key stakeholders (Laura Krejci, Office of Patient Care Services; and Stephen Ezeji-Okoye, Veterans Administration Central Office Field Advisory Committee on Complementary and Alternative Medicine), with input from a technical expert panel. Clinical conditions were chosen in consultation with stakeholders for their high relevance to the Veteran population and the potential for yoga to benefit these conditions.

The final key questions were:

- 1. What are the extent, distribution, and methodological designs of intervention studies that evaluate yoga for the following conditions?
  - Low back pain
  - Prevention of falls
  - Mental illness:
    - Depressive disorders
    - Anxiety disorders (generalized anxiety disorder and panic disorder)
    - Posttraumatic stress disorder (PTSD)
  - Insomnia
- 2. What are the extent, distribution, and designs of studies that assess the adverse effects of yoga?

#### **SEARCH STRATEGY**

We conducted separate searches for each health condition of interest using Medical Subject Headings (MeSH) terms, keywords, and selected free-text terms for yoga, systematic reviews, and RCTs, combined with terms for the health condition. This allowed us to gain an idea of the amount of literature available for each condition, as well as the degree of overlap in the literature across conditions. To ensure completeness, search strategies were developed in consultation with an experienced librarian and were conducted in PubMed, the Cochrane Database of Systematic Reviews, and Embase. Condition-specific searches were supplemented by a search of PubMed





for systematic reviews that addressed the adverse effects associated with yoga and a search of the Allied and Complementary Medicine Database (AMED) using the single term "yoga." The exact search strategies used are provided in Appendix B. When we did not identify any systematic reviews for eligible health conditions, we searched PROSPERO (an international prospective register of systematic review protocols) and the Cochrane Database for Systematic Reviews for protocols related to the specified health conditions. Searches were completed in July 2014.

#### STUDY SELECTION

Using prespecified inclusion and exclusion criteria, 2 investigators assessed titles and abstracts for relevance to the key questions. Full-text articles identified by either investigator as potentially relevant were retrieved for further review and examined by 2 investigators against the eligibility criteria. Disagreements on inclusion or exclusion were resolved by discussion or by a third investigator. The criteria used to screen articles for inclusion or exclusion at both the title-and-abstract and full-text screening stages are detailed below. All results were tracked in both DistillerSR, a web-based data synthesis software program (Evidence Partners Inc., Manotick, ON, Canada), and EndNote® reference management software (version X5, Thomson Reuters, Philadelphia, PA).

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. <sup>14-16</sup> 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,
  PTSD, or insomnia. We used inclusive criteria for these conditions; for example, we
  included a range of depressive disorders, including subsyndromal depression (minor
  depression), adjustment disorder with depressed mood, and significant depressive
  symptoms as determined by a validated screening instrument.
- Interventions: Yoga generally consists of 3 components: 1) physical exercises and bodily positions or postures; 2) breath control practices; and 3) meditation. We included studies that self-identified the intervention as yoga, including yoga interventions that use exercises only for breath control, or have multiple components. We excluded studies that reviewed CAM therapies in general without a specific focus on yoga, as well reviews where yoga was only one of many interventions evaluated. Although mindfulness-based stress reduction and mindfulness-based cognitive therapy share some features with yoga, these therapies are mostly considered distinct from yoga and are typically reviewed separately from yoga. They were excluded from this review.
- 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). We excluded studies that addressed solely mechanism of action, provider outcomes, patient acceptance, prevalence, use, or costs without reporting health outcomes as defined above.
- 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.
- Settings: Healthcare-related or community settings.
- Limits: English-language publications.

#### **DATA ABSTRACTION**

Data from published systematic reviews were abstracted into a customized Excel spreadsheet database by one investigator and verified by a second. Disagreements were resolved by consensus or by obtaining a third investigator's opinion when consensus could not be reached. Data elements included study characteristics (eg, search date, eligibility criteria, or assessment for publication bias), synthesis methods (eg, meta-analysis, sensitivity analyses), results (eg, number and design of included primary studies, sample characteristics, intervention characteristics, treatment effects, or risk of bias assessments), funding source, conflict of interest, and authors' conclusions (Appendix C).

#### **QUALITY ASSESSMENT**

We used the following key quality criteria adapted from the Quality of Reporting of Metaanalyses (QUOROM)<sup>17</sup> and Assessment of Multiple Systematic Reviews (AMSTAR)<sup>18</sup> instruments to categorize each systematic review as good, fair, or poor quality (Appendix D):

- Search methods adequate for replication and comprehensive;
- Selection bias avoided;
- Data abstracted reliably:
- Characteristics of primary literature reported;
- Quality assessed appropriately;
- Results synthesized using appropriate methods;
- Publication bias assessed;
- · Conflict of interest reported; and
- Conclusions supported by results.

Two investigators performed quality assessments independently. Disagreements were resolved between the 2 investigators by discussion.

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**

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 voga for a clinical condition of interest. Using this process for systematic reviews. coupled with our search for additional RCTs, we identified the total number of systematic reviews and unique primary studies applicable to each condition. We used systematic reviews, prioritizing the most recent good-quality review, to describe the number of studies, study designs, patient populations, intervention characteristics, and treatment effects. To evaluate treatment effects, we focused on RCTs. When non-RCTs were included in systematic reviews, we report descriptive data for these studies. When systematic reviews conducted meta-analyses, they reported treatment effects as standardized mean differences (SMDs). This approach is appropriate because the primary studies used differing scales to assess conceptually similar outcomes. The SMD is calculated by subtracting the average score of the treatment group from the average score of the control group and dividing the result by the pooled standard deviations of the 2 groups. SMDs of 0.2 can be considered small treatment effects; 0.5, moderate effects: and ≥0.8, large effects. 19 Authors sometimes also reported Cochran's Q and I2 statistics, which are measures of heterogeneity, or variability, in treatment effect. The latter measure, the I2 statistic, describes the percentage of total variation across studies due to heterogeneity rather than to chance. A rough guide to interpreting the I2 statistic<sup>20</sup> is:

- 0% to 40%: heterogeneity might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

We evaluated the systematic reviews initially by condition, then used these results to create summary tables and figures that illustrate the number of RCTs, study characteristics, and estimates of treatment effect across conditions.

We used these data to make judgments about possible next steps for evaluating yoga for the clinical conditions of interest as follows:

- If no or only a few good-quality RCTs identified: consider RCTs.
- If >3 RCTs and no good-quality systematic review identified: consider a systematic review.
- If a good-quality systematic review along with subsequently published RCTs identified: consider using formal methods<sup>21,22</sup> to determine the need for an updated review.
- If a good-quality systematic review, but no additional RCTs identified: consider surveillance of the primary literature to identify the need for an updated review.

#### **PEER REVIEW**

A draft version of the report was reviewed by technical experts and clinical leadership. A transcript of their comments, along with our responses, is included in Appendix E.





#### **RESULTS**

In this section of the report, we report the results of the literature search, followed by a metasynthesis describing the volume of studies across all conditions. We then describe the findings by condition, prioritizing findings from systematic reviews.

