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# **Is Yoga Effective in Reducing Fibromyalgia-Related Symptoms in Women with Fibromyalgia?**

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

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## **ABSTRACT**

**Objective:** The objective of this selective EBM review is to determine whether or not yoga is effective in reducing fibromyalgia-related symptoms in women with fibromyalgia.

**Study design:** Review of two published double blind, randomized controlled trials published in 2010 and one before-after study published in 2012 were used for this review and selected based on their relevance to the clinical question

**Data source:** Studies were found using PubMed, AMED, and CINAHL Plus.

**Outcomes measured:** All three studies measured improvement of fibromyalgia symptoms based on a variety of well-validated measures, most notably the Fibromyalgia Impact Questionnaire, the Quality of Life Profile for the Chronically Ill (PLC), and the Patient Global Impression of Change (PGIC).

**Results:** Studies by Carson et al. and Rudrud found that fibromyalgia-related symptoms significantly decreased with yoga therapy as compared to standard fibromyalgia treatment. However, a study by Schmidt et al. found that the group participating in yoga therapy had little to no improvement as compared to the control groups.

**Conclusions:** Although inconclusive, the results of these three studies demonstrate a possible benefit of yoga in reducing fibromyalgia-related symptoms. The use of this treatment modality warrants further investigation.

**Key words:** yoga, fibromyalgia

## INTRODUCTION

Fibromyalgia is a disorder characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory, and mood issues.<sup>1</sup> This paper evaluates two randomized controlled trials (RCTs) and one before-after study comparing the efficacy of yoga as a therapy for improving fibromyalgia-related symptoms in women with fibromyalgia.

Fibromyalgia affects as many as 5 million Americans ages 18 and