

Restorative Yoga for Symptom Management in Fibromyalgia: Results of an 8-week Intervention

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Abstract

Objective: The aim of this study was to determine the feasibility of an 8-week restorative yoga intervention and to collect preliminary data on its effects on the fibromyalgia-related symptoms of chronic widespread pain, sleep disturbance, and fatigue, and health-related quality of life.

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 at a 1-month follow-up telephone interview.

Results: In this group of participants ($N = 12$), recruitment, retention, and adherence rates were comparable to those of other fibromyalgia yoga studies: recruitment 57.14%; retention 75%; adherence to group class 87.5%; and home practice adherence 93.33%. A ratio of 1:2 yoga instructor to participants was required for the five-posture 90-minute class sequence as compared with a ratio of 1-2:10-25 yoga instructors to study participants reported in other fibromyalgia yoga studies. Statistically significant trends and minimal clinically important differences were found at week 8 when comparing participant baseline to week 8 self-report questionnaire scores for the Revised Fibromyalgia Impact Questionnaire total score ($p = 0.01$; 18.51%), the Pain Numeric Rating Scale for the subscales pain now ($p = 0.04$; 36.36%) and average pain over the past week ($p = 0.04$; 19.61%), the General Sleep Disturbance Scale total score ($p = 0.04$; 17.40%), and the Pittsburgh Sleep Quality Index total score ($p = 0.02$; 27.06%).

Conclusion: Although the 8-week, five-posture, 90-minute restorative yoga group class was found not to be feasible as a symptom self-management strategy in this study, the findings support the need for further investigation of the home practice format. Future longitudinal, randomized, controlled trials of a restorative yoga home practice format to establish intervention efficacy and symptom-self management potential as well as those examining restorative yoga intervention resource utilization in persons with fibromyalgia are recommended.

Keywords: 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].

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 [4,7,17]. Disrupted sleep cycles, reported as one of the most bothersome FM-related symptoms [18-21], cause individuals to wake up feeling

unrefreshed [22] and have been correlated with increases in perceived severity of FM-related pain, fatigue, and depressed mood [22-28]. A 2014 study [29] 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 [23,27,30,31]. 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 [32]. Disease impact on psychological, physical, and social aspects of the lives of those with FM impairs daily function and diminishes HQoL [33-36]. These functional impairments also may lead to changes in work status, declining mental health, and deterioration of social and personal relationships [9].

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Received April 04, 2015; Accepted June 08, 2015; Published June 15, 2015

Citation: Fischer-White TG, Anderson JG, Lewis JE, Rose KM, Taylor AG (2015) Restorative Yoga for Symptom Management in Fibromyalgia: Results of an 8-week Intervention. J Yoga Phys Ther 5: 185. doi:10.4172/2157-7595.1000185

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Studies suggest non-pharmacologic therapies may increase functional status and self-efficacy in these individuals [9,37-39]. In addition, modest symptom relief and undesirable side effects associated with drugs used to treat FM [40-42] cause those diagnosed with FM to seek out complementary health-enhancing therapies such as yoga at a higher rate than other chronic disease populations [43-45].

Rheumatologists and other FM experts recommend a multidisciplinary and multimodal approach to symptom management for persons diagnosed with FM [46-48]. Complementary mindfulness-based movement practices such as yoga show promise as a part of this multimodal approach [49]. Restorative yoga (RY) is a gentle, health-enhancing style of yoga that may be especially well suited for the management of FM-related symptoms. RY uses postures held for up to 20 minutes or longer in a warm, dark, and quiet environment, and incorporates specific breathing patterns and techniques that promote non-attachment to thoughts while the body is supported by pillows, blankets, bolsters, and other yoga props. Different from other movement-based forms of yoga, an RY practice encourages total relaxation of the muscles without stretching while invoking the relaxation response. Yin yoga, a style of yoga that appears initially to be more similar to RY than movement-based yoga styles, uses static-based postures and sometimes yoga props, but is done in a cool environment and is intended to be a cooling practice that focuses on the joints and promotes stretching of deep connective tissue. Thus, Yin yoga as well as movement-based styles of yoga that stretch and activate the muscles are functionally different from RY [50,51]. Unlike RY, some forms of exercise and styles of yoga are inappropriate for persons with FM because of their decreased strength [52,53] and aerobic capacity [54] and can result in exercise-induced pain that furthers functional decline [55,56]. RY minimizes muscular and aerobic demands while providing an opportunity for the reintegration of the 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 [57] and promote parasympathetic dominance [58]. 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 [59-61].