#### LITERATURE FLOW

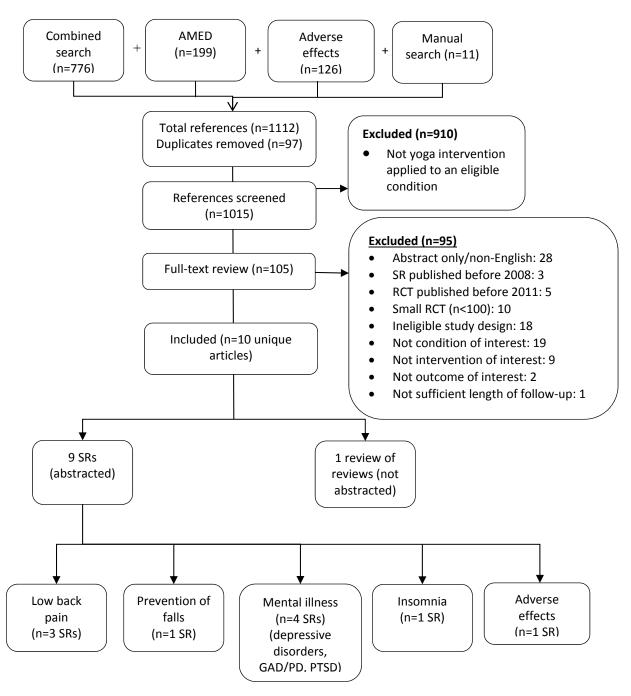
The flow of articles through the literature search and screening process is shown in Figure 1. A combined search of PubMed, the Cochrane Database of Systematic Reviews, and Embase on the 7 conditions of interest yielded 776 articles. By condition, there were 76 articles on low back pain, 48 on prevention of falls, 176 on depressive disorders, 226 on anxiety disorders (generalized anxiety disorder or panic disorder), 28 on PTSD, and 157 on insomnia. The AMED search on yoga in general (n=199), the search in PubMed on adverse effects (n=126), and a review of the bibliographies of key articles (n=11) provided an additional 336 articles, for a total of 1112 articles. After removing duplicates—articles identified for more than one condition or in more than one database (n=97)—the final dataset contained 1015 unique citations.

After applying inclusion and exclusion criteria at the title-and-abstract level, 105 full-text articles were retrieved. Of these, 95 were excluded, leaving 10 articles consisting of 9 systematic reviews and one recent "review of reviews" that was used to evaluate the completeness of our literature review. No additional eligible reviews were identified in this review of reviews.<sup>23</sup> We did not identify any eligible RCTs (n≥100) that were not included in an eligible systematic review. The search of PROSPERO and the Cochrane Database of Systematic Reviews identified only one relevant systematic review protocol, registered in 2013, to address yoga for chronic low back pain.<sup>24</sup> The search of ClinicalTrials.gov identified 15 studies which were either completed but unpublished (n=9) or ongoing (n=6). These are detailed in Appendix F.





Figure 1. Literature Flow Chart



Abbreviations: AMED=Allied and Complementary Medicine Database; GAD=generalized anxiety disorder; PD=panic disorder; PTSD=posttraumatic stress disorder; RCT=randomized controlled trial; SR=systematic review





#### **OVERVIEW OF RESULTS**

We identified 9 systematic reviews that pertained to a Key Question (Table 1). 25-33 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); one focused on insomnia but did not identify any primary studies that included patients with a clinical diagnosis of insomnia; and one focused on adverse effects. 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 11 patients with PTSD (Figure 2). The eligible systematic reviews did not include any RCTs of yoga for prevention of falls, generalized anxiety disorder, panic disorder, or insomnia. Good-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 fair- to poorquality systematic reviews. Detailed quality ratings for each systematic review are provided in Appendix G. There were no RCTs with n≥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 (Appendix H); 3 of these focused on low back pain, <sup>34-36</sup> 2 on prevention of falls, <sup>37,38</sup> 2 on major depressive disorder, <sup>39,40</sup> one on generalized anxiety disorder,41 and 2 on PTSD.42,43





Table 1. Characteristics of Systematic Reviews Evaluating Yoga for All Eligible Conditions

Characteristic	Cramer 2013 <sup>30</sup>	Holtzman 2013 <sup>29</sup>	Posadzki 2011 <sup>31</sup>	Jeter, 2014 <sup>33</sup>	Cramer, 2013 <sup>25</sup>	Balasubra- maniam, 2013 <sup>26</sup>	Cabral, 2011 <sup>27</sup>	da Silva, 2009 <sup>28</sup>	Cramer, 2013 <sup>32</sup>
Condition(s)	Low back pain	Low back pain	Low back pain	Prevention of falls	Depressive disorders	Multiple mental illnesses; insomnia	Multiple mental illnesses	Mood and anxiety disorders	Adverse effects
Search date	January 2012	November 2011	March 2011	June 2012	January 2013	June 2011	Not reported	July 2008	February 2013
Databases searched	PubMed Embase Cochrane Library CAMbase	CINAHL MEDLINE Global Health Cochrane Central Register of Controlled Trials Embase PsycINFO	PubMed Cochrane Central Register of Controlled Trials Clinical Trial Registry of Indian Council Embase CINAHL AMED PsycINFO	PubMed IndMED Web of Knowledge Embase EBSCO Science Direct Google Scholar	PubMed Scopus Cochrane Library PsycINFO IndMED Gray literature	MEDLINE Cochrane Central Register of Controlled Trials Embase PsycINFO	PubMed Cochrane Central Register of Controlled Trials Google Scholar EBSCO	PubMed PsycINFO	PubMed CAMbase IndMED Scopus Cases Database
Study designs included	RCTs	RCTs	RCTs	RCTs; non- randomized studies	RCTs	RCTs	RCTs	RCTs; non- randomized studies	Case reports; case series
Studies included All disorders Relevant studies*	10	8	7	15	12	16	10	34	37
	10	8	7	0	12	2	4	3	37
Meta-analysis performed?	Yes	Yes	No	No	Yes	No	Yes	No	No
Systematic review quality	Good	Good	Good	Fair	Good	Moderate	Low	Low	Good

<sup>\*</sup>RCTs evaluating yoga for adults with low back pain, prevention of falls, depressive disorders, generalized anxiety disorder, panic disorder, PTSD, or adverse effects. The mental illnesses had to be diagnosed by a clinician, meet DSM or similar criteria, or score above a threshold on a validated screening instrument.

Abbreviations: DSM=Diagnostic and Statistical Manual of Mental Disorders; PTSD=posttraumatic stress disorder; RCTs=randomized controlled trials





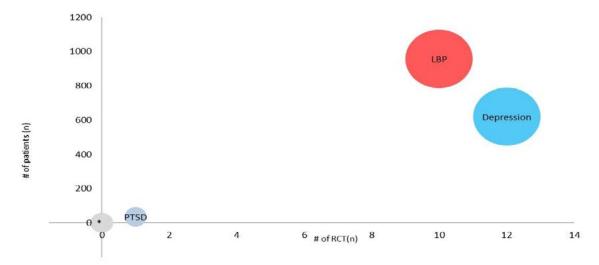


Figure 2. RCTs Evaluating Yoga

Notes to Figure 2:

\*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 2). 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 10 to 20 hours of yoga 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.



