The Efficacy of Mindfulness Meditation Plus Qigong Movement Therapy in the Treatment of Fibromyalgia: A Randomized Controlled Trial

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ABSTRACT. ***Objective.*** To test the short and longterm benefits of an 8 week mind-body intervention that combined training in mindfulness meditation with Qigong movement therapy for individuals with fibromyalgia syndrome (FM).

Methods. A total of 128 individuals with FM were randomly assigned to the mind-body training program or an education support group that served as the control. Outcome measures were pain, disability (Fibromyalgia Impact Questionnaire), depression, myalgic score (number and severity of tender points), 6 minute walk time, and coping strategies, which were assessed at baseline and at 8, 16, and 24 weeks.

Results. Both groups registered statistically significant improvements across time for the Fibromyalgia Impact Questionnaire, Total Myalgic Score, Pain, and Depression, and no improvement in the number of feet traversed in the 6 minute walk. However, there was no difference in either the rate or magnitude of these changes between the mind-body training group and the education control group. Salutary changes occurring by the eighth week (which corresponded to the end of the mind-body and education control group sessions) were largely maintained by both groups throughout the 6 month followup period.

Conclusion. While both groups showed improvement on a number of outcome variables, there was no evidence that the multimodal mind-body intervention for FM was superior to education and support as a treatment option. Additional randomized controlled trials are needed before interventions of this kind can be recommended for treatment of FM. (J Rheumatol 2003;30:2257–62)

Key Indexing Terms:
MEDITATION MOVEMENT THERAPY FIBROMYALGIA

Fibromyalgia syndrome (FM) is characterized by chronic widespread musculoskeletal pain and multiple tender points[1]. In studies performed in the general population, prevalence ranges between 0.5% and 5%, with women showing significantly greater prevalence than men[2]. Patients with FM frequently present with multiple symptoms including depression, sleep disturbance, and fatigue, with resulting high disability and disruption in social and work roles as well as extensive use of medical services.

Causes of FM remain poorly understood, with treatment typically focused almost exclusively on symptom management[3-6]. Common therapeutic approaches include use of antidepressants (tricyclics and selective serotonin reuptake inhibitors)[7], as well as selected pain and sleep medications. There are significant side effects associated with a number of these pharmacological approaches, however, and the therapeutic benefits tend to be small and relatively shortlived[5,8]. Patient dissatisfaction with conventional pharmacologic and biomedical approaches to FM has also been suggested as one factor underlying the relatively high rates of use of complementary/alternative therapies by this population[9-12]. There is some evidence from 2 recent systematic reviews to suggest that 2 forms of these complementary/alternative therapies — aerobic exercise and an array of psychological/"mind-body" therapies (e.g., biofeedback, relaxation, cognitive-behavioral therapy) — may be effective adjuncts to pharmacologic treatment, particularly in terms of helping foster a greater sense of control and self-efficacy to meet the challenges of FM[13,14].

Results of a pilot study (n = 28) of an 8 week intervention in FM patients focusing on the practice of mindfulness meditation and Qigong movement therapy (described below) showed significant reductions in pain, fatigue, sleep disturbance, and depression, as well as reductions in tender point scores that persisted through 24 weeks[15]. However,

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these findings were limited by the lack of any control or comparison group and by the absence of any longer-term followup data.

Based on these promising preliminary findings, a randomized trial was conducted to further examine the short and longterm effects of an integrated program of stress reduction based on training in mindfulness meditation and the Chinese movement therapy, Qigong. Mindfulness was originally selected as a primary component of this multimodal intervention based on studies by Kabat-Zinn, *et al* suggesting the potential efficacy of this form of meditation in treating chronic pain conditions in general[16,17] and FM specifically[18]. Research suggesting that physical exercise may be particularly beneficial in FM when combined with mind-body/psychosocial approaches[13] led naturally to the inclusion of Qigong into the intervention, based upon its gentle movements and its purported capacity to increase energy levels in practitioners, all of which were hypothesized to be a potentially effective approach with FM patients.

MATERIALS AND METHODS

To control for group and facilitator attention (as well as standard threats to internal validity such as regression to the mean and natural history of the disease), we randomized subjects to the mind-body treatment or the education/support control group. Individuals with a diagnosis of FM were recruited by radio/newspaper advertising and through networking with local physicians. Criteria for study inclusion were: (1) Clinical diagnosis of FM by patient's own health care provider. (2) Fulfillment of American College of Rheumatology (ACR) classification criteria for FM verified by rheumatologic examination: (a) widespread pain (axial plus upper and lower segment plus left and right side pain for ≥ 3 mo; (b) tenderness at ≥ 11 of the 18 specific tender point sites. (3) Age between 18 and 70 years. (4) Able to read and speak English fluently. (5) Able to attend group intervention session if assigned to that group. (6) Able to give informed consent.