To date, few studies using a yoga intervention in individuals diagnosed with FM have been published [49,62]. Six studies investigating therapeutic yoga styles for persons with FM have been identified; none have investigated RY [63-68]. 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). 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 study¹. The

¹ A detailed description of the protocol used in the study reported on in this article can be found in Fischer-White TG, Anderson JG, Lewis JE, Rose KM, Taylor AG (2015) Protocol for a feasibility study of restorative yoga for symptom management in fibromyalgia. *J Yoga Phys Ther* 5: 183. doi:10.4172/2157-7595.1000183

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

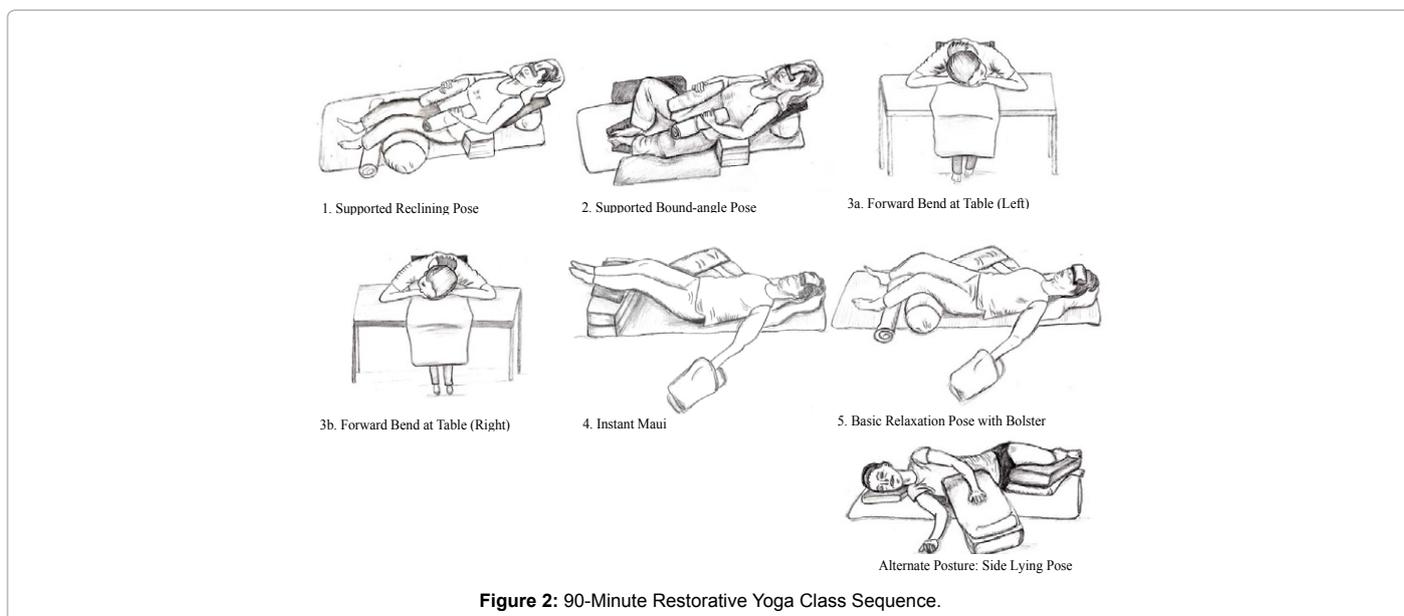
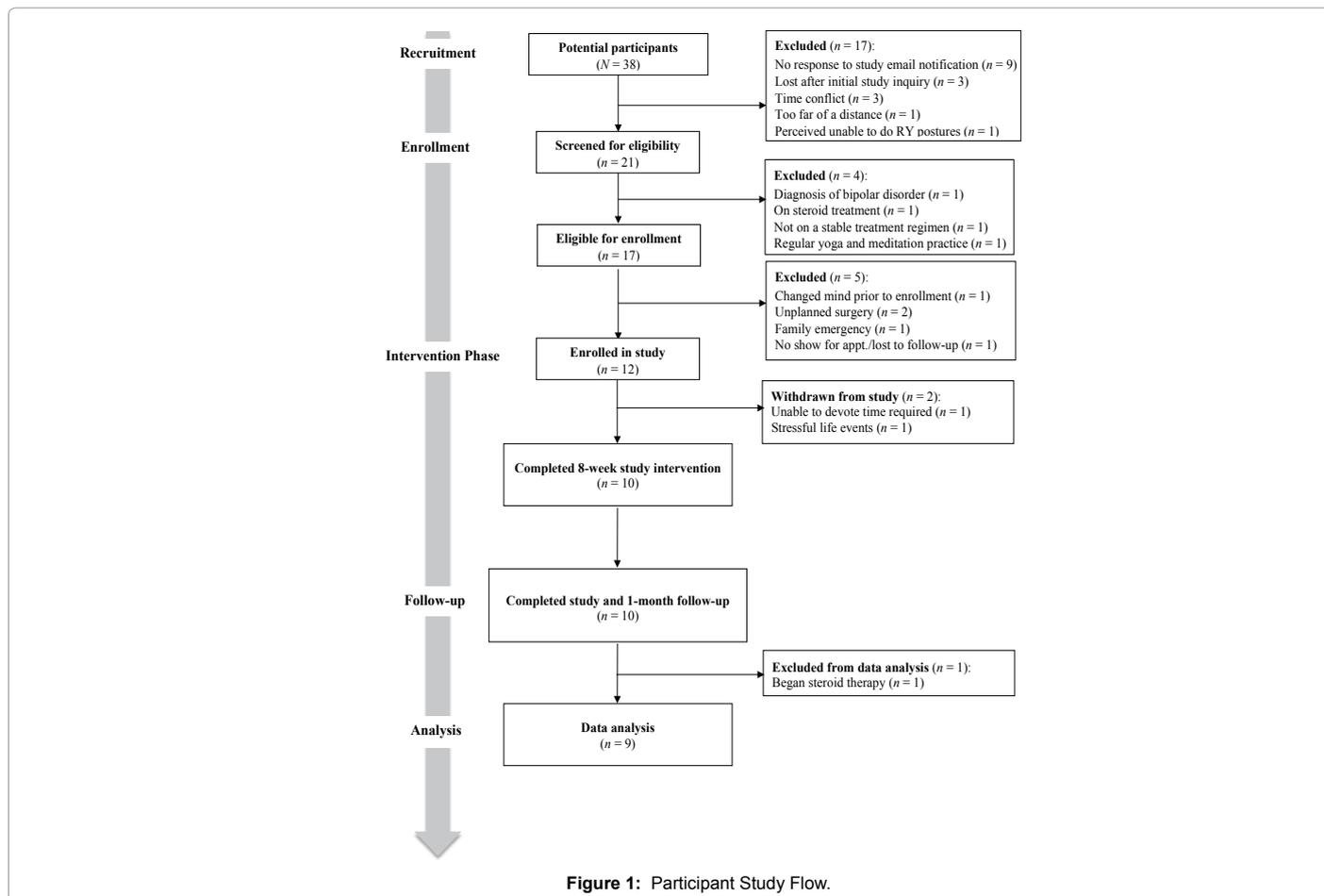
Beginning in May and ending in September of 2014, a consecutive convenience sample of 12 persons diagnosed with FM was enrolled. The first 6 persons participated in the June through August 8-week intervention group; the second 6 persons participated in the September through November 8-week intervention 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. Inclusion criteria were as follows: (a) adult 21 to 75 years of age, (b) diagnosis of FM by a physician (confirmed by J.E.L.), (c) stable non-steroidal treatment regimen for 3 months or longer prior to the start date of the study period, and (d) English speaking and writing. Prospective study participants were excluded from the study for the following reasons: (a) any physical limitation that would prevent the person from doing the required RY postures, (b) currently pregnant, (c) current diagnosis or history of diagnosed bipolar disorder or schizophrenia, (d) currently using steroids, and (e) mindfulness or yoga practice two or more times per week for 6 months or more within the past 3 years. 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. The two 8-week RY intervention sessions were taught by the same instructor who was assisted by the same trained assistants.

