Restorative Yoga for Symptom Management in Fibromyalgia

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ABSTRACT

Background: Fibromyalgia (FM) is a widespread chronic pain condition that occurs in 2.5% to 7.9% of adults in the United States. Associated symptoms include sleep disturbance, fatigue, stiffness, depressed mood, anxiety, and impaired cognitive function. The etiology and mechanism of FM are unclear. Because of the complex and individualized nature of FM, a multimodal treatment methodology that includes both pharmacological and non-pharmacological therapies is recommended for symptom management. Selected styles of yoga are among those non-pharmacological therapies recommended. Because stress is thought to be a triggering and sustaining factor in FM, a yoga style that aims to reduce stress may be appropriate for this population. Restorative yoga (RY) is one such style of yoga. Six articles reporting on yoga intervention studies conducted in persons diagnosed with FM have been published. None of these studies investigated the use of RY for symptom management in this disorder.

Objective: The primary aim of this study was to determine the feasibility of an 8-week RY intervention for symptom management in persons diagnosed with FM. The secondary aim of this study was to gather preliminary data on the perceived effects of RY on FM-related symptoms of pain, sleep disturbance, fatigue, functional status, and health-related quality of life.

Design and Methods: A mixed methods, one-group, prospective, feasibility design informed by the Theory of Planned Behavior was used to investigate the feasibility of an 8-week twice weekly 90-minute group RY class and a 20-minute RY home practice on the five non-class nights. Self-report questionnaires were completed at baseline and at

weeks 4 and 8. A pre- and post-intervention interview and a 1-month follow-up were conducted.

Results: Rates for recruitment, retention, and adherence were consistent with those of other yoga interventions conducted for persons with FM; however, the RY intervention required a higher than average number of staff members and resources for the group classes as compared with other yoga styles. Statistically significant trends and minimal clinically important differences were found from baseline to week 8 in the Revised Fibromyalgia Impact Questionnaire total score, the Pain Numeric Rating Scale for the subscales pain now and average pain over the past week, the General Sleep Disturbance Scale total score, and the Pittsburgh Sleep Quality Index total score.

Conclusion: Although the study findings do not support the feasibility of delivery of RY, in a five-posture, 90-minute group class format for persons with FM, the findings support the need for further investigation of a home practice format of RY. A longitudinal, randomized, controlled trial of a home practice format RY intervention to establish intervention efficacy and symptom-self management potential for those with FM is recommended.

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CHAPTER ONE: INTRODUCTION

The 2010 U.S. census data reveal that over 7.5 million adults suffer from fibromyalgia (FM); an estimated 85% of these are women (Haviland, Banta, & Przekop, 2011; Lawrence et al., 2008; Sarzi-Puttini, Buskila, Carrabba, Doria, & Atzeni, 2008). This chronic condition is characterized by widespread pain as well as sleep disturbances, fatigue, morning stiffness, depressed mood, and impaired cognitive function, all of which contribute to an overall decrease in health-related quality of life (HQoL) (Wolfe et al., 2010) and have a large impact on health care resource utilization (Berger, Dukes, Martin, Edelsberg, & Oster, 2007; Sanchez et al., 2011; Sicras-Mainar et al., 2009; Spaeth, 2009). Genetics and environmental stressors are thought to act as triggers and sustaining factors in FM (Bazzichi, Sernissi, Consensi, Giacomelli, & Sarzi-Puttini, 2011; Clauw, 2007, 2014), leading FM researchers and clinicians to believe that chronic stress is a major contributing factor to the dysregulation of the central nervous system that is observed in persons diagnosed with FM (Bazzichi et al., 2011; Wolfe et al., 2010).

The constellation of FM-related symptoms influences multiple aspects of daily life for those experiencing this chronic disease. Those experiencing chronic pain score lower on measures of HQoL than those with other chronic diseases, with the exception of cancer (Phillips & Harper, 2011). The more pain the individual with FM experiences, the greater the impairment of functional status (Wolfe et al., 1997), leading to decreased HQoL (Pagano, Matsutani, Ferreira, Marques, & Pereira, 2004) as well as a decline of other psychological, physical, and social aspects of their lives (Mease, 2005).

The unique aspects of each individual's life combine to present a highly personalized profile of pain and other FM-related symptoms (Anderson, McCrae, Staud, Berry, & Robinson, 2012; Wolfe et al., 2010; Wolfe, Ross, Anderson, Russell, & Hebert, 1995). Types of neuropathic pain experienced may include varying degrees of allodynia, hyperalgesia, and parethesia. The differing combinations of FM-related symptoms and pain manifestations create treatment challenges for health care providers given that physical, emotional, psychological, and social factors influence an individual's response to treatment (Edwards, Bingham, Bathon, & Haythornthwaite, 2006; Lipkovich, Choy, Van Wambeke, Deberdt, & Sagman, 2014; Montoya, Larbig, Braun, Preissl, & Birbaumer, 2004).

Because conventional drug therapies offer modest symptom relief, at most, and have undesirable side effects (Arnold, Clauw, Dunegan, & Turk, 2012; Clauw, 2014; Harris et al., 2007; Staud, 2010), a significant number of those diagnosed with FM seek out complementary health-enhancing therapies such as yoga (Hauser et al., 2012; Lind, William, Tyree, Diehr, & Grembowski, 2007; Saad & de Medeiros, 2013). Health care professionals and researchers recommend that treatment plans for those diagnosed with FM include both pharmacological and non-pharmacological therapies, including self-care strategies (Arnold, 2008; Clauw, 2014; Jones, Kindler, & Liptan, 2012; Sarzi-Puttini, Atzeni, & Perrot, 2012; Sarzi-Puttini et al., 2008; Staud, 2010; Wahbeh, Elsas, & Oken, 2008).

As the evidence for yoga as a therapeutic modality in chronic disease symptom management expands, research is needed to identify yoga styles that have the greatest potential for feasibility, acceptability, and efficacy. Functionally distinct from movement-

based forms of yoga such as Hatha yoga, classic Iyengar, and Ashtanga yoga, restorative yoga (RY) is composed of static supported poses. As opposed to movement and muscle contraction, which can create stress within muscles and joints as well as increase muscle tension and produce microtraumas within the muscle fibers (Umeda, Corbin, & Maluf, 2014), RY supports the muscles without creating tension while eliciting the relaxation response (Benson, Beary, & Carol, 1974; Benson & Klipper, 1992; Benson & Proctor, 2010; Lasater, 1995). The reclining and inverted supported poses used in RY are intended to diminish the muscle guarding found in painful chronic diseases such as FM, decrease sympathetic nervous system activity, and promote parasympathetic nervous system dominance, thereby facilitating relaxation and sleep (Cole, 1989; Cole, 2005; Gharib et al., 1988; Vybiral, Bryg, Maddens, & Boden, 1989).

Two recent study findings suggest that (a) FM-related pain is neuropathic in nature and may be caused by small fiber changes in intraepidermal nerve fibers (Uceyler et al., 2013) and (b) that arteriole-venule shunting with the consequent ischemia to surrounding tissue may be responsible for the deep tissue pain and muscle fatigue experienced by those with FM (Albrecht et al., 2013). Authors of both studies suggest a causal link between chronic stress and their study findings (Albrecht et al., 2013; Uceyler et al., 2013). Given these results, inducing the relaxation response with RY (Lasater, 1995) becomes a compelling rationale for assessing the feasibility of a RY intervention as a means of symptom self-management in individuals with FM. To our knowledge, this study was the first to assess the feasibility of a RY symptom self-management intervention in individuals diagnosed with FM.

This dissertation is the synthesis of a scholarly process that began with a review of the literature on yoga interventions for persons diagnosed with FM and progressed through the design, implementation, analysis, and interpretation of a study using RY with a sample of persons diagnosed with FM. In accordance with the 2012-2013 PhD Student Handbook for Academic Policies and Procedures of the University of Virginia School of Nursing, this dissertation follows the manuscript dissertation design.

Chapter Two: *Compliance with Delphi Survey Key Components of Yoga Interventions for Musculoskeletal Disorders: A Systematic Review of Fibromyalgia and Yoga Interventions* is a manuscript that examines the English language publications of original studies examining yoga interventions in persons diagnosed with FM. Because yoga research is an emerging area, guidelines to assure study rigor and to improve study replication potential remain under development. Studies using a variety of yoga styles and practices make identification of feasible, efficacious yoga interventions challenging for chronic disease populations. In 2014, a Delphi survey of rheumatology, research, and yoga experts resulted in recommended guidelines consisting of 33 key components that should be included in the design and reporting of all yoga studies for persons diagnosed with musculoskeletal conditions. Chapter Two contains a discussion of the yoga styles that have been investigated in samples of persons diagnosed with FM. In addition, using the Delphi survey 33 key components of yoga interventions for musculoskeletal conditions as a guideline, the potential for study replication was evaluated. Issues of particular interest are the rationale for the selection of each yoga style investigated and whether or not any studies of RY have been conducted in persons with FM. Also included in the manuscript is a brief description of RY and the rationale for its potential

use as a novel, self-management, adjunctive therapy for symptoms experienced by individuals with FM.

Chapter Three: *Restorative Yoga for Symptom Management in Persons Diagnosed with Fibromyalgia: Protocol for a Prospective Mixed-methods Feasibility Study* provides the design and detailed methods of the study conducted, including information about the theoretical framework (Theory of Planned Behavior) (Ajzen, 1991) used to inform the study design and data analysis.

Chapter Four: *Results of an 8-week, Mixed-methods Feasibility Study: Restorative Yoga for Symptom Management in Persons Diagnosed with Fibromyalgia* presents the results of the 8-week RY intervention related to feasibility and the study participants' perceptions of the experience of participating in the intervention. Adherence to the RY home practice at 1-month post-intervention also is reported.

Chapter Five: *Conclusion* incorporates the components of the dissertation into a cohesive document providing lessons learned, implications for nursing, and future directions related to research and theory development for symptom self-management using complementary health-enhancing approaches for persons with FM.

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CHAPTER TWO: Literature Review

Manuscript One

Compliance with Delphi Survey Key Components of Yoga Interventions for Musculoskeletal Conditions: A Systematic Review of Fibromyalgia and Yoga Interventions

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Abstract

Objective: The objective of this systematic review was to (a) examine the quality and replication potential of yoga studies using the Delphi survey 33 key component recommendations of yoga interventions for musculoskeletal conditions ("33 key components") and (b) identify the yoga styles that have been investigated in persons diagnosed with fibromyalgia.

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 diagnosed 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% ± 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 the lack of intervention details, the need to report a disease-

specific rationale for the selection of a particular yoga style, 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

Introduction

Fibromyalgia (FM), recognized as one of the leading and most difficult chronic pain disorders to diagnose and treat, has no known cure.[1,2] An estimated 2.5% to 7.9% of adults in the United States suffer from FM.[3,4] Differential diagnosis of this chronic condition has proven to be challenging, thus contributing to the belief that currently reported prevalence rates for FM may be underestimated, especially among men.[4-6] 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. One theory posits that a decrease in the pain inhibitory network's connectivity and an impaired descending pain modulatory system are responsible for FM-related pain.[7] Comorbid conditions and other central sensitization disorders such as irritable bowel syndrome, migraine headaches, and interstitial cystitis are found at higher rates in those with a diagnosis of FM as compared with other chronic conditions.[8,9] The complexity of FM manifests in substantial personal burden and an overall decrease in health-related quality of life that is inversely correlated with age.[10,11] FM has been associated with major personal burden, increased use of direct and indirect health care resources, and substantial national economic burden.[12,13]

Given that prescription drugs for FM-related symptom management have only modest efficacy rates (30% to 50%), undesirable side effects, and little effect on

decreasing symptom severity over the long term,[14-17] it is not surprising that persons with FM are the third largest group suffering with chronic pain (superseded only by those with chronic back pain and headaches) to seek out non-pharmacologic modalities, including complementary health-enhancing approaches such as yoga.[18-20] A 2014 international Internet survey investigating yoga use among persons diagnosed with FM revealed that out of 2543 respondents, 2029 (79.8%) stated they had considered doing yoga and 1469 (57.8%) had attended at least one yoga class.[21] Consistent with recommendations from rheumatology experts for a multi-modal treatment approach, health care providers are increasingly recommending yoga as one of the non-pharmacologic interventions for FM-related symptom management.[22-24]

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).[25,26] Yet, too few studies have investigated the use of yoga therapy to establish evidence-based treatment protocols for specific diseases.[27] 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,[27-29] has been identified as a limitation of the published research.[27,30-32]

In an approach similar to that taken by those conducting acupuncture research, yoga researchers have begun to develop yoga-specific research guidelines. In 2012,

Sherman[29] 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 and colleagues[33] 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 purpose of this systematic review was to use the 33 key components[33] to assess the study quality and replication potential of studies investigating yoga interventions for persons diagnosed 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.[34] 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." Table 1 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[35,36] were identified: one reporting the findings of a RCT 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.[35,36] Duplication of all relevant methodological information for our analysis was found in the two articles; therefore, the 2010 article by Carson and colleagues[35] was selected for inclusion in this analysis and the 2012 article by these authors[36] 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[37] (applicable to RCT and comparative effectiveness studies) and the Methodological Index for Non-randomized Studies (MINORS).[38] Two risk of bias assessment tools were used: the Cochrane Collaboration 'risk of bias' tool[39] (applicable to the RCT and comparative effectiveness studies) and the Risk of Bias Assessment Tool for Non-randomized Studies (RoBANS)[40] (applicable to non-randomized, non-comparative studies).

The Jadad scale has been used to assess study quality in previous systematic reviews of yoga interventions.[41-43] 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 ≥ 3 points on the scale indicates an average to high quality study; a score < 3 indicates a low quality study.[37,43]

Non-comparative, non-randomized study quality was evaluated using the MINORS.[38] This quality measure was developed initially for surgical research but has been recommended for quality assessment of non-randomized, non-comparative intervention studies.[44] The maximum total score is 16 for non-comparative studies and 24 for comparative studies.[38] No cut-off point for determining study quality using the MINORS has been published. As with previous systematic reviews[45,46] using the MINORS, the mean score of the studies was used as the demarcation between average to high quality studies and low to very low quality studies.

Using the Cochrane Collaboration 'risk of bias tool'[39] modified for a yoga intervention, one RCT and two randomized comparative effectiveness trials were assessed for the following six domains: method used to generate randomization sequence,

allocation concealment; blinding to allocation during outcome measure assessment, completeness of outcome data, selective reporting of outcomes, and other bias. Performance blinding is not possible in a yoga intervention; thus, the domain for performance bias evaluation (i.e., for blinding of participants and study personnel to the intervention) was not included in this assessment. A rating of high or unclear bias is considered high bias risk. A study had to have a majority of criteria rated as low risk for bias (≥ 4 domains) to achieve an overall low risk of bias study rating.[39,47]

Risk of bias assessment for non-randomized, non-comparative studies was conducted using the RoBANS.[40] The RoBANS evaluates six study domains: participant selection, confounders, intervention measurement, outcome assessment blinding, incomplete outcome data, and selective reporting of outcome data. The RoBANS has been used to assess quasi-experimental and pre- and post-intervention, non-randomized studies in complementary therapy systematic reviews.[48,49] For purposes of this review, a study was determined to have an overall low risk of bias if it was rated low risk in ≥ 4 of the domains.

Data Collection and Data Extraction

Data were extracted and categorized by the 33 key components. The 33 key components are organized according to five themes, two of which have subthemes (Table 2). Although the use of accepted reporting guidelines such as the CONSORT guidelines for RCTs is included as key component 32, Ward and colleagues[33] do not indicate that the 33 key components are to be used with a particular study design. Precedent exists for the use of non-randomized studies in comparative effectiveness and systematic reviews

when few RCTs are available.[50,51] Because only one RCT and two comparative effectiveness trials of yoga interventions in participants with FM were found, cohort studies are included in this review.

Analysis Methodology

The authors analyzed the articles according to the 33 key components, which are grouped into themes and related subthemes.[33] In the event further interpretation was necessary to evaluate a particular component, the authors discussed the criteria to reach a consensus as to the intended meaning of the description. Inter-rater comparison was used to confirm consistent interpretation of the key components across studies.

Results

Study and Participant Characteristics

Study characteristics and demographic information for the six studies included in this systematic review are reported in Table 3. Three of the studies were conducted in the United States;[35,52,53] the other studies were conducted in Brazil,[54] Canada,[55] and India.[56] The six studies represented two comparative analyses,[54,56] one RCT,[35] and three cohort studies,[52,53,55] with the majority of these studies designated by the researchers as pilot studies.[35,52,53,55,56] One study used an intention-to-treat analysis.[55] All six were single-site studies.

Heterogeneity of study participants has been identified as a common limitation in FM research.[57,58] Inconsistencies were identified in the demographic variables collected and how these variables were reported across studies. Some authors reported study participants' age ranges,[53,56] while others reported mean ages and standard

deviations.[35,52,54,55] All authors reported the gender composition of study groups. Four of the studies enrolled only female participants.[35,53-55] Race and ethnicity were reported for only three of the studies.[35,54,55] In those studies for which race and ethnicity were reported, the study groups were composed primarily of White participants (71% to 92%). The authors of three articles reported the education level/years of education of the study participants.[35,54,55] The majority of study participants reported a college degree or some level of college education. Participant socioeconomic data were reported in two of the six articles, but the authors used different reporting categories and ranges.[54,55] Two articles included information on participant employment rate, 48% and 35.7%, respectively.[35,55] Study sample sizes ranged from 10 participants[53] to 53 participants.[35]

Methodological Quality and Risk of Bias Assessment

Two of the six studies met the review criteria for average to high methodological quality.[35,55] Among the remaining four studies, one[54] was determined to be low quality and three[52,53,56] met the criteria for very low quality using the Jadad[37,59] and the MINORS[38] assessments. A mean score of 5.33 ± 2.31 was found for the three studies[52,53,55] evaluated using the MINORS assessment. Studies scoring ≥ 6 on the MINORS assessment were classified as average to high quality studies and those scoring < 6 were classified as low to very low quality studies. Study quality assessments using the Jadad and the MINORS are presented in Tables 4a and 4b, respectively.

One[35] of the six studies evaluated for risk of bias met the review criteria for low risk, four of the studies[52-54,56] had a high risk of bias, and the risk of bias was assessed as unclear in the remaining study.[55] Whether or not study participants were consecutively

recruited was unclear in all but one study.[35] Risk of bias evaluations using the modified Cochrane Collaboration risk of bias tool for yoga interventions and the RoBANS assessment are shown in Figures 2a and 2b and in Figures 3a and 3b, respectively.

Study Characteristics by the 33 Key Components

Overall, reporting and design compliance with the 33 key components ranged from 39.4%[56] to 84.8%,[35] with a mean compliance rate of 62.63% ± 17.74. The studies reviewed had inconsistent compliance rates within specific key components of each theme and subtheme. For example, within the theme *Defining the yoga intervention* and subthemes of *types of intervention parameters* and *appropriateness for intervention for musculoskeletal population*, high rates of design and reporting compliance were found. Yet, for this same theme, compliance rates for the subtheme *minimum parameter values* were low because of a lack of compliance with the home practice recommendations (key components numbers 8 and 9) under theme 1, subtheme 2. Compliance rates for design and reporting components were low for the theme *Delivery of the yoga protocol* and the subtheme *yoga instructors.* Although three of the articles reported the teaching certifications and qualifications of the instructors,[35,52,55] only one of these specified the certifying or registering organization.[55] No reports of teaching experience specific to musculoskeletal disorders or to FM were included in the articles reviewed. Additionally, authors did not include descriptions for fidelity monitoring during the delivery of the yoga intervention. Differences in compliance by key component were non-specific to the study design (i.e., RCT, comparative intervention, or cohort) and were unrelated to the total number of study participants.

Findings of the analysis of the 33 key components follow. For clarity and consistency, the findings of the analysis are presented using the themes and subthemes (presented in Table 2) as the headings and subheadings.

Theme 1: Defining the yoga intervention.

Theme 1 Subthemes 1 and 2: Types of intervention parameters* and *minimum parameter values. While the majority of articles reported intervention parameters such as dosage, duration, session length, and frequency of the instructor-directed portion of the yoga intervention, the studies had low compliance rates with length of practice and home practice parameters. Among the studies, the total group yoga session dosage (i.e., total intervention hours) ranged from a median of 6 hours 40 minutes[54] to 24 hours,[56] with a mean of 15.33 ± 7.09 hours for the group yoga sessions. Although each of the articles reported the duration of the yoga intervention, one[56] study had a 4-week intervention period as compared with the recommended 8-week duration for a yoga intervention. However, in this study, six yoga sessions were conducted in each of the 4 weeks as compared with one[35,52,54] or two[53,55] sessions per week over an 8-week period for the other five studies. The recommendation for a minimum 60-minute session was met by all studies except one.[54] Session lengths ranged from a median of 50 minutes for an individualized yoga session[54] to 120 minutes[35] for instructor-led group yoga sessions, with a mean session length of 76 ± 26.79 minutes.[35] Authors of one article[53] did not report the session length (dose) for the instructed portion of the intervention. All six studies met the recommended minimum frequency of one instructor-led yoga session each week.

Ward and colleagues[33] noted that a consensus for home practice recommendations had been the most challenging aspect of the Delphi survey process during development of the 33 key components. The authors of one[35] of the six articles reported the inclusion of a home practice in their yoga intervention. Specifically, these investigators encouraged the study participants to maintain a daily home practice for 20-40 minutes, 5-7 days per week, and to track their home practice using a diary that was collected on a weekly basis.[35] The remaining five studies[52-56] did not include formal home yoga practice in their study designs; although the investigators of one of these studies "encouraged" home practice,[52] no details as to frequency, duration, or composition of the home practice were reported. Authors of another article[55] reported that participants were purposefully neither encouraged nor discouraged to participate in home practice.