Exclusion criteria included pregnancy, substance abuse, major psychiatric disorder (that would prevent compliance), involvement in impending litigation or judgment for disability workers' compensation, or uncontrolled hypertension, diabetes, congestive heart failure or other severe chronic medical conditions judged by the clinician to place the patient at risk of possible severe consequences of his/her disease. Patients were not excluded for the presence of concomitant rheumatic disease.

Recruitment was carried out by Integrative Medical Research (IMR) under the direction of staff at the Complementary Medicine Program, University of Maryland School of Medicine. Initial eligibility was determined by telephone screening of all interested subjects. Clinic appointments at IMR were subsequently scheduled for all eligible participants. With written informed consent (approved by the Human Subjects Safety Committee of the University of Maryland), a semistructured clinical interview was carried out by an IMR staff physician to determine ACR criteria for FM[1] and to verify eligibility. Subjects meeting these criteria were then seen by a research assistant who administered the series of self-report measures (see below) and a 6 minute walk time test.

Power calculations were carried out based upon baseline-to-end of treatment changes in the Fibromyalgia Impact Questionnaire in our earlier pilot study. However, owing to the relatively high attrition rate, we recruited an additional 18 subjects to arrive at our final sample size of 128. This sample size produced an estimated power level of slightly more than 80% for the effect size obtained in the original pilot study for the 8 week assessment, and power equal to 75% for the final 24 week assessment.

Primary outcome measures.

Tender point count: the total number of times a patient verbally indicates "it hurts" during palpation of the 18 tender point sites recognized by the ACR to be one criterion for classification of FM[1].

Total myalgic score: obtained by summing tenderness scores for each of the 18 tender points as defined by ACR criteria for FM. The score for each site can range from 0 to 3, for an overall score range of 0–54 (higher scores indicating more pain).

FM Impact Questionnaire (pain and functioning): a 10 item validated disease-specific scale that assesses physical functioning, pain, depression, anxiety, fatigue, morning tiredness, stiffness, job difficulty, and overall well being, with confirmed reliability and validity[19].

Pain: from the appropriate subscale of the Medical Outcome Study Short-form-36 (SF-36).

Six minute walk time test (objective measure of function): subjects are asked to walk as far and as quickly as possible within 6 minutes. A measure of performance recorded in number of feet covered.

Beck Depression Inventory: a 21 item questionnaire that is well established and validated in assessing depression[20].

Medical care history: an interview-administered questionnaire regarding outpatient visits, inpatient care, use of prescription and over the counter (OTC) drugs, and use of complementary/alternative therapies. With regard to clinical encounters, detailed questions are asked about the reason for the visit, the physician who was seen, and whether any specific medical procedures were completed. At baseline, patients were asked about the previous 6 months. At followup visits, patients were questioned about the time since their previous visit.

Secondary outcomes.

Coping Strategies Questionnaire: a 50 item validated instrument with 8 subscales that assess cognitive and behavioral pain coping mechanisms and strategies[21].

The mind-body intervention. The active treatment for this study consisted of 2 principal components, mindfulness meditation training and Qigong. The intervention was delivered through weekly group meetings (group sizes ranged from 10 to 20 participants). Sessions were 2.5 hours long. The first 90 minute period of each session was based closely on the mindfulness-based stress reduction program developed by Kabat-Zinn and colleagues at the University of Massachusetts Medical Center[22]. As with the original program, these group sessions were centered on the principles and practice of mindfulness meditation, which involves the cultivation of moment-to-moment, nonjudgmental awareness of one's present-moment experience. The goal of this practice is to cultivate a stable and nonreactive awareness of one's internal (e.g., cognitive-affective-sensory) and external (social-environmental) experiences as contrasted with the tendency humans have to react quite reflexively (habitually or automatically) to the myriad situations and experiences (whether stressful or challenging, or not) encountered in daily life. Weekly didactic and experiential sessions involved the learning of 2 formal meditation practices (a body scan and sitting meditation) along with discussions about the practical applications of this type of mindful awareness for coping with pain, psychological distress, with the challenges of FM, and with stressful life events in general.

