

# AN INTEGRATED METHODOLOGY TO ASSESS COMPLIANCE WITH DELPHI SURVEY KEY COMPONENTS OF YOGA INTERVENTIONS FOR MUSCULOSKELETAL CONDITIONS AS APPLIED IN A SYSTEMATIC REVIEW OF FIBROMYALGIA STUDIES

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**Objective:** The objective of this article was to present a methodology incorporating existing guidelines and tools for systematic reviews and to evaluate the Delphi survey 33 key component recommendations of yoga interventions for musculoskeletal conditions as a tool for a systematic review in fibromyalgia studies.

**Data Sources:** Databases searched included PubMed, Ovid Medline, PsychINFO, the Cochrane Library, CINAHL, ALT HealthWatch, PEDro, and Web of Science.

**Article Selection:** Selected were articles published between November 14, 2004 and November 13, 2014, written in English, reporting original research of yoga interventions for adults with fibromyalgia.

**Data Extraction and Synthesis:** Six articles met the inclusion criteria, revealing that three yoga styles ("Relaxing" yoga, Yoga of Awareness, and Hatha yoga) have been assessed in persons with fibromyalgia. Overall, reporting compliance with the 33 key components ranged from 39.4% to 84.8%, with a mean

adherence rate of  $62.63\% \pm 17.74$ . None of the authors used an accepted reporting guideline; specific components of asana, pranayama, relaxation, and mindfulness practices that would have been incorporated into the interventions tested were identified in only 33.33% of the articles reviewed; and none of the articles included detailed, replicable descriptions of the interventions.

**Conclusions:** This systematic review supports the need for comprehensive yoga research guidelines. Findings reveal a lack of reporting of intervention details, the need to report a disease-specific rationale for selection of the particular yoga style used for the intervention, and that a limited number of yoga styles have been investigated in persons with fibromyalgia.

**Key words:** Yoga, fibromyalgia, systematic review, complementary therapy, musculoskeletal condition

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## INTRODUCTION

Information about yoga and its usefulness as a health promotion and therapeutic modality has grown rapidly in recent years, and this growth has made the need for evidence of the appropriateness, efficacy, and effectiveness of the various styles of yoga more essential than ever.<sup>1</sup> The significance of this is that recommendations for multimodal treatment approaches in many chronic diseases have risen, with healthcare providers increasingly recommending yoga as one of the nonpharmacologic interventions for symptom management and stress reduction.<sup>2</sup> Paradoxically, limited evidence exists to support these recommendations,<sup>3</sup> and the paucity of yoga intervention studies by discrete chronic condition<sup>2,3</sup> lends support to the view that a rigorous methodological approach to the systematic review of these

studies is needed. In this article, the authors highlight some of the challenges and issues identified when applying the Delphi survey-recommended key components for the design and reporting of yoga interventions for musculoskeletal conditions<sup>4</sup> to a systematic review of studies in which the study samples were persons with fibromyalgia (FM).

Fibromyalgia was selected as the condition to use in modeling our systematic review because it is recognized as one of the leading and most difficult chronic pain disorders to diagnose and treat, and it has no known cure.<sup>5,6</sup> An estimated 2.5–7.9% of adults in the United States suffer from FM.<sup>7,8</sup> The hallmark symptom of FM is intractable, chronic widespread pain, which is generally accompanied by sleep disturbances, fatigue, morning stiffness, anxiety, depressed mood, and impaired cognitive function, although the connections among these are not fully understood. The etiology and mechanistic underpinnings of FM remain unclear; however, research findings support the theory of dysregulation of the central nervous system as the source of altered pain processing.<sup>5,9</sup>

Given that prescription drugs for FM-related symptom management have only modest efficacy rates (30–50%),

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undesirable side effects, and little effect on decreasing symptom severity over the long term,<sup>10–13</sup> it is not surprising that persons with FM are the third largest group suffering from chronic pain (superseded only by those with chronic back pain and headaches) seeking out nonpharmacologic modalities, including complementary health-enhancing approaches such as yoga.<sup>14–16</sup> A 2014 international Internet survey investigating yoga use among persons diagnosed with FM revealed that out of 2543 respondents, 2029 (79.8%) stated that they had considered doing yoga and 1469 (57.8%) had attended at least one yoga class.<sup>17</sup> Consistent with recommendations from rheumatology experts for a multimodal treatment approach, healthcare providers are increasingly recommending yoga as one of the nonpharmacologic interventions for FM-related symptom management.<sup>18–20</sup>