Theme 1 Subtheme 3: Appropriateness of the intervention for fibromyalgia. All six of the articles clearly identified FM as the condition that had been studied. All but one article[56] included wording that indicated the chosen yoga style was appropriate for persons diagnosed with FM. Although not one of the 33 key components, three[35,52,55] of the articles included a description of the physiologic rationale for the use of yoga for persons with FM, but only one article[35] linked the yoga style and yoga components selected to the rationale given.

Definition of study expectations for persons potentially enrolling in the study were reported most often by including a statement about the informed consent process; the investigators for one study[53] listed participant requirements in the research article but did not report that they obtained informed consent from study participants, and another

article[54] did not report defining expectations for study participants through any means. The authors of one article[55] provided clarification of expectations not only through the informed consent process, but also by further detailing expectations in a letter to the participants. All six studies were designed to permit yoga posture modifications for FM-related limitations.

Theme 2: Types of yoga practices included. Yoga practice recommendations included the broad categories of yoga postures (asana), breathing (pranayama), relaxation techniques, and mindfulness. All of the six studies incorporated at least one of these yoga practices. One study protocol[56] used only asana practice as the intervention. The singular term 'mindfulness' (meaning the specific practice of directed attention) was included as a key component because the Delphi survey experts believed it was more appropriate as a recommendation for novice yoga practitioners than meditation or mindfulness meditation.[33] The authors of one article[55] reported the inclusion of mindfulness exercises, while the authors of another article[35] reported the inclusion of "mindfulness meditation" as part of their study protocol. Neither of these two articles gave a description of the specifics of these mindfulness practices. Four of the study protocols did not specify any form of mindfulness practice.[52-54,56]

Theme 3: Delivery of yoga protocol.

Theme 3 Subtheme 1: Yoga instructors. Qualifications of the teachers, instructors, or therapists ("yoga instructors") directing the yoga intervention were reported for three[35,52,55] of the six studies. The authors of two of the articles[35,50] did not report the certifying or registering organization for the yoga instructors or the number of

hours of training the yoga instructors had completed for the certification or registration.[35,52] One article[55] included a detailed description of the certifying organization and the number of certification hours the yoga instructor had completed. The authors of another article[35] reported the yoga instructor's extensive experience in teaching but did not specify if that experience was with persons suffering from musculoskeletal disorders or diagnosed with FM. None of the six articles included specific descriptions of the yoga instructors' experiences working with persons diagnosed with FM. Therefore, the criteria for compliance with the recommendation that authors report the yoga instructors' experiences specific to the study population was not met. In one study,[35] the yoga instructor used a manual with detailed guidelines for the yoga sessions, although monitoring fidelity of the yoga intervention delivery (key component number 20) was not reported in any of the six articles.

Theme 3 Subtheme 2: Best practice instruction. The 33 key components emphasize both integration of yoga practices within the intervention delivery and integration of principles of yoga into the participants' daily lives. While the authors of five of the articles[35,52-55] reported emphasizing integration of the yoga practices of body, breath, and mind during the intervention delivery, only two articles[35,52] included descriptions of the integration of principles of yoga learned during the yoga sessions into the participants' daily lives.

More than postural alignment, safety was stressed in carrying out the yoga practices in four of the studies.[35,53-55] The authors of five articles emphasized that allowances were made for FM-related or other physical limitations,[35,52-55] and four[35,53-55]

reported emphasizing safety during yoga practice. None of the authors of the articles specifically addressed principles of postural alignment pertinent to the yoga style under investigation.

Theme 3 Subtheme 3: Study participant resources. Written home practice instructions were distributed to participants in two of the studies,[35,52] although only one[35] of these included home practice as a part of the study design. A detailed written description of the home practice, DVDs, and CDs were made available to the study participants in one of these two studies.[35] The other study[52] in which participants were encouraged to engage in home practice gave the participants written handouts with instructions each week during the group class, but practice details, examples, or descriptions of the specific content of the handouts were not provided.

Theme 4: Outcome measures to include (by domain). Five of the studies[35,52-54,56] included outcome measures that assessed at least five of the recommended domains: physical function, activities of daily living, pain, quality of life, and psychological well-being. One study[55] included a biomarker (i.e., collection of salivary cortisol).[55] Key component number 31 requires both biomedical and psychosocial outcome measures; therefore, the four[35,52-54] studies that included only psychosocial measures did not fulfill the compliance requirement for this key component.

Theme 5: Reporting of yoga interventions for musculoskeletal conditions. Specific reporting guidelines such as the CONSORT statement guidelines[60,61] (available at the time these articles were published) were not followed by the authors of any of the six articles. Five[52-56] of the six studies included in the analysis were not RCTs and,

therefore, limited in the selection of rigorous reporting guidelines to follow. The RCT[35] included a CONSORT[62] study flow figure. Another article reporting on one cohort study[55] provided a similar study flow figure. None of the articles specifically identified the extended CONSORT for reporting trials assessing non-pharmacologic treatments.[60]

Discussion

Although yoga is an ancient practice, yoga and yoga therapy have emerged only recently as areas of research interest. Given the increasing popularity of yoga as both a health-enhancing and therapeutic modality, as well as the generally promising research results for yoga in both healthy and disease populations, establishing the safety of yoga therapy and its treatment efficacy is a high priority.[25] Rigorous research studies with reproducible outcomes upon which other evidence-based therapeutic protocols can be developed are needed. Robust reporting and timely dissemination of study results, as well as timely translation into practice, are important considerations in advancing yoga as a therapeutic modality.[24,63,64] However, the complexity and heterogeneity of both the FM population and yoga practices combine with the current funding environment to present FM researchers with distinct challenges.

Yoga as a therapy for chronic disease conditions shows promise. Results of studies of persons with Parkinson's disease,[65] breast and ovarian cancer,[66,67] cardiovascular disease and metabolic syndrome,[68] and musculoskeletal chronic pain conditions[69] suggest that yoga may decrease perceived severity of disease-related symptoms and increase overall health-related quality of life. Individuals diagnosed with FM show a high level of interest in yoga and yoga therapy,[21] yet to date, study findings

specific to yoga interventions provide little high quality evidence to support the recommendation of yoga therapy for these individuals.[29] In addition, given the many distinct styles of yoga, selection of an intervention yoga style must (a) align with the study objective(s), (b) consider the underlying mechanism(s) of the condition to be studied, and (c) incorporate yoga practices that are functionally appropriate for the condition being investigated. While the authors of the six articles reviewed describe the desired physiologic responses to a yoga practice, it is unclear why the specific style of yoga was selected for those with FM.

Based upon the findings of this systematic review, an understanding of the mechanistic basis of particular yoga styles does not prevail among those conducting yoga intervention studies; however, looking beyond yoga research into fields such as sports, exercise, and psychology may provide some insight into the potential mechanisms of particular yoga practices. For example, research in healthy athletes has been done to determine the mechanistic actions of RY poses in sleep promotion.[70] Particularly in persons with FM, exercise has been reported to be beneficial,[71] yet overuse of muscles and the introduction of microtrauma to the muscles have been reported to increase FM-related pain.[72] Therefore, it is essential that yoga therapies for FM be based upon yoga practices that support the muscles and prevent trauma to the muscle tissues. Stress, too, is thought to be a trigger and sustaining factor in FM symptoms.[73] Thus, yoga styles and practices such as RY that focus on stress reduction[74] and invoke the relaxation response[75] may decrease sympathetic dominance and increase parasympathetic activity, which can

theoretically help to balance the central nervous system dysregulation thought to be responsible for many of the symptoms experienced by those with FM.

Development of guidelines that account for the complexities of a yoga therapy intervention are necessary to bolster the replication potential of studies required to establish high quality evidence of intervention feasibility and efficacy. The recommendations by Ward and colleagues[33] constitute one such guideline. Specified for use in designing and reporting high quality yoga intervention research,[33] the authors posit that this guideline has the potential to increase yoga study rigor for those with musculoskeletal conditions.[33] Key component number 32 is a recommendation that an additional guideline such as the extended CONSORT statement for non-pharmacologic trials[60] guide the study design and reporting. This statement for non-pharmacologic trials has a checklist of 22 additional items for rigorous reporting of RCTs. If not used in combination with these additional CONSORT items, the usefulness of the 33 key components for evaluating study rigor may be limited. As demonstrated in this review, a high compliance rate with the 33 key components does not necessarily reflect high methodological quality or a low risk of bias in a given study. Combining another reporting guideline such as the extended CONSORT statement becomes cumbersome and introduces questions regarding the weighting of individual criteria vis-à-vis one guideline to another.

Creating guidelines that incorporate both the yoga-specific 33 key components by Ward and colleagues[33] or the recommendations by Sherman[29] with existing accepted guidelines, that is, guidelines that inform the selection of efficacious yoga styles for

specific disorders as well as study design and reporting, can potentially result in rigorous, replicable yoga therapy studies. This review illustrates that while guidelines[37,59] are being used to evaluate the quality of yoga studies, allowance for the inability to blind study participants to the intervention, the desire for a non-prescriptive approach to interventions, and the lack of specific detailed reporting guidelines for discrete yoga practice elements, make accurate assessment of yoga interventions unlikely. As noted by others, development of guidelines in an approach similar to that taken by acupuncture researchers in the development of the STRICTA standards[76] is needed for yoga therapy research.

Replication potential of the six reviewed studies was limited by the lack of yoga intervention detail. This lack of detail extended to posture modifications, which are of utmost importance in chronic disease populations such as FM. With the exception of two articles,[35,52] descriptions of posture modifications were not included, and the descriptions that were given in the two articles are such that it is unclear what the modifications entailed. The maximum word count imposed by many journals is often cited as the reason for the lack of detail that authors can provide. Also, yoga therapy experts have voiced concerns that too much structure provided for a yoga intervention may diminish the results obtained by those receiving the intervention by virtue of it being too prescriptive.[33]

Although yoga experts agree that yoga instructors' qualifications are important to intervention delivery and fidelity,[33] this key component had one of the lowest rates of compliance. The yoga instructor has much influence on intervention outcomes, thus, it is

important that details of the instructor's training and experience be included in the reporting of yoga studies. Identifying a yoga instructor with similar training and experience to that of the original study is key to accurate study replication. In addition, descriptions of the instructors' qualifications and the monitoring of the fidelity of the intervention delivery are among the most crucial details in understanding and accounting for instructor-related study bias.[28,29]

Suggestions by other yoga researchers for improving the reporting of details necessary for replication include publishing the intervention teaching manuals or supplying online links to supplemental materials.[33] Additional solutions may be found in the general or research literature reporting on similar challenges. Another group that has faced challenges in communicating form and movement is dance choreographers, who developed *labanotation,* a notation system for communicating precise dance poses and movement. This system is used also in physical therapy and in sports to communicate body movement, timing, and repetition.[77] Such systematic approaches may enhance communication in yoga therapy, increasing study replication potential and the opportunity to generate sound data. Incorporating methods that allow modifications and personalization of an intervention protocol may alleviate the concern of yoga therapy experts that these protocols may be too prescriptive.

Review Limitations

This review may have been limited by the databases accessed, language restrictions, and the potential for publication bias. Other limitations include the small number of yoga intervention studies for persons with FM, the heterogeneity of the yoga

styles investigated, and the lack of available yoga research-specific guidelines at the time the studies were conducted. In addition, interpretation of the 33 key components was based on the review authors' understanding of the information contained in the article by Ward and colleagues.[33]

Conclusion

Application of the recommended 33 key components across study designs (RCT, comparative interventions, and cohort studies) reveals that adherence rates with these components are not necessarily specific to research designs. That is, it was possible to meet the majority of the 33 key component recommendations regardless of study design. Additional assessment criteria from an accepted formal guideline such as the CONSORT statement can supplement the 33 key components, thereby creating a yoga-specific guideline that assures study rigor and replication of future yoga studies.

This review underscores the strengths and weaknesses of six published yoga intervention studies in persons diagnosed with FM. Comparisons among these studies is challenging because of differing yoga styles, varied study design, small sample sizes, and the lack of detailed reporting. This review identified that only three yoga styles have been investigated in FM studies, although there may be other, more efficacious styles of yoga that address FM-specific limitations, theorized FM etiology and pathophysiology, and FM-related symptoms.

Overall, in this review, the 33 key components were found useful for understanding the strengths and weaknesses of the six studies that have been conducted using yoga interventions for persons with FM; this information may be used to inform

future directions in FM and yoga therapy research. Findings from this review support the need for more rigorous studies with appropriate study design, a full description of the interventions used, and comprehensive reporting of details sufficient to enable study replication and, in particular, to promote identification of the most appropriate and efficacious yoga styles for persons diagnosed with FM.

Conflict of Interest

The authors all declare no conflict of interest.

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Table 1. Search strategy for PubMed

	PubMed
#1	(yoga) (All Fields) AND Fibromyalgia (All Fields)
#2	#1 AND English [Language]
#3	#2 AND 2004/11/14 to 2014/11/13 [Publication Date]

Table 2. Analysis using the 33 key components

		Da Silva et al., 2007	Carson et al., 2010	Hennard, 2011	Curtis et al., 2011	Rudrud, 2012	Palekar & Basu, 2014	Compliance by Key Component
Theme 1: Defining the Yoga Intervention								
Subtheme 1: Types of intervention parameters	**1) Dosage of yoga (hours intervention)**	Approximately 6 hours and 40 minutes (based on median duration)	16 hours class time (plus home practice)	10 hours	20 hours	Not reported	24 hours	5 (83.33%)
	2) Duration of yoga intervention (total number of weeks)	8 weeks	8 weeks	8 weeks	8 weeks	8 weeks	4 weeks	6 (100%)
	3) Duration of yoga session (minutes/session)	Median duration of 50 minutes per session	120 minutes per session	75 minutes per session	75 minutes per session	Not reported	60 minutes	5 (83.33%)
	4) Frequency of sessions (number of sessions/week)	1 session per week	1 session per week	1 session per week	2 sessions per week	2 sessions per week	6 sessions per week	6 (100%)
Subtheme 2: Minimum parameter values	**5) Recommended minimum for number of weeks for the intervention: 8 weeks**	Yes	Yes	Yes	Yes	Yes	No	5 (83.33%)
	6) Recommended minimum for minutes per session: 60 minutes per session	No	Yes	Yes	Yes	Not reported	Yes	4 (66.67%)
	7) Recommended minimum number of sessions per week: 1 time per week	Yes	Yes	Yes	Yes	Yes	Yes	6 (100%)

		Da Silva et al., 2007	Carson et al., 2010	Hennard, 2011	Curtis et al., 2011	Rudrud, 2012	Palekar & Basu, 2014	Compliance by Key Component
	8) Number of home practice sessions per week (Recommended minimum: 3 times per week)	Not reported	Yes	Not reported	Neither encouraged nor discouraged	Not reported	Not reported	1 (16.67%)
	9) Duration of each home practice session (Recommended minimum: 30 minutes per session)	Not reported	Yes	Not Reported	Not reported	Not reported	Not reported	1 (16.67%)
Subtheme 3: Appropriateness of intervention for musculoskeletal population (fibromyalgia)	**10) Expectations of study participants clearly defined for the participants**	Not reported	Yes	Yes	Yes	Yes	Yes	5 (83.33%)
	11) Yoga style appropriate for FM limitations	Yes	Yes	Yes	Yes	Yes	Not reported	5 (83.33%)
	12) Protocol allowed for individual modifications to account for limitations	Yes	Yes	Yes	Yes	Yes	Not reported	5 (83.33%)
	13) FM clearly defined as condition under investigation	Yes	Yes	Yes	Yes	Yes	Yes	6 (100%)
Theme 2: Types of yoga practices included								
	14) Yoga postures/asana	Yes	Yes	Yes	Yes	Yes	Yes	6 (100%)
	15) Yoga breathing/ pranayama	Yes	Yes	Yes	Yes	Yes	Not reported	5 (83.33%)

		Da Silva et al., 2007	Carson et al., 2010	Hennard, 2011	Curtis et al., 2011	Rudrud, 2012	Palekar & Basu, 2014	Compliance by Key Component
	16) Yoga relaxation techniques	Yes	Yes	Yes	Yes	Yes	Not reported	5 (83.33%)
	17) Yoga mindfulness	Not reported	+"Mindfulness meditation"	Not reported	Yes	Not reported	Not reported	2 (33.33%)
Theme 3: Delivery of the yoga protocol								
Subtheme 1: Yoga instructors	**18) Recognized teaching qualification and/or certification**	Not reported	Yes	Yes	Yes	Not reported	Not reported	3 (50%)
	19) Experience teaching yoga to persons with FM or other rheumatologic diseases	Not reported	No	Not reported	Not reported	Not reported	Not reported	0 (0%)
	20) Instructors monitored for fidelity of delivery of the yoga intervention	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	0 (0%)
Subtheme 2: Best practice instruction	**21) Emphasizes integration of yoga practices of body, breath, and mind**	Yes	Yes	Yes	Yes	Yes	Not reported	5 (83.33%)
	22) Emphasizes principles of safety in carrying out yoga practices	Yes	Yes	Not reported	Yes	Yes	Not reported	4 (66.67%)
	23) Emphasizes principles of postural alignment	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	0 (0%)

		Da Silva et al., 2007	Carson et al., 2010	Hennard, 2011	Curtis et al., 2011	Rudrud, 2012	Palekar & Basu, 2014	Compliance by Key Component
	24) Emphasizes principles of integrating yoga practice into participants' daily lives	Not reported	Yes	Yes	Not reported	Not reported	Not reported	2 (33.33%)
Subtheme 3: Study participant resources	**25) Written instructions for home practice**	No home practice reported	Yes	Yes	No	No home practice	No home practice	2 (33.33%)
Theme 4: Domains of Outcome Measures to Include								
	26) Physical function	Yes	Yes	Yes	Yes	Yes	No	5 (83.33%)
	27) Activities of daily living	Yes	Yes	Yes	Yes	Yes	No	5 (83.33%)
	28) Pain	Yes	Yes	Yes	Yes	Yes	Yes	6 (100%)
	29) Psychological well-being	Yes	Yes	Yes	Yes	Yes	Yes	6 (100%)
	30) Quality of life	Yes	Yes	Yes	Yes	Yes	No	5 (83.33%)
	31) Both biomedical and psychosocial	Psychosocial only	Psychosocial only	Psychosocial only	Yes	Psychosocial only	No	1 (16.67%)
Theme 5: Reporting of Yoga Interventions for Musculoskeletal Conditions								
	32) Recognized guideline used for reporting	Not reported	++ Not reported	Not reported	++Not reported	Not reported	Not reported	0 (0%)
	33) Names of all yoga practices should be clearly detailed in the study write-up	+++ Yes	+++ Yes	Not reported	Not reported	+++ Not Reported	Not reported	2 (33.33%)

	Da Silva et al., 2007	Carson et al., 2010	Hennard, 2011	Curtis et al., 2011	Rudrud, 2012	Palekar & Basu, 2014	Compliance by Key Component
Total Compliance by Study (%)	20 (60.6%)	28 (84.8%)	23 (69.7%)	24 (72.7%)	18 (54.55%)	11 (33.33%)	

**Delphi Recommendations for Design and Reporting of Yoga Interventions for Musculoskeletal Conditions*[33] (pp. 7-8).

+ Definition and boundaries between use of the terms "mindfulness," "meditation," and "mindfulness meditation" were unclear amongst Delphi panelists. Mindfulness was considered important and appropriate for persons new to yoga, while meditation was considered a less appropriate practice for a yoga naïve practitioner.

++ CONSORT and CONSORT-like flow charts were included in the articles for these studies; however, specific reference to a guideline used in the study design and reporting was not included.

+++ While names or descriptions of some of the yoga practices incorporated into the intervention were provided by these investigators, clarity and level of detail necessary to replicate the intervention was not present. Carson and collegues[35] made no reference to additional intervention details. Hennard[53] stated details of the yoga intervention could be obtained by contacting the first author. DaSilva and colleagues[55] referenced the *Encyclopaedia of Traditional Asanas* by M.L. Gharote for intervention details; an out-of-print book that the publisher does not plan to reprint).