Table 2. Summary of Primary RCTs for All Eligible Conditions

Characteristic	Low Back Pain	Prevention of Falls	Depressive Disorders	Anxiety Disorders	PTSD	Insomnia
Number of systematic	3	1	4*	2*	2*	1
reviews						
Number of RCTs (number	10 (956)	0 (0)	12 (639)	0 (0)	1 (11)	0 (0)
of patients)						
Systematic review quality						
Good	3	-	1	_	0	_
Moderate	0	-	1	_	0	-
Low	0	-	2	-	1	-
Meta-analysis performed?	Yes	No	Yes	Yes	No	No
Geographical location						
North America	6	-	5	_	1	_
Europe	2	-	1	_	0	-
Asia	2	-	6	_	0	-
Other/NR	0	-	0	-	0	-
Sample size of RCTs						
1-50	4	-	8	_	1	_
51-100	3	-	4	_	0	-
>100	3	-	0	-	0	-
Yoga style						
lyengar	3	-	1	_	0	_
Hatha	2	-	1	_	0	-
Viniyoga	2	-	0	_	0	_
SKY	3	-	2	_	0	-
Other/NR	0	_	8	_	1	_
Treatment duration						
<4 weeks	2	_	3	_	0	_
5-12 weeks	6	_	8	_	0	_
>12 weeks	2	_	0	_	0	_
NR	0	_	1	-	1	-

<sup>\*</sup>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: NR=not reported; PTSD=posttraumatic stress disorder; RCTs=randomized controlled trials; SKY=Sudarshan Kriya Yoga

# KEY QUESTION 1: What are the extent, distribution, and methodological designs of intervention studies that evaluate yoga for the following conditions?

- Low back pain
- Prevention of falls
- Mental illness:
  - Depressive disorders
  - o Anxiety disorders (generalized anxiety disorder and panic disorder)
  - o Posttraumatic stress disorder (PTSD)
- Insomnia





#### Yoga for Low Back Pain

We identified 3 eligible systematic reviews that evaluated yoga for low back pain (Table 3).<sup>29-31</sup> All 3 included only RCTs, and all focused exclusively on chronic low back pain. Additional RCTs with n≥100 were not identified outside those included in the systematic reviews; 3 recent RCTs with n<100 were identified, but are not considered here because they did not meet eligibility criteria (Appendix H).<sup>34-36</sup> Our search of ClinicalTrials.gov identified one small (n=10) completed but unpublished trial (NCT01963871) and one large (n=320) planned active but not recruiting clinical trial (NCT01343927; Appendix F).

Table 3. Characteristics of Systematic Reviews Evaluating Yoga for Low Back Pain

Characteristic	Cramer 2013 <sup>30</sup>	Holtzman 2013 <sup>29</sup>	Posadzki 2011 <sup>31</sup>
Condition(s)	Chronic low back pain	Chronic low back pain	Chronic low back pain
Search date	January 2012	November 2011	March 2011
Databases searched	PubMed Embase Cochrane Library CAMbase	CINAHL MEDLINE Global Health Cochrane Central Register of Controlled Trials Embase PsycINFO	PubMed Cochrane Central Register of Controlled Trials Clinical Trial Registry of Indian Council Embase CINAHL AMED PsycINFO
Study designs included	RCTs	RCTs	RCTs
Studies included	10	8	7
Meta-analysis performed?	Yes	Yes	No
Systematic review quality	Good	Good	Good

Abbreviation: RCTs=randomized controlled trials

We focus our discussion on the most recent, good-quality review by Cramer et al, 30 which evaluated all of the RCTs included in the other 2 reviews (Appendix I). This review searched 5 computerized databases and the gray literature for eligible RCTs published through January 2012. The review included 10 RCTs that evaluated yoga compared with active or inactive controls in adult patients with a clinical diagnosis of low back pain of a nonspecific origin. Eligibility criteria allowed a range of symptom duration, pain intensity, and functional deficits. The review included trials of yoga interventions of any tradition, intensity, style, or duration. Other treatments (eg, medications) concurrent with yoga were allowed in all trials. Studies were included if they reported one of the following patient-centered outcomes: pain, back-specific disability, quality of life, generic disability (eg, activities of daily living, work absenteeism), and global improvement. Data on adverse effects were reported when available. When there were sufficient studies, the systematic review authors computed summary estimates of treatment effects using a random-effects meta-analysis with RevMan 5.1 software.<sup>44</sup>

Ten RCTs that randomized 956 patients with low back pain were included. Of these, 8 were included in meta-analyses; the other 2 were excluded due to poor quality. Detailed study





characteristics for each study are presented in Appendix J and summarized in Table 4, below. Most trials enrolled midlife adults (median age 48.0), and all focused specifically on chronic low back pain. No study enrolled Veterans or active duty military. More women (median proportion 69.3%) than men were enrolled.

Yoga was conducted by certified or experienced yoga teachers in 9 trials; the instructor's qualifications were not clearly reported in one trial. The median number of hours planned for the yoga intervention was 15 (range 3 to 72), delivered in programs that ranged from one to 24 weeks (median 11 weeks). Eight studies reported a co-intervention with yoga. Co-interventions consisted of usual or routine care (n=3), education (n=3), and lifestyle and diet changes (n=2). Most of the included studies used a 2-arm study design (n=8); 2 studies used a 3-arm design. In the 2-arm studies, yoga was compared with wait-list control (n=3) plus routine care or education; standard care (n=1); education (n=1); lifestyle change (n=1); or physical therapy and exercise (n=1). In both 3-arm studies, yoga was compared with exercise in one arm and an educational intervention in the other. Three RCTs used exercise as a comparator. A combination of short- and long-term outcomes were assessed at a median of 12 weeks (range one week to 6 months) for short-term outcomes (n=10) and at a median of 28 weeks (range 26 weeks to one year) for long-term outcomes. In 9 of the 10 RCTs, the authors specified that certified or experienced teachers served as instructors.

The systematic review authors judged 8 RCTs to be at low risk of bias, and 2 to be at high risk of bias. Compliance with the intervention was found to be unclear or unacceptable in 4 of the 10 studies. Statistical methods to assess publication bias were not used because there were too few studies in the final analyses.

Table 4. Characteristics of RCTs Evaluating Yoga for Low Back Pain Included in Cramer et al<sup>30</sup>

Characteristic	Studies (n=10)
Condition	
Low back pain <3 months	1
Low back pain ≥3 months	6
Low back pain ≥6 months	1
Low back pain ≥3 months plus a physical functional deficit	2
Population age	
Adults	10
Geographical region	
North America	6
Europe	2
Asia	2
Sample size	
25-50	4
>50-100	3
>100	3
Yoga style	
lyengar	3
Hatha	2
Viniyoga	2
Other	3





Characteristic	Studies (n=10)
Treatment duration	
≤4 weeks	2
5-12 weeks	6
>12 weeks	2
Treatment intensity	
<10 hours	1
10-20 hours	9
Timing of outcome assessment <sup>a</sup>	
≤3 months	3
>3-6 months	6
>6 months	5

a Some studies assessed outcomes at multiple time points.

Abbreviation: RCTs=randomized controlled trials

Meta-analysis showed consistent evidence for short-term benefits of yoga on pain (n=6; SMD -0.48; 95% CI, -0.65 to -0.31; I2=0%). Long-term effects of yoga revealed evidence for reduction in pain (n=5; SMD -0.33; 95% CI, -0.59 to -0.07; I2=48%) and back-specific disability (n=5; SMD -0.35; 95% CI, 0.55 to -0.15; I2=20%). Yoga also improved short-term back-specific disability (n=8; SMD -0.59; 95% CI, -0.87 to -0.30), but with moderate heterogeneity in treatment effects (I2=59%). No short-term (n=4; SMD 0.41; 95% CI, -0.11 to 0.93) or long-term effect (n=2; SMD 0.18; 95% CI, -0.05 to 0.41) was found for health-related quality of life. Most adverse effects were mild to moderate. Severe adverse effects consisted of a herniated disk (n=1) and severe pain (n=1). One study reported dropouts due to respiratory tract infections (n=2). The authors concluded: "This systematic review found strong evidence for short-term effectiveness and moderate evidence for long-term effectiveness of yoga for chronic [low back pain] in the most important patient-centered outcomes. Given the low number of adverse events, yoga can be recommended as an additional therapy to patients who do not improve with education on self-care options."