In light of the high level of interest, yoga is one of the complementary health-enhancing approaches for alleviating chronic pain and inflammatory processes identified as a high research priority by the National Center for Complementary and Integrative Health (NCCIH).<sup>21,22</sup> Yet, too few studies have investigated the use of yoga therapy to establish evidence-based treatment protocols for specific diseases.<sup>2,3</sup> Yoga-specific study designs and reporting guidelines to promote consistency in addressing the complexity and heterogeneity of yoga therapy are in development. At present, the lack of study rigor, including a rationale for the specific yoga style and its appropriateness for the needs and limitations of the study population,<sup>3,23,24</sup> has been identified as a limitation of the published research.<sup>3,25–27</sup>

In an approach similar to that taken by those who conduct acupuncture research, yoga researchers have begun to develop yoga-specific research guidelines. In 2012, Sherman<sup>24</sup> identified eight areas for inclusion in the design and reporting of all yoga-based, randomized controlled trials (RCTs). Using Delphi survey methodology, in 2014 Ward et al.<sup>4</sup> developed a guideline consisting of 33 key components for ensuring robust yoga research study designs and reporting for musculoskeletal disorders (hereinafter referred to as the “33 key components”). Thus, the objective of this article was to present a methodology that applies selected guidelines and assessment tools for a systematic review in the evaluation of the 33 key components<sup>4</sup> as a measure to assess study quality and replication potential of studies investigating yoga interventions for persons with FM.

## METHODS

### Search Strategy

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.<sup>28</sup> Eight electronic databases (PubMed, Ovid Medline, PsychINFO, the Cochrane Library, CINAHL, ALT HealthWatch, PEDro, and Web of Science) were searched for articles published between November 14, 2004 and November 13, 2014, using the key words “yoga” AND “fibromyalgia.” Supplementary Table S1 provides an example of the complete search strategy used for the PubMed database.

### Eligibility Criteria

Articles included in this systematic review met the following criteria: (a) reported original research, (b) reported yoga as the primary therapeutic intervention, (c) enrolled participants diagnosed with FM who were 18 years of age or older, (d) written in English, (e) published in a peer-reviewed journal, (f) available as a full-text article, and (g) published between November 14, 2004 and November 13, 2014. Articles were excluded for the following reasons: (a) non-research; (b) review, systematic review, or meta-analysis; (c) focus not relevant to the current review; or (d) short communication of a research study. No restrictions were placed on the country in which the study was conducted.

The electronic search process of all databases resulted in identification of 218 records. Duplicates were deleted and the remaining records were screened to determine potential eligibility. After initial screening, full-text articles that potentially met the eligibility criteria were read in entirety to make a final determination for inclusion or exclusion. Two reviewers initially determined final article eligibility. In the case of disagreement between the two reviewers, a third reviewer determined the inclusion or exclusion of an article. A total of six records met the study criteria ( $n = 6$ ). A flow diagram of the selection process is shown in Figure 1. Two articles reporting findings from the same study<sup>29,30</sup> were identified: one reporting the findings of an RCT<sup>29</sup> using a wait list control and the second reporting the results of the active intervention for the wait list control group of the same RCT.<sup>30</sup> Duplication of all relevant methodological information for our analysis was found in the two articles; therefore, the 2010 article by Carson et al.<sup>29</sup> was selected for inclusion in this analysis and the 2012 article by these authors<sup>30</sup> was excluded.

### Assessment of Quality and Risk of Bias

Two reviewers independently evaluated the six selected articles for study quality and risk of bias. Evaluations were compared and a consensus reached. If the two evaluators disagreed, a third reviewer determined the rating assigned to the article.

Two quality assessment tools were used: the Jadad scale<sup>31</sup> (applicable to RCT and comparative effectiveness studies) and the Methodological Index for Nonrandomized Studies (MINORS).<sup>32</sup> Two risk of bias assessment tools were used: the Cochrane Collaboration “risk of bias” tool<sup>33</sup> (applicable to the RCT and comparative effectiveness studies) and the Risk of Bias Assessment Tool for Nonrandomized Studies (RoBANS)<sup>34</sup> (applicable to nonrandomized, noncomparative studies).

The Jadad scale has been used to assess study quality in previous systematic reviews of yoga interventions.<sup>35–37</sup> Because it is not possible to blind participants in most mind–body interventions, the Jadad scale rating for study quality was modified to reflect this limitation. Accordingly, a score of  $\geq 3$  points on the scale indicates an average- to high-quality study; a score  $< 3$  indicates a low-quality study.<sup>31,37</sup>

Noncomparative, nonrandomized study quality was evaluated using the MINORS.<sup>32</sup> This quality measure was developed initially for surgical research but has been

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