Table 3. Study demographics and characteristics

	Author(s)					
	Da Silva et al., 2007	**Carson et al., 2010**	**Hennard, 2011**	**Curtis et al., 2011**	**Rudrud, 2012**	**Palekar & Basu, 2014**
Country	Brazil	USA	USA	Canada	USA	India
Type of study	Randomized comparative effectiveness study	Pilot randomized control trial	One-group pilot study	One-group pilot study Time series design	One-group, mixed-methods study	Pilot randomized comparative effectiveness study
Musculoskeletal condition	Fibromyalgia	Fibromyalgia	Fibromyalgia	Fibromyalgia	Fibromyalgia	Fibromyalgia
Style of yoga identified	"Relaxing" yoga	Yoga of Awareness (Kripalu-based)	Not identified	Hatha yoga	Hatha yoga (blended Vinyasa, Kundalini, Iyengar)	Not identified
Participant study compensation described (if any)	Not reported	$25 for post-treatment assessment completion	Not reported	Not reported	Not reported	Not reported
Sample size/gender	40 Females	53 Females	10 Female 1 Male	22 Female	10 Female	15 Female 5 Male

	Author(s)					
	Da Silva et al., 2007	**Carson et al., 2010**	**Hennard, 2011**	**Curtis et al., 2011**	**Rudrud, 2012**	**Palekar & Basu, 2014**
Attrition rate (rounded to the nearest whole number)	18%	Intervention group = 12% Wait list control group = 7.1%	36%	13.64%	40%	Attrition not reported
Mean age	RY (n=17) 46.3 ± 8.9 RYT (n=16) 44.4 ± 11.0	Yoga (n = 25) 51.4 ± 13.7 Control (n=28) 55.8 ± 8.9	One group Mean age = 51 No std dev given	One group 47.4 ± 13.73	39 to 64 years mean age not reported	20-50 years Mean age not reported
Years since diagnosis	Not reported	Yoga 10.6 ± 7.5 Control 12.5 ± 7.0	Not reported	13.16 ± 8.55	Not reported	Not reported
Years symptomatic	Not reported	Yoga 1-5 yrs = 3 (5.7%) 6-10 years = 14 (26.4%) 10+ = 36 (67.9%) Control 1-5 yrs = 2 (8.0%) 6-10 years = 6 (24.0%) 10+ = 17 (68%)	Not reported	Not reported	Not reported	Not reported

	Author(s)					
	Da Silva et al., 2007	**Carson et al., 2010**	**Hennard, 2011**	**Curtis et al., 2011**	**Rudrud, 2012**	**Palekar & Basu, 2014**
Race/ethnicity	RY (n=17) Caucasian = 12 (71%) Mixed = 3 (17%) Black = 1 (5.9%) Asian = 1 (5.9%) RYT (n=16) Caucasian = 11 (69) Mixed = 3 (19%) Black = 1 (6%) Asian = 1 (6%)	Yoga Caucasian = 23 (92.0%) Native American = 2 (8.0%) Other = 1(4.0%) Control Caucasian = 26 (92.9%) Native American = 1 (3.6%) Other = 1 (3.6%)	Not reported	African Canadian = 1 (4.5%) South Asian -= 1 (4.5%) East Asian = 1 (4.5%) Middle Eastern/north = 1 (4.5%) Caucasian = 16 (72.7%) Hispanic = 1 (4.5%) West Indian = 1 (4.5%)	Not reported	Not reported
Marital status	Not reported	Yoga Married/partnered = 21 (84%) Divorced/separated = 3 (12.0%) Never married = 1 (4.0%) Widowed = 0 Control Married/partnered = 16 (57.1%) Divorced/separated = 8 (28.6 %) Never married = 3 (10.7%) Widowed = 1 (3.6%)	Not reported	Not reported	Not reported	Not reported

	Author(s)					
	Da Silva et al., 2007	**Carson et al., 2010**	**Hennard, 2011**	**Curtis et al., 2011**	**Rudrud, 2012**	**Palekar & Basu, 2014**
Education	RY Less than 8 = 3(1%) 8-10 = 6 (35%) more than 10 = 5(29%) University degree = 3 (18%) RYT Less than 8 = 6(38%) 8-10 = 3(19%) more than 10 = 4(25%) University degree = 3 (19%)	Yoga Less than college = 1 (4.0%) Some college = 9 (36.0%) College degree = 9 (36%) Graduate studies = 6 (24%) Control Less than college = 3 (10.7%) Some college = 8 (28.6%) College degree = 3 (10.7%) Graduate studies = 1 (3.6%)	Not reported	Grade-school = 1 (4.5%) High-school = 3 (13.6%) University/college = 14 (63.6%) Post-graduate school = 4 (18.2%)	Not reported	Not reported
Income (US $$)	(does not indicate if this is weekly, monthly or annual) RY $300 or less = 3(18%) $300-$600 = 9 (53%) $600-$900 = 5 (29%) $900+ = 0	Not reported	Not reported	Socio-economic class (parameters not defined) High = 0 Middle-high = 1 (4.5%) Middle = 13 (59.1%) Middle-low = 2 (9.1%) Low = 5 (22.7%)	Not reported	Not reported

	Author(s)					
	Da Silva et al., 2007	**Carson et al., 2010**	**Hennard, 2011**	**Curtis et al., 2011**	**Rudrud, 2012**	**Palekar & Basu, 2014**
	RYT $300 or less = 3(19%) $300-$600 = 7 (44%) $600-$900 = 4 (25%) $900+ = 2 (13%)					
Employment status	Not reported	Yoga Employed = 12 (48%) Control Employed = 10 (35.7%)	Not reported	Employed 8 (36.4%)	Not reported	Not reported
Major life event in past year	Not reported	Not reported	Not reported	11 (50%)	Not reported	Not reported
Presence of other ongoing pain problems	Not reported	Not reported	Not reported	16 (72.6%)	Not reported	Not reported

Table 4a. Jadad methodologic assessment of randomized control and comparative effectiveness studies

Authors	Described as randomized (+1)	Appropriate randomization method (+1)	Inappropriate randomization method (-1)	Subjects blinded to the intervention (+1)	Evaluator(s) blinded to the intervention (+1)	Description of withdrawals or dropouts (+1)	Jadad total score (max = 5)
DaSilva et al., 2007	1	0	0	0*	0	1	2
Carson et al., 2010	1	1	0	0*	1	1	4
Palekar and Basu, 2014	1	0	0	0*	0	0	1

*Blinding of subjects is not possible for a yoga intervention

Table 4b. Methodological Index for Non-randomized Studies: MINORS assessment for non-randomized, non-comparative studies

Author(s)	Clearly stated study aim	Inclusion of consecutive participants	Prospective data collection	Endpoints appropriate for study aim	Unbiased assessment of study endpoint	Follow-up period appropriate for study aim	Loss to follow-up less than 5%	Prospective calculation of study size confidence interval (95%)	Total score (max = 16)
Hennard, 2011	1	0	1	1	0	0	1	0	4
Curtis et al., 2011	2	1	2	2	0	0	0	1	8
Rudrud, 2012	2	0	2	0	0	0	0	0	4

Key
0 = not reported
1 = reported but inadequate
2 = reported and adequate

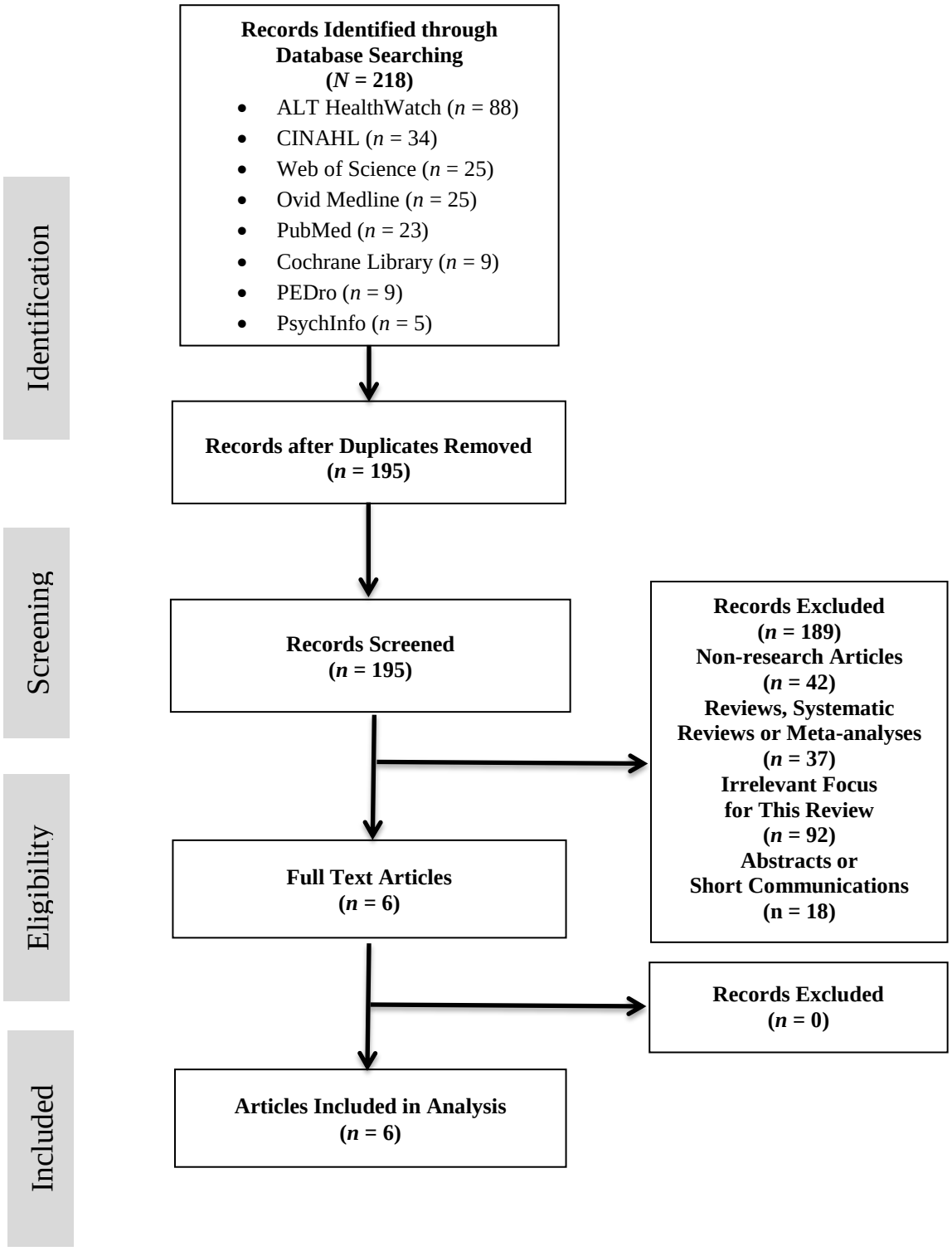

Figure 1. Flow diagram of article selection process according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA)

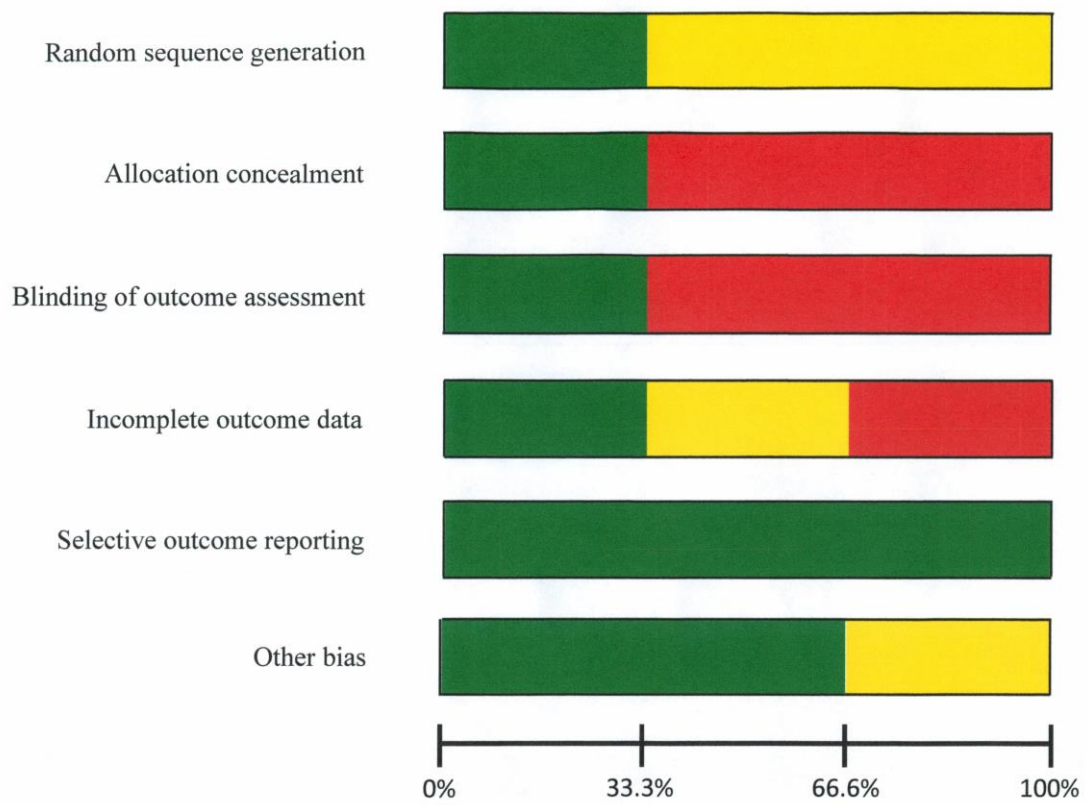

Figure 2a. Summary of Cochrane Collaboration tool for assessing risk of bias in randomized trials

= Low risk of bias = Unclear risk of bias = High risk of bias

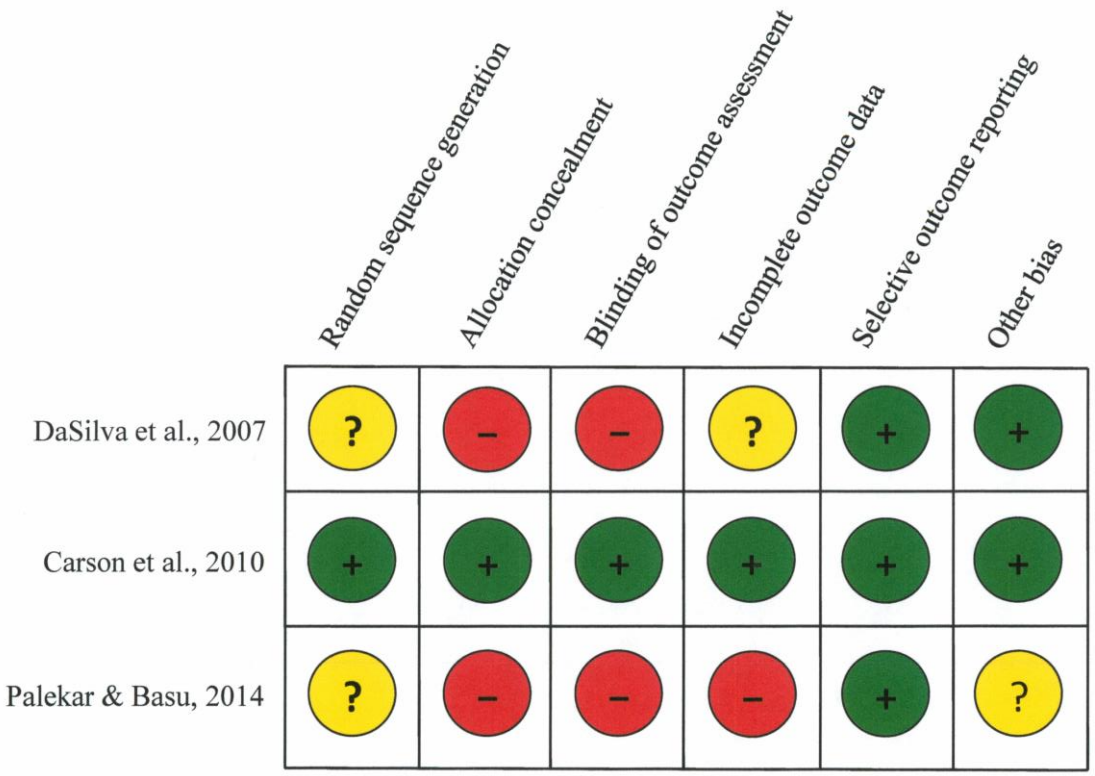

Figure 2b. Graph of Cochrane Collaboration tool for assessing risk of bias in randomized trials

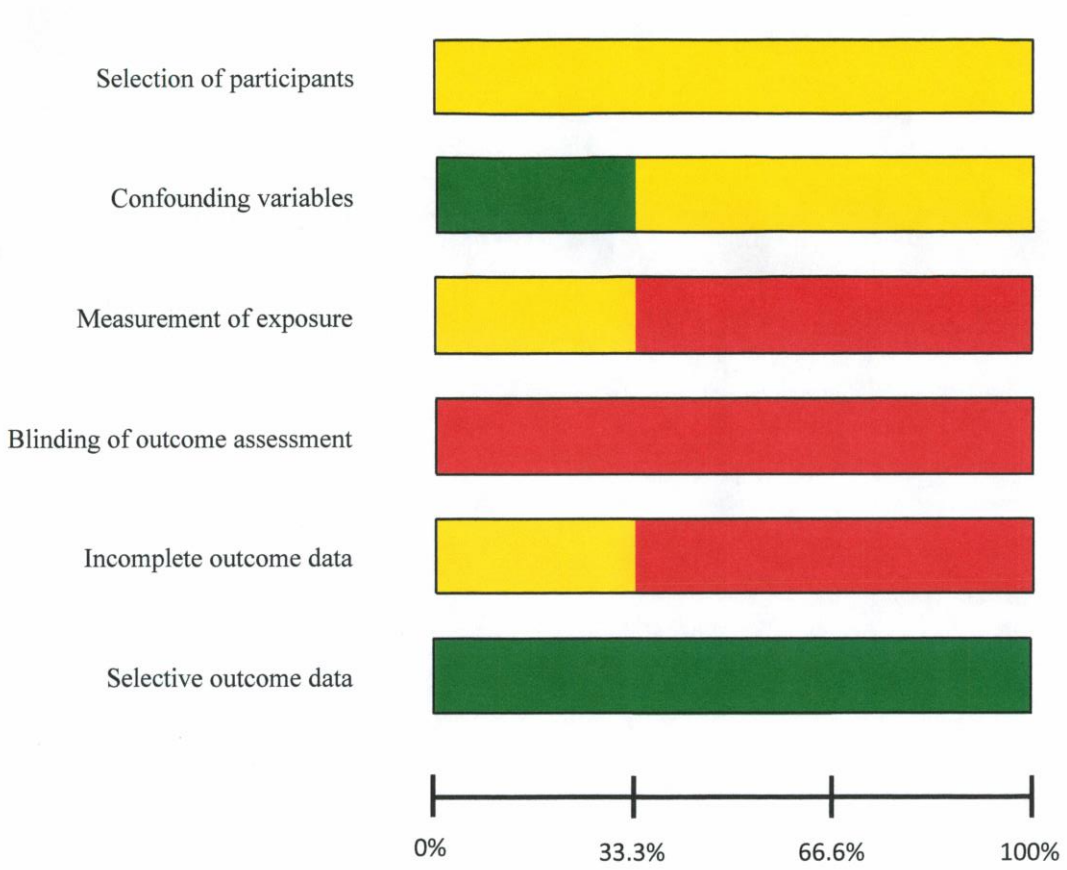

Figure 3a. Risk of Bias Assessment Tool for Non-randomized Studies: RoBANS summary

= Low risk of bias = Unclear risk of bias = High risk of bias

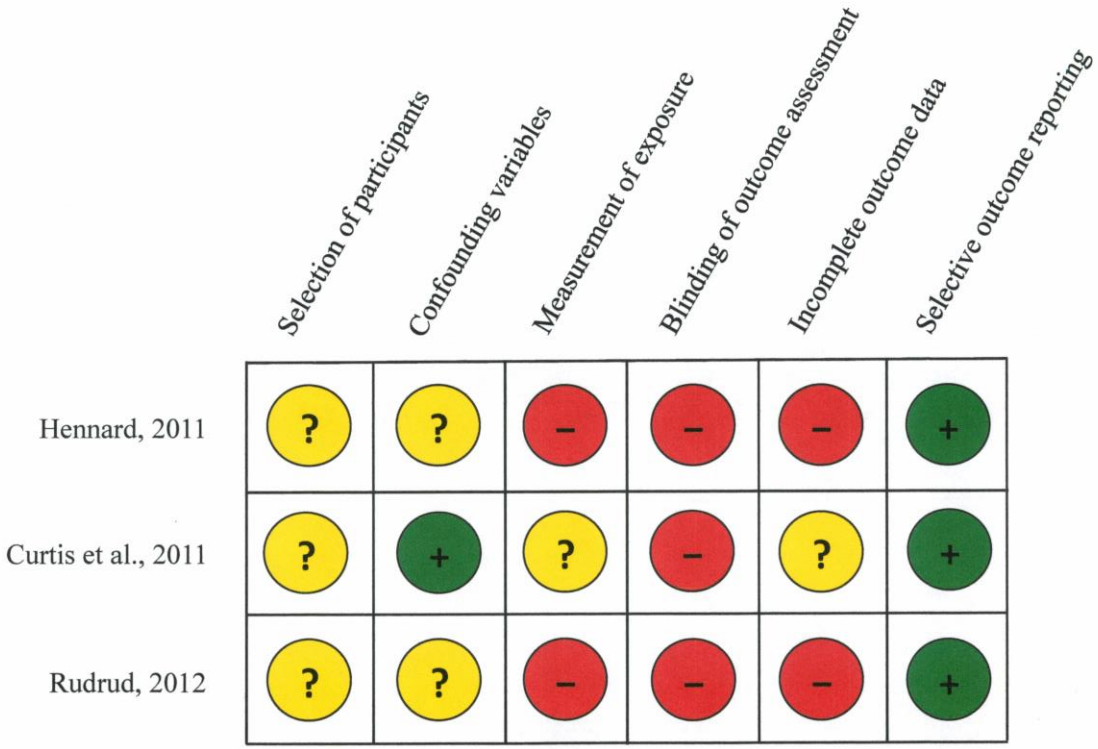

Figure 3b. Risk of Bias Assessment Tool for Non-randomized Studies: RoBANS graph

+ = low bias risk – = high bias risk ? = unclear bias risk

CHAPTER THREE: METHODOLOGY AND PROTOCOL

Manuscript Two

Protocol for a Feasibility Study of Restorative Yoga

for Symptom Management in Fibromyalgia

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Abstract

Objective: Increasingly, yoga is among the therapies included in recommended multimodal treatment approaches for persons with fibromyalgia. Given the numerous yoga lineages, styles, practice components, and the relatively scant empirical evidence of the effectiveness of yoga therapy for persons diagnosed with fibromyalgia, rigorous studies are needed to support these recommendations. The development of sound methodological designs and protocols to ensure study rigor, enhance replication potential, and synthesize results across studies for establishing evidence-based best practices is needed. Thus, this article presents the design and protocol used in an 8-week intervention study aimed at determining the feasibility of restorative yoga as an appropriate intervention for persons diagnosed with fibromyalgia. A secondary aim was to collect preliminary data on the perceived effects of restorative yoga to inform future fibromyalgia yoga therapy research.

Method: Using a prospective, mixed-methods, single-arm design, the investigators assessed the feasibility of an 8-week restorative yoga intervention for persons diagnosed with fibromyalgia. Twelve (12) persons with physician-diagnosed fibromyalgia took part in twice weekly, 90-minute restorative yoga group classes and a 20-minute home practice on the five non-class evenings. The Theory of Planned Behavior informed the study design. Quantitative findings for feasibility included recruitment, study completion, and adherence rates during the 8-week intervention and at a 1-month follow-up. These findings were corroborated by qualitative findings from semi-structured pre- and post-intervention interviews. Data regarding the perceived effects of restorative yoga were collected using self-report questionnaires at intervention baseline and at weeks 4 and 8.