The review by Cramer et al included separate analyses for both short- and long-term effects of yoga in comparison to usual care, education, or exercise. Yoga showed short-term benefit for low back pain, back-specific disability, and health-related quality of life compared with education. For the other comparators, there was not a consistent pattern of benefit for pain, disability and health-related quality of life. Over the longer term, yoga was beneficial for low back pain compared with education. However, the subgroup analyses were conducted on small groups of studies, and testing for significance of these subgroups was not specified. These subgroup analyses should be considered exploratory, and the observed variability in treatment effects was not adequately explained.

The other 2 systematic reviews<sup>29,31</sup> evaluated the same question and similar literature as Cramer et al, but did not add important additional information about the effect of yoga on chronic low back pain. The review by Holtzman et al<sup>29</sup> was published in 2013 and included all but one<sup>45</sup> of the studies included in Cramer et al. Similar results for short- and long-term pain and back-specific function were found in Holtzman et al compared with Cramer et al; however, the review by Holtzman et al did not assess short- or long-term effects of yoga on health-related quality of life among patients with chronic low back pain. The review by Holtzman et al concluded that "the results of the present





study indicate that yoga may be an efficacious adjunctive treatment for chronic low back pain." The quality of this review was fair because the study selection process was not adequately described. The review by Posadzki et al<sup>31</sup> was published in 2011 and did not include a timeframe for the search strategy. Seven of the 10 studies from the review by Cramer et al are included in the review by Posadzki et al; the 3 studies not included were published in 2009,<sup>46</sup> 2010,<sup>47</sup> and 2011,<sup>48</sup> and may not have been within this review's search timeframe. The review by Posadzki et al concluded that "the evidence that yoga alleviates chronic [low back pain] in the majority of studies is positive." Two studies by Groessl<sup>49,50</sup> conducted on Veterans were not included in these previous reviews and did not meet eligibility criteria for this review. Both of these studies were open-label pre-/ post-intervention trials. One was conducted in the general VA population and the other specifically in women Veterans. The findings from both studies suggest that yoga may improve the health of Veterans,<sup>50</sup> and that women may experience a greater effect from yoga than men.<sup>49</sup>

#### Summary of Findings for Low Back Pain

Although we rated the review by Cramer et al<sup>30</sup> as good quality, there were some limitations. The subgroup analyses were conducted on small groups of studies—groups that fall below the recommended minimal threshold for these analyses.<sup>51</sup> Decreased intervention compliance and dropout rate were found to be unclear or not acceptable in 4 out of 10 studies; however, no sensitivity analysis was conducted to determine if this might have had a significant influence on pooled study estimates.

Overall, we conclude that the evidence suggests potential benefit of yoga in midlife adults with chronic nonspecific low back pain for short- and long-term pain and back-specific disability, but the effects of yoga for short- and long-term health-related quality of life are uncertain. The effects of yoga for acute or subacute low back pain or for the prevention of low back pain are also uncertain, as we did not identify eligible systematic reviews or RCTs that evaluated yoga for these stages of low back pain. For chronic low back pain, yoga appears to be a reasonable treatment option; however, given the multidimensional nature of chronic low back pain, yoga as a monotherapy may not be sufficient. Cognitive behavioral therapy has good evidence in the treatment of chronic low back pain and may be an interesting comparator or add-on therapy. There were few studies addressing long-term outcomes; therefore larger, good-quality RCTs with longer term outcomes that include functional status and health-related quality of life should be considered. Without additional studies, further systematic reviews are not needed.

## Yoga for Prevention of Falls

Our literature search identified one eligible systematic review of yoga for the prevention of falls. Jeter et al<sup>33</sup> examined yoga for balance in a healthy population. This review, which searched 7 computerized databases and the gray literature for eligible trials published before August 2014, included 15 studies involving 687 subjects with an age range of 10 to 93 years. Five studies were RCTs, 4 were quasi-experimental, 2 were cross-sectional, and 4 were single-group designs. All but one of the included studies had an n<100, and none specifically studied a Veteran population. Although search terms included falls prevention, this review focused on use of yoga in a healthy population, whereas the area of interest for the purpose of our report is on patients who have had falls or who are at high risk of falls, thereby limiting the applicability of these results to our area of interest. The studies included in this systematic review used a variety of measures of balance





as a surrogate measure for risk of falls. An outcome measure of frequency of falls would be preferred to surrogate measures of balance.

Given the lack of studies directly applicable to the population of interest, further investigation with larger, good-quality RCTs focused on patients who have had falls, or who are at high risk of falls, would be needed to address the efficacy of yoga for prevention of falls. We identified one RCT with n<100 of yoga for falls prevention;<sup>38</sup> another appeared to be eligible based on review of the abstract,<sup>37</sup> although we were unable to confirm eligibility, as the full manuscript was not available (Appendix H). Our search of ClinicalTrials.gov identified one small (n=40) completed but unpublished trial (NCT01806922) and no ongoing trials (Appendix F).

#### Yoga for Mental Illness

We discuss the following conditions in this section: depressive disorders, anxiety disorders (generalized anxiety disorder and panic disorder), and PTSD.

#### Yoga for Depressive Disorders

We identified 4 systematic reviews that evaluated yoga for depressive disorders (Table 5).<sup>25-28</sup> Three of these<sup>25-27</sup> evaluated RCTs only, and the fourth<sup>28</sup> included both RCTs and nonrandomized studies.<sup>25</sup> Our independent search did not identify any additional RCTs with n≥100; 2 published<sup>39,40</sup> (Appendix H) and 2 completed but unpublished RCTs (NCT01210651; NCT00482482) with n<100 (Appendix F) were identified. In addition, one ongoing trial with a planned enrollment of 150 patients was identified from ClinicalTrials.gov (NCT01384916; Appendix F).

Table 5. Characteristics of Systematic Reviews Evaluating Yoga for Depressive Disorders

Characteristic	Cramer, 2013 <sup>25</sup>	Balasubramaniam, 2013 <sup>26</sup>	Cabral, 2011 <sup>27</sup>	da Silva, 2009 <sup>28</sup>
Condition(s)	Depressive disorders	Multiple mental illnesses	Multiple mental illnesses	Mood and anxiety disorders
Search date	January 2013	June 2011	Not reported	July 2008
Databases searched	PubMed Scopus Cochrane Library PsycINFO IndMED Gray literature	MEDLINE Cochrane Central Register of Controlled Trials Embase PsycINFO	PubMed Cochrane Central Register of Controlled Trials Google Scholar EBSCO	PubMed PsycINFO
Study designs included	RCTs	RCTs	RCTs	RCTs and non- randomized studies
Studies included All disorders Depressive disorders	12 12	16 4	10 5	34 16
Meta-analysis performed?	Yes	No	Yes	No
Systematic review quality	Good	Moderate	Low	Low

Abbreviations: RCTs=randomized controlled trials





We focus our discussion on the most recent, good-quality review by Cramer et al,<sup>25</sup> which included all of the RCTs identified in the 4 systematic reviews (Appendix K). The Cramer review searched 5 computerized databases and the gray literature for eligible RCTs published through January 17, 2013. Eligible studies included RCTs that evaluated yoga compared with active or inactive controls in adult patients with depressive disorders meeting DSM-IV or ICD-10 criteria, or with elevated levels of depressive symptoms as measured by a validated questionnaire. The review included RCTs of any duration and yoga interventions of any intensity or style. Mindfulness-based stress reduction or mindfulness-based cognitive therapy interventions—techniques that are related to some forms of yoga—were excluded. Outcomes considered were depression symptom severity, remission rates, anxiety symptoms, health-related quality of life, and adverse effects. When there were sufficient studies, summary treatment effects were estimated using a fixed-effect meta-analysis.

