Follow-up of Yoga of Awareness for Fibromyalgia
Results at 3 Months and Replication in the Wait-list Group

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Objectives: Published preliminary findings from a randomized-controlled trial suggest that an 8-week Yoga of Awareness intervention may be effective for improving symptoms, functional deficits, and coping abilities in fibromyalgia. The primary aims of this study were to evaluate the same intervention's posttreatment effects in a wait-list group and to test the intervention's effects at 3-month follow-up in the immediate treatment group.

Methods: Unpaired *t* tests were used to compare data from a per protocol sample of 21 women in the immediate treatment group who had completed treatment and 18 women in the wait-list group who had completed treatment. Within-group paired *t* tests were performed to compare posttreatment data with 3-month follow-up data in the immediate treatment group. The primary outcome measure was the Fibromyalgia Impact Questionnaire Revised (FIQR). Multilevel random-effects models were also used to examine associations between yoga practice rates and outcomes.

Results: Posttreatment results in the wait-list group largely mirrored results seen at posttreatment in the immediate treatment group, with the FIQR Total Score improving by 31.9% across the 2 groups. Follow-up results showed that patients sustained most of their posttreatment gains, with the FIQR Total Score remaining 21.9% improved at 3 months. Yoga practice rates were good, and more practice was associated with more benefit for a variety of outcomes.

Discussion: These findings indicate that the benefits of Yoga of Awareness in fibromyalgia are replicable and can be maintained.

Key Words: fibromyalgia, pain, yoga, mindfulness, acceptance

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The successful management of fibromyalgia (FM) patients is still a work in progress. At present, most clinicians and researchers recommend some sort of progressive program that involves both pharmacotherapy and nonpharmacological modalities.[1] Although 3 drugs (pregabalin, duloxetine, milnacipran) have been approved for use by the US Food and Drug Administration, all 3 drugs have been rejected by the European Medicines Agency.[2] Exercise and cognitive-behavioral therapy have been the mainstay of nonpharmacological therapies in both continents.[3] However, there has been a growing interest on both sides of the Atlantic in incorporating age-old Asian mind/body practices, such as tai chi, qigong, and yoga.[4–6]

We have previously reported on the results of a randomized controlled trial of a "Yoga of Awareness" (YoA) intervention in FM patients.[7] YoA emphasizes coping tools drawn from the traditional discipline of yoga—such as meditation, breathing exercises, and the application of yogic principles in daily life—in addition to gentle, modified versions of yoga poses.[8,9] YoA is designed to promote emotional and behavioral optimization, and enhanced physical fitness. Upon completing the intervention, patients in the immediate treatment group experienced improvement in symptomatology, physical strength, and coping abilities, as compared with wait-list controls. The primary purposes of the present study were to conduct per protocol evaluations of YoA's effects in (1) the wait-list group, to determine whether the posttreatment results observed in the immediate treatment group could be replicated and (2) the immediate treatment group after 3 months of unsupervised follow-up, to determine whether this group's posttreatment improvements were sustained at the medium term. An additional goal was to examine associations between yoga home practice rates and treatment outcomes.

MATERIALS AND METHODS

Participants

The participants were 39 women at least 21 years of age who had been diagnosed with FM by American College of Rheumatology criteria[10] for at least 1 year, and who had been on a stable regimen of pharmacological and/or nonpharmacological treatment for FM ≥ 3 months before study enrollment. This sample represents 21 of the 25 randomized to the immediate treatment group and 18 of the 28 randomized to the wait-list treatment group, who participated in the original published study.[7] The characteristics of the sample are summarized in Table 1. Patients with any of the following conditions were excluded from the study: (1) residing > 70 miles from the research site or unavailable to attend the intervention at one of the scheduled times; (2) engaged in intensive yoga practice (practice > 3 d/wk); (3) actively contemplating suicide (none was excluded on this basis); (4) undergoing disability application, determination, or litigation; (5) scheduled for elective surgery during the study period; (6) physically disabled in a manner that precluded meaningful participation in the intervention (eg, quadriplegic paralysis); (7) unwilling to forgo changing their voluntary pharmacological and/or

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TABLE 1. Characteristics of the Sample, Combined and by Treatment Condition

Characteristics	n (%)/M (SD)		
	Total Sample (n = 39)	Immediate Treatment (n = 21)	Wait List (n = 18)
Age, y	55.4 (11.3)	53.3 (13.0)	57.8 (8.7)
Years since diagnosis	11.2 (7.6)	10.4 (7.6)	12.1 (7.6)
Years symptomatic			
1-5 y	2 (5.1%)	1 (4.8%)	1 (5.6%)
6-10 y	11 (28.2%)	6 (28.6%)	5 (27.8%)
> 10 y	26 (66.7%)	14 (66.7%)	12 (66.7%)
Race/ethnicity			
White	35 (89.7%)	19 (90.5%)	16 (88.9%)
Native American	3 (7.7%)	2 (9.5%)	1 (5.6%)
Other	1 (2.6%)	1 (4.8%)	1 (5.6%)
Education			
Less than college	4 (10.3%)	1 (4.8%)	3 (16.7%)
Some college	14 (35.9%)	8 (38.1%)	6 (33.3%)
College degree	12 (30.8%)	7 (33.3%)	5 (27.8%)
Graduate studies	9 (23.1%)	5 (23.8%)	4 (22.2%)
Marital status			
Married/partnered	28 (71.8%)	17 (81.0%)	11 (61.1%)
Divorced/separated	7 (17.9%)	3 (14.3%)	4 (22.2%)
Never married	3 (7.7%)	1 (4.8%)	2 (11.1%)
Widowed	1 (2.6%)	0 (0.0%)	1 (5.6%)
Employment status			
Employed	16 (41.0%)	9 (42.9%)	7 (38.9%)

nonpharmacological treatments for the length of their participation in the study; or (8) non-English speaking.