Discussion: The study protocol provides a template for future feasibility studies of restorative yoga for persons diagnosed with musculoskeletal conditions, and one that can inform future yoga intervention studies aimed at identifying the most efficacious and feasible yoga style(s) for persons diagnosed with fibromyalgia.

KEY WORDS: Fibromyalgia, restorative yoga, yoga, protocol, relaxation response, mind-body therapies, sleep, pain, health-related quality of life, symptom self-management

Introduction

The Institute of Medicine characterizes pain as a costly and pervasive condition in the United States that is associated with conditions such as fibromyalgia (FM) [1]. Prevalence rates for FM have been estimated at 2.5% to 7.9% of adults in the United States, with a female to male ratio of 7:1 [2,3]; however, with recent changes in the American College of Rheumatology criteria, diagnostic rates among men have increased [4,5]. FM-related symptoms include chronic widespread pain, sleep disturbance, fatigue, morning stiffness, anxiety, depressed mood, and impaired cognitive function. These symptoms result in a decreased ability to engage in daily activities, functional decline, and a diminished health-related quality of life (HQoL) [6,7].

The etiology of FM remains unclear; however, research findings support the primary mechanism in FM as a dysregulation of the central nervous system (CNS) [8-10]. CNS and peripheral nervous system changes as well as altered immune and neuroendocrine function are implicated in the widespread pain and other symptoms experienced by those with FM [9,11,12]. Genetics, too, may predispose individuals to development of FM, but environmental and psychological stressors are thought to act as triggers and sustaining factors [8,13,14]. Chronic psychological stress has been implicated as a primary contributing factor to the CNS dysregulation and increased sensitization that occurs [15].

A multidisciplinary treatment plan for FM that includes pharmacologic and non-pharmacologic interventions is recommended [8,16-18]. Although exercise is highly recommended, those with FM demonstrate a reduced aerobic capacity [19] and diminished strength [20]. In addition, some forms of exercise may intensify FM-related

pain [21,22]. Given that increases in pain severity have been associated with functional decline in persons with FM [23], it is important to identify exercises that are appropriate for FM-related aerobic and strength limitations and those that do not promote or exacerbate pain. Increasingly, persons with FM are seeking gentle forms of mind-body movement therapies such as yoga to meet their specific exercise requirements [24].

Gentle forms of yoga that incorporate mindfulness practices may be especially useful for those with FM [25] because low intensity movement serves to prevent pain-enhancing eccentric and concentric muscle contractions and minimizes energy expenditure while promoting balance and joint mobilization [21]. Equally important, the mindfulness practices incorporated into a yoga program may help individuals manage stress and decrease perceived pain severity [26-28]. One gentle yoga style is restorative yoga (RY), which is noted for its ability to invoke the relaxation response, making it especially well suited for persons diagnosed with FM [29,30]. A typical full RY practice session is designed to move the spine in all directions, promote relaxation of the muscles, increase blood flow and oxygen exchange to the abdominal organs, reverse the effects of gravity, and decrease stress [30]. As opposed to stretching or contracting muscles, RY is designed to support muscles, thereby minimizing the muscle guarding commonly found in chronic pain conditions. A decrease in levels of perceived stress and fatigue and improved sleep quality has been demonstrated using RY for women with ovarian and breast cancer and for women experiencing menopausal hot flushes and associated menopausal insomnia [31-33].

Individual components of RY practice have been investigated as non-pharmacologic means for sleep promotion in competitive athletes [34]. The warm and

quiet environment in which RY practices are conducted promotes skin warming, core cooling, and relaxation of skeletal muscles contributing to shortened sleep latency [35]. Repeating a sound or word(s) during a lengthened exhale promotes habituation and sensory withdrawal and nurtures a state of calmness [29,34]. Encouragement to adopt a passive attitude toward thoughts and to focus on one's breath are techniques used during RY practices to elicit the relaxation response [29]. The dark environment and supine, inverted restorative postures reduce activity of the reticular activating system, resulting in a state of decreased brain arousal [34]. As compared with upright postures, reclining and inverted RY postures stimulate baroreceptor responses, which, in addition to decreasing brain arousal, decrease sympathetic nervous system activity, promote parasympathetic nervous system dominance, and diminish other physiologic responses characteristic of CNS arousal and stress states [36-41]. Given that baroreceptor responses have been shown to be impaired in persons with FM during stress [42], and that this impairment has been implicated in the hyperalgesia and autonomic nervous system dysregulation found in those with FM [42,43], baroreceptor stimulating practices such as RY may be important in FM-related symptom management.

Although investigators report that yoga shows promise for use in FM-related symptom management, only seven articles reporting on six studies were found in the literature [26,27,44-48]. These studies investigated three styles of yoga ("Relaxing" yoga, Yoga of Awareness, and Hatha yoga [26,44,45,47]) for symptom management in FM. Although one study [44] identifies the yoga intervention as *relaxing yoga*, a yoga therapy delivered as a one-on-one participant to therapist intervention, the description of the intervention given includes stretching and, therefore, is not consonant with a RY practice.

Thus, the primary aim of this study was to establish whether or not the practice of an 8-week RY intervention was feasible for persons diagnosed with FM. The secondary aim of this study was to gather preliminary data on the study participants' perceptions of the effects of RY on the FM-related symptoms of pain, sleep disturbance, fatigue, functional status, and HQoL. In 2014, accepted and recognized yoga research guidelines did not exist; therefore, recommendations for yoga therapy research proposed by Sherman [49] and the Delphi survey recommendations for yoga therapy research for musculoskeletal disorders by Ward and colleagues [50] guided the design of this study protocol.

Methods

Theoretical Framework

The Theory of Planned Behavior (TPB) [51] provided a heuristic framework for this study design. As posited by the TPB, psychosocial determinants of behavior (behavioral beliefs, normative beliefs, and control beliefs) are the antecedents to intention. According to the TPB, the more positive a person's beliefs are toward a behavior, the higher the level of readiness to perform that behavior. Intention is the construct in the TPB that indicates the level of readiness to engage in a behavior and is the immediate antecedent to engagement in the behavior. Thus, the stronger the intention to perform a behavior, the more likely a person is to engage in that behavior. The TPB has been used in over 200 studies to predict adherence to exercise and health-related behaviors and to understand reasons for non-adherence to those same behaviors [52-57]. In addition, it has been used in both quantitative and qualitative yoga studies specifically as a guide for selection of behavioral measures and also to predict and explain

acceptability, retention, and past, current, and future adherence to yoga behaviors in healthy and chronic disease populations [52,57].

The TPB informed development of semi-structured questions for pre- and post-intervention interviews [51]. Interview questions were designed to elicit attitudes toward RY (positive or negative), expectations of important others or groups toward the participant's practice of RY, and the study participant's perception of her/his ability to perform RY. These data were used to corroborate, explain, and add expanded meaning to observed recruitment, retention, and adherence rates and also to inform future studies and to enhance understanding of intention toward exercise-related behavior in persons diagnosed with FM.

Study Design

A mixed-methods, single-arm, prospective design using a concurrent triangulation strategy [58] was used. Investigators of this sub-study, which incorporated 16 study visits of the 20-visit parent study (PI A.G. Taylor), aimed to collect feasibility and preliminary perceived effects data of an 8-week RY intervention for persons diagnosed with FM.

Feasibility was operationalized as recruitment, retention, and adherence rates. Resource utilization and intervention safety also were incorporated into feasibility calculations. Pre- and post-interview data were used to help explain observed RY behavior and to identify participant-perceived facilitators and barriers to RY practice. Feasibility has been operationalized similarly in RY intervention studies for women with menopausal hot flushes and for women with breast and ovarian cancer [31-33].

Two 8-week RY intervention sessions were conducted. Self-report outcome measures were completed at intervention baseline and at weeks 4 and 8. Pre- and post-

intervention, one-on-one, in-person, audio-recorded interviews and a 1-month follow-up were conducted.

The Institutional Review Board for Health Sciences Research (IRB-HSR) for the university approved the study protocol and all study materials. Informed consent was obtained from all study participants prior to their participation in any study activities.

Setting. All group RY classes were held in a room appropriate for a RY intervention [30] at the school of nursing (SON) within a research-intensive university located in central Virginia. Consent and pre- and post-interview study visits were held in a private room located within research facilities at the same university. Free parking and direct elevator access was available to participants for all study visits.

Study Population. A consecutive convenience sample of six persons between the ages of 21 and 75 with physician-diagnosed FM were recruited for each of two 8-week RY intervention sessions. Potential study participants were persons who (a) were being seen in the university rheumatology clinic, (b) agreed to be contacted for future FM studies, or (c) responded by e-mail or telephone to a posting on the university's clinical trials Web site. All interested persons who contacted the investigators were sent an informational study brochure that included a telephone number to call for study eligibility prescreening. Those persons who contacted the investigators by telephone were prescreened and study eligibility determined according to the inclusion and exclusion criteria listed in Table 1 and, if eligible, a 30-minute consent visit was scheduled. A letter confirming the consent visit date and time, along with a copy of the informed consent document, was sent via e-mail or postal service. Appointment reminders were e-mailed 2 days prior to the appointment and telephone reminder calls were made 1 day prior to the

appointment. Persons who declined to participate or those who withdrew from the study were asked to provide their reasons for non-participation or withdrawal voluntarily. Study participant flow is presented in Figure 1.

Study Participant Compensation. Study participants were compensated $20 per study visit, which was paid incrementally at four protocol-designated time points and in accordance with the guidelines for payment to human subjects.

Yoga Instructor and Assistant Qualifications and Training. All yoga classes were taught by a registered nurse who is a registered yoga teacher with Yoga Alliance and a certified Relax and Renew® Trainer for RY. Relax and Renew® is the service mark associated with Judith Lasater's RY training. The yoga instructor is an experienced yoga practitioner who has taught both healthy persons and those with chronic disorders, including musculoskeletal conditions. The yoga instructor taught the class assistants, who also had nursing and research expertise, the principles of RY. During the two 8-week sessions, the assistants set up for the class sessions, collected and reviewed for clarity and completeness all completed study materials, took participants' pre- and post-class pulse and respiration rates, and assisted participants with RY posture transitions.

Treatment Fidelity. The yoga instructor and assistants used a RY training and class manual designed by the first author. Prior to contact with study participants, assistants attended a 3-hour training class, completed assigned readings [29,30,34], and demonstrated a grasp of RY positioning. The yoga instructor conducted all classes according to a script. Sequencing and timing of postures remained the same for every class. To ensure a consistent RY dose, a stopwatch was used to time the RY postures. The yoga instructor and assistants each took the pulse and respiratory rates and assisted

the same two participants over the entirety of the 8-week intervention. The yoga instructor maintained a class attendance log. One of the assistants (KA) observed the yoga instructor for intervention delivery fidelity throughout the 8-week session and, along with the yoga instructor, monitored study participants for adverse events (AEs). Individual deviations from the intervention protocol during a class, posture modifications, or other treatment fidelity issues were noted in a log maintained by the yoga instructor. The yoga instructor and assistants met briefly after each class to discuss any posture modifications needed and to resolve any challenges that may have occurred during the class session.

All study participants attended an orientation class during which the yoga instructor provided instructions for both class and home practice. Participants were instructed in centering, breath/body awareness, asana, and pranayama. Individual posture modifications were determined and participants' questions were answered. The yoga instructor and assistants observed the study participants, giving feedback and assistance as needed to ensure that they were able to perform the RY class and home postures and practices. Treatment fidelity also was assessed during weekly telephone calls.

AE Reporting. For this study, an AE was considered to be any undesirable sign, symptom, or medical condition considered related to the RY intervention. Medical conditions/diseases present before starting the intervention were considered AEs only if these worsened after starting the study and that worsening was considered to be related to the RY intervention. An AE was also any undesirable and unintended effect of the research occurring in human subjects as a result of the collection of identifiable private information for the study. The yoga instructor and assistants monitored participants for

AEs during the twice-weekly group RY classes. The yoga instructor monitored for AEs during the weekly telephone calls to the participants. Adverse events, had any occurred, would have been reported to the IRB-HSR office in the appropriate time period based on the severity of the event and in accordance with the IRB-HSR guidelines.

Intervention. Study participants continued to receive their usual medical care during the intervention period and were asked not to begin any new therapies for the duration of the RY study period. The RY intervention consisted of one 90-minute orientation session followed by 8 weeks of twice-weekly 90-minute group classes and one 20-minute home practice 5 days a week on non-class days. The 90-minute class sequence consisted of centering and breath/body awareness exercises followed by a 75-minute sequence of five RY postures (asanas) that incorporated 3 minutes of a yoga breathing technique (pranayama).

Pulse and respiration rates were taken before and after each of the RY class sessions to assess the extent that the relaxation response was achieved during the RY practice [29,59]. Classes were held each week on Monday and Thursday between 5:30 and 7:00 P.M., which met the Delphi survey key component recommendations for minimum dose, duration, and frequency of a yoga intervention for a musculoskeletal condition [50].

The home practice consisted of (a) a basic relaxation pose with a bolster, which participants were asked to do at approximately the same time each day, immediately prior to their bedtime, and (b) recording in their daily logs (1) the length of each RY practice and (2) how they felt before and after each practice. The key component recommendations for home practice are 3 times per week for 30 minutes [50]. This study

used a 20-minute home practice 5 times per week. The 20-minute practice time was purposefully selected based upon RY practice principles and the time necessary to elicit the relaxation response [29,30,60].

The class postures and sequence, designed by the first author, were adapted for persons diagnosed with FM from the RY practice for insomnia published by Judith Lasater [30]. The selection of the insomnia sequence and the late afternoon and evening timeframes to engage in RY were purposefully selected to address the FM-related symptoms of fatigue and sleep disturbance and the bi-directional association between disturbed sleep and perceived increase in pain severity [61-63]. The RY posture and sequence selection were based on the ability of study participants to safely and easily move from one posture to another. Any posture modifications, to the extent necessary, were implemented on the basis that the modified posture would have an equivalent functional purpose to that of the sequence posture. RY postures are considered safe and have few contraindications. Comorbid conditions were assessed for each participant and individual modifications were made as needed. The nomenclature identifying the postures in the intervention is the same as that used in Relax and Renew® training. To the authors' knowledge, no studies have reported using RY for musculoskeletal conditions.

RY props used in the group class sessions included yoga mats, bolsters, towels, blankets, sand bags, petite eye pillows, and standard size eye pillows. Each participant's props were stored separately between the class sessions. Petite eye pillows were distributed for home use. At the orientation class, a demonstration was given showing study participants how to use items at home as RY props for the home practice (e.g.,

comforters, blankets, pillows, towels). Each participant received a home practice manual showing step-by-step instructions for proper postural alignment and positioning of the basic relaxation pose using a bolster. Participants were encouraged to create a dedicated quiet RY practice space in their homes where the home practice setup could remain throughout the 8-week intervention.

Participants were assigned a mat space, a place at a table, and a chair with arms for each class. Prior to each class session the instructor and assistants set up the mats for the first RY posture, making provisions for modifications for individual physical needs and limitations. Upon arrival, study participants sat in their designated seats and entered their pre-practice data in their practice logs. At 5:30 P.M. the class session commenced. During class, the yoga instructor and assistants aided the participants in assuming each posture, giving attention to postural alignment and comfort. The yoga instructor tracked individual posture modifications. After completion of the 90-minute class and assessment of post-intervention pulse and respiration rates, the participants were asked to lie on their side for 5 to 6 complete breaths, then come to a seated position for 5 to 6 complete breaths, and then stand and return to their designated chairs and tables to fill out the post-practice portion of their weekly practice logs. Class details are presented in Table 2.

Outcome Measures. Outcome measures for this study protocol were selected in accordance with the study aims and recommendations of the Outcome Measures in Rheumatology (OMERACT) working group for FM. OMERACT recommendations for assessments in all FM studies include the core domains of pain, tenderness, fatigue, sleep disturbance, and patient global multidimensional function [64]. In addition, the selection of outcome measures was informed by the Delphi survey guidelines for musculoskeletal

disorders [50], use and reliability of the outcome measure in past FM research, ease of completion, and study participant burden (defined as time required to complete the questionnaire).

Baseline Assessments. Baseline assessments included self-reported demographic and health history information collected using an investigator-developed paper form.

Primary Outcome Measures. Primary outcome measures were defined as rates of recruitment, retention, and adherence as well as resource utilization and safety of the RY intervention for persons diagnosed with FM. Study participant-perceived acceptability and continued practice at the 1-month follow-up telephone call were also included in the feasibility assessment.

Recruitment. Recruitment was defined as the number of potential participants screened for study eligibility versus the number of persons who enrolled in the study. Two [26,45] of six [26,44-48] identified yoga intervention studies for persons with FM have reported recruitment rates: one at 82.8% [26] and the other at 38.6% [45]. Therefore, a recruitment rate above 40% was considered an acceptable rate to support this aspect of feasibility.

Retention. Retention was defined as the number of participants enrolled who completed the 8-week RY intervention and all study measures. Attrition rates for studies of yoga interventions in persons with FM have ranged from 14% to 40% with a mean of 25.35% ± 10.57% [26,44-46]; therefore, a retention rate ≥ 75% was considered an acceptable retention rate to support the feasibility of the RY intervention.

Protocol adherence. Adherence to the study protocol was determined by class attendance rates and participants' home practice rates as reported in their daily practice

logs. Adherence to home practice and class attendance was encouraged during the weekly telephone calls. Reasons for missing classes or non-adherence to home practice were tracked. Rates of class and home practice adherence have not been well documented in previous FM and yoga studies. Two studies [26,45] reported class adherence rates of 87.5% [26] and 86% [45], but no rates of home practice have been reported. Thus, an adherence rate of ≥ 80% for the RY group class was considered indicative of intervention feasibility. Given the lack of home practice data, the class adherence rate of ≥ 80% was used for the home practice parameter, too.

Resource utilization. Costs associated with conducting the RY intervention and feedback from the yoga instructor and assistants were included in feasibility calculations. Feasibility related to staffing requirements for the full 90-minute RY intervention practice as an at-home symptom self-management strategy or in a community class setting was operationalized as the ability to transition independently between RY postures by the end of the 8-week intervention and performing the 90-minute class practice at home once the 8-week intervention period had ended.

Safety of the RY intervention. The occurrence or non-occurrence of an AE and the number and types of AEs determined safety of RY for persons diagnosed with FM.

Perceived feasibility. Perceived feasibility was based on participant-identified facilitators and barriers, the types and number of these, and on participants' levels of satisfaction with the RY intervention.

Descriptive Data Collection. Pre- and post-intervention, one-on-one audio recorded interviews were used to gain a perspective of those living with FM and their experiences of participating in the 8-week RY intervention. Semi-structured sample

interview questions assessed predictors of behavior according to the TPB. Questions were developed to capture data about the participants' (a) behavioral beliefs of RY based on knowledge or experience, (b) perceived and actual behavioral control regarding their participation in the RY class sessions and home practices and use of RY as a means of symptom self-management, and (c) perceptions of societal attitudes and beliefs and the beliefs and attitudes of those around them that influenced their behavior during the 8-week RY intervention (see Table 3).

Secondary Outcome Measures. Secondary outcome measures provided preliminary data on participants' perceived effects of RY on FM-related symptoms. These measures, completed at baseline and at weeks 4 and 8, included self-report questionnaires that incorporated the recommended OMERACT core domains for research studies of persons diagnosed with FM [64].

Treatment Expectancy Scale. The pre-intervention Treatment Expectancy Scale is a 3-item questionnaire of participants' expectations of the 8-week RY intervention. Participants responded to 3 questions: (1) Do you think the RY intervention as described will help reduce your pain, stress, negative emotion, fatigue, and sleep disturbance (yes or no); describe why or why not? (2) How confident are you that RY will be successful in improving your FM symptoms (11-point Likert scale where 0 = not at all confident to 10 = very, very confident)? and (3) What degree of improvement do you expect from the RY intervention (11-point Likert scale where 0 = no improvement in symptoms to 10 complete improvement in symptoms)? The higher the total score (range 0 to 20), the higher the level of outcome expectancy [65].

The post-intervention Treatment Expectancy Scale is an 8-item questionnaire of participants' experiences and expectations following the 8-week RY intervention. Using a 10-point Likert scale (1 to 10 where 1 = not at all, none, or no improvement and 10 = extremely, complete improvement, complete relief, or complete reduction in symptoms), participants answered six questions: (1) How logical does this type of treatment seem to you? (2) How confident were you at the beginning of the study that the treatment would be successful? (3) How confident would you be in recommending RY to a friend with FM? (4) What degree of improvement did you expect from RY? (5) Before beginning the RY sessions, how much change in your FM symptoms did you expect from the RY sessions? and (6) After beginning the RY sessions, how much change did you expect? (7) Do you believe you received any benefit from the RY 8-week intervention, yes or no? (8) If yes, describe the perceived benefits resulting from completing the RY sessions.

Revised Fibromyalgia Impact Questionnaire (FIQR). The FIQR is an updated version of the Fibromyalgia Impact Questionnaire (FIQ) [66-68] consisting of 21 questions intended to assess perceived FM-related impact on the participants' daily life over the past 7 days [61]. Using an 11-point numeric rating scale (0 to 10 with 10 being the *worst* outcome for each question or situation assessed), participants ranked three linked domains: functional status (9 questions), overall impact (2 questions), and symptoms (10 questions). The combined score of these three domains indicates the individual's perceived overall HQoL [68]. Validation and reliability of the FIQR has been established [68].

Numeric Rating Scale for Pain (Pain NRS). Pain intensity was measured using the Pain NRS. Using an 11-point scale (0 = no pain to 10 = worst pain imaginable), participants responded to three questions: (1) intensity of present pain; (2) average pain intensity over the past week; and (3) worst pain intensity experienced during the past week. The Pain NRS has been used in studies comparing clinical and evoked pain measures in individuals diagnosed with FM and has been found to be a simple, reliable, and sensitive measure of pain intensity [69].