The review included 12 trials that randomized 619 patients with depression. Of these trials, 9 were included in meta-analyses; the other 3 were excluded due to differences in quality. Detailed study characteristics for each study are presented in Appendix L and summarized in Table 6, below. Most trials enrolled young to midlife adults (median age 33.7) who met the criterion standard for a depressive disorder. No study enrolled Veterans or active duty military. Substantially more women (median proportion 76.5%) than men were enrolled.

Yoga interventions were classified as nonphysical (no postures), exercise-based (postures only), or complex (postures plus meditation or breathing or both). Yoga was conducted by certified yoga teachers (n=5) or clinical psychologists (n=1); the remaining studies did not report the instructors' qualifications. The median number of hours planned for the yoga intervention was 11 (range 4 to 18), delivered in programs that ranged from 3 days to 12 weeks (median 8 weeks). Antidepressant co-medication was allowed in 3 studies, any co-intervention was allowed in 1 study, no co-interventions in 6 studies, and co-interventions were not reported in 2 studies. Yoga was compared with no treatment, standard care, or an unspecified control in 6 studies; with relaxation in 4 studies; and with aerobic exercise in 2 studies. One study compared yoga with an active comparator: a tricyclic antidepressant medication or electroconvulsive therapy. Outcomes were assessed at a median of 10 weeks (range 3 days to 9 months).

The systematic review authors judged 3 RCTs to be at low risk of bias and 9 to be at high risk of bias. Statistical methods to assess publication bias were not used because there were too few studies. The review did not include a search of clinical trial registries to look for completed but unpublished trials.

Table 6. Characteristics of RCTs Evaluating Yoga for Depressive Disorders Included in Cramer et al<sup>25</sup>

Characteristic	Studies (n=12)
Condition Major depressive disorder or dysthymia Elevated depressive symptoms	6 6
Population age Adults Older adults (mean age >65)	11 1





Characteristic	Studies (n=12)
Geographical location	
North America	5
Europe	1
Asia	6
Sample size	
25–50	8
>50	4
Yoga classification	
Complex (eg, Ashtanga or Hatha yoga)	3
Exercise-based (eg, Bikram or Power yoga)	4
Not physical (eg, Pranayama only or	5
Restorative yoga)	
Treatment duration	
≤4 weeks	3
5–12 weeks	8
NR	1
Treatment intensity	
<10 hours	3
10–20 hours	6
NR	3
Timing of outcome assessment	
≤4 weeks	4
5–12 weeks	6
>12 weeks	1
NR	1

Abbreviations: NR=not reported; RCTs=randomized controlled trials

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. Remission rates were reported infrequently. Short-term remission with yoga did not differ from electroconvulsive therapy in one study but was higher with yoga than with usual care and relaxation in one study each. One study found higher longer-term remission rates with yoga compared with usual care but no difference compared with group therapy. Only one study reported effects on health-related quality of life and found that patients assigned to the yoga group were more likely to have a 50% improvement than patients assigned to relaxation control. Although adverse effects were a prespecified outcome for the review, no results were reported for this outcome. The authors of this systematic review concluded: "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."

To explore the observed variability in short-term effects on depression severity, subgroup analyses were conducted in studies of patients with DSM-IV disorders versus those with elevated depressive symptoms and by category of yoga (*ie*, complex, exercise-based, not physical). These analyses suggested that yoga may be more effective in individuals with elevated depressive symptoms not meeting criteria for a DSM-IV disorder, but analyses were limited by very small subgroups





(n≤3) and should be considered hypothesis-generating. Another subgroup analysis was conducted by control group (usual care, relaxation, or aerobic exercise); the benefits of yoga were similar across the different control groups. The authors concluded: "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."

The other 3 eligible systematic reviews evaluated a broader set of mental illnesses but did not add important information about depressive disorders. All had search dates that substantially preceded the January 2013 search in Cramer et al.<sup>25</sup> The review by Cabral et al<sup>27</sup> included only 2 of 12 RCTs evaluated in the Cramer review. Three other trials included by Cabral et al – 2 nonrandomized<sup>52,53</sup> and one in patients with alcohol dependence<sup>54</sup> – were appropriately excluded from the Cramer review. The review by da Silva et al<sup>28</sup> included 7 of the 12 RCTs evaluated by Cramer and additional nonrandomized studies (Appendix M). Most of the nonrandomized studies were small, short-term, open trials. The review by Balasubramaniam et al<sup>26</sup> included only one of the RCTs identified by Cramer and colleagues and no unique studies compared with the other reviews. A table showing the unique studies included in each review is in Appendix K.

#### Summary of Findings for Depressive Disorders

Although we rated the review by Cramer et al<sup>25</sup> as good quality, there were some limitations. Metaanalyses were conducted separately for yoga versus usual care and versus relaxation controls. Depending on the usual care treatments given (not described in the report), it may have been reasonable to group these controls together. As with the review by Cramer et al for back pain, 30 subgroup analyses for depression were conducted on small groups of studies. Finally, although adverse effects were a prespecified outcome, no data on this outcome were presented. Given the limitations of the analyses, the high risk of bias in 9 of the 12 primary trials, the unexplained variability in treatment effects, and an incomplete array of short-term, patient-important outcomes, we reached a different conclusion than the review authors. We think these studies suggest potential benefit for yoga in young to midlife adults with depression, but our confidence in the treatment effect is low. Without new trials, further systematic reviews are not currently needed, but a literature scan in 3 to 5 years could be done to re-evaluate the need for an updated systematic review. 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. Ideally, these studies should include Veterans or patients with demographic and clinical characteristics comparable to the Veteran population. Given that yoga may require a time commitment similar to evidence-based short-term psychotherapies such as cognitive-behavioral or problem-solving therapy, careful consideration should be given to the appropriate comparator. For subsyndromal depression, yoga may be a reasonable option as monotherapy, and comparators could include attention control or active treatments. For major depressive disorder, yoga could be an alternative to other active treatments or used as an add-on therapy for patients treated with antidepressants.

#### Yoga for Anxiety Disorders (Generalized Anxiety Disorder and Panic Disorder)

We identified 2 systematic reviews that met our selection criteria for anxiety disorders (Table 7).<sup>27,28</sup> These reviews also evaluated yoga for depressive disorders and PTSD; the methodological approach for these reviews was described in the earlier section on depressive disorders. Both systematic reviews were rated poor quality and included studies that enrolled patients with





anxiety symptoms outside the generalized anxiety disorder or panic disorder spectrum. For these reasons, we provide only a brief description of each systematic review, accompanied by a description of the primary studies relevant to generalized anxiety disorder or panic disorder. Our independent search identified one additional RCT with n<10041 (Appendix H).