In the last hour of each session, participants were introduced to the practice of Qigong. Qigong is an ancient Chinese health care system that integrates physical postures, breathing techniques, and focused intention. The word Qigong (Chi Kung) is made up of 2 Chinese words. "Qi" (pronounced chee) is usually translated to mean the life force or vital-energy that flows through all things in the universe. The second word, "Gong" (pronounced gung), means accomplishment, or skill that is cultivated through steady practice. Together, Qigong means cultivating energy. It is a system practiced for health maintenance, healing, and increasing vitality. The Qigong was taught by a Chinese master of this discipline using a specific form ("Dance of the Phoenix") that she developed in the pilot study specifically for patients with FM.

The education/support control group. The control arm was described to potential participants as an "education-support" group. As with the mind-body intervention, group sessions were held once a week for 8 weeks and were 2.5 hours long. The facilitator presented short lectures on a different topic each week (topics were drawn principally from the book *Your personal guide to living well with fibromyalgia: A handbook for self-care and treatment*[23], which is used as a text in the Arthritis Self-Help Course). Topics included stress, exercise, pain cycle/emotions, sleep, work, intimacy, and review of current research. Following these presentations, there was time for questions as well as more unstructured and open-ended sharing and discussion among group participants.

Following completion of all diagnostic examinations and self-administered questionnaires, eligible patients were randomly assigned to one of the 2 trial arms. Blocks of 2, 4, or 6 groups of patients were first randomly selected with a computer program and then patients were randomly assigned to blocks. A total of 128 patients were enrolled into the study in 4 recruitment waves.

Clinical staff at IMR were not given access to patients' group assignments at the baseline assessment, and remained blinded to the randomization scheme for the duration of the trial and all subsequent followup. All baseline assessments were repeated by IMR at the completion of the intervention (8 weeks), and at followup assessments at 16 and 24 weeks.

Data analysis. While an intent-to-treat analysis was planned, compliance was not sufficient among individuals who dropped out of the study prior to the 8 week assessment to permit this, hence the analyses were performed only upon individuals who completed the entire protocol. For each of the 5 primary outcome variables, 2 (group: mind-body vs education control) × 4 (time: baseline and 8, 16, and 24 week assessments) analyses of variance were performed, with the latter factor represented as a repeated measure. In this particular analysis, the 2 terms of interest were the time main effect (which indicated whether changes on an outcome variable occurred as a function of time irrespective of the treatment received) and the time × treatment interaction (which indicated whether subjects in one treatment group changed more than their counterparts in the other group over time). This latter term was employed to contrast the performance of the 2 groups, since it assessed whether (or not) subjects in the mind-body group improved more (or less) over time than those subjects in the education-control group.

RESULTS

As illustrated in Tables 1 and 2, the sample was primarily female and Caucasian, and possessed multiple comorbidities (the most common of which were depression, thyroid problems, and hypertension). The average age of participants was 47.7 (SD 10.6) years and over 80% had taken at least some college courses. There were no statistically significant differences between the mind-body and education-control groups with respect to baseline values for any of the demographic, clinical, or outcome variables.

Of 128 individuals randomized to the 2 groups, 50 (39%) withdrew prior to the 8 week (end of treatment) assessment, 61 (48%) withdrew by week 16, and 63 (49%) failed to complete the 24 week assessment schedule. Overall, 25.8% of the sample never attended even one class (18.8% of the mind-body group; 32.8% of the controls). Given this high attrition rate, we compared those individuals who chose to withdraw from the study to those who did not with respect to their baseline demographic, clinical, and outcome values. This analysis indicated that individuals who completed their 8 week assessment schedule, compared to those who dropped out prior to this assessment, were slightly older (age 49 vs 45 yrs; $p = 0.05$). There were no statistically significant differences on any of the other variables.

As indicated in Table 3, both groups registered statistically significant improvements across time for (a) the Total Fibromyalgia Impact Questionnaire [$F = 15.0$ (3, 189), $p < 0.001$]; (b) the Total Myalgic Score [$F = 4.7$ (3, 156), $p = 0.004$]; (c) Pain [$F = 10.5$ (3, 189), $p < 0.001$]; and (d) Depression [$F = 17.0$ (3, 186), $p < 0.001$]. There was no improvement in the number of feet traversed in the 6 minute

Table 1. Demographic characteristics of the patients with FM (n = 128). There was no statistically significant between-group difference on the demographic variables.