Numeric Rating Scale for Stress (Stress NRS). Perceived levels of stress were measured using the Stress NRS. Using an 11-point scale (0 = no stress to 10 = worst stress imaginable), participants rated their perceived average level of stress that day. The Stress NRS has been used in research of individuals with FM and has been found to be a reliable and valid measure of perceived stress levels for this population [70].

Short Form 36v2 (SF-36v2™). The SF-36v2™ was used to assess the participant's perceived health and well-being based upon its 36-item questionnaire, which is a reliable and valid generic measure of perceived functional health and well-being [71-73]. Eight subscales (physical function, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health) are grouped into two summary measures (physical health and mental health).

Daily Stress Inventory (DSI). The DSI, a measure of perceived daily stress, is a 58-item, self-report questionnaire used to assess the occurrence and perceived level of stressfulness of a variety of events. Reliability and validity of the DSI has been established [74,75].

General Sleep Disturbance Scale (GSDS). The GSDS is a 21-item scale intended to measure the frequency of subjective sleep disturbances over the past 7 days. Participants rated their sleep disturbances using an 8-point Likert scale with a numeric range of 0 through 7 (0 = never and 7 = every day). Total scores indicate the level of sleep disturbance, with a higher total score indicating a higher level of sleep disturbance. Persons scoring above 42 are classified as poor sleepers. The GSDS has established reliability and validity [76,77].

Pittsburgh Sleep Quality Index (PSQI). The PSQI has 19 self-report items rated from 0 to 3 (0 = not during the past months, 1 = less than once a week, 2 = once or twice a week, and 3 = three or more times a week) that generate seven subscale scores: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleeping medication, and daytime dysfunction [78]. The subscales yield one global score ranging from 0-21 points, with higher scores indicating worse sleep quality [78]. The PSQI has established reliability and validity and is useful in studying relationships between sleep quality and other variables.

Positive and Negative Affect Scale (PANAS). The PANAS is used to measure affect. Participants rate aspects of affect using a 1-5 scale (1 = slightly or not at all and 5 = extremely). Each schedule, positive affect (PA) and negative affect (NA), is composed of 10 items. Total scores for the PA and NA schedules are calculated by summing the participant ratings for each schedule. Total scores range from 10 (minimum) to 50 (maximum), representing the emotional extremes of PA and NA. In clinical research the PANAS has been found to be a valid and reliable measurement for assessing positive and negative aspects of mood [79].

Patient Global Impression of Change Scale (PGIC). The PGIC is a reliable and valid measurement for assessing clinically significant change over time for an intervention study and is especially useful in conditions such as chronic pain where meaningful improvement is based upon the patient's perceived improvement in her/his condition [80-82]. Study participants were asked to identify their most bothersome symptoms over the past week, to describe any changes since beginning the RY intervention by choosing one of seven descriptions of change on a scale of 1 to 7 (1 = no change to 7 = a great deal better, and a considerable improvement that has made all the difference), and to rate the degree of change since beginning the RY classes on an 11-point Likert scale ranging from 0 to 10 (0 = much better to 10 = much worse).

Participant Logs and Diaries. Participants completed daily sleep diaries and practice logs during the 8-week intervention. The research assistants collected completed logs and diaries each week and distributed log forms for the next week at the first RY class each week.

Daily Sleep Diary. A daily sleep diary was used to collect data on sleep duration, sleep interruptions, and sleep initiation. Sleep diaries are widely used and can be found in a variety of forms. Bedtime, sleep latency, number of sleep interruptions, time of arising, and how rested the study participant felt upon awaking were recorded in a daily sleep diary.

Daily Practice Log. All participants completed daily practice logs recording their feelings before and after completion of each RY practice, time spent in the RY practice, and whether it was a home practice or RY class.

Weekly Telephone Calls and Log. Each week during the 8-week RY intervention, the study coordinator contacted each participant for the purposes of monitoring (a) overall study and treatment fidelity, (b) any changes in medications, (c) occurrence of any AEs, (d) home practice and encouraging class attendance, and (e) participant questions or concerns. The six questions asked during the telephone call are shown in Table 4.

1-Month Follow-up. One month after completing the 8-week RY intervention, the investigator contacted each study participant by telephone and asked four questions (Table 4) designed to assess continued adherence to the RY 20-minute home RY practice and feasibility of a 90-minute home RY practice in lieu of a 90-minute group class.

Data Analysis.

Quantitative analysis. Study sample characteristics at baseline were analyzed using SPSS version 22. Means and standard deviations are reported for age, age diagnosed with FM, and years since diagnosis with FM. Frequencies are reported for sex, race, ethnicity, years of education, partner status, living situation, and comorbidities.

Feasibility data were entered into an Excel spreadsheet for simple ratio calculations of screening, recruitment, retention, and intervention adherence and 1-month post-intervention intention/continuation rates. Reasons for declining to participate in an 8-week RY intervention were tabulated using frequency calculations.

Given the small sample size, Wilcoxon non-parametric tests were run on the secondary outcome measures. Individual scores and overall group means were calculated at 3 time points (baseline to week 4, baseline to week 8, and week 4 to week 8) to identify statistically meaningful trends in levels of perceived pain, stress, sleep

disturbances, and HQoL. Statistically significant trends over the 3 time points were based on a two-tailed test with a *p*-value of $p \leq 0.05$. Outcome measures for perceived levels of pain, sleep disturbance, and disease impact on HQoL were assessed for clinically meaningful trends. Clinically meaningful trends in the FIQR were identified as a percent change raw scores from pre- to post-intervention of ≥ 14% [63]. Changes in scores of pain measures of 10-29% were considered minimally important, 30-49% moderately important, and ≥ 50% a substantial improvement [83]. A change in the SF36 of ≥ 12% from baseline scores [84] and a change in sleep measures (PSQI and GSDS) ≥ 6% [85] were considered minimal clinically important differences. Clinically significant improvement using the PGIC was defined as selection of the categories of "better" or "a great deal better," and minimal improvement was defined as "moderately better" [81,82].

Qualitative explication. To corroborate and elaborate upon the quantitative feasibility findings, study participants' descriptions of expectations, perceptions, and the lived experience of the 8-week RY intervention were assessed using a hermeneutic phenomenological methodology. As a heuristic framework guiding the development of the semi-structured interview questions, the antecedents of intention posited by the TPB informed the theoretical coding, analysis, and interpretation of the qualitative data. Study participant pre- and post-interviews were transcribed and checked for accuracy against the original recordings. NVivo software version 10 was used to sort and organize these data. Textual analysis of transcripts from the semi-structured interviews was conducted using a primary (open) and a secondary (theoretical-TPB) coding strategy. Interview transcripts were coded until saturation using steps outlined by Giorgi [86], and a reflective diary [87] to support neutrality of researcher analysis was maintained

throughout the coding process. This process involved several steps, including the identification of meaning units, and concluded with the identification of themes.

***Results interpretation*.** Using a concurrent triangulation strategy [58], the quantitative and qualitative study findings were compared for cross-corroboration and interpretation. The mixed-methods approach provided a contextual and expanded understanding of the feasibility findings and provided an explanation of actual behavior, perceived facilitators and barriers to practice, and beliefs related to a RY intervention used as a symptom self-management strategy for those diagnosed with FM.

Discussion

The study protocol was designed to assess the feasibility of a RY intervention for persons diagnosed with FM and to collect preliminary data on its perceived effects on FM-related symptoms. While the rationale for selecting RY as a feasible and safe yoga style is compelling, the six yoga studies previously conducted in the FM population (none of which investigated RY) support the need for an assessment of the feasibility of a RY intervention in this population. Given limited present day resources, it is practical to first engage in feasibility studies [88]. The heterogeneity of yoga styles and philosophical differences in yoga lineages, as well as the numerous yoga components (e.g., asana, pranayama, yoga nidra, pratyahara, mindfulness, mantra, mudra) and combinations of these, produce an almost endless array of possible interventions. Therefore, feasibility studies that use sound methodologies and guidelines are needed to evaluate potential yoga interventions in specific clinical populations. Findings from these less resource-intensive studies allow investigators to direct their limited resources towards

investigating those yoga styles that show the greatest potential for efficacy and effectiveness in a given population [88].

Yoga experts caution against the use of strict methodological and intervention structure, citing that the interventions may become too prescriptive [49,50]. Prior to a large, resource-intensive study, feasibility studies offer the opportunity for researchers to test guidelines and methodologies and to refine acceptable modifications that support individualization of the intervention. Because persons diagnosed with FM have a high incidence of comorbidities [89] and a heterogeneous symptom experience, as well as the fact that the underlying etiology and pathophysiology of FM remains unclear, the selection of a yoga style that can be modified easily for individual needs and limitations is especially important.

Yoga and yoga therapy research guidelines are emerging, but more work is needed to improve the rigor of yoga therapy study designs and the reporting of the findings. The protocol for the current study was developed using the TPB [90] theoretical framework, the CONSORT statement extension for non-pharmacologic intervention treatments [91], guidelines for yoga research proposed by Sherman [49], and the Delphi survey recommendations for musculoskeletal conditions proposed by Ward and colleagues [50]. Use of frameworks and guidelines such as those reported here form the basis for replicable research and validation of intervention outcomes leading to evidence-based best practices for the clinical application of yoga therapy.

The study protocol described here is a single-arm feasibility study with a small sample recruited using a convenience sampling methodology, which limits generalizability of findings. Potential for self-selection exists for yoga interventions;

however, the limitations resulting from this design are appropriate for the study aims assessing feasibility. The design is consistent with acceptable research practices. Based on the preliminary nature of the study and its purpose to determine feasibility [88] by answering the questions: “Can persons with FM participate in an 8-week RY intervention?” and “Will persons with FM participate in an 8-week RY intervention?” Assessing individual behavioral beliefs, behavioral control (actual and perceived), and social norms provides an expanded contextual understanding of feasibility.

Conclusions

This study protocol was designed to align with currently available guidelines for yoga and yoga therapy research and those specific to individuals diagnosed with FM. The selection of a theoretical framework provided structure, guidance for outcome measure selection, and interpretation of the study findings. The intervention design allows for individual modification of the RY intervention postures while maintaining the essential functional elements of the RY sequence and practice. The outcomes of this feasibility study will be used to inform the design of a future larger, randomized, controlled trial to investigate the efficacy of a RY or other yoga style intervention for self-management of FM-related symptoms.

Conflict of Interest

All authors declare they have no competing interests.

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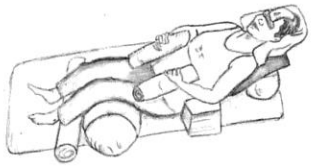
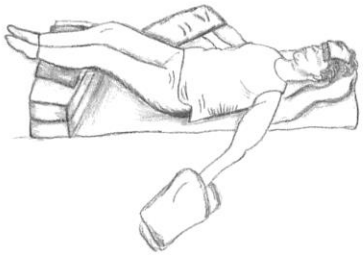
Table 1. Inclusion and Exclusion Criteria and Rationale

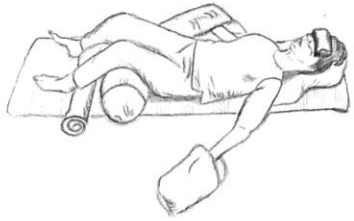
Inclusion Criteria	Rationale
Adults between the ages of 21 to 75	A diagnosis of fibromyalgia (FM) is not common in individuals under 21 years. Individuals are generally diagnosed later in life as FM symptoms worsen. FM increases with age, peaking in individuals between 70 to 79 years of age.[3] Individuals over 75 years of age are not seen in large numbers in the clinic population and show increased numbers of comorbidities that may have confounded the results of this feasibility study.
Diagnosis of FM by a physician (confirmation by physician or by self-report of name of diagnosing physician and years since diagnosis)	Only those individuals who had been diagnosed by a physician were included to establish a confirmed diagnostic baseline for the study.
Stable non-steroidal treatment regimen for 3 months or longer prior to the study period start date	Without a stable treatment regimen (i.e., no expected changes in medication and/or dosage during the intervention period), it would not be possible to determine if any effects on pain, sleep, stress, and health-related quality of life were the result of other treatments or the restorative yoga intervention being evaluated.
English speaking/writing	This feasibility study did not have the resources necessary to evaluate and accommodate non-English speaking/writing participants.

Exclusion Criteria	Rationale
Any physical limitation that prevents the person from doing the required RY postures (e.g., spondylolisthesis or spondylolysis, herniated disc disease)	Although many poses can be modified, all participants must be able to do some form of each posture to induce the functional response being sought; numbers of those excluded for this reason were tracked and considered a part of the feasibility calculations for this study.
Currently pregnant	Many yoga poses are not safe for pregnant women, and hormones are thought to play a role in the mechanisms of FM; therefore, the hormones present during pregnancy could potentially alter outcomes.
Current diagnosis or history of diagnosis of bipolar disorder or schizophrenia	Yoga mindfulness practices may increase the potential for a negative psychological event and thus require instructors skilled in the treatment of these disorders.
Current use of steroids	Inflammation is suggested to be involved in the mechanism of FM. By reducing inflammation in the body, the use of steroids has the potential to alter the outcomes for pain and sleep, confounding the results of this study.
Mindfulness or yoga practice 2 or more times per week for 6 months or more within the past 3 years	Recent or current mindfulness or yoga practice may confound the study findings.

Table 2. Restorative Yoga Sequence and Instructions

Component	Yoga Practice/Posture	Timing	Other Instructions
	Take pulse and respiration rate	~ 2 min.	
Centering	Seated in a chair	~ 2 min.	Instructor cues study participants to let go of all thoughts and activities from the day and bring their focus to the room. Next, bring their focus to their body; notice how they feel seated in the chair. Finally, connect with their breath, inhaling in through the nose, expanding their stomach toward the front of the room; then exhale, drawing the navel toward the spine (repeat the breath one more time and transition without pause into breath awareness).
Breath Awareness	Seated in a chair	~ 3 min.	12 counted breaths with a prolonged exhale. Instructor cues the counted breath: Inhale 1, 2. Exhale 1, 2, 3 (with each count representing 2 seconds).
Mindfulness (Directed Attention)	Seated in a chair	~ 6 min.	Twice for each identified body part, alternating from right to left side: foot, ankle, knee, hip, hand, elbow, shoulder. Instructor cues study participants to take their breath and focus into each body part as instructed: Inhale into the [body part] for 1, 2. Exhale 1, 2, 3. Inhale [right foot] for 1, 2. Exhale 1, 2, 3. Inhale into the [body part] for 1, 2. Exhale 1, 2, 3. Inhale [left foot] 1, 2. Exhale 1, 2, 3 (with each count representing 2 seconds).
	Transition	~ 3 min.	

Component	Yoga Practice/Posture	Timing	Other Instructions
Restorative Yoga Sequence	1) Supported reclining pose 	15 min. Timed with stopwatch	Instructor cues study participants to focus on their breath. "Inhale and exhale through your nose. On exhale, repeat the sound 'A-U-M,' or the word 'One' or a word or phrase that is meaningful to you." Instructor also cues the study participants to notice any thoughts they become conscious of, acknowledge the thoughts without attaching meaning or judgment to the thoughts, and then let the thought drift off by returning their focus to their breath. Repeat instructions during restorative posture transitions.
	Transition	~ 2 min.	
	2) Supported bound-angle pose 	15 min. Timed with stopwatch	
	Transition	~ 2 min.	
	3) Instant Maui 	10 min.	
	Transition	~ 3 min.	

Component	Yoga Practice/Posture	Timing	Other Instructions
	4a and 4b) Forward bend at a table  	5 min. left; 5 min. right (10 min. total) Timed with stopwatch	Study participants have heads turned to the right and then to the left (5 minutes on each side). The instructor cues turn.
	Transition	~ 3 min.	
	5) Basic relaxation pose with bolster 	12 min. Timed with stopwatch	

Component	Yoga Practice/Posture	Timing	Other Instructions
	Modified nadi shodhana (remain in savasana)	3 min. Timed with stopwatch	Modified nadi shodhana is done without using the hands to valve the nostrils. The instructor cues the study participants to inhale through the left nostril and exhale through the right nostril and then inhale through the right nostril and exhale through the left nostril. The instructions are repeated for 3 minutes, ending on an exhale through the left nostril.
	Take pulse and respiration rate	~ 2 min.	
	Alternate posture Side lying pose 		

Table 3. Pre- and Post-intervention Semi-structured Interview Questions

Pre-Intervention Interview Questions	Post-Intervention Interview Questions
1. What are your thoughts on complementary healing approaches such as restorative yoga for persons like yourself? 2. What comes to mind when you think about having fibromyalgia? 3. What comes to mind when you think about yoga as an intervention to aid you in symptom control; about restorative yoga? 4. Have you ever practiced yoga or seen it practiced? 5. What do you think will happen during the 8-week restorative yoga study? How do think it might make you feel physically and mentally? 6. What are some of the things that might motivate you to be more active? 7. Do you think the people who are important to you support your participation in the restorative yoga study? Yes ___ No___ Explain 8. In the past, have you been able to participate in an activity that was helpful? If yes, please describe that activity.	1. Tell me about your experiences with the restorative yoga sessions. 2. Tell me about your motivation level throughout the 8 weeks of restorative yoga sessions. 3. Did you experience any barriers to continuing in the study during the restorative yoga sessions? If yes, what were these? 4. What symptoms, if any, did you experience following the restorative yoga sessions? 5. What did you enjoy most about the restorative yoga sessions? What did you enjoy the least? 6. Did your initial impression of restorative yoga change over the course of the 8 weeks of restorative yoga sessions? 7. What future plans do you have related to restorative yoga? 8. If you had the opportunity, would you recommend restorative yoga to others with fibromyalgia?

Table 4. Weekly and 1-month Follow-up Telephone Call Questions

Weekly questions

- How are you today?
- Are you having any problems completing the daily practice log or sleep diary?
- Are you having any difficulties with the two weekly classes?
- Are you having any difficulties with the home yoga practice?
- Have you had any changes in your medications?
- Do you have any questions or concerns?

1-**month follow-up questions**

- Are you still practicing restorative yoga?
  - If yes, how many times per week?
  - If yes, can you share with me what motivates you to continue your home restorative yoga practice?
  - If no, can you share with me the reasons you decided not to continue your restorative yoga home practice?

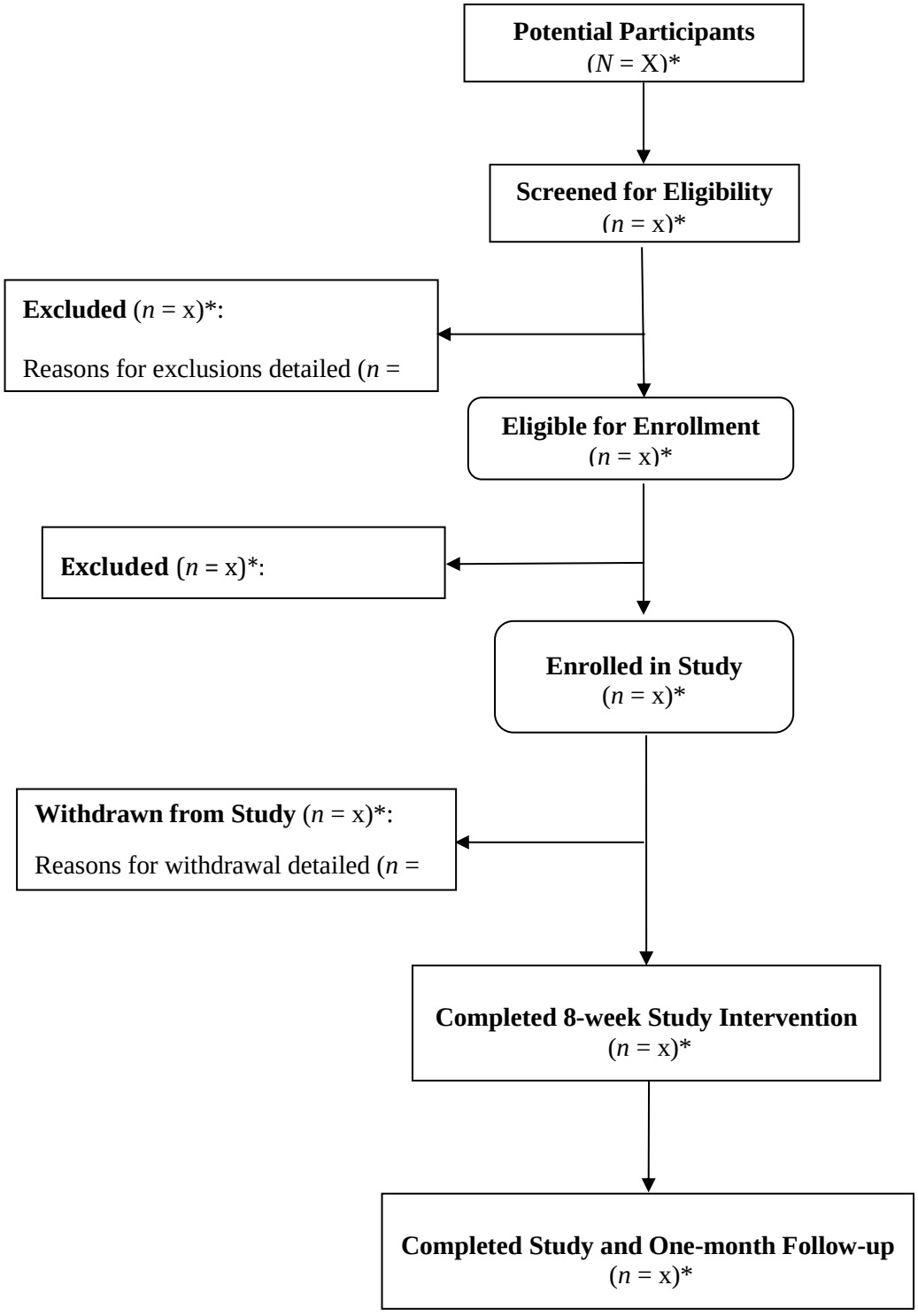


Figure 1. Participant Study Flow adapted for a single-arm study from the CONSORT statement extension for nonpharmacologic treatment.