Table 7. Characteristics of Systematic Reviews Evaluating Yoga for Anxiety Disorders

Characteristic	da Silva, 2009 <sup>28</sup>	Cabral, 2011 <sup>27</sup>
Conditions	Mood and anxiety disorders	Multiple mental illnesses
Search date	July 2008	NR
Databases searched	PubMed PsycINFO	PubMed Cochrane Central Register of Controlled Trials Google Scholar EBSCO
Study designs included	RCTs and nonrandomized studies	RCTs
Studies included All disorders Anxiety disorders	34 8	10 4
Meta-analysis performed?	No	Yes
Systematic review quality	Poor	Poor

Abbreviations: RCTs=randomized controlled trials

The poor-quality review by da Silva et al included studies of any design that evaluated yoga of any style or practice element for mood disorders, PTSD, and anxiety disorders. Yoga styles included Hatha yoga, SKY, Iyengar, Vinyasa, and Vivekananda. Active and inactive comparators were included. Meta-analysis was not performed, and qualitative analysis of studies was limited to brief descriptions of findings. Practice elements of the intervention, as well as session number, duration, and frequency, were not reported.

Of the 8 included studies that evaluated yoga for an anxiety disorder, only 4 were relevant to our study question. The other 4 studies addressed yoga as a treatment for "snake phobia," yoga as a treatment for "psychoneurosis" (a psychoanalytic term not currently recognized in the DSM-IV), and yoga as a mindfulness-based stress reduction intervention. We focus on the 4 studies evaluating yoga for patients with symptoms in the generalized anxiety disorder or anxiety neurosis categories (Table 8).

Of these 4 studies (n=174 participants), 3 enrolled individuals with "anxiety neurosis," while a small case series enrolled patients with generalized anxiety disorder. All studies enrolled both sexes, and the overall age range of participants was 18 to 47 years of age. Study designs included 2 nonrandomized comparative studies, 55,56 a single-arm trial, 57 and a case series. 58 Comparators were placebo capsule and drug therapy with diazepam. 56 Yoga interventions were delivered for 3 months to 6-8 months, offering 28 to 112 hours of yoga, although 2 studies emphasized self-directed practice. The yoga interventions examined were heterogeneous, including 2 breathing exercises, 55, an Asana series, 56 and transcendental meditation. 57 Outcomes measured include anxiety severity measures, 55-57 physiologic measures, 55 psychiatric assessment of symptoms, 56 and self-reported medical symptoms. 56 All of the studies demonstrated some positive effects of



**4 )** 

yoga for anxiety symptoms, but statistically significant differences were not always sustained, and high attrition represented a significant study limitation. The review authors concluded that the evidence for the benefit of yoga is still preliminary for anxiety disorders.

Table 8. Characteristics of Nonrandomized Studies Evaluating Yoga for Anxiety Disorders Included in da Silva et al<sup>28</sup>

Characteristic	Studies (n=4)
Condition Anxiety neurosis General anxiety disorder	3 1
Population age Adults	4
Geographical location North America Asia (India)	2 2
Sample size <25 50–100	2 2
Yoga classification Physical postures Breathing exercise (Pranayama) Meditation Unspecified	1 1 1 1
Treatment duration 3 months 6–8 months	3 1
Treatment intensity 25-50 hours >50 hours NR	2 1 1
Timing of outcome assessment 3 months 12 months NR	2 1 1

Abbreviation: NR=not reported

Cabral et al<sup>27</sup> included RCTs on yoga for multiple conditions: depression, anxiety-related disorders, PTSD, bipolar disorder, and schizophrenia. Yoga interventions of any style and any practice element were included, and comparators considered were unspecified "controls." Ten studies (343 participants) for various psychiatric disorders were included. Based on summary tables in the systematic review, supplemented by our review of the primary studies, 4 of the 10 included studies<sup>52,53,59,60</sup> evaluated yoga for anxiety, including 3 that evaluated yoga for both depression and anxiety.<sup>52,53,59</sup> None of the studies enrolled patients with generalized anxiety disorder or panic disorder, and none used a validated instrument for anxiety symptoms to identify eligible patients. Thus, these studies do not address the conditions of interest in this report, but rather address less defined emotional distress and anxiety symptoms.





#### Summary of Findings for Anxiety Disorders

Our analysis identified 2 poor-quality systematic reviews that included studies evaluating various yoga practices for anxiety disorders. Our search identified one additional RCT (total n=12) published in 2013. Both reviews included studies that did not employ diagnostic criteria for anxiety as eligibility criteria, or used diagnoses tangentially related to the anxiety disorders of interest (eg, snake phobia, psychoneurosis). In the case of Cabral et al, 7 none of the included studies met our criteria for inclusion as primary studies. The remaining studies from da Silva et al were nonrandomized studies or case series. There was a relatively high degree of heterogeneity in sample size, type of yoga practice employed, intervention intensity, and outcome measures related to anxiety among these studies. The studies did illustrate improvement in anxiety scores for those receiving a yoga-related intervention, although those improvements were not always sustained. There were numerous limitations in the primary studies, including high attrition rate, limited detail about intervention intensity (participant fidelity to practices), switching interventional approach with initial negative findings, subjective analysis of symptom severity, lack of control group, and lack of randomized control.

We agree with the assessment by da Silva et al<sup>28</sup> that the evidence in support of potential effectiveness of yoga for anxiety disorders is preliminary. The 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. We did not find sufficient studies to support an updated systematic review. Notably, RCTs that address yoga interventions for populations with generalized anxiety disorder or panic disorder were found to be lacking in our review. Existing studies might, however, serve as pilot studies to inform future RCTs that report intervention duration and intensity and employ well-validated outcomes measures. Our search of ClinicalTrials.gov identified one large (n=230) ongoing 3-arm RCT comparing yoga to mindfulness-based stress reduction and cognitive-behavioral therapy in patients with generalized anxiety disorder (NCT01912287; Appendix F).

#### Yoga for PTSD

We identified 2 eligible systematic reviews that evaluated yoga for treatment of PTSD or PTSD symptoms (Table 9).<sup>27,28</sup> These reviews also evaluated yoga for depressive disorders; the methodological approach for these reviews was described in the earlier section on depressive disorders. Collectively, the 2 reviews identified a small RCT involving 8 PTSD patients<sup>61</sup> and 2 nonrandomized studies involving a combined total of 22 PTSD patients.<sup>62,63</sup> The small RCT did not report between-group treatment effects, and neither review drew conclusions specific to the efficacy of yoga for PTSD. Our independent search identified 2 additional RCTs conducted in the United States and evaluating yoga in women with PTSD, but both trials enrolled fewer than 100 subjects.<sup>42,43</sup>





Table 9. Characteristics of RCTs and Nonrandomized Studies Evaluating Yoga for PTSD

Characteristic	RCTs (n=1)	Nonrandomized Studies (n = 2)
Condition PTSD	1	2
Population age Adults Older adults (mean age >65) NR	1 0 0	1 0 1
Geographical location North America Europe Asia Australia NR	0 0 0 0 1	0 0 0 1 1
Sample size <25 25–50 >50	1 0 0	2 0 0
Yoga classification Complex Exercise-based Not physical	0 1 0	1 1 0
Treatment duration ≤4 weeks 5–12 weeks NR	0 0 1	0 1 1
Treatment intensity <10 hours 10–20 hours NR	0 1 0	1 0 1
Timing of outcome assessment ≤4 weeks 5–12 weeks >12 weeks NR	0 0 0 1	0 0 1 1

Abbreviations: NR=not reported; PTSD=posttraumatic stress disorder; RCTs=randomized controlled trials

#### Summary of Findings for Posttraumatic Stress Disorder

Both systematic reviews we identified<sup>27,28</sup> were of poor quality, and the limited number of studies using different study designs, interventions, and outcomes were not amenable to meaningful meta-analysis. Neither review drew any summary conclusions about the efficacy of yoga for PTSD. We identified 2 additional RCTs published in 2014 that enrolled 3843 and 6442 women, respectively.