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 also were 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 to 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 rates, 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 (K.A.) 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 1).

On the five non-class nights, participants were asked to practice for 20 minutes immediately prior to bedtime using the 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 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).

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 reported at the 1-month follow-up telephone interview, (d) resource utilization, (e) safety, and (f) participant perceived feasibility of the 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.

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. Because the primary aim of the study was to

Designated Posture	Sequence Order	Complaint/ limitation		*Number of Participants
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	Added 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 <i>Relax and Renew: Restful Yoga for Stressful Times</i> (Lasater, 1995, Rodmell Press, Berkeley, CA)	2
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	Created a bolster with a smaller diameter by rolling up blanket(s)	2
Supported reclining pose, supported bound-angle pose	1 and 2	Sensitive elbows	Provided extra cushioning for restorative yoga blocks with towels	2

*Modifications were made for all participants, with the minimum number of modifications being one for one participant and the maximum number being four for another participant.

Table 1: Modifications and General Adjustments for RY Postures.

assess feasibility and the study was not powered to detect statistically significant differences, *p*-values ≤ 0.05 were considered as trends rather than using the Bonferroni adjustment to account for a potential type I error.

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 ≥ 14% [92]; (b) NRS Pain ≥ 10% [93]; (c) SF36v2 ≥ 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 [69]. A reflective diary was maintained to support investigator neutrality [96]. 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 women, five of whom were married. Over one-half of the participants had some level of post-secondary education (college). 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 2.

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 interview. 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,

Demographic Characteristic	Overall (N = 9)	
	Mean	SD
Age	49.6	12.0
Age Diagnosed with FM	40.1	11.5
Years Since FM Diagnosis	9.4	7.4
Demographic Characteristic	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%
Medications Taken	n	%
Fibromyalgia Specific (Lyrica, Cymbalta)	5	55.6%
Sedatives/Hypnotics (Ambien, Desyrel, Elavil, Tylenol PM)	6	66.7%
Antidepressants/Analgesics		
SNRIs (Celexa, Lexapro, Zoloft)	3	33.3%
Tricyclic (Pamelor, Norpramine)	2	22.2%
Other antidepressant (Wellbutrin)	2	22.2%
Anxiolytics		
Benzodiazapine (Ativan, Klonopin)	4	44.4%
Analgesics		
NSAIDs (Advil, Aleve, Motrin)	5	55.6%
Other (Ultram, Neurontin)	7	77.8%
Muscle Relaxants (Flexeril)	2	22.2%
Migraine Medications (Zomig)	1	11.1%
Non-prescription vitamins, minerals, and natural supplements (HTP5, Magnesium, SAMe, Vit B12, Vit D, Vit D3)	8	88.9%
Comorbidities	n	%
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%

Seven study participants reported one comorbidity

*One study participant reported two comorbidities

+One study participant reported three comorbidities.

Table 2: Demographic Characteristics, Medications Taken, and Comorbidities of Study Participants.

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 three 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 that 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 USD and \$445 USD, 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.

One yoga instructor and two to three 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 one assistant to two 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. During the 1-month follow-up telephone interview, 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 assistance and thus had never attempted it. During the intervention and at the 1-month follow-up, 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. 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 (K.A.) 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 3). 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 ($r = 0.70$; $p = 0.04$), and a significant inverse correlation was found between mean practice minutes each day and PSQI total score change from baseline to week 8 ($r = -0.69$; $p = 0.04$). 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 [69] as a heuristic framework for data interpretation. Quotes from participants are provided as supporting data for theme development.