*****Study flow shown is according to the study design. Number of participants will replace 'x' when results are reported.

CHAPTER FOUR: RESULTS

Manuscript Three

Restorative Yoga for Symptom Management in Fibromyalgia:

Results of an 8-week Intervention

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Abstract

Objective: The objective of this study was to determine the feasibility of an 8-week restorative yoga intervention and its effects on fibromyalgia-related symptoms of chronic widespread pain, sleep disturbance, stiffness, and fatigue, which decrease health-related quality of life for those diagnosed with fibromyalgia.

Methods: In a mixed methods, single-arm, feasibility study, participants completed pre- and post-intervention semi-structured interviews and self-report assessments at baseline, weeks 4 and 8, and a 1-month follow-up. Quantitative findings were compared with qualitative findings to corroborate and explain outcomes related to the restorative yoga intervention feasibility study.

Results: Rates for recruitment, retention, and adherence were consistent with those of other yoga interventions conducted for persons with fibromyalgia: recruitment 57.14%; retention 75%; adherence to group class attendance 87.5%; and adherence to home practice 93.33%. The restorative yoga intervention required a higher than average number of staff members and resources for the group classes as compared with other yoga styles. A ratio of 1:2 yoga instructor to participants was required to complete the five-posture sequence in 90 minutes as compared with a ratio of 1-2:10-25 yoga instructors to study participants reported in other yoga interventions for persons with fibromyalgia. Statistically significant trends and minimal clinically important differences were found from baseline to week 8 in the Revised Fibromyalgia Impact Questionnaire total score ($p = 0.011$; 18.51%), the Pain Numeric Rating Scale for the subscales pain now ($p = 0.041$; 36.36%) and average pain over the past week ($p = 0.040$; 19.61%), the

General Sleep Disturbance Scale total score (p = 0.038; 17.40%), and the Pittsburgh Sleep Quality Index total score (p = 0.020; 27.06%).

Conclusion: Although the findings do not support the feasibility of delivery of restorative yoga in a five-posture, 90-minute group class format for persons with fibromyalgia, the study findings support the need for further investigation of a home practice format of restorative yoga. A longitudinal, randomized, controlled trial of a home practice format restorative yoga intervention to establish intervention efficacy and symptom-self management potential for those with fibromyalgia is recommended.

KEY WORDS: Fibromyalgia, restorative yoga, yoga, relaxation response, mind-body therapies, mindfulness, sleep, pain, health-related quality of life, symptom self-management

Introduction

Fibromyalgia (FM) occurs in an estimated 2.5% to 7.9% of the adults in the United States, but recent findings indicate this chronic disease may be underdiagnosed [1-4]. Recognized as one of the leading and most difficult chronic pain disorders to diagnosis and treat, FM has no known cure [5,6]. Characterized by the hallmark symptom of chronic widespread pain and associated symptoms of sleep disturbance, fatigue, morning stiffness, anxiety, depressed mood, and impaired cognitive function, FM affects the individual's ability to engage in normal daily activities, leading to an overall decrease in functional status and diminished health-related quality of life (HQoL) [7-9].

The etiology and pathophysiology of FM remains unclear; however, dysregulation of the central nervous system, changes in the peripheral nervous system, and altered immune and neuroendocrine system functions have been implicated as causative factors in the symptom cluster experienced by those with FM [6,10-14]. Chronic stress-induced dysregulation in hypothalamic-pituitary-adrenal axis function may drive the neuroinflammation thought to be responsible for the chronic pain, pain amplification, and altered pain processing found in FM [15,16]. A 2013 study [17] of females diagnosed with FM found that the excessive sympathetic nervous system innervation caused by chronic stress was linked to decreased blood flow, ischemia changes, and pain in the palmar glabrous tissue. This finding suggests a link between chronic stress and the pain and deep muscular fatigue experienced by those with FM and posits a physiological mechanism from which these symptoms may arise [17].

The physical, emotional, psychological, and social aspects of each individual's life coalesce and manifest as a wide range of highly personalized symptom experiences

among those with FM [4,7,18]. Disrupted sleep cycles, reported as one of the most bothersome FM-related symptoms [19-22], cause individuals to wake up feeling unrefreshed [23] and have been correlated with increases in perceived severity of FM-related pain, fatigue, and depressed mood [23-29]. A 2014 study [30] found that the strongest predictor of new onset widespread pain in older adults was non-restorative sleep but that a return to a restorative sleep pattern resulted in resolution of the widespread pain. Further, sleep deprived healthy subjects have been shown to exhibit symptoms similar to those found in FM, including decreased pain tolerance [24,28,31,32]. The bidirectional relationship between sleep disturbance and pain fosters a continuation of the vicious cycle, ultimately resulting in a decreased HQoL for those persons diagnosed with FM.

Chronic pain sufferers score lower on measures of HQoL than those diagnosed with other chronic diseases, with the exception of cancer [33]. Disease impact on psychological, physical, and social aspects of the lives of those with FM impairs daily function and diminishes HQoL [34-37]. These functional impairments also may lead to changes in work status, declining mental health, and deterioration of social and personal relationships [9]. Studies suggest non-pharmacologic therapies may increase functional status and self-efficacy in these individuals [9,38-40]. In addition, modest symptom relief and undesirable side effects associated with drugs used to treat FM [41-43] cause those diagnosed with FM to seek out complementary health-enhancing therapies such as yoga at a higher rate than other chronic disease populations [44-46].

Rheumatologists and other FM experts recommend a multidisciplinary and multimodal approach to symptom management for persons diagnosed with FM [47-49].

Complementary mindfulness-based movement practices such as yoga show promise as a part of this multimodal approach [50]. Restorative yoga (RY) is a gentle, health-enhancing style of yoga that may be especially well suited for the management of FM-related symptoms. Unlike RY, some forms of exercise and styles of yoga are inappropriate for persons with FM because of their decreased strength [51,52] and aerobic capacity [53] and can result in exercise-induced pain that furthers functional decline [54,55]. RY minimizes muscular and aerobic demands while providing an opportunity for the reintegration of mind, body, and breath connection that is often disrupted in chronic pain conditions. The environment, passive attitude toward thoughts, breath techniques, and supine and inverted postures used during a RY practice session decrease brain arousal [56] and promote parasympathetic dominance [57]. Decreased rumination, increased coping skills and self-efficacy, improved sleep quality, and an overall improvement in HQoL have been reported in RY intervention studies for persons experiencing cancer-related pain, fatigue, and sleep disturbances and in women experiencing menopausal-related sleep disturbances [58-60].

To date, few studies using a yoga intervention in individuals diagnosed with FM have been published [50,61]. Six studies investigating therapeutic yoga styles for persons with FM have been identified; none have investigated RY [62-67]. Therefore, the primary aim of this study was to establish whether or not an 8-week RY intervention was feasible for persons diagnosed with FM. A secondary aim was to gather preliminary data on the perceived effects of RY on the FM-related symptoms of pain, sleep disturbance, fatigue, functional status, and HQoL.

Methods

This study was a component of an ongoing larger parent study (PI: A.G. Taylor). Details of the methods used and protocol for this component of the parent study have been published separately [68]. To review briefly, the Institutional Review Board for Health Sciences Research (IRB-HSR) at a research-intensive academic medical center in Central Virginia approved the protocol, procedures, and materials of this mixed methods, single-arm, prospective feasibility study. The Theory of Planned Behavior (TPB) [69] informed the study design and interpretation of the results. A concurrent triangulation strategy [70] was used as the mixed methods approach. The participants had physician-diagnosed FM, were between the ages of 21 and 75 years, and were being seen for medical treatment in the rheumatology clinic associated with the academic health system or lived in the surrounding geographic area. Written informed consent was obtained from all participants prior to participation in any study activities.

Recruitment and Sampling Methods

Beginning in May and ending in September of 2014, a consecutive convenience sample of 12 persons diagnosed with FM was recruited. The first 6 persons recruited participated in the June through August 8-week intervention group; the second 6 persons recruited participated in the September through November 8-week intervention group. Participants were recruited (a) by study brochures placed in the rheumatology clinic waiting area or distributed to potential participants by their physicians at the rheumatology clinic, (b) by email or letter notification of the study to a group of persons who had agreed to be contacted for FM-related studies, and (c) from persons responding to a notice on the clinical trials Web site maintained by the academic health system for

this purpose. Interested persons contacted the investigators and were screened for eligibility according to the study inclusion and exclusion criteria presented in Table 1. In accordance with the CONSORT statement guidelines [71], the study flow is shown in Figure 1.

Participant compensation was provided as part of the larger parent study at the rate of $20 per study visit. Payments were made upon completion of designated study activities at four time points during the parent study period.

Study Intervention

Participants completed one of two RY intervention sessions of an 8-week, twice weekly, 90-minute RY group class and a one-posture, 20-minute evening home practice on the five non-class days each week. A registered Yoga Alliance yoga teacher experienced in teaching yoga to persons with musculoskeletal conditions and who is a certified Relax and Renew Trainer® for restorative yoga and a registered nurse taught the 90-minute group class. Trained assistants with nursing education and research knowledge assisted during the group classes.

Prior to beginning the intervention, participants attended a 90-minute orientation session to learn about the class structure, breath/body awareness, centering, and pranayama techniques used in the group classes. The number, types, and placement of the RY props needed for their individual physical requirements were evaluated at the orientation class. Also, a demonstration of the one-posture home practice was provided. This demonstration showed the participants how to get into the home practice posture without assistance and use items in their homes as RY props. Participants were also given an opportunity to ask questions about the RY intervention.

The 8-week RY intervention commenced the week following the orientation session. Participants received weekly telephone calls to monitor for changes in treatment regimens, encourage home practice and class attendance, answer participants' questions and concerns, and monitor for overall treatment safety (i.e., adverse events [AEs]), and treatment fidelity.

A standard sequence was used during the group classes (Figure 2). Participants were encouraged to come to class early to provide seated recovery of pulse and respiration rate, which were taken immediately prior to the start and at the end of the 90-minute practice to assess achievement of the relaxation response [72]. One of the assistants (KA) was trained to monitor the yoga instructor for intervention delivery fidelity during each class. The same assistant and the yoga instructor monitored the participants for AEs. No breaches in intervention delivery or AEs occurred during the 8 weeks of group classes. Modifications that maintained the functional purpose of the postures were made as necessary to ensure the safety and comfort of participants (Table 2).

On the five non-class nights, participants were asked to practice for 20 minutes immediately prior to bedtime using a basic relaxation pose with a bolster, or the alternate side lying pose, as the RY posture. Each participant was given an eye pillow to keep for their home practice and a home practice manual that included pictures and detailed instructions for both the practice and how to get into the posture unassisted. Participants were encouraged to identify an area in their homes where they could leave the RY set up for the 8 weeks. They were instructed that this space should be conducive to an RY

practice (i.e., private, quiet, dark, and warm). Additional intervention details can be found in an earlier publication [68].

Data Collection

Baseline demographic and health history data were collected prior to beginning the study. One-on-one, audio-recorded, pre-intervention, semi-structured interviews were also conducted at the pre-intervention visit. Self-report questionnaires and daily sleep diaries and practice logs were completed during the 8-week intervention. Paper forms, logs, and questionnaires were used for data collection. Given the characteristics of a yoga intervention, blinding of the participants to the RY intervention was not possible. Also, the investigators and data analysis could not be blinded because of the single-arm design; however, all data were de-identified.

Primary outcome measures. The primary aim of this study was to determine the feasibility of an 8-week RY intervention for persons diagnosed with FM. Feasibility was assessed by a combination of the following: (a) recruitment rate, (b) retention rate, (c) class and home practice adherence rates during the 8 weeks and at the 1-month follow-up, (d) resource utilization, (e) safety, and (f) participant perceived feasibility of an RY intervention.

Secondary outcome measures. Reliable and valid secondary outcome measures were selected based on the Outcome Measures in Rheumatology (OMERACT) working group for FM [73] and the recommendations of a Delphi survey guideline for yoga research of musculoskeletal disorders [74]. Self-report questionnaires were collected at baseline and at weeks 4 and 8 and included the following: Pre and Post Treatment Expectancy Scale [75], Revised Fibromyalgia Impact Questionnaire (FIQR) [76];

Numeric Rating Scale for Pain (Pain NRS) [77]; Numeric Rating Scale for Stress (Stress NRS) [78]; Short Form 36v2™ (SF36v2™) [79,80]; Daily Stress Inventory (DSI) [81,82]; General Sleep Disturbance Scale (GSDS) [83,84]; Pittsburgh Sleep Quality Index (PSQI) [85-87]; Positive and Negative Affect Scale (PANAS) [88]; and Patient Global Impression of Change Scale (PGIC) [89-91]. In addition, the participants kept daily sleep diaries to capture duration and quality of sleep and daily practice logs to document minutes of RY practice per day. Study population characteristics were obtained using demographic and health history forms. The authors have provided details of the outcome measures in an earlier publication [68].

Statistical Analysis

Data were analyzed using SPSS v. 22. Descriptive statistics for continuous variables were analyzed for means and standard deviations while categorical variables were analyzed using frequency and percent calculations. Retention, recruitment, and adherence rates were entered into an Excel spreadsheet, and ratios, means, and standard deviations were calculated.

Given the small sample size, the nonparametric Wilcoxon signed-rank test was used to compare the symptom-related outcomes that were measured at 3 time points during the 8-week RY intervention (baseline to week 4, week 4 to week 8, and baseline to week 8). Individual scores and overall group means were evaluated for statistically and clinically meaningful trends. A p-value of ≤ 0.05 was considered a statistically meaningful trend. Clinically meaningful trends were defined as minimal clinically important differences (MCIDs) in mean scores from baseline to week 8 for the following outcome measures: (a) Total FIQR $\geq$ 14% [92]; (b) NRS Pain $\geq$ 10% [93]; (c) SF36v2 $\geq$

12% [94]; (d) Sleep measures (PSQI and GSDS) ≥ 6% [95]; and (e) the selection of PGIC categories “moderately better,” “better,” or “a great deal better” at week 4 and/or week 8 [89,91]. The nonparametric Spearman’s ranked correlation was conducted to explore potential correlations between those outcome measures showing statistically meaningful trends and mean minutes per day of RY practices.

Qualitative Explication

A hermeneutic phenomenological methodology was used as the qualitative approach for this study. Pre- and post-intervention audio-recorded interviews were transcribed. The transcriptions were then checked for accuracy against the original interview recordings. Using NVivo version 10, textual explication of interview transcripts was completed. Data were extracted using primary (open) and secondary (theoretical) coding. Theoretical coding was done according to the constructs of the TPB [96]. A reflective diary was maintained to support investigator neutrality [97]. An iterative approach was used to identify codes that were grouped into meaning units. Upon further explication, meaning units were grouped into themes. Themes identified were compared against quantitative feasibility findings to corroborate, explain, and expand on feasibility findings and to provide contextual meaning to the participants’ experiences of participating in an 8-week RY intervention as a person living with FM.

Mixed Methods Approach

Concurrent triangulation [70] was used as the mixed methods approach for this study. Quantitative and qualitative data were collected concurrently into separate databases and the findings compared to corroborate and to cross-validate the study findings and to explain and expand on the meaning of quantitative feasibility findings

Results

Sample

The study sample was composed of 12 non-Hispanic, mostly White, married women. Over one-half of the participants had some level of post-secondary education (college). Data on comorbidities were also collected at baseline. Eight of the nine (88.89%) participants reported they had been diagnosed with another disease or disorder in addition to their FM diagnosis. Group baseline demographic characteristics are presented in Table 3.

Recruitment, Retention, and Adherence

A recruitment rate of 57.14% was realized for the study. The retention rate for the study was 75%. All participants completing the 8-week RY intervention also completed the 1-month follow-up telephone call. The mean number of group classes attended was 14.00 ± 1.33 (87.5%) out of a total of 16 possible group classes per participant. The mean adherence rate for home practice was 93.33%, with a mean of 37.33 ± 3.20 home practice sessions completed out of the potential 40 sessions per participant.

Reasons for not attending the group class sessions included illness, FM-related symptoms, and feeling stressed and tired, with the latter being the primary reason for missing a home practice. Over the course of the 8 weeks, two participants reported (one time each) FM-related pain as the reason for missing a home practice.

At the 1-month follow-up, five of the nine participants maintained a RY home practice ranging between 3 nights per week to every evening, with a mean of 4.4 ±1.64 nights each week. One participant had engaged in home practice approximately seven times at the 1-month follow-up and another had practiced two times a week for the first

two weeks and then not at all the second two weeks. Both of these individuals stated that their home environment was not conducive to RY practice because of family members currently living with them, but that they still intended to practice RY when they were able. One participant had not practiced RY since the final class of the intervention, but said she still used the RY breathing to help her with stress and to fall asleep more quickly. Another participant stated RY did not make "a big enough difference" in her symptoms to continue.

Safety and Confidentiality

No AEs or breaches of confidentiality were reported during this study. The participants were able to complete the required class components without experiencing untoward study-related physical or psychological events. Four participants developed upper respiratory infections unrelated to the RY intervention during the 8 weeks.

Resource Utilization

This study required space suitable for RY practice, which for this study was a large carpeted room without windows that was equipped with a thermostatic control allowing adjustments for warmth. The space was purposefully chosen for its location near an elevator that gave participants direct access from and to the parking garage. However, even with the decreased elevator traffic because of the class time (e.g., 5:30 P.M.), participants reported that noise associated with elevator activity during the RY group classes was a distraction.

Each participant's RY setup required two to six yoga mats, six to seven towels, one to two blankets as cover, three to five rolled blankets as props, two eye pillows (one was for the home practice sessions), one forehead pillow, three to four rectangular

bolsters, one square bolster, one round bolster, two sandbags, and four to six blocks. Cost associated with these supplies for each participant ranged between $311 and $445, depending upon individual physical and comfort requirements. Two yoga mats were initially placed on the carpeted floor for the participants; however, five participants required additional padding of up to six yoga mats with a blanket before pressure points were relieved. In addition, extra soft towels and blankets were used to adjust alignment and cushion sensitive body parts. Overall, the group required a greater than average number of RY props to achieve an acceptable level of comfort compared with the number of props used in group community classes.

One yoga instructor and 2-3 assistants were present at every RY 90-minute group class, except as noted below. The yoga instructor and assistants assisted the same participants over the course of the 8-week intervention. The number of staff required to transition participants between postures while meeting the 90-minute format was a ratio of 1 assistant to 2 participants. A total of 15 minutes was incorporated into the study design to allow for the four posture transitions. Three of the participants required assistance getting up from the floor during posture transitions. One class session of each study session was conducted with the yoga teacher and only one class assistant, increasing the assistant to participant ratio to 1:3. Posture transition times increased accordingly and the class time was extended by 5-7 minutes. Participants were generally limited in their ability to shift and re-position themselves when reclining; therefore, only two of the nine participants were able to adjust themselves to reach an acceptable comfort level without substantial assistance from the yoga teacher and class assistants.

At the completion of the 8-week intervention, participants were given a manual detailing the 90-minute RY practice for their home use. At the 1-month follow-up telephone call, one participant stated she had tried to complete the 90-minute practice at home independent of assistance but that it was too difficult to transition between the postures without assistance. Two said they had thought about trying the 90-minute practice but felt they would be unable to do it without the assistance and thus had never attempted it. During the intervention and at the 1-month follow-up telephone call, participants reported that they continued to perform successfully the 20-minute home practice of one posture without assistance.

Study Fidelity

Study fidelity was maintained throughout the study design, training, and intervention as described previously [68]. Study logs and checklists were maintained by the study team to document study fidelity. Classes and postures were delivered according to the RY manual developed by the first author. In addition, the yoga instructor used the same script for each class and included the same oral instructions, phrasing these as close to identical for every class as possible. One of the assistants (KA) with training in research fidelity observed each class and reported no deviations from the script or other fidelity concerns during the 36 RY group classes.

Relaxation Response

Heart rate and respiratory rate per minute pre- and post-RY group class were assessed as a physiologic measure for successfully invoking the relaxation response [72]. Participants' mean decline in heart rate per minute from pre-class to post-class during the 8-week intervention was 10.34 ± 2.35. Decline of participants' mean respiratory rates per

minute was 2.35 ± 1.29. Overall, participants consistently achieved relaxation, as reflected by changes in their heart and respiratory rates, consistent with physiologic indicators supporting successful attainment of the relaxation response [72].

Participants' Perceived Effects of RY on FM-related Symptoms

Self-report questionnaires from week 1 compared with week 8 showed statistically meaningful trends and MCIDs for means of (a) the Pain NRS subscales average pain in the past week and present pain, (b) the GSDS subscales for sleep quality and daytime function and GSDS total score, (c) PSQI total score, and (d) FIQR total score (Table 4). Using the PGIC, five of the nine participants reported that they perceived a "moderately better, and a slight but noticeable change" in their FM symptoms attributable to RY. A significant correlation was found between mean practice minutes each day and FIQR total score change from baseline to week 8 ($r = 0.700$; $p = 0.036$), and a significant inverse correlation was found between mean practice minutes each day and PSQI total score change from baseline to week 8 ($r = -0.693$; $p = 0.039$). Correlations for GSDS total score and Pain NRS subscales (present pain and average pain) were not significant. An illustration of change in FIQR total score from baseline to week 8 by mean practice minutes each day is shown in Figure 3.

Qualitative Findings

Meaning units pertinent to the participants' perceptions of feasibility and acceptability were explicated from participants' interviews. Accordingly, themes were developed related to feasibility and acceptability using the TPB as a heuristic framework for data interpretation. Quotes from participants are provided as supporting data for theme development.

Attitudes toward behavior.