Study Flow

Figure 1 shows the CONSORT diagram illustrating the progression of participants through the treatment study. Potential participants who had indicated their interest in enrolling in research studies were identified between October 2009 and January 2010 from a database of FM patients referred to our university tertiary care center. An e-mail message (or standard mail if e-mail addresses were unknown) was sent to 382 women whose street addresses were within the catchment area, inviting them to attend an informational meeting about the study. Sixty-four women attended and were briefly assessed for eligibility. Fifty-six of these enrolled in the study and initially seemed eligible; however, 3 were subsequently excluded on the basis of a priori criteria: 2 were not on stable FM treatment regimens for ≥ 3 months (1 = newly diagnosed trigeminal neuropathy; 1 = started pain coping class, changed doctors and medications) and 1 had an excessively disabling vestibular diagnosis (physician had prohibited walking up stairs and other postural elevation changes). The remaining 53 were randomized (immediate treatment = 25, wait-list treatment = 28).

Study Design and Procedure

The study protocol was approved by the Oregon Health & Science University Institutional Review Board. Participants completed the baseline assessment after signing informed consent forms. Those who met the inclusion and exclusion criteria were randomly assigned to either start the yoga program 2 weeks later (immediate treatment group) or 3 months later (wait-list group). All participants continued to receive the usual care provided by their health care providers, and thus patients in the wait-list group were receiving ongoing FM medical care (rather than no treatment at all). We selected a wait-list control because of the preliminary nature of the study and because participants assigned to a wait list are often motivated to remain in a trial so that they may ultimately receive a desired intervention.[11,12] The second assessment was completed within 1 week after the immediate treatment group had finished the 8-week intervention. Patients in the wait-list group were then invited to begin the intervention 2 weeks later. Participants completed the third assessment 3 months after the second assessment, coinciding with the week after the wait-list group had completed the yoga intervention. Throughout the study, the research assistants who collected assessment data were kept blind with regard to condition assignments. Patients received $25 each time they completed either the second or the third assessments.

Treatment Conditions

Immediate Treatment Group

Those participants who had completed the 8-week YoA intervention (see description on the following page) and the second assessment were contacted for follow-up at 3 months, without any supervision or additional contact between the second and the third assessments. During this period, they continued with their usual medical care and had been encouraged to continue with their daily yoga practice using the same professionally produced DVD and CDs as they used in the treatment phase of the study protocol.

Wait-list Control Group

Between the baseline and second assessments, the wait-list control group continued to receive their routine FM medical care as usual, on the understanding that they would begin the YoA intervention in about 3 months' time. They were contacted by phone at the midpoint between the baseline and the second assessments to answer any questions and to set up the second assessment. After the second assessment, these patients were invited to participate in the

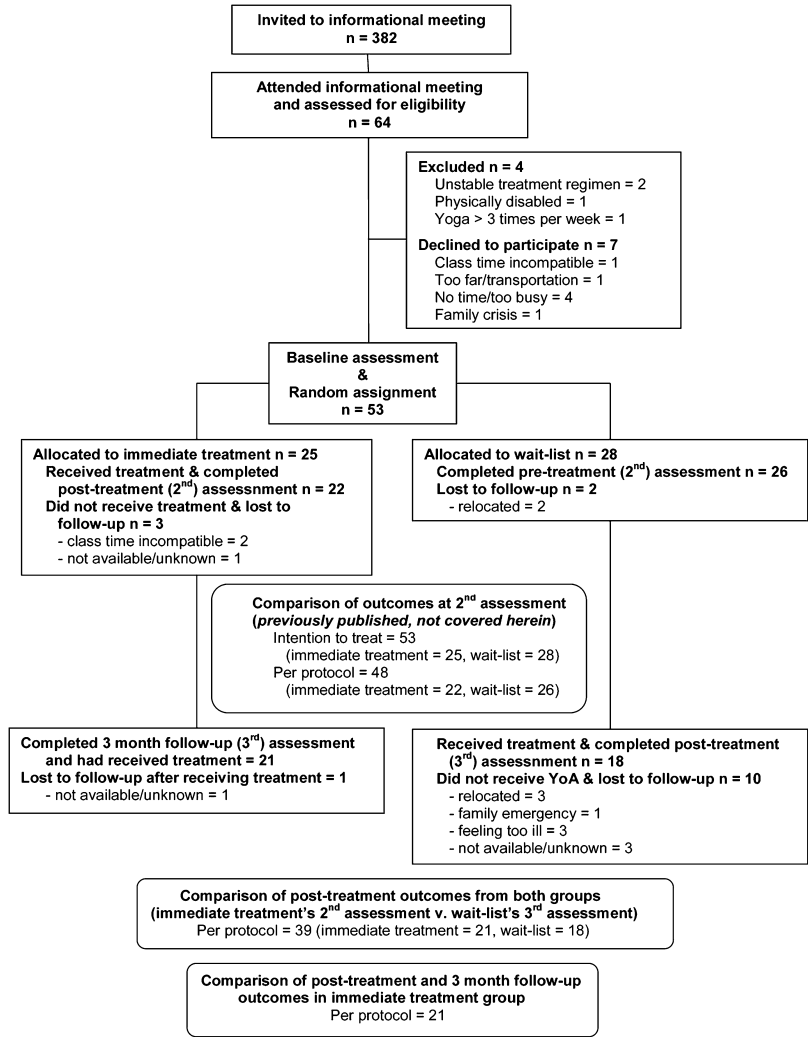

FIGURE 1. Study participant flow.

YoA program, which was provided to them in exactly the same format as it had been provided to participants in the immediate treatment group.