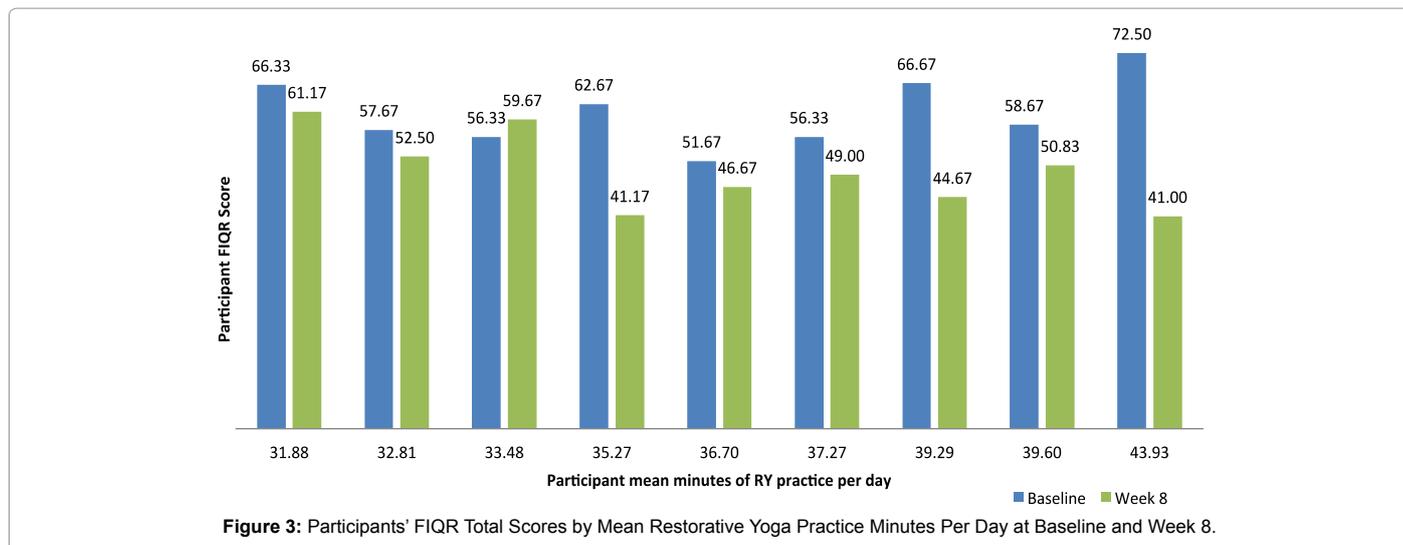
	Means at Baseline (Std Dev)	Means at Week 4 (Std Dev)	Means at Week 8 (Std Dev)	Percent Difference in Means (Baseline to Week 4)	Percent Difference in Means (Week 4 to Week 8)	Percent Difference in Means (Baseline to Week 8)
Pain NRS						
Pain now	4.89 (1.69)	4.33 (2.60)	3.11 (1.45)	11.36%* $p = 0.81$	28.21%* $p = 0.15$	36.36%* $p = 0.04^{**}$
Pain avg	5.67 (0.87)	5.11 (1.45)	4.56 (1.13)	9.80% $p = 0.32$	10.87%* $p = 0.39$	19.61%* $p = 0.04^{**}$
Pain worst	7.67 (1.00)	7.11 (1.45)	6.67 (1.00)	7.25% $p = 0.26$	5.80% $p = 0.41$	13.04%* $p = 0.05$
Stress NRS[^]						
Stress now	3.56 (2.19)	3.33 (2.00)	4.33 (1.66)	6.46% $p = 0.73$	-30.03%* $p = 0.20$	-21.63% $p = 0.32$
FIQR Total						
	60.98 (6.55)	49.74 (15.21)	49.69 (7.20)	18.43%* $p = 0.04^{**}$	0.10% $p = 0.59$	18.51% $p = 0.01^{**}$
FIQR Symptom Subscale Components[^]						
Pain	6.44 (0.88)	5.00 (2.00)	5.11 (1.69)	22.36% $p = 0.09$	-2.20% $p = 0.83$	20.65% $p = 0.06$
Energy	7.11 (2.15)	6.67 (1.80)	6.11 (2.21)	6.19% $p = 0.33$	8.40% $p = 0.60$	14.06% $p = 0.34$
Stiffness	7.44 (1.13)	5.67 (2.45)	5.44 (2.19)	23.79% $p = 0.02^{**}$	4.06% $p = 0.48$	26.88% $p = 0.03^{**}$
Sleep	8.33 (1.73)	7.78 (1.20)	6.56 (1.59)	6.60% $p = 0.35$	15.68% $p = 0.20$	21.25% $p = 0.08$
Depression	6.56 (1.81)	4.78 (1.86)	6.11 (2.47)	27.13% $p = 0.04^{**}$	-27.82% $p = 0.29$	6.86% $p = 0.57$
Memory problems	7.33 (2.18)	6.67 (2.29)	5.78 (1.48)	9.00% $p = 0.35$	13.34% $p = 0.22$	21.15% $p = 0.06$
Anxiety	5.78 (2.77)	5.00 (1.80)	4.33 (2.12)	8.26% $p = 0.40$	21.38% $p = 0.34$	27.88% $p = 0.02^{**}$
Tenderness to touch	6.78 (1.99)	6.22 (2.64)	4.98 (2.47)	8.26% $p = 0.53$	21.38% $p = 0.31$	27.88% $p = 0.02^{**}$