The limited number of studies with relatively few patients precludes any definitive conclusions regarding the potential benefit of yoga for PTSD or PTSD symptoms. Further research with well-conducted RCTs would be needed to evaluate the efficacy of this intervention. Our search of ClinicalTrials.gov identified one small (n=103) completed but unpublished trial (NCT00962403)





and 3 trials (n=30 to 200) that have not yet begun recruitment (NCT01521442; NCT01512303; NCT01957371; Appendix F). An updated systematic review that included the 3 published trials together with 4 trials identified in ClinicalTrials.gov may be warranted once these studies are completed.

#### Yoga for Insomnia

We identified one eligible fair-quality systematic review that included search terms for insomnia.<sup>26</sup> This review did not find any primary studies that had a clinical diagnosis of insomnia as a subject eligibility criterion. It included one cluster RCT and 2 patient-level RCTs that evaluated yoga for individuals at increased risk for insomnia, many of whom had sleep complaints. The review searched 4 computerized databases (MEDLINE, Cochrane Central Register of Controlled Trials, Embase, and PsycINFO) for eligible RCTs published through June 2011 and included 3 trials that randomized 236 patients at high risk for sleep complaints. All 3 RCTs were judged to be of poor quality by the systematic review authors (evidence level 2 according to Oxford Center for Evidence-based Medicine). Study characteristics are summarized in Table 10, below. The trials enrolled midlife patients with cancer (139 participants) or older adults (median age 69 years) living in a nursing home (69 participants) or in the community (139 participants). No study enrolled Veterans or active duty military. The review did not describe detailed patient characteristics. Metaanalysis on sleep complaints was not performed due to the small number and high heterogeneity of the studies. Statistical methods to assess publication bias were not used because there were too few studies. There was no other assessment for publication bias.

The review reported improved sleep with yoga in all RCTs examined. Significant improvements in total Pittsburgh Sleep Quality Index (PSQI) score and the subscales on sleep quality and latency were reported in 2 RCTs. Significant improvement in sleep duration and daytime disturbance were also observed in at least one RCT. The third showed improved withingroup changes for sleep quality, latency, and duration but few changes between yoga and the control group. No adverse effects were reported. The review authors concluded: "Based on our assessment of the available literature according to the RAND/UCLA Appropriateness method, Grade C Evidence supporting a potential benefit for yoga exists for sleep complaints." Grade C evidence was defined as low-grade data without the volume to recommend more highly and subject to revision with further studies. Our search of ClinicalTrials.gov identified 4 small (n=20, 40, 48, 50) completed but unpublished trials (NCT00033865; NCT01073423; NCT00994279; NCT01556074; Appendix F).

Table 10. Characteristics of RCTs Evaluating Yoga for Insomnia or Sleep Complaints Included in Balasubramaniam et al<sup>26</sup>

Characteristic	Studies (n=3)
Condition	
Diagnosis of insomnia	0
Sleep complaints	3
Population age	
Adults (18-64)	1
Older adults (age >60)	2





Characteristic	Studies (n=3)
Geographical location	
North America	1
Asia	2
Sample size	
25–50	1
50-100	1
>100	1
Yoga classification	
Postures, breathing, and meditation	3
Postures only	0
Breathing or meditation only	0
Treatment duration	
≤8 weeks	1
24 weeks	2
Treatment intensity	
<10 hours	1
50–100 hours	1
>100 hours	1
Timing of outcome assessment <sup>a</sup>	
≤8 weeks	1 1
5–12 weeks	1 1
>12 weeks	2

<sup>&</sup>lt;sup>a</sup> Some studies assessed outcomes at multiple time points.

Abbreviation: RCTs=randomized controlled trials

#### Summary of Findings for Insomnia

Our literature review identified only one fair-quality systematic review that used search terms for insomnia. It included 3 RCTs of yoga for sleep complaints in a variety of different patient populations. Interventions that included all 3 major elements of yoga practice regardless of style appear to have a positive effect on mild deficits in sleep quality, latency, and duration in patients at high risk for insomnia. Although the literature to date is inconclusive, these studies suggest that yoga may improve sleep quality and may be a reasonable intervention to test in individuals with insomnia. Larger, higher quality RCTs with active comparators and longer term outcomes enrolling individuals with insomnia would be needed to address this question.

# KEY QUESTION 2: What are the extent, distribution, and methodological designs of studies that assess the adverse effects of yoga?

We identified a single good-quality systematic review that specifically addressed adverse effects associated with yoga.<sup>32</sup> This review included case reports and case series reporting adverse effects experienced by individuals engaged in yoga practices or postures, or practices with sufficient descriptions for the review authors to conclude that they were yoga. Reports included individuals with and without pre-existing medical conditions prior to beginning yoga. The authors searched MEDLINE/PubMed, CAMbase, IndMED, Scopus, and the Cases Database, all from inception through February 15, 2013; they identified 35 case reports and 2 case series,





representing 76 individual adverse effects. Most of the reports (20 of 37) came from North America, while a quarter (9 of 37) were from Asian countries. The age range for included individuals was 14 to 87 years and 67% were women. Nine adverse effects were exacerbations of established medical conditions, one case occurred in someone with congenital connective tissue hyperelasticity, and 66 people had no reported baseline disorders or abnormalities. Six cases occurred with meditation or breathing alone (Siddha yoga, Pranayama, or breathing), while 7 involved more exercise-based techniques (Hatha, Vinvasa, or Bikram voga); most reports did not specify the type of yoga being performed. The headstand (Sirsasana) was associated most commonly with adverse outcomes (10 cases), and 3 reports involved the shoulder stand, 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 types of effects. Notably, 7 of the adverse effects involving the eye and 2 of 3 reports concerning the posterior cerebrovascular system occurred during inversion poses (head or shoulder stand). In conclusion, the authors did not find evidence to support discontinuation of yoga by healthy people, but they warned beginner practitioners against headstand, lotus position, and advanced breathing techniques initially. In people with a history of glaucoma, they advised avoiding any inversion posture, and for those with baseline musculoskeletal disorders, they cautioned against "forceful or competitive yoga forms."

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. In the review of low back pain by Cramer et al,<sup>30</sup> 3 studies reported 26 adverse effects among 248 included participants.<sup>48,64,65</sup> Most adverse effects were mild to moderate, while 3 were severe. Severe adverse effects consisted of a worsening of back pain,64 a new diagnosis of herniated disc,<sup>66</sup> and 2 subjects discontinuing the study due to respiratory tract infections.<sup>67,68</sup> 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.