The yoga teacher followed a manual, including detailed class guidelines, that was developed to standardize delivery of the intervention in research settings. The intervention consisted of 8 once-per-week classes, each lasting 120 minutes, in groups of 7 to 12 patients. Each class included approximately 40 minutes of gentle stretching poses, 25 minutes of meditation, 10 minutes of breathing techniques, 20 minutes of didactic presentations on the application of yogic principles to optimal coping, and 25 minutes of group discussions. The sequence of yoga poses consisted of low-intensity, low-impact postures that were modified to avoid movements that are known to aggravate pain in FM.[13] The sequence included 2 versions that could be performed either in a chair or out of a chair. The teacher emphasized the importance of gentle practice when one's body is challenged by illness. Patients were supplied with yoga mats, blankets, eye pillows, and bolsters for doing the poses.

Patients were encouraged to practice specific yoga techniques at home 20 to 40 minutes per day, 5 to 7 days per week, guided by a professionally produced DVD and a CD. Applications of yoga to daily life were also assigned each week. As need be, the teacher contacted patients who missed sessions to negotiate attendance barriers or to address home practice barriers (if average practice < 20 min). Attendance was generally good during the wait-list group's intervention (mean = 7 of 8 classes, range 5 to 8) as was home practice (daily total practice mean = 36 min, range 1 to 91 min), and these data were similar to the immediate yoga group's adherence values (attendance mean = 7 of 8, range 4 to 8; daily total practice mean = 46 min, range 14 to 101 min). For further intervention details, including a list of yoga poses used, see our previous trial report.[7]

Assessment Procedures

Outcome assessments were administered 3 times: the baseline assessment was collected 2 weeks before the immediate treatment group began the YoA intervention; the second assessment was completed the week after the immediate treatment group's intervention had ended; and the third assessment was collected 3 months later, coinciding with the week after the YoA intervention for the wait-list group had ended. Three types of measurements—standardized questionnaires, physical tests, and daily diaries—were used to

gather data about FM symptoms and functional deficits, and pain coping strategies. These instruments are briefly described below; for a fuller description, see our earlier paper.[7]

Questionnaires Assessing FM Symptoms and Functional Deficits

FM Symptoms and Functional Deficits

The primary treatment outcome measure was the Total Score of the FIQR, a 21-item instrument assessing FM-related pain, fatigue, stiffness, poor sleep, depression, poor memory, anxiety, tenderness, poor balance, and environment sensitivity.[14,15] Scores range from 0 to 100, with higher scores indicating more symptom burden and functional limitations. The FIQR also includes subscales for Symptoms, Function, and Overall Impact.

Overall Improvement in FM Symptoms

The Patient Global Impression of Change asked patients to rate overall improvement in FM symptoms during the study using a single 7-point scale anchored by 1 = "very much worsened" and 7 = "very much improved."[16] This measure was not administered during the baseline assessment.

Physical Tests of FM Symptoms and Functional Deficits

Myalgic Tender Points

The number of tender points and extent of tenderness was measured to derive the Total Myalgic Score as determined by patients' responses to digital application of 4 kg of pressure over 4 seconds at 18 sites as described in the American College of Rheumatology criteria for FM.[10] A single examiner (K.D.J.) performed all tests. Scores range from 11 to 53, with higher scores indicating greater pain.

Strength Deficits

Functional strength deficits were measured by the Timed Chair Rise.[17] In this test, seated participants are asked to rise to full height with arms crossed over their chest as many times as possible within 30 seconds.

Balance Deficits

Functional balance deficits were measured by the Sensory Integration for Balance Test,[18] during which participants stand on a NASA-grade 60 cm × 60 cm block of 4 in, medium-density Tempur foam with eyes open, then closed. The scores for Balance-Eyes Open and Balance-Eyes Closed are the number of seconds the position is held, up to 30 seconds maximum.

Questionnaires Assessing Pain Coping Strategies

Pain Acceptance

Pain acceptance was measured by the 20-item Chronic Pain Acceptance Questionnaire (CPAQ).[19] The Acceptance Total Score combines the Activity Engagement Despite Pain and Pain Willingness subscales, with scores ranging from 0 to 120, with higher scores indicating greater pain acceptance.

Pain Catastrophizing

The 6-item catastrophizing scale of the Coping Strategies Questionnaire was used to capture the frequency of patients' responses to pain that characterize it as being awful, horrible, and unbearable.[20] Scores range from 0 to 36, with higher scores indicating greater pain catastrophizing.

Adaptive and Maladaptive Pain Coping Strategies

Pain coping strategies were measured with 10 scales from the Vanderbilt Multidimensional Pain Coping Inventory[21] assessing strategies that are usually adaptive (Problem Solving, Positive Reappraisal, Distraction, Use of Religion, and Use of Social Support) or maladaptive (Distancing, Self-blame, Self-isolation, Confrontation, and Disengagement).[22] Higher scores on each scale indicate greater use of the corresponding strategy.

Daily Diaries

Using an online service, SurveyMonkey.com, real-time daily measures were collected during evening hours for 1 week at each of the 3 assessment periods. The diaries were completed by 18 of the 21 immediate treatment participants and 17 of the 18 wait-list participants. Completion rates were good among both groups (87% in the immediate treatment group, range 48% to 100%; 90% in the wait-list group, range 57% to 100%). The diary outcomes included pain, fatigue, emotional distress, vigor, success at coping through acceptance, and success at coping through relaxation.[8,9,23] All diary variables were scored on 0 to 10 single items, in which higher scores reflected greater amounts. Minutes spent in home yoga practice (postures, meditation, and breathing exercises) were also assessed among those who had received the YoA intervention. Participants were called during the first week of each diary recording period to inquire about any difficulties completing the online diaries. Five participants who had limited home internet access completed pen-and-paper equivalent diaries, which were returned each day using prestamped envelopes.