Balance problems	4.44 (2.46)	3.67 (2.87)	3.22 (1.56)	17.34% $p = 0.36$	12.26% $p = 0.86$	27.48% $p = 0.20$
Sensitivity to external stimuli (light, noise, odors, cold)	6.56 (2.65)	4.33 (1.73)	5.22 (2.17)	33.99% $p = 0.03^{**}$	-20.55% $p = 0.17$	20.43% $p = 0.14$
DSI[^]						
FREQ	20.44 (5.29)	19.44 (7.14)	22.11 (8.89)	4.89% $p = 0.59$	-13.73% $p = 0.18$	-8.17% $p = 0.41$
SUM	58.89 (30.51)	53.00 (35.91)	54.22 (29.27)	10.00% $p = 0.37$	-2.30% $p = 0.78$	7.93% $p = 0.52$
AIR (SUM/FREQ)	2.76 (0.84)	2.51 (1.05)	2.36 (0.81)	9.06% $p = 0.14$	5.98% $p = 0.78$	14.49% $p = 0.11$
GSDS						
Sleep quality	4.33 (1.30)	4.17 (1.24)	3.51 (0.96)	3.70% $p = 0.78$	15.83%* $p = 0.21$	18.94%* $p = 0.17$
Daytime function	4.00 (1.63)	4.00 (1.63)	3.55 (1.30)	0.00% $p = 1.00$	11.25%* $p = 0.63$	11.25%* $p = 0.63$
Sleep medication	1.02 (0.87)	1.06 (0.87)	1.06 (0.99)	-3.92% $p = 0.58$	0.00% $p = 0.93$	-3.92% $p = 1.00$
Total	3.39 (0.79)	3.22 (0.82)	2.80 (0.43)	5.01% $p = 0.31$	13.04%* $p = 0.12$	17.40%* $p = 0.04^{**}$
PANAS[^]						
Negative affect	23.11 (7.94)	18.00 (3.91)	19.56 (7.28)	22.11% $p = 0.11$	-8.67% $p = 0.37$	15.36% $p = 0.10$
Positive affect	21.00 (4.74)	21.56 (6.11)	23.33 (6.02)	-2.67% $p = 0.57$	-8.21% $p = 0.33$	-11.10% $p = 0.18$
SF36v2						
Physical component score	33.00 (5.61)	34.78 (4.63)	35.33 (2.78)	-5.39% $p = 0.53$	-1.58% $p = 0.79$	-7.06% $p = 0.34$
Mental component score	37.33 (7.84)	41.56 (6.69)	41.78 (7.61)	-11.33% $p = 0.27$	-0.53% $p = 0.94$	-11.92% $p = 0.18$
PSQI Total						
	13.56 (2.92)	11.00 (2.50)	9.89 (1.90)	18.88%* $p = 0.03^{**}$	10.09%* $p = 0.20$	27.06%* $p = 0.02^{**}$