"In the beginning I did not think it was going to work" was a theme that quickly emerged from the interview data. All participants revealed at the post-intervention interview that prior to the intervention they did not believe RY would have any effect on their FM-related symptoms. Several participants stated that between weeks 2 and 4 they began to experience effects from the RY and an associated change in their attitudes toward it. "In the beginning I did not think it was going to work . . . but that was like the first or second session . . . 8 weeks did make a huge difference in how I feel and what I'm able to do." Words used most often to describe participants' attitudes toward the RY intervention were "great," "useful," "helpful," "liked," "wonderful," "nice," and "positive." One participant stated the RY intervention gave her "hope." She exclaimed, "I would shout it from the rooftops because I really, really am pleased with the class." However, two of the participants did not have the same experiences as the other seven. At the post-intervention interviews, these individuals shared the following, "Overall I liked it and I thought it was at least a little helpful" and "I don't know that I was ever totally sold . . . nothing else has worked in 3 years . . . there was nothing that gave me an instant gratification." At the 1-month follow-up telephone interview, the same two participants stated the difference in how they felt was too insignificant for them to continue to practice RY.

"I think the practice itself was nice. It did help me relax. It helped me get to sleep better." A common theme evidenced in the participants' interviews was the presence of positive changes in FM-related symptom outcomes that some participants attributed to the RY intervention. The ability to relax during the practice was the most

commonly identified benefit of the restorative practice, with the participants reporting it to be a key factor in releasing muscle tension and letting go of obsessive or anxiety producing thoughts that made it difficult to go to sleep. When asked what it was about the RY practice sessions that helped with relaxation, one participant responded, "I was very shocked that it helped me as much as it did as far as my sleep patterns . . . the yoga, it helped me relax and use that breathing [counted breath associated with the RY practice] and use it to my advantage as far as getting myself to relax before I go to bed." Another said, "When I breathe and tell myself . . . as I'm doing so, 'let it go, let it go,' I would feel . . . energized and relaxed all at the same time."

The participants stated learning to breathe was an important part of the RY intervention. One participant noted, "I said, 'Oh breathing, breathing's not going to help.' But it does. It really does. You see a tremendous difference." Another participant added "I can just do the breathing any time," confirming that the participants viewed the breath component of the RY practice as a tool to calm the mind and enable relaxation, shortening the time it took them to fall asleep. One of the women noted, "I've tried the balancing breath to try and go to sleep. That helps me because it gives me a little small thing to focus on. It takes away from everything that's going on in my mind and helps calm me down so I can fall asleep."

On a day she was feeling especially unwell, one participant stated that she had pushed herself to show up for the class, remarking, "I knew that once I got here and I started the relaxation poses and the breathing that I would start to feel better." The majority of the participants identified the relaxation that they were able to achieve as a

primary motivator for attending the RY classes, adhering to home practice, and for their stated intention to continue the RY practice after the end of the study period.

Perceived behavioral control.

"It's just a good feeling to think that I'm not doing nothing." Eight of the nine participants expressed that the RY intervention provided them with a sense of control by adding another coping mechanism for management of their FM-related symptoms. Following is one participant's perspective of the 8-week RY intervention and its effect on her experience of living with FM.

> People with fibro and CFS [chronic fatigue syndrome] are sort of left in this awful limbo where you try lots of different docs, lots of different therapies, and none of them work. Then you're stuck . . . you're in a place where you really don't have a realistic hope of getting better and you're depressed about how limited your life has become and full of regret. You never have a day where you feel as though you've made progress or that you've done something to improve your lot. So I think this [RY intervention] had that advantage, that benefit for me also, that I felt as though I were doing something positive and it wasn't going to hurt me.

Other participants conveyed similar messages, with one woman noting, "It's a tool you can use to your advantage." Another stated, "It helps me relax. It may not help with the pain, but it did seem to help with the sleep, which is a big component . . . that's why I'm continuing with it." Another related, "I'd be kind of silly to stop, especially when I'm feeling better."

Actual behavioral control.

"They were very comfortable positions, easy enough for fibro people to do." vs. "That last pose was the hardest one." While most of the participants said the RY postures were comfortable, two participants found the positions uncomfortable. One developed pressure points that could not be relieved effectively using the class RY props. She required additional, softer padding (a yoga blanket). She attributed her discomfort to the unpredictable nature of her FM-related symptoms, "The worst part was . . . never having consistent symptoms . . . that you could address . . . that was disappointing for me." Another reported she was unable to comfortably maintain the RY posture and became more tense and anxious as the practice progressed. She stated, "The last pose was usually the hardest one and I don't know if it's because I can't sit for a long time. I can't stand for a long time . . . it started to make me wonder if that's why I sleep so badly." Others found the adjustments of the RY props were sufficient to make them comfortable, as evidenced by one participant's comment: "In the beginning I was leery because I can't lay [*sic*] on a flat floor . . . she [pointing to the assistant] would change things around and was very attentive to what each person needs. . . . I think that was real important." Although class posture transitions required adjustments for comfort, the majority of the participants indicated these adjustments were sufficient to make the postures comfortable, with one participant noting, "Once I would get into the positions, and they were very comfortable positions, easy enough for us fibro people to do."

Getting up and down from the chair to the floor presented a challenge for several of the participants, but all were able to make the transition with assistance. Two of the participants reported physical improvements that they attributed to the 8-week RY

intervention. One noted, "I had a problem getting up and down and [the instructor] had been helping me. Last night I told her I can do this by myself. . . . I look a little silly, but I can get up by myself." Another participant reported that the discomfort caused by a recent injury had resolved by the end of the 8 weeks, noting, "I injured my knee last spring . . . so going sideways was hard on my knee . . . [we] pushed the bolster up [for more support] . . . by the end I was able to spread my knees without all that discomfort."

"What does quiet mean to you?" Achieving relaxation during the RY classes and home practice was challenging for several of the participants because of distractions. Some expressed that they had difficulty letting go of external stimuli to bring their attention inward. In addition, the RY classroom location was near elevators for ease of access but proved to be a source of distraction for some because of talking by those using the elevators. Over time, most of the participants said they were able use their breath as a focal point and to "let go" of the external distractions. A few continued to experience the noise at the elevator as a barrier to achieving relaxation during the RY practice for the entirety of the 8 weeks, "I wanted to put a sign up at the elevator [asking] 'What does quiet mean to you?'" related one of the participants, who was aware that the study team had signs posted outside the study room that read "Quiet Please—Study in Progress."

Four of the participants said they experienced noise disruption at home—noises made by other persons or animals in their households. One participant in particular did not have a room in her home suitable for her RY practice. She shared that in the bedroom her husband snored and in the living room her daughter and the daughter's boyfriend would walk in and out of the room during her RY practice. However, the remaining participants reported they were able to come up with solutions at home to create a quiet

space such as using headphones or repurposing a space for RY practice area. One participant explained, “I have a walk-in closet where I leave everything set up. And nobody goes in there. It’s mine.”

Subjective norm.

“Get in the car . . . I’m taking you!” All of participants reported they perceived some level of support and encouragement from family members or others. Two characterized the support as more of a lack of interference than active support. For example, one woman characterized her husband as a “lazy supporter.” When asked to elaborate, she stated, “He's going to tell me he thinks it's a good thing but he's not going to be the person who says, ‘Hey, you got to get this done.’ ” This was echoed by another participant, who said, “Everybody was happy for me . . . [but] all my same obligations were my same obligations . . . they just didn’t interfere, which seems like the standard for anything I’m up to.” Alternatively, several participants said they were actively encouraged to engage in the RY practice. One participant had an outpatient procedure done during the 8-week program that prevented her from getting up and down from the floor. Her husband modified her bed to enable her to continue her home RY practices. Another participant’s son drove her to almost every group class and, on a day that she was contemplating skipping the class, she related that he told her, “Get in the car . . . I’m taking you!”

Participant-identified barriers to the RY practice.

The most often cited barrier that was encountered during the 8-week RY intervention was the distance traveled to and from the group class location. One participant missed a class because of a traffic accident. Another found that the travel

distances prevented her from going home for the 2-hour period between the end of her workday and the beginning of the group class. She expressed, "Sometimes it was really hard for me . . . I'd be waiting in town for 2 hours and I just thought, 'Oh, I want to go home so bad.'" The majority reported that following the RY class they experienced a calmer attitude on the drive home but that the travel time and distance negated some of the benefits of the class practice. One participant noted, "I live 45 minutes away. So, after being all relaxed and calm and good, I had to drive all the way home." Another related, "I wouldn't of came [*sic*] back if I didn't think [it was doing something] . . . me driving 40 miles twice a week." Two of the participants came up with strategies to help them cope with the challenges introduced by the travel distance, one by having a family member drive her to and from the study and the second by doing a 20-minute practice immediately prior to her bedtime in addition to that day's 90-minute RY class.

Discussion

Feasibility is determined by participant satisfaction, continued behavioral adherence, appropriateness and practicality of the intervention for the limitations of the population under investigation, and by actual rates of recruitment, retention, and adherence [98]. In this study, the authors found rates of recruitment (57.14%), adherence (class 87.5%; home practice 93.33%), and retention (75%) were consistent with those reported in other FM and yoga studies investigating feasibility of a yoga intervention for persons diagnosed with FM [62-67]. Recruitment rates of 82.8% [63] and 38.6% [64], class adherence rates of 87.5% [63] and 86% [64], and a mean attrition rate of 25.23% ± 10.64% [62-66] were reported in other studies as positive findings for feasibility of the yoga style investigated. Only one of those studies [66] included qualitative data providing

participant acceptability data, and none addressed feasibility of the intervention outside of the research setting.

The ability to meet the highly individualized comfort needs of those with FM, including limitations in mobility when in reclining and supine positions, difficulty moving from a lying to standing position, and staffing ratios required for a group class, do not support feasibility of an RY intervention in a group class format. As a practical matter, community yoga studios offering RY classes most likely would not be able to meet the staffing or prop requirements of a group similar to the participants in this study. In addition, while some studios may offer private or semi-private RY sessions, these sessions are not covered by any form of insurance and those with FM have high rates of unemployment [99], making payment for private sessions challenging.

Consistent with reports of increased health care costs and resource use associated with a diagnosis of FM [100,101], study findings show a high average cost and resource use for this RY intervention. Costs associated with the purchase of RY equipment available to this study (> $4,000), although high as an initial expenditure, can be amortized over the useful life of the RY equipment, making this initial cash outlay an investment toward future RY intervention classes for other populations, too. However, the requirements for up to six yoga mats with additional extra padding and the ratio instructor to participant of 1:2 is much higher than the normal one to two yoga mats with no additional padding provided in community yoga classes and the 1-2 yoga instructors for class sizes ranging between 11 to 22 persons reported by other FM/yoga studies [63-65]. This higher ratio is consistent with that of the traditional delivery of individualized yoga therapy, suggesting that persons with FM may be better suited to individualized RY

therapy sessions as opposed to a group RY delivery design. Also, the findings suggest that the home practice component of the intervention was feasible for most of the participants during the 8 weeks. That is, the participants were able to perform the one posture home practice independently as designed and were able to identify RY props from items found in their homes so that no cost was incurred on their part.

Although the investigators did not measure body mass index (BMI) in this study, participants were much less mobile in reclined positions than had been anticipated, and the participants' excessive body mass became a consideration for the safety of the instructor and assistants as they assisted participants during posture transitions. Once the issue was identified, a change was made in the intervention sequence to minimize the risk of injury to the yoga instructor and assistants. Past study findings show that physical function declines as BMI increases in persons with FM, and this decreased physical function increases the report of pain, creating a cycle that further limits physical function and results in a higher BMI [102]. Additionally, the high levels of disease impact on function and the high body mass of the participants may have had some effect on the findings of limited mobility. A FIQR total score of ≥ 59 indicates severe disease impact on daily function. Our participants had baseline FIQR total scores ranging from 51.67 to 72.5, with a mean of 60.98 ± 6.55.

It was anticipated that, as the study progressed, participants would be able to transition between postures with less assistance. While some participants made progress in independently transitioning between the postures, the progress was not substantial. At the 1-month follow-up, the inability to transition easily between postures was given as a

reason for not attempting the 90-minute practice and, in the case of the one participant who did attempt it at home, was given as the reason for not continuing.

The TPB posits that attitude toward behavior is, in part, associated with perceived outcomes of participating in the behavior and that intention to participate in a behavior increases as perceived outcomes become more positive [96]. The more positive the outcomes experienced by the participants, the more positive their attitude and intention to act was toward the RY intervention. Participants who verbalized the highest satisfaction with their RY experiences had the highest adherence rates for both class and home practice and showed the largest change in FIQR total scores and PGIC response at week 8. Likewise, the more support and encouragement that the participants received from their social support systems, the higher their adherence rates. The two participants who reported the least difference in symptom change reported the least family support, were less positive about the RY intervention, missed the most days of both the group class sessions and the home practice, and reported the least mean minutes of daily practice during the 8 weeks. The more control and ability to cope with or to manage the FM-related symptoms that the participants reported, the higher the number of minutes of daily practice and the greater the number of days each week that the individuals continued to practice RY at the 1-month follow-up. Those women who spent on average more minutes each day in RY practice also reported a significant improvement in HQoL.

The heterogeneity of FM symptoms makes symptom management challenging for health care providers [103]. The perceived benefits of RY on FM-related symptoms were inconsistent among the participants. Although two participants stated the benefit or improvement in symptoms was not ‘big enough’ to motivate them to continue the RY

practice, all participants said they would recommend RY to others like themselves and that those with FM should be offered the opportunity to experience RY.

Studies of yoga interventions tend to be self-selecting and by virtue of this may introduce bias into the study. In addition, the sample size was small for this study and there was no control group. However, the purpose of this study was not to provide a basis for generalizing the findings or to measure treatment efficacy, but to determine whether or not an 8-week RY intervention could be feasible for persons diagnosed with FM. Some researchers suggest that the use of a randomized, controlled trial in a feasibility study is an unnecessary expenditure of limited research resources and that one-group studies should be considered an acceptable design option [98]. In consideration of available resources, this feasibility study was designed as a one-group study.

The high level of attention and assistance required to implement a 90-minute, five-posture RY class might have introduced confounding effects on the study outcomes. Group-based exercise intervention studies of women with FM have found that the psychosocial support inherent in the group-based design may have an impact on FM-related symptom severity [104]. Although participants were asked not to talk during the RY class practice, it was not possible to prevent the group from talking to each other as they came into and exited from the class. Thus, we were unable to account for a potential group effect completely in this study.

Conclusions

The findings of this study suggest that the benefits derived from an RY practice warrant further investigation. Trends indicating a perceived improvement in FM-related function and decreases in sleep disturbances and some measures of pain were identified.

Qualitative findings were consistent with patterns identified in class attendance and home practice adherence. Qualitative and quantitative findings corroborate that those with the highest mean minutes of RY practice each day reported the strongest intention. A protocol for delivery of RY that meets the limitations of those with FM is needed. Home practices that incorporate technology for enhancing the RY home practice experience, promote long-term adherence, and quantify and verify home practice patterns are needed. The preliminary findings that the authors report support the need for future randomized controlled studies to determine the efficacy of RY for FM-related symptoms and to evaluate the potential for RY as a long-term symptom self-management strategy for persons diagnosed with FM.

Conflict of Interest

All authors declare no conflict of interest for this study.

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Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• Adults between the ages of 21 to 75 • Diagnosis of fibromyalgia by a physician (confirmation by physician or by self-report of name of diagnosing physician and year of diagnosis) • Stable non-steroidal treatment regimen for 3 months or longer prior to the study period start date • English speaking/writing	• Any physical limitation that prevents the person from doing the required restorative yoga postures (e.g., spondylolisthesis or spondylolysis, herniated disc disease) • Currently pregnant • Current diagnosis or history of diagnosis of bipolar disorder or schizophrenia • Currently using steroids • Mindfulness or yoga practice two or more times per week for 6 months or more within the past 3 years

Table 2. Modifications and General Adjustments for RY Postures

Designated Posture	Sequence Order	Complaint/limitation	Modification	Number of Participants Using Modification
Supported reclining pose	1	Falling asleep/snoring	Side lying pose	1
Supported cobblers pose	2	Falling asleep/snoring	Side lying pose	1
Forward bend at table	3	Unable to bend forward	Increase height of supporting blankets	2
Instant Maui	4	Cold/URI	Side lying pose	1
Instant Maui	4	Cold/URI	Supported elevation of the torso and head	1
Basic relaxation pose with bolster	5	Cold/URI	side lying	1
Basic relaxation pose with bolster	5	Cold/URI	Supported reclining pose	1
Supported reclining pose, supported bound-angle pose, instant Maui, basic relaxation pose with bolster	1,2,4, and 5	Pressure points from floor/mat	Add mats, blankets, or towels to pressure points until comfort was achieved	5
General (not associated with a posture)	N/A	Headache	Head wrap as demonstrated on page 91 of *Relax and Renew:Restful Yoga for Stressful Times* (Lasater, 1995 Rodmell Press, Berkley, CA)	2

Designated Posture	Sequence Order	Complaint/limitation	Modification	Number of Participants Using Modification
Supported reclining pose, supported bound-angle pose, basic relaxation pose with bolster	1, 2, and 5	Bolsters too large to fit under knees/support thighs	Create a bolster with a smaller diameter by rolling up blanket(s)	2
Supported reclining pose, supported bound-angle pose	1 and 2	Sensitive elbows	Provide extra cushioning for restorative yoga blocks with towels	2

Table 3. Demographic Characteristics and Comorbidities of Study Participants

Demographic Characteristic	Overall (*N* = 9)	
	Mean	**SD**
Age	49.56	12.04
Age Diagnosed with FM	40.11	11.51
Years Since FM Diagnosis	9.44	7.36
	n	**%**
Sex		
Female	9	100%
Race		
Black or African American	1	11.1%
White	8	88.9%
Ethnicity		
Non-Hispanic	9	100%
Years of Education		
9-12 (High)	4	44.4%
13-18+ (College)	5	55.6%
Partner Status		
Married	5	55.6%
Divorced	2	22.2%
Separated	1	11.1%
Single	1	11.1%
Living Situation		
With someone	9	100%
Comorbidities:		
Osteoarthritis*	4	44.4%
Arthritis (undefined)	1	11.1%
Degenerative disc disease	1	11.1%
Hashimoto's thyroiditis*	1	11.1%
Irritable bowel syndrome*	1	11.1%
Depression*	1	11.1%
Anxiety disorder (panic attacks)*	1	11.1%
Dystonia	1	11.1%
Lyme disease	1	11.1%

*Comorbidities occurring in combination for one or more study participants

Table 4. Fibromyalgia Symptom Means and Standard Deviations, Percent Differences in Means, and Significance of Mean Differences from Baseline to Week 8

	Means at Baseline (Std Dev)	Means at Week 4 (Std Dev)	Means at Week 8 (Std Dev)	Percent Difference in Means (Baseline to Week 4)	Percent Difference in Means (Week 4 to Week 8)	Percent Difference in Means (Baseline to Week 8)
Pain NRS						
Pain now	4.89 (1.69)	4.33 (2.60)	3.11 (1.45)	11.36%* $p = 0.798$	28.21%* $p = 0.151$	36.36%* $p = 0.041$**
Pain avg	5.67 (0.87)	5.11 (1.45)	4.56 (1.13)	9.80% $p = 0.319$	10.87%* $p = 0.394$	19.61%* $p = 0.040$**
Pain worst	7.67 (1.00)	7.11 (1.45)	6.67 (1.00)	7.25% $p = 0.260$	5.80% $p = 0.414$	13.04%* $p = 0.054$
Stress NRS^						
Stress now	3.56 (2.19)	3.33 (2.00)	4.33 (1.66)	6.46% $p = 0.732$	-30.03%* $p = 0.201$	-21.63% $p = 0.323$
FIQR Total	60.98 (6.55)	49.74 (15.21)	49.69 (7.20)	18.43%* $p = 0.038$**	0.10% $p = 0.594$	18.51%* $p = 0.011$**
DSI^						
FREQ	20.44 (5.29)	19.44 (7.14)	22.11 (8.89)	4.89% $p = 0.593$	-13.73% $p = 0.182$	-8.17% $p = 0.406$
SUM	58.89 (30.51)	53.00 (35.91)	54.22 (29.27)	10.00% $p = 0.374$	-2.30% $p = 0.767$	7.93% $p = 0.515$
AIR (SUM/FREQ)	2.76 (0.84)	2.51 (1.05)	2.36 (0.81)	9.06% $p = 0.139$	5.98% $p = 0.767$	14.49% $p = 0.110$

	Means at Baseline (Std Dev)	Means at Week 4 (Std Dev)	Means at Week 8 (Std Dev)	Percent Difference in Means (Baseline to Week 4)	Percent Difference in Means (Week 4 to Week 8)	Percent Difference in Means (Baseline to Week 8)
GSDS						
Sleep quality	4.33 (1.30)	4.17 (1.24)	3.51 (0.96)	3.70% $p = 0.767$	15.83%* $p = 0.213$	18.94%* $p = 0.155$
Daytime function	4.00 (1.63)	4.00 (1.63)	3.55 (1.30)	0.00% $p = 1.00$	11.25%* $p = 0.633$	11.25* $p = 0.633$
Sleep Medication	1.02 (0.87)	1.06 (0.87)	1.06 (0.99)	-3.92% $p = 0.581$	0.00% $p = 0.932$	-3.92% $p = 1.00$
Total	3.39 (0.79)	3.22 (0.82)	2.80 (0.43)	5.01% $p = 0.313$	13.04%* $p = 0.122$	17.40%* $p = 0.038$**
PANAS^						
Negative Affect	23.11 (7.94)	18.00 (3.91)	19.56 (7.28)	22.11% $p = 0.107$	-8.67% $p = 0.372$	15.36% $p = 0.095$
Positive Affect	21.00 (4.74)	21.56 (6.11)	23.33 (6.02)	-2.67% $p = 0.573$	-8.21% $p = 0.327$	-11.10% $p = 0.182$
SF36v2						
Physical component score	33.00 (5.61)	34.78 (4.63)	35.33 (2.78)	-5.39% $p = 0.526$	-1.58% $p = 0.779$	-7.06% $p = 0.342$
Mental component score	37.33 (7.84)	41.56 (6.69)	41.78 (7.61)	-11.33% $p = 0.259$	-0.53% $p = 0.944$	-11.92% $p = 0.182$
PSQI Total	13.56 (2.92)	11.00 (2.50)	9.89 (1.90)	18.88%* $p = 0.028$**	10.09%* $p = 0.200$	27.06%* $p = 0.020$**