Demographic and Clinical Variables

At baseline, we collected information about standard demographic and clinical variables (age, years since diagnosis, years symptomatic, race/ethnicity, marital status, education, employment). At all 3 assessments, we collected information about any changes in medications or in medical or nonpharmacological treatments for FM.

Statistical Analyses

The Total Score of the FIQR was the primary treatment outcome measure.[14,15] As recorded in our earlier report on this trial,[7] analyses of baseline dependent measures and demographic and clinical characteristics had confirmed that randomization procedures had produced roughly equivalent groups (Tables 1 and 2). Results comparing the baseline and second assessments had been analyzed using both intention to treat and per protocol methods (per protocol was restricted to participants who had completed the second assessment, and if assigned to immediate treatment, had attended ≥ 4 of the 8 classes). Findings from these 2 sets of analyses, which were very similar, were published in our earlier paper and hence will not be reproduced here.[7]

After the second assessment, the wait-list group was offered the intervention. Thus, the third assessment collected the posttreatment outcomes from the wait-list group, in contrast to collecting follow-up outcomes from the immediate treatment group (3 mo after their treatment had ended). Outcomes from the third assessment were therefore analyzed using distinct approaches that were applied to the

TABLE 2. Baseline Values for Outcome Measures for the Immediate Treatment and Wait-list Groups (No Significant Differences)

	Mean (SD)	
Variables	**Immediate Treatment**	**Wait-list**
FM Symptoms and Deficits		
FIQR Total Score	49.0 (17.9)	43.5 (16.5)
Symptoms (FIQR)	27.2 (8.0)	24.4 (8.9)
Function (FIQR)	12.6 (7.4)	11.0 (5.9)
Overall Impact (FIQR)	9.2 (4.7)	8.1 (5.0)
Pain (FIQR)	5.4 (2.2)	4.6 (1.9)
Fatigue (FIQR)	6.2 (2.1)	6.0 (2.1)
Stiffness (FIQR)	6.4 (2.0)	5.1 (2.3)
Poor Sleep (FIQR)	6.8 (2.5)	5.3 (2.8)
Depression (FIQR)	2.9 (2.7)	3.6 (2.6)
Poor Memory (FIQR)	5.5 (2.6)	5.1 (2.9)
Anxiety (FIQR)	4.0 (3.2)	4.0 (2.9)
Tenderness (FIQR)	6.0 (2.6)	4.4 (1.8)
Poor Balance (FIQR)	4.7 (2.3)	4.6 (2.2)
Environment Sensitivity (FIQR)	6.5 (3.0)	6.1 (2.5)
Overall Improvement (PGIC)	—	—
Total Myalgic Score	38.7 (8.0)	36.0 (7.5)
No. Tender Points	17.4 (1.3)	17.2 (1.3)
Strength (Timed Chair Rise)	9.8 (3.2)	10.4 (3.7)
Balance-Eyes Open (SCBT)	27.3 (5.2)	29.4 (2.4)
Balance-Eyes Closed (SCBT)	25.5 (8.3)	24.8 (9.2)
Pain-coping strategies		
Acceptance Total (CPAQ)	68.9 (15.5)	65.4 (20.6)
Activity Engagement (CPAQ)	42.7 (11.1)	38.7 (12.7)
Pain Willingness (CPAQ)	26.1 (6.5)	26.7 (9.0)
Pain Catastrophizing (CSQ)	1.4 (1.1)	1.5 (1.2)
Problem Solving (VMPCI)	2.7 (0.9)	2.4 (0.8)
Positive Reappraisal (VMPCI)	2.8 (0.8)	2.4 (0.5)
Distraction (VMPCI)	2.8 (0.8)	2.4 (0.8)
Use of Religion (VMPCI)	2.1 (1.4)	1.3 (1.3)
Use of Social Support (VMPCI)	1.8 (0.9)	1.9 (0.7)
Distancing (VMPCI)	2.6 (0.8)	1.9 (0.9)
Self-blame (VMPCI)	2.9 (0.6)	2.4 (0.7)
Self-isolation (VMPCI)	2.3 (1.1)	2.0 (1.3)
Confrontation (VMPCI)	1.2 (1.0)	1.3 (0.8)
Disengagement (VMPCI)	1.1 (0.8)	1.0 (0.7)
Daily diary variables		
Daily Pain	5.6 (1.4)	4.3 (1.7)
Daily Fatigue	6.1 (1.2)	4.6 (1.4)
Daily Distress	3.5 (1.7)	3.1 (1.3)
Daily Vigor	3.6 (1.5)	4.2 (1.1)
Daily Relaxation	4.1 (0.9)	5.2 (1.7)
Daily Acceptance	7.3 (2.2)	7.1 (1.7)

CPAQ indicates Chronic Pain Acceptance Questionnaire; CSQ, Coping Strategies Questionnaire; FIQR, Fibromyalgia Impact Questionnaire Revised; FM, fibromyalgia; PGIC, Patient Global Impression of Change; SCBT, sensory integration for balance test; VMPCI, Vanderbilt Multidimensional Pain Coping Inventory.

per protocol patients in the 2 groups (restricted to participants who had completed the intervention [attended ≥ 4 of the 8 classes] and all 3 outcome assessments).

First, to test whether the posttreatment effects seen in the immediate treatment group were replicated in the wait-list group, we used between-groups *t* tests (unpaired) to directly compare their respective posttreatment assessments (second assessment in the immediate treatment group vs. third assessment in the wait-list group). Second, to evaluate whether 3-month follow-up outcomes in the immediate treatment group indicated sustained improvements versus significant decay relative to this group's posttreatment data, we used within-group paired *t* tests to compare these participants' second and third assessments (with the exception of the Patient Global Impression of Change, which is a measure that is not administered at baseline). We considered using distinct types of statistical procedures for the above analyses according to whether data from the various measures met normality goodness-of-fit criteria. However, we found that *t* tests and bootstrap regression models based on 5000 random data resamples[7] produced identical (or nearly identical) results.