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

[^]No published consensus criterion for MCID

**Meets $p \leq 0.05$

Table 3: Fibromyalgia Symptom Means and Standard Deviations, Percent Differences in Means, and Significance of Mean Differences from Baseline to Week 8.



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 [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, 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 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 [97]. 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 [63-68]. Recruitment rates of 82.8% [64] and 38.6% [65], class adherence rates of 87.5% [64] and 86% [65], and a mean attrition rate of 25.23% ± 10.64% [63-67] were reported in other studies as positive findings for feasibility of the yoga style investigated. Only one of those studies [67]

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. 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. 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 [98], making payment for private sessions challenging.

Consistent with reports of increased health care costs and resource use associated with a diagnosis of FM [99,100], 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 USD), 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 instructor to participant ratio 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 one to two yoga instructors for class sizes ranging between 11 to 22 persons reported by other FM/yoga studies [64-66]. 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 [101]. 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

telephone interview, 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.

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 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 at the 1-month follow-up telephone interview, the higher the number of minutes of daily practice and the greater the number of days each week that the participants continued to practice RY. 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 [102]. 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 [97]. 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 [103]. 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

Although the five-posture, 90-minute group class RY intervention was found not to be feasible as a symptom self-management strategy in this group of study participants, the findings of this study suggest that the benefits derived from an RY home practice warrant further investigation. Clinically meaningful trends indicating a perceived improvement in FM-related function and decreases in sleep disturbances and some measures of pain were identified. These preliminary results

support the need for further investigation of the high use of resources (staff and yoga props) in the RY group class setting as well as future randomized controlled studies to determine the efficacy of home practices of RY for FM-related symptoms and those that evaluate the potential for RY as a long-term symptom self-management strategy for persons diagnosed with FM.

Acknowledgments

This study was made possible through a grant from the University of Virginia Contemplative Sciences Center and by funding from the University of Virginia Center for the Study of Complementary and Alternative Therapies. The authors gratefully acknowledge the assistance of Katharine Adelstein, MSN, ANP-BC, RN, and Olivia Pagano and Jessica Denomme (two undergraduate students) in the setup and implementation of the restorative yoga sessions and Dana Mowdy-Spencer for her illustrations of the restorative yoga postures. The authors also would like to thank the University of Virginia School of Nursing for the use of its facilities.

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