	Education Group, n (%)	Mind-Body Group, n (%)
Age, yrs		
18–29	3 (4.7)	3 (4.7)
30–39	12 (18.8)	13 (20.3)
40–49	20 (31.3)	12 (18.8)
50–59	24 (37.5)	28 (43.8)
≥ 60	5 (7.8)	8 (12.5)
Male	0 (0)	1 (1.6)
Female	64 (100)	63 (98.4)
Highest grade completed		
No high school diploma	1 (1.6)	2 (3.1)
High school diploma	8 (12.5)	11 (17.2)
Some college	26 (40.6)	19 (29.7)
Bachelor's degree	15 (23.4)	15 (23.4)
Above Master's degree	14 (21.9)	17 (26.6)
Marital status		
Unmarried	26 (40.6)	28 (43.8)
Married	38 (59.4)	36 (56.3)
Race		
Caucasian	58 (90.6)	54 (84.4)
African American	4 (6.3)	10 (15.6)
Other	2 (3.2)	0 (0)

Table 2. Baseline clinical characteristics of the sample (n = 128).

	Mind-Body Group, mean (SD)	Control Group, mean (SD)
No. of comorbidities	2.16 (1.60)	2.02 (1.96)
Time since FM diagnosis	4.89 (4.15)	5.22 (7.31)
No. of different medications taken in past 6 months	1.25 (0.84)	1.45 (1.34)
Fibromyalgia Symptom Checklist	49.56 (7.11)	49.47 (7.63)

Table 3. Both study groups showed statistically significant improvements over time. Data are mean (SD).

	Baseline	8 Week	14 Week	24 Week
Fibromyalgic Impact Questionnaire				
Mind-body, n = 32	57.8 (10.8)	48.8 (15.4)**	48.3 (17.3)**	46.4 (19.5)**
Control, n = 33	58.7 (13.5)	50.1 (18.3)**	48.0 (17.7)†	50.0 (18.2)**
Total Myalgic Score				
Mind-body, n = 26	17.9 (5.0)	15.5 (3.5)**	15.7 (4.5)**	15.7 (4.3)**
Control, n = 28	16.8 (5.1)	15.6 (3.4)	15.9 (3.4)	15.9 (4.5)
MOS SF-36 pain score				
Mind-body, n = 32	32.3 (14.4)	39.8 (17.7)*	42.5 (17.4)**	41.6 (22.2)*
Control, n = 33	31.4 (16.7)	40.8 (18.7)**	42.2 (19.4)**	42.4 (22.5)**
6 minute walk				
Mind-body, n = 24	1314 (289)	1336 (366)	1319 (347)	1355 (317)
Control, n = 26	1323 (297)	1261 (306)	1229 (360)	1317 (308)
Beck Depression Inventory				
Mind-body, n = 31	16.7 (7.4)	13.1 (7.9)*	12.1 (7.5)†	12.3 (7.6)†
Control, n = 33	17.2 (9.1)	14.3 (8.4)**	12.9 (9.2)**	14.0 (9.2)**

* $p < 0.05$, ** $p < 0.01$, † $p < 0.001$.

walk. The only subscale of the Coping Strategies Questionnaire that showed a significant change over time was "catastrophizing." There were no statistically significant group by time interactions for any of the outcome variables, indicating that, while both groups improved over time for the majority of the variables, there was no difference in either the rate or magnitude of these changes between the mind-body and the education-control group.

An examination of the pattern of means in Table 3 (illustrated in Figure 1) indicates that the salutary changes occurring by the 8th week (which corresponded to the end of the mind-body and education-control group sessions) were largely maintained throughout the followup period. Within-group analyses were correspondingly performed individually contrasting 8th, 16th, and 24th week assessments with baseline values. As indicated in Table 3, both groups improved significantly at each of these assessment periods for the Fibromyalgia Impact Questionnaire, pain, and depression. Only the mind-body group improved significantly with respect to the Total Mylagic Score, however, and neither group improved with respect to performance on the 6 minute walk.

DISCUSSION

Findings for the efficacy of a multimodal mind-body intervention combining mindfulness meditation and Qigong movement therapy did not suggest that this treatment modality was superior to education and support in the treatment of FM. While participants who completed the study in the mind-body group showed significant improvements in most outcomes post-intervention and at 16 and 24 week followup times, patients randomized to the education-support group showed comparable gains. As a result, there were no significant between-group differences on any study outcome.

Our finding of comparable improvements in both the mind-body and education-support control groups can be interpreted in several ways. First, it could be argued that because there were no significant between-group differences, the positive changes observed in the meditation/Qigong group post-intervention and at followup were not a function of the intervention per se but were the result of some placebo or expectancy effect (e.g., simply being enrolled in the study produced an expectation of relief from pain, disability, etc.), regression to the mean, natural history of the disease, or demand characteristics (e.g., attempting to please the investigators). Since the positive changes were for the most part maintained at 6 month followup, explaining the results in terms of natural history of the disease seems less plausible, although our study design cannot definitively rule out this possibility, nor regression to the mean.