Finally, a series of multilevel random-effects analyses were conducted to examine whether home yoga practice rates were predictive of outcome variables. These analyses combined all data from both groups that had been collected after treatment was completed, that is, posttreatment and 3-month follow-up from the immediate treatment group (second and third assessments) and posttreatment from the wait-list group (third assessment). In this type of advanced regression model, observations are nested within individual patients and regression values are computed independently for each patient in the sample, and then aggregated to derive fixed effects (adjusted mean values) for the average patient.[24–26] Multilevel models are robust in accurately estimating fixed effects even in datasets that are not normally distributed.[27] Because of the various multiple comparisons across multiple measures and the need to balance between type I and type II errors, we applied 2-sided tests with α set at ≤ 0.01 to all statistical analyses.

RESULTS

Among the 25 patients randomized to immediate treatment, 21 qualified as per protocol participants, having participated in the intervention and completed all 3 assessments. Among the 28 assigned to the wait-list condition, 18 qualified as per protocol participants, receiving the YoA intervention after their second assessment, and completing the 3 assessments (see Fig. 1 for details on attrition in both groups). The only predictor of attrition at the third assessment was age, with noncompleters likely to be younger (M = 43 vs. 56 y, $P = 0.003$).

Posttreatment Comparisons of the Immediate Treatment and Wait-list Groups

The results, which are shown in Table 3, replicate and substantiate most of the significant posttreatment improvements in FM symptoms, functional deficits, and coping abilities that had previously been reported in the immediate treatment group.[7] To facilitate interpretation of these data, measures previously found to be significantly improved in the immediate treatment group are presented first in the table, followed by measures that did not significantly improve. Among 30 outcomes that had previously improved in the immediate treatment group, 2 demonstrated significantly different scores across the groups, indicating more use of religious coping and more daily acceptance in the immediate treatment group than the wait-list group after their respective interventions. Trends toward significance were found for 3 more outcomes, indicating that after their corresponding interventions, the immediate treatment group recorded somewhat lower daily

TABLE 3. Posttreatment Outcomes Collected From Each Group Directly After Completion of Their Respective Yoga Interventions

	Mean (SD)		
Variable	**Immediate Treatment**	**Wait-list**	***P***
Measures previously found to be significantly improved in the immediate treatment group*			
FM symptoms and deficits			
FIQR Total Score	34.5 (16.8)	28.3 (13.3)	0.217
Symptoms (FIQR)	19.5 (7.9)	16.8 (6.4)	0.259
Overall Impact (FIQR)	5.6 (3.2)	3.7 (2.3)	0.048
Pain (FIQR)	4.1 (2.1)	3.4 (2.1)	0.334
Fatigue (FIQR)	4.4 (2.2)	3.9 (2.0)	0.527
Stiffness (FIQR)	4.6 (1.8)	4.1 (2.6)	0.431
Poor Sleep (FIQR)	5.3 (3.0)	4.1 (2.6)	0.203
Depression (FIQR)	1.8 (2.1)	1.9 (1.6)	0.766
Poor Memory (FIQR)	4.2 (2.7)	3.8 (1.9)	0.643
Anxiety (FIQR)	2.3 (2.5)	2.2 (2.0)	0.879
Tenderness (FIQR)	5.0 (2.8)	3.4 (2.3)	0.070
Poor Balance (FIQR)	3.0 (2.4)	2.8 (1.8)	0.752
Environment Sensitivity (FIQR)	4.2 (2.6)	3.8 (2.3)	0.570
Overall Improvement (PGIC)	5.0 (0.7)	5.4 (1.1)	0.188
Strength (Timed Chair Rise)	12.3 (4.3)	13.1 (4.3)	0.580
Pain-coping strategies			
Activity Engagement (CPAQ)	46.4 (8.9)	45.2 (8.7)	0.669
Pain Catastrophizing (CSQ)	1.0 (0.9)	0.9 (0.7)	0.726
Problem Solving (VMPCI)	2.8 (0.5)	2.7 (0.6)	0.403
Positive Reappraisal (VMPCI)	2.9 (0.6)	2.6 (0.4)	0.119
Use of Religion (VMPCI)	2.4 (1.4)	1.2 (1.2)	0.007†
Self-isolation (VMPCI)	1.6 (0.9)	1.9 (0.9)	0.346
Confrontation (VMPCI)	0.9 (0.7)	1.1 (0.8)	0.297
Disengagement (VMPCI)	0.8 (0.6)	0.8 (0.4)	0.839
Daily diary variables			
Daily Pain	4.1 (2.6)	3.7 (1.6)	0.505
Daily Fatigue	4.5 (2.3)	4.3 (1.3)	0.319
Daily Distress	2.6 (2.3)	2.3 (1.4)	0.098
Daily Vigor	4.4 (2.0)	5.0 (1.3)	0.164
Daily Relaxation	5.6 (2.0)	5.5 (1.5)	0.228
Daily Acceptance	8.4 (1.6)	7.9 (1.6)	0.006†
Measures previously found not to be improved in the immediate treatment group*			
FM symptoms and deficits			
Function (FIQR)	9.5 (7.7)	7.8 (5.8)	0.464
Total Myalgic Score	29.0 (12.9)	15.4 (6.4)	< 0.001‡
No. Tender Points	15.5 (2.5)	11.9 (4.5)	0.003‡
Balance-Eyes Open (SCBT)	30.0 (0.0)	29.9 (0.5)	0.286
Balance-Eyes Closed (SCBT)	29.5 (2.2)	28.3 (7.1)	0.468
Pain-coping strategies			
Acceptance Total (CPAQ)	74.4 (12.1)	76.1 (12.5)	0.673
Pain Willingness (CPAQ)	28.0 (7.2)	30.9 (5.7)	0.178
Distraction (VMPCI)	2.4 (0.7)	2.3 (0.7)	0.692
Use of Social Support (VMPCI)	1.8 (0.9)	1.8 (0.8)	0.787
Distancing (VMPCI)	2.4 (0.6)	2.2 (0.6)	0.301
Self-blame (VMPCI)	2.6 (0.6)	2.5 (0.5)	0.384

Higher *P* values from unpaired *t* tests indicate relatively closer replication of scores across groups.