*Meets study criteria for Minimal Clinically Important Difference (MCID)

^No published consensus criterion for MCID

**Meets $p \leq 0.05$

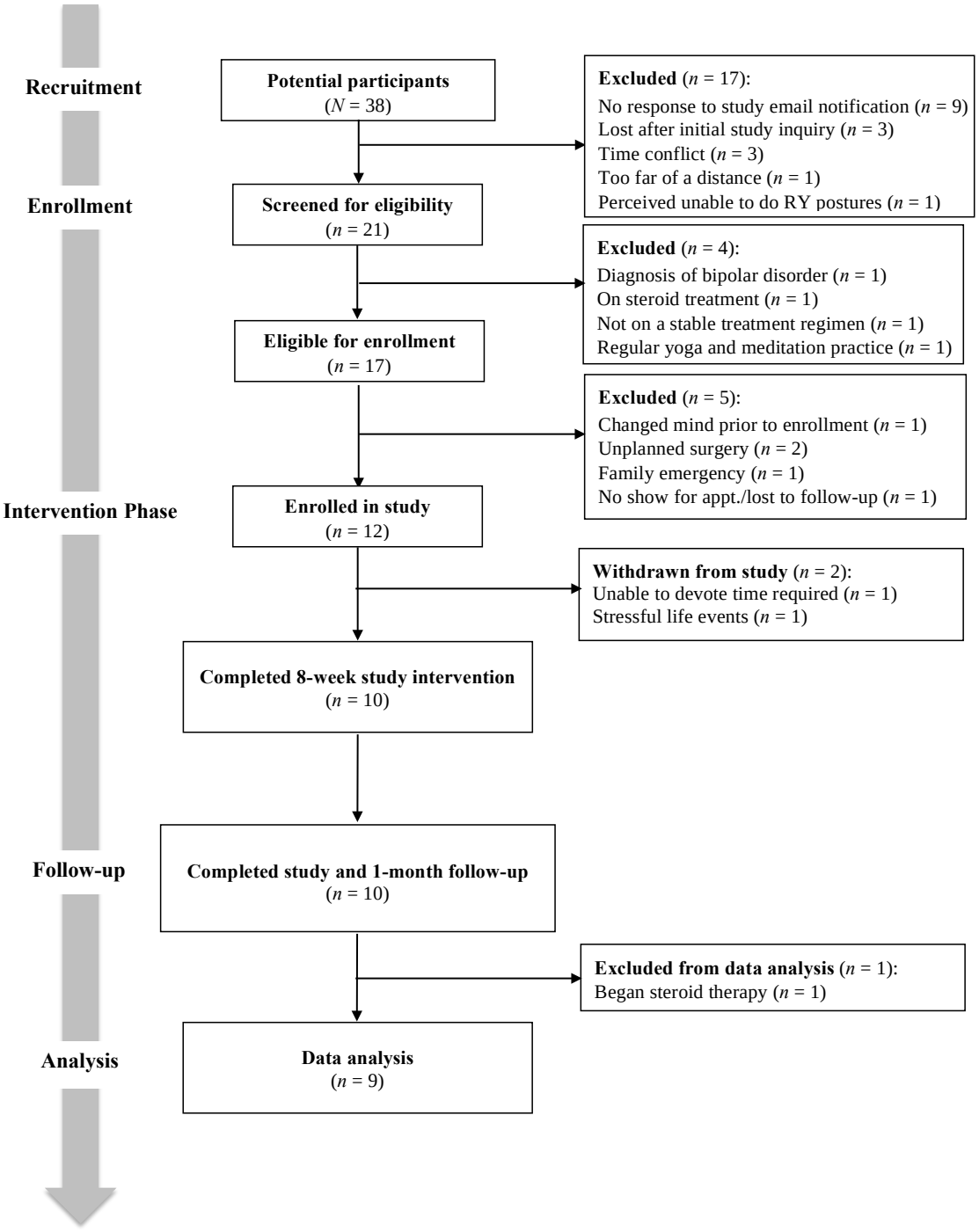

Figure 1. Participant Study Flow

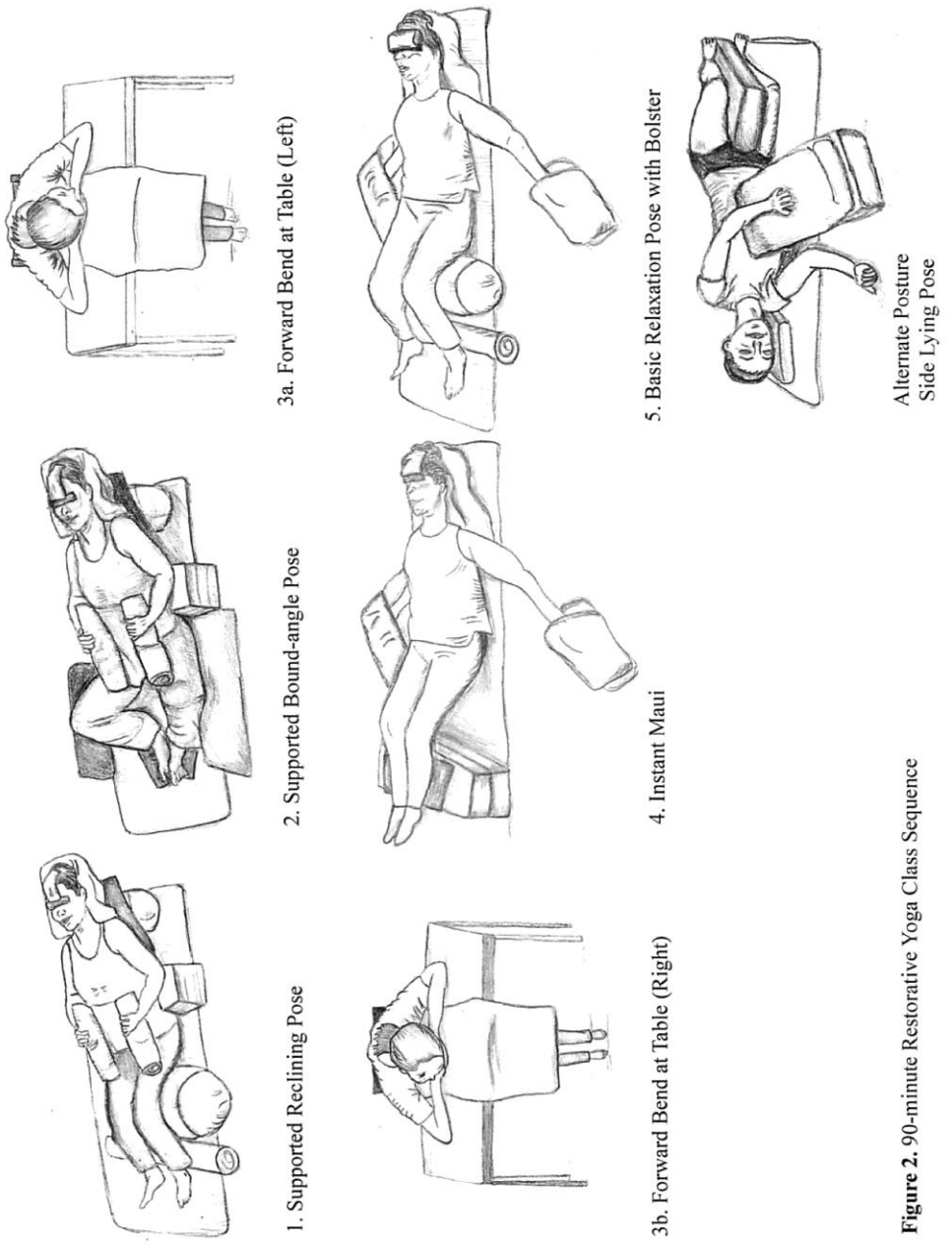

Figure 2. 90-minute Restorative Yoga Class Sequence

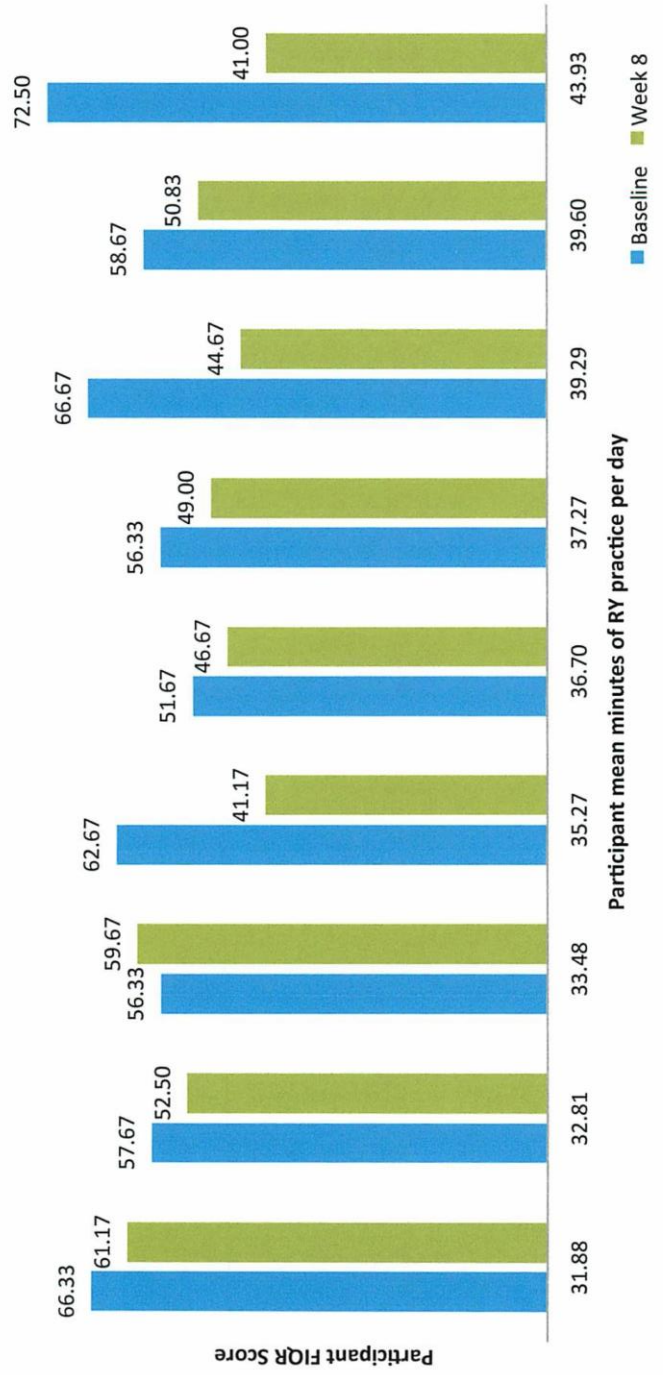

Figure 3. Participants' FIQR Total Scores by Mean Restorative Yoga Practice Minutes per Day at Baseline and Week 8

CHAPTER FIVE: CONCLUSION

The purpose of the research study conducted to fulfill requirements for this dissertation was to assess the feasibility of a restorative yoga (RY) intervention for symptom self-management by persons diagnosed with fibromyalgia (FM). Findings of the study are consistent with reports of symptom heterogeneity reported by researchers investigating treatments for FM. Participants of this study reported differing and inconsistent FM symptoms. Each individual reported variable levels of feasibility, acceptability, and perceived effects of RY for their FM-related symptoms.

RY classes were designed to introduce participants to a twice a week 90-minute, five-posture RY practice, which, after the 8-week intervention concluded, could be done independently at home. The intervention also included an independent 20-minute, one posture RY home practice to be done on non-class nights. Resource allocation and utilization and participant feedback at 1-month post-intervention indicated that the participants perceived they would not be able to implement the 90-minute RY practice independently as designed. They reported that the five-posture RY practice was too complicated, would require another person to assist them in the posture transitions, and that they, therefore, would not be inclined to attempt it on their own. One participant attempted the 90-minute practice at home only one time. Hence, a 90-minute home practice by persons with FM was determined not feasible.

The 20-minute, one-posture, RY home practice was designed to be done independently and did not require the purchase of special props. The participants reported a 93.33% adherence rate to the home practice. Given the perceived effects of the RY

intervention on FM-related symptoms and the report by all participants that RY should be offered to those with FM, the independent RY home practice was determined to be feasible. Thus, a RY home practice warrants further investigation as a means of FM-related symptom self-management.

Background information to support the investigation of RY as an appropriate, novel yoga style for FM symptom management was presented in Chapter Two, *Compliance with Delphi Survey Key Components of Yoga Interventions for Musculoskeletal Conditions: A Systematic Review of Fibromyalgia and Yoga Interventions.* As an emerging area of research interest, the literature was examined to assess the 'state of the art' in FM and yoga research. The studies identified were assessed for styles of yoga investigated and for study quality and replication potential using a guideline of 33 key components for yoga interventions for musculoskeletal conditions developed in 2014 from a Delphi survey of rheumatology, research, and yoga experts (hereinafter referred to as the '33 key component guideline'). Of the six studies reviewed, only one was assessed as a high quality study and no study was determined to be replicable. Given the gap identified in the literature, RY was selected as a style of yoga that warranted investigation in persons with FM as a means of symptom self-management.

Chapter Three, *Protocol for a Feasibility Study of Restorative Yoga for Symptom Management in Fibromyalgia,* presented the physiological and mechanistic rationale for the choice of RY as an appropriate yoga style for symptom management in persons with FM. The study design incorporated the 33 key component guideline recommendations discussed in Chapter 2. The Theory of Planned Behavior (TPB) was introduced as the

heuristic framework informing the study design, selection of outcome measures, and interpretation of the feasibility findings. Content analysis of the data collected through pre- and post-intervention interviews was guided by the constructs of the TPB to substantiate and create expanded meaning of the quantitative feasibility data.

Chapter Four, *Restorative Yoga for Symptom Management in Fibromyalgia*, describes the implementation process and the feasibility findings of an 8-week RY intervention for persons diagnosed with FM. Feasibility data were collected as recruitment, retention, and adherence rates during the 8-week intervention and at the 1-month follow-up. Pre- and post-intervention interview data were collected to corroborate, explain, and expand meaning of the quantitative findings. Recruitment, retention, and adherence rates were consistent with findings of other FM and yoga intervention studies and supported feasibility; however, the expanded meaning gleaned from the hermeneutic process and via the heuristic application of the TBP constructs revealed barriers that affected the final RY feasibility determination. Also described are findings related to the participants' perceived effects of RY on their FM-related symptoms. These data were collected using self-report questionnaires and pre- and post-intervention interviews. A significant change in total scores for disease impact, sleep, and pain measures were reported from baseline to week 8. Changes for disease impact and for sleep were inversely correlated with the mean number of minutes of overall RY practice each day.

Lessons Learned

As complementary health-enhancing therapies such as yoga gain popularity, it is important that health care practitioners understand and can identify those therapies that are safe and appropriate for those in their care. FM is heterogeneous in its presentation

and there is not a one size fits all treatment available for these individuals. Because persons with FM know that a cure for their chronic condition does not exist, they look for approaches and skill sets that they can incorporate into their symptom management regimen. If asked, those with FM are able to provide inquiring health care practitioners with a list of the various modalities and drugs they have tried and the reasons that some may or may not have helped to reduce their symptoms and, in some cases, the harm that they experienced as a result of these modalities or drugs. One of the benefits of RY related by the participants in this study was that although some of the postures may not always have been comfortable because of the variability of their symptoms, RY did not harm them. For many, this was the first treatment modality they had tried that had no harmful side effects. Many reported that in their experience even a therapy as gentle as hydrotherapy had hurt because the resistance of the water led to increased muscle soreness and pain.

The 8-week RY experience introduced some level of perceived control into the lives of the women enrolled in the study. An unexpected finding was that participants singled out the breathing practices as the major takeaway from the intervention. They reported integrating the counted breath into their daily lives for stress management, as a means of dealing with ruminating thoughts, and as a method to achieve a state of relaxation. At the 1-month follow-up, all of the women reported using the counted breath to manage stress and promote sleep, even those who did not continue the nightly RY practice because of the interference of life events or those who reported that RY did not make enough of difference for them to continue the practice. The participants related that once they had experienced the benefits of the counted breath practice done at the

beginning of every 90-minute RY class, they began to use it throughout the day to help them achieve relaxation, let go of disturbing or repetitive thoughts, and to reduce stress. Use of the breath to achieve these outcomes had not been an instruction given during the 8-week intervention.

The varying levels of perceived efficacy of the RY intervention underscore the individuality of the disease. Participants reported perceived effects at both extremes, ranging from statements such as “I can’t believe the difference it made” to “It didn’t make a big enough difference.” Although the intervention was the same for every class session over the course of the 8 weeks, participants often presented at each class with different symptom-related needs, which were managed using the modifications documented in Chapter Four, with good outcomes overall.

The participants related that one of the most important aspects of the experience for them had been the modifications of the postures to meet their individual needs. They reported that the accepting, compassionate attitude of the yoga instructor and assistants was a novel experience for them. The non-judgmental attitude inherent in any yoga practice and the ability to modify the RY postures to meet the person where s/he is physically and emotionally on a given day was an integral thread that ran throughout the class experience. This same thread was brought to the home RY experience by providing participants with modifications and alternatives and reinforcement that individualization of the postures to meet individual needs was a part of the purpose of the 8-week intervention, was expected, and was a part of the teachings of a traditional RY practice.

Implications for Practice

The findings of this study may help to guide those who are engaged in the diagnosis and treatment of persons with FM. As health care providers, it is important to acknowledge and validate the person's disease-related experience by listening carefully to what is being said and to respond appropriately. Through this approach, which is inherent in the philosophy associated with a yoga therapy such as RY, the investigators were able to establish a therapeutic relationship and to (a) overcome the hesitancy of the women to express their needs, (b) meet the needs of the majority of the women during the 90-minute RY classes, and (c) help the women address challenges encountered during the 20-minute home practice.

Recommendations for therapeutic exercise are frequently part of the multimodal treatment approach prescribed for those with FM. Yoga is often included as one of the forms of exercise. However, unless the recommendations are specific, these may be confusing to those with FM. Therapeutic yoga recommendations that are based upon authentic knowledge of the yoga styles and practices available are needed to guide the individual in the selection of an appropriate yoga style. Yoga therapy is an emerging area of research, and it is therefore prudent to make recommendations accordingly. Health care providers can learn about promising styles of therapeutic yoga from the scientific literature as well as experience the styles themselves and, thus, gain an understanding of the differences between yoga as an exercise form and yoga as a form of therapy. A combination of experiential and mechanistic knowledge of yoga styles, combined with knowledge of the most recent findings related to the pathophysiology and etiology of FM,

may assist health care practitioners in identifying appropriate forms of therapeutic yoga styles for a specific individual's symptoms.

Breath work was identified as a useful tool to aid in achieving relaxation, decrease rumination, and decrease sleep latency. During the 8 weeks, one woman reported using the counted breath to help her manage her postoperative pain after an outpatient procedure, using less pain medication than expected. Teaching a breathing technique to those with FM as an adjunct to other therapeutic practices may contribute to the overall plan of care for symptom management for some persons with FM.

Future Research

The findings of this feasibility study will inform future research and study design for persons diagnosed with FM. Identification of appropriate comparative analysis interventions, control group identification, incorporation of technology to assist in validating self-report data, technology-based intervention delivery, motivational tools that enhance intention, dosage of RY for those with FM, and the promotion of relaxation and sleep are aspects of future study design for which this study provides guidance and preliminary data.

Capitalizing on aspects of the intervention that were feasible and examining the preliminary data using the TPB as a framework informs and directs modifications to promote the development of successful symptom self-management tools for those with FM. Reducing travel time and its negative effects on an RY session through development of a home-based RY practice was one of the modifications identified through this study. Identification of an appropriate control group can be challenging for researchers, but, as an extension of study findings, an appropriate choice for a future study could be a usual

care group that would receive the intervention after completion of the active intervention by the experimental group. A comparative effectiveness study of a group of participants using breath work alone compared with a group that does both a RY posture and the associated breath work would be appropriate given the findings of this study.

The participants reported that guided home practice, which includes instructions to help them focus on their breath and that encourages non-attachment to thought, would be helpful. Future study designs incorporating a form of guided home-based RY practice using available technology such as smart phone apps or other media could be used to meet this need. Verification of adherence to a RY home practice could be incorporated into the same smart phone app that is used for intervention delivery. For example, an app that could track participant movement and body pressures to validate the time spent in the RY posture could be used for this purpose. This app could also be developed to track heart rate and respiratory rate to monitor for the relaxation response during the RY practice.

Use of actigraphy to validate self-reported sleep outcomes would be a valuable addition to future studies of the effects of RY on sleep in this population. Comparison of sleep data with perceived levels of pain for investigation of the bi-directional relationship between sleep and pain deserves monitoring during RY studies. RY is reported to increase restorative sleep through stimulation of the baroreceptor response.

In conclusion, FM is complex and difficult to treat. It has an unclear etiology and pathophysiology. Yoga therapy, too, is complex, and the mechanistic basis for its efficacy is just beginning to be investigated. While the results of yoga therapies for FM-related symptom self-management appear promising, it is incumbent upon health care

researchers and practitioners to make recommendations based upon sound scientific evidence. The findings and reported outcomes of the participants toward a RY practice are promising; however, these findings need to be validated through future studies that have a larger number of participants and also incorporate control or comparative referent groups. Futures studies should also investigate optimal dose of RY by correlating desired outcomes to minutes and number of days of RY practice needed to achieve the desired outcomes. A longitudinal design may establish efficacy and long-term acceptability of RY for FM-related symptom self-management. This study revealed methodological and practical barriers to implementation. Using a guiding theoretical framework such as the TPB, future studies that address these barriers and enhance intention to use RY for symptom management may be developed.