A second interpretation is that some aspect or aspects of the control group actually became therapeutic for partici-

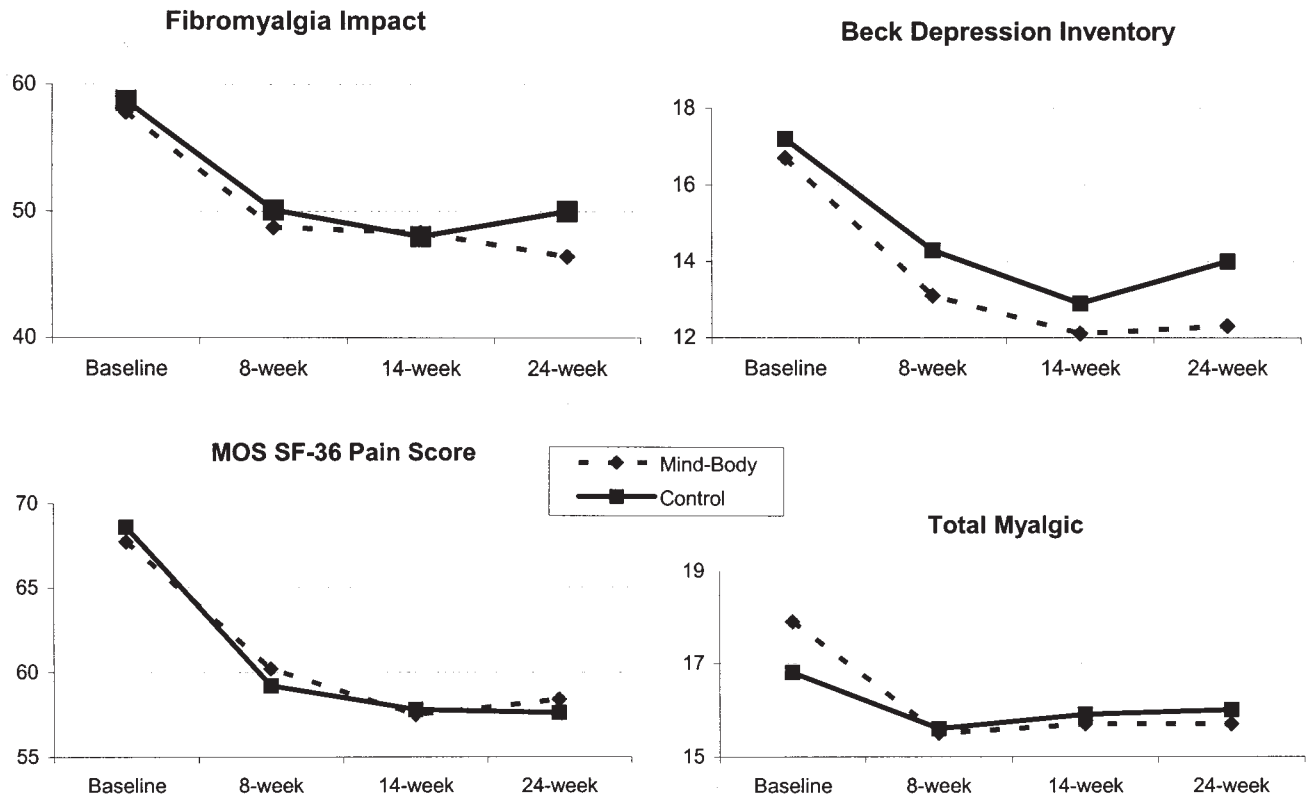

Figure 1. The salutary changes in test measures occurring by the 8th week in both study groups were largely maintained throughout the followup period.

pants, the possibility in this case being that both interventions were uniquely responsible for the positive therapeutic changes that were observed. Based on our findings, it is not clear, however, whether the apparent changes were the result of some shared or similar features in the 2 groups (e.g., attention of facilitator, group emotional support) or the result of particular components that were unique to each of the groups.

The principal limitation of the study was the high attrition rate. While this higher than expected dropout rate may have introduced bias into the findings, our analysis failed to reveal any significant difference between completers and dropouts, with the exception of age, completers being slightly older. However, as noted, the majority of those who failed to complete the study never actually attended any of the sessions (i.e., dropped out after randomization but before participating in the group meetings).

While this study provides no firm evidence for the efficacy of a mindfulness meditation/Qigong intervention for the treatment of FM, the paucity of other viable treatment options, the possibility that the educational-support control we employed may have itself had therapeutic properties, and the statistically significant (if clinically small) improvements in both groups suggest the need for further, high quality randomized trials employing other nonpharmacologic interventions in the treatment of FM.

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