*For more information on these analyses, see our previous publication comparing the immediate treatment group's posttreatment scores relative to the wait-list group's pretreatment scores.[7]

†Immediate treatment group significantly better ($\alpha \leq 0.01$).

‡Wait-list group significantly better ($\alpha \leq 0.01$).

CPAQ indicates Chronic Pain Acceptance Questionnaire; CSQ, Coping Strategies Questionnaire; FIQR, Fibromyalgia Impact Questionnaire Revised; FM, fibromyalgia; PGIC, Patient Global Impression of Change; SCBT, sensory integration for balance test; VMPCI, Vanderbilt Multidimensional Pain Coping Inventory.

distress and the wait-list group recorded somewhat better scores on the FIQR Overall Impact subscale and the FIQR symptom item for tenderness.

Among 11 outcomes that had not previously improved in the immediate treatment group, there were 2 significant differences between the groups. Both the total myalgic score and number of tender points were lower in the wait-list group at the end of their intervention.

Posttreatment and 3-Month Follow-up Comparison in the Immediate Treatment Group

Overall, these results, which are displayed in Table 4, indicate sustained improvement in the medium term of most of the significant posttreatment improvements in FM symptoms, functional deficits, and coping abilities that had reported in the immediate treatment group.[7] Among 30 outcomes that had significantly improved at posttreatment,

TABLE 4. Outcomes for the Immediate Treatment Group at Posttreatment and 3-Month Follow-up

Variable	Immediate Treatment Group		
	Posttreatment Mean (SD)	3-mo Follow-up Mean (SD)	*P*
Measures previously found to be significantly improved at posttreatment*			
FM symptoms and deficits			
FIQR Total Score	34.5 (16.8)	38.2 (20.6)	0.122
Symptoms (FIQR)	19.5 (7.9)	22.5 (10.0)	0.034
Overall Impact (FIQR)	5.6 (3.2)	5.5 (5.0)	0.223
Pain (FIQR)	4.1 (2.1)	4.5 (2.2)	0.196
Fatigue (FIQR)	4.4 (2.2)	5.2 (2.9)	0.068
Stiffness (FIQR)	4.6 (1.8)	5.4 (2.3)	0.060
Poor Sleep (FIQR)	5.3 (3.0)	5.9 (3.5)	0.381
Depression (FIQR)	1.8 (2.1)	2.5 (2.7)	0.179
Poor Memory (FIQR)	4.2 (2.7)	4.6 (2.7)	0.486
Anxiety (FIQR)	2.3 (2.5)	3.0 (3.0)	0.198
Tenderness (FIQR)	5.0 (2.8)	5.3 (2.6)	0.376
Poor Balance (FIQR)	3.0 (2.4)	3.4 (2.4)	0.384
Environment Sensitivity (FIQR)	4.2 (2.6)	5.1 (3.0)	0.125
Overall Improvement (PGIC)	5.0 (0.7)	4.7 (1.1)	0.049
Strength (Timed Chair Rise)	12.3 (4.3)	13.9 (4.0)	0.039
Pain-coping strategies			
Activity Engagement (CPAQ)	46.4 (8.9)	43.9 (9.8)	0.126
Pain Catastrophizing (CSQ)	1.0 (0.9)	1.3 (1.2)	0.133
Problem Solving (VMPCI)	2.8 (0.5)	2.6 (0.5)	0.048
Positive Reappraisal (VMPCI)	2.9 (0.6)	2.7 (0.6)	0.112
Use of Religion (VMPCI)	2.4 (1.4)	2.3 (1.3)	0.280
Self-isolation (VMPCI)	1.6 (0.9)	1.7 (0.9)	0.680
Confrontation (VMPCI)	0.9 (0.7)	0.9 (0.9)	0. 895
Disengagement (VMPCI)	0.8 (0.6)	0.9 (0.7)	0.125
Daily diary variables			
Daily Pain	4.1 (2.6)	4.1 (2.0)	0.675
Daily Fatigue	4.5 (2.3)	4.7 (1.5)	0.638
Daily Distress	2.6 (2.3)	2.9 (1.9)	0.415
Daily vigor	4.4 (2.0)	4.4 (1.7)	0.935
Daily Relaxation	5.6 (2.0)	5.6 (1.8)	0.995
Daily Acceptance	8.4 (1.6)	8.5 (1.6)	0.907
Measures previously found not to be improved at posttreatment*			
FM symptoms and deficits			
Function (FIQR)	9.5 (7.7)	9.2 (7.5)	0.796
Total Myalgic Score	29.0 (12.9)	18.7 (9.3)	< 0.001†
No. Tender Points	15.5 (2.5)	12.9 (4.5)	< 0.001†
Balance-Eyes Open (SCBT)	30.0 (0.0)	29.8 (1.1)	0.329
Balance-Eyes Closed (SCBT)	29.5 (2.2)	27.2 (7.3)	0.139
Pain-coping strategies			
Acceptance Total (CPAQ)	74.4 (12.1)	72.6 (14.1)	0.468
Pain Willingness (CPAQ)	28.0 (7.2)	28.7 (6.1)	0.651
Distraction (VMPCI)	2.4 (0.7)	2.6 (0.7)	0.159
Use of Social Support (VMPCI)	1.8 (0.9)	1.7 (0.8)	0.554
Distancing (VMPCI)	2.4 (0.6)	2.3 (0.6)	0.549
Self-blame (VMPCI)	2.6 (0.6)	2.5 (0.6)	0.838

Higher *P* values from paired *t* tests indicate relatively greater similarity between scores.