#### SUMMARY AND DISCUSSION

#### SUMMARY OF EVIDENCE BY KEY QUESTION

#### **Key Question 1 (Effectiveness)**

We identified 9 systematic reviews that evaluated the effectiveness of yoga for one or more of our eligible conditions. These reviews in turn identified and summarized 23 unique RCTs. These RCTs were conducted primarily in North America and Asia. Typical enrollment was 25 to 50 adults, and the majority of subjects were white, female, and middle-aged. Interventions typically provided a total of 10 to 20 hours of yoga instruction and assessed outcomes across a wide range of follow-up periods. Yoga has been studied most extensively for low back pain and depressive disorders. The majority of the low back pain studies were judged by the 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. Meta-analyses showed consistent short-term benefits of yoga for low back pain (SMD -0.48; 95% CI, -0.65 to -0.31; 12=0%) and more variable benefits for back-specific disability (SMD -0.59; 95% CI, -0.87 to -0.30; 12=59%). 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 (I2=86%). For the other conditions, the lack of RCTs precluded estimates of treatment effects. Other outcomes such health-related quality of life were reported infrequently.

The conditions selected for this report are high impact—they are prevalent in Veterans, <sup>69,70</sup> cause considerable functional impairment, <sup>71</sup> and are associated with increased utilization of medical resources. <sup>72,73</sup> Effective treatments are available for these conditions, but some patients do not respond adequately to first- or second-line treatment, and the availability of some established treatment options (*eg*, physical therapy or cognitive behavioral therapy) is limited or the cost is high. Furthermore, some patients may prefer alternatives to current treatment options. Understanding whether and how yoga may fit into the current treatment options is a worthwhile goal. As a first step, we surveyed current evidence, focusing on RCTs, and through this process, identified gaps in evidence. As described in the "Limitations" section below, there are important issues related to patient selection, trial reporting, short-term outcomes, and incomplete reporting of clinically important outcomes including effects on function and adverse effects.

#### **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 of adverse effects, representing 76 individual adverse effects occurring in patients engaged in yoga. The headstand was associated most commonly with adverse outcomes, but most reports of adverse effects did not have clear descriptions of the postures involved. Musculoskeletal injuries, orbital involvement, and headache were the most common adverse effects. In the systematic reviews identified for clinical conditions of interest, only the studies of yoga for low back pain reported adverse effects.





#### **LIMITATIONS**

#### **Limitations of Our Approach**

We evaluated the published literature as reflected by English-language systematic reviews and recently published, large RCTs. There may be pertinent information from small RCTs or observational studies that were not included in published systematic reviews and did not meet our eligibility criteria. Although we verified selected data from the primary publications, we largely relied on the information provided in the eligible systematic reviews; we do not know if there were data abstractions or synthesis errors in one or more of the systematic reviews.

We included studies that used the term "yoga" to describe one or more interventions, but we may have missed studies that evaluated yoga as described or defined using a different term. We did not include studies of interventions that included components highly related to yoga, such as mindfulness-based stress reduction training. Another limitation is that yoga is typically practiced along with other interventions (eg, relaxation, exercise, dietary changes), but most of the studies included in this report attempted to evaluate the independent effect of yoga. Our search and eligibility criteria were designed to identify studies conducted in patients with clinical disorders or at least sufficient symptoms where individuals were at high risk for the disorder (eg, a positive depression screen). During our screening process for eligible studies, we identified studies that evaluated yoga for wellness or general health benefits in study samples that did not meet these eligibility criteria. Some of these studies measured the effects of yoga for symptoms of depression, anxiety, or sleep quality. Although not eligible for this review, studies of this nature could provide useful information on the effect of yoga on mood, sleep quality or global well-being in generally healthy individuals.

# **Study Quality**

We rated the systematic reviews for quality, but for the primary studies we relied on the quality ratings assigned by the authors of the systematic reviews. Based on the systematic reviewers' ratings of the primary studies, low back pain is the only condition where the preponderance of evidence comes from studies at low risk of bias. The quality of the evidence as reflected in both the primary studies and the systematic reviews is generally poor for all of the conditions except for low back pain.

# Heterogeneity

Individual studies included in systematic reviews for each condition of interest varied greatly in terms of the yoga styles studied, comparison groups used, duration and intensity of interventions, and other methodological aspects. The clinical populations were relatively similar across the primary studies of chronic low back pain, but the screening and diagnostic instruments used for the other conditions varied widely. The systematic reviews and primary studies reported limited information about the training of yoga instructors, the level of instruction provided to subjects, the amount of time subjects practiced yoga during the intervention periods, and other information necessary to evaluate the dosing of interventions. Given the limited reporting of this information, it is difficult to assess the variability across studies in this respect, but it is reasonable to assume that studies differed in terms of the training of yoga instructions and the nature and amount





of practice performed by the subjects. Authors of several of the systematic reviews assessed included studies for heterogeneity, but those findings are limited because of the relatively small number of studies included in each systematic review. Overall, methodological and clinical heterogeneity was relatively high for all of the conditions of interest.

#### **Publication Bias**

Assessment of possible publication bias was not reported by the authors of the systematic reviews, and we did not assess publication bias independently. Funnel plots and other formal assessments of publication bias are generally indicated only for meta-analyses that include 10 or more studies, but the largest meta-analysis reviewed in this report included only 8 studies of yoga for low back pain. Our search of ClinicalTrials.org identified 9 completed studies for which we did not identify a peer-reviewed publication, suggesting possible publication bias.

#### Applicability of Findings to the VA Population

None of the primary studies that were 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 Table 11, we summarize key gaps in the literature and the types of studies that might address those gaps. If the VA or other organizations were to prioritize further research on yoga for these conditions, we recommend considering the study designs listed in the table, with careful attention paid to study design and reporting. For example, 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 conditions for which RCTs are lacking, pilot studies could be conducted to provide preliminary evidence of potential effectiveness (or lack thereof) of yoga as a therapeutic intervention. 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.





Table 11. Key Research Gaps by Clinical Condition

Condition	Gap	Surveillance for Updated SR	Recommended Study Designs	Outcomes
Low back pain	Acute back pain Subgroups (eg, young adults, or specific back pain etiologies)	Yes	Large RCTs, including pragmatic comparative effectiveness trials or type 2 hybrid implantation studies	Long-term functional status
Prevention of falls	No good-quality SR No RCTs	Yes*	Pilot trials	Falls
Depressive disorders	Existing trials poor quality	Yes	Large RCTs, including pragmatic comparative effectiveness trials	Long-term functional status
Anxiety disorders (GAD/PD)	No good-quality SR 1 RCT	Yes*	Pilot trials	Standardized outcome measures
PTSD	No good-quality SR Few RCTs	Yes*	Systematic review when ongoing trials completed	Standardized outcome measures
Insomnia	No good-quality SR RCTs only in those at risk for sleep disorders	Yes*	Pilot trials	Sleep quality

<sup>\*</sup>No good-quality systematic review identified. If surveillance identifies new RCTs, a new, good-quality systematic review is recommended.

Abbreviations: GAD=generalized anxiety disorder; PD=panic disorder; PTSD=posttraumatic stress disorder; RCT(s)=randomized controlled trial(s); SR=systematic review

#### 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 (from nonrandomized studies and studies in samples related to the target population) that suggests that yoga may be beneficial for patients with symptoms of anxiety or insomnia. We found few 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.<sup>23</sup> The authors of this review of reviews concluded, as we do, that the quality of existing systematic reviews is generally high, whereas the quality of the primary studies is generally low.





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