*For more information on these analyses, see our previous publication comparing the immediate treatment group's posttreatment scores relative with the wait-list group's pretreatment scores.[7]

†Three-month follow-up significantly better ($\alpha \leq 0.01$).

CPAQ indicates Chronic Pain Acceptance Questionnaire; CSQ, Coping Strategies Questionnaire; FIQR, Fibromyalgia Impact Questionnaire Revised; FM, fibromyalgia; PGIC, Patient Global Impression of Change; SCBT, sensory integration for balance test; VMPCI, Vanderbilt Multidimensional Pain Coping Inventory.

none was significantly different at 3-month follow-up and 6 outcomes showed trends toward significance. These trends indicated somewhat greater improvement at follow-up in the physical test of strength and somewhat lessened gains in the FIQR Symptoms subscale, individual FIQR items for fatigue and stiffness, the Overall Improvement score, and use of problem solving.

Among 11 outcomes that had not been improved at posttreatment, there were 2 significant findings. Both the total myalgic score and number of tender points were lower at 3-month follow-up.

Yoga Home Practice Rates and Associations With Outcomes

Average Practice Rates

When completing their online daily diary measures (pain, fatigue, distress, vigor, acceptance, relaxation) for 7

days at each assessment period, participants also reported on the number of minutes spent each day in doing yoga practices at home. In the immediate treatment group, the average practice rates at posttreatment (second assessment) were: total = 46 minutes (range, 14 to 101 min), poses = 16 minutes (range, 0 to 48 min), meditation = 17 minutes (range, 0 to 39 min), and breathing exercises = 13 minutes (range, 2 to 30 min). At the 3-month follow-up (third assessment), the immediate treatment group's average practice rates were: total = 31 minutes (range, 0 to 148 min), poses = 10 minutes (range, 0 to 43 min), meditation = 12 minutes (range, 0 to 75 min), and breathing exercises = 9 minutes (range, 0 to 30 min). Finally, in the wait-list group, the average practice rates after completing their treatment (third assessment) were: total = 36 minutes (range, 1 to 91 min), poses = 14 minutes (range, 0 to 51 min), meditation = 13 minutes (range, 0 to 30 min), and breathing exercises = 9 minutes (range, 0 to 28).

Associations Between Practice Rates and Outcomes

Multilevel models analyzing data combined from both groups produced 1 significant association: more engagement in yoga poses was associated with greater daily relaxation ($t = 3.49$, $P = 0.001$). More use of yoga poses also showed trends toward significance related to lower daily pain ($t = -2.31$, $P = 0.027$), lower daily fatigue ($t = -2.02$, $P = 0.052$), lower daily distress ($t = -2.07$, $P = 0.047$), higher daily vigor ($t = 2.68$, $P = 0.011$), lower FIQR fatigue scores ($t = -1.86$, $P = 0.072$), lower FIQR Impact subscale scores ($t = -2.09$, $P = 0.045$), and lower pain catastrophizing ($t = -1.86$, $P = 0.072$). Additional trends toward significance included associations between more meditation and lower FIQR fatigue scores ($t = -2.03$, $P = 0.051$), more breathing practice and higher Activity Engagement Despite Pain scores (CPAQ subscale; $t = 1.74$, $P = 0.092$), and associations between higher total practice rates and lower FIQR fatigue scores ($t = -2.06$, $P = 0.048$) and lower pain catastrophizing ($t = -1.75$, $P = 0.090$).

DISCUSSION

The results reported provide encouraging evidence that the main findings of our preliminary YoA analyses[7]—that is, broad posttreatment improvements in FM symptoms, functional deficits, and coping abilities—are replicable and can be maintained during the medium term by unsupervised home yoga practice. YoA is a mind/body program that, along with physical exercises, includes mindful meditation and other coping tools drawn from the yoga tradition. Thus, it provides FM patients with both exercise and coping skills components of nonpharmacological therapy. Through increased in-the-moment awareness, YoA aims to develop a deep level of understanding of one's self, including sensory and emotional cues, and also of one's surroundings. YoA seeks to promote a soothing sense of bodily relaxation, refreshed vitality, a greater ability to tolerate symptoms, and the ability to find poise even amidst the tumult of life's challenges. Our trial adds to the growing body of research demonstrating the benefits of yoga-based interventions for chronic pain conditions.[28]

The clinical significance of several of the observed improvements was substantive. The posttreatment reduction in the primary outcome, the FIQR Total Score, was 31.9% across the 2 groups relative to baseline—substantially more than the 14% minimal clinically important difference criterion recommended by Bennett et al.[29] The corresponding improvement at 3-month follow-up (immediate treatment group) was 21.9%. Likewise, daily pain improved by 20.5% at posttreatment across the groups, and was 23.2% improved at 3-month follow-up, both qualifying as moderately important clinical changes according to the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT).[16] Similar size or larger reductions were recorded in all the FIQR subscales and most of the FIQR symptoms and daily diary items, for example: FIQR Impact subscale, 45.9% improvement at posttreatment and 29.4% at 3-month follow-up; FIQR anxiety, 43% improvement at posttreatment and 27.1% at 3-month follow-up; FIQR poor balance, 37.9% improvement at posttreatment and 29.4% at 3-month follow-up; daily distress, 26.3% improvement at posttreatment and 17.0% at 3-month follow-up; and daily vigor, 21.2% improvement at posttreatment and 22.5% at 3-month follow-up. Although there are no established criteria for what constitutes clinically important changes in these additional subscales and symptoms, the pattern of improvements is promising.

The most notable significant differences between the 2 groups' posttreatment scores, and also between posttreatment and 3-month follow-up scores in the immediate treatment group, were in the myalgic scores (total myalgic score and number of tender points). In the posttreatment comparison, myalgic scores were significantly lower in the wait-list group. At 3-month follow-up, myalgic scores had also significantly improved in the immediate treatment group, and yet, these changes were delayed relative to the group's posttreatment improvements in pain. Many previous studies have reported a disconnect between pain improvement and myalgic scores.[30] In the present study, the assessments that contained improved myalgic scores (posttreatment in the wait-list group, 3-month follow-up in the immediate group) were both collected in June, when the local weather (Portland, OR) was substantially warmer relative to January and March, when the comparison assessments were collected. Population-based research and clinical reports indicate that seasonal changes may affect FM symptomatology; hence, it is possible that these myalgic scores' improvements were driven by weather-related changes, rather than treatment effects.[31]

Exercise, especially exercise with an aerobic component, has repeatedly been shown to be beneficial to FM patients.[32,33] The reported initial benefits of aerobic exercise include reductions in pain, fatigue, depression, and improvements in quality of life and physical fitness. But most follow-up studies have shown minimal or no maintenance of most benefits, with a conclusion that continuing exercise is needed to maintain positive effects on pain.[33] However, engaging FM patients in a regular program of exercise is difficult and getting them to adopt exercise as a long-term lifestyle is even more problematic.[34] The reasons for not persisting with a therapy that an individual identifies as being beneficial is not at all clear, as FM patients tend to persist with other modalities, especially medications, over the long term.[35] Perhaps conventional forms of exercise are perceived as too time consuming or produce insufficient activation of the ventro-striatal reward system in those patients who experience exertional pain.[36] FM patients often complain of increased pain on exercise, and it is now apparent that a subset of FM patients experience significantly increased pain in relation to low levels of repetitive physical activity

that is hypothesized to be due to upregulation of nociceptive information from muscles.[37]

Our participants reported good adherence, both at the end of treatment and 3 months later, in home practice of yoga physical exercises, and meditation and breathing strategies. Analyses suggested a dose/response relationship with yoga physical poses, with more engagement in poses associated with significantly more benefit in terms of relaxation, with trends for a variety of other outcomes. In interpreting this pattern, it is important to consider the context in which yoga poses were taught in this study. YoA used a series of poses that were tailored to avoid movements that are known to aggravate pain in FM, with the intention of minimizing fear of movement and repetition-induced pain. Moreover, in this intervention, yoga poses served not simply as healthy physical movements, but also as a forum for developing nonreactive awareness of bodily sensations, including pain, and other challenging experiences. Mindfulness strategies and the application of other yogic principles (eg, acceptance) were directly integrated into the practice of the poses so that participants could become aware of and modulate subtle patterns of unskillful reactivity (eg, fear, guarding). Therefore, it is likely that the observed association between home poses practice and relaxation and other outcomes involved effects over and beyond the purely physical impact of the poses themselves. Likewise, although the reasons for good adherence in this program are unknown, I postulate is that the use of tailored poses in the context of substantive mindfulness training rendered physical exercise more tolerable, meaningful, and sustainable for patients.

Cognitive-behavioral therapy is increasingly being advocated as a useful adjunct to FM treatment strategies.[38] Although robust improvements in pain and fatigue are not generally seen, it does offer an engaging intervention that can improve coping with pain, moderate depressive symptoms, and reduce inappropriate health care-seeking behavior.[39,40] The combined use of exercise and cognitive-behavioral therapy has been reported as especially effective.[41] The combination of exercise, although gentle, and training in coping tools is also realized in each session of YoA and also in some forms of tai chi.[4] Notably, a recent FM trial of Mindfulness-Based Stress Reduction (MBSR) produced null findings.[42] MBSR primarily emphasizes meditation training, and yet, does include yoga poses in 2 of its 8 sessions.[24] It may be that for nonpharmacological therapies to effectively modulate FM symptomatology, a more robust and tailored exercise component is required than that provided by MBSR.

The idea that improvement in coping strategies might be associated with FM symptom improvements was explored in this study with several questionnaires. In general, the changes were modest. The scales that improved most consistently were a measure of pain catastrophizing and a measure of pain acceptance (Activities Engagement Despite Pain subscale of the CPAQ). These results are in keeping with recent research elucidating important roles for catastrophizing and acceptance in modulating functional impairments and emotional distress associated with pain (eg, fear of pain).[43,44] Additional evidence suggesting that decreased catastrophizing and increased acceptance may have substantial effects comes from the strong change in this study in the Impact subscale of the FIQR. There are 2 items in this subscale: "Fibromyalgia prevented me from obtaining my goals for the week" and "I was completely overwhelmed by my fibromyalgia symptoms." It is reasonable to postulate that less catastrophizing and greater acceptance would lead to being less overwhelmed.

There are several limitations in the interpretation of this study. The principal limitation is that there was no active control arm; thus, nonspecific effects such as expectancy for improvement, attention from an intervention provider, intent to please, a placebo effect, or a combination of such effects cannot be ruled out as explanations for results. However, the robust replication of the improvements in the wait-list group and the continuation of improvements at 3-month follow-up make these explanations less likely. Other notable limitations in this study include overreliance on self-report data, possible therapist effects due to use of a single intervention provider, the small sample that was mostly white, well educated, and middle class, and potential selection bias, given that all participants expressed interest in participating in a yoga study. Caution is in order, therefore, in generalizing these results to diverse populations.

In conclusion, the evidence this study provides for the maintenance and replicability of YoA's effects on FM is very promising. Larger, more rigorous, and longer-term trials are warranted to conclusively determine the efficacy of YoA for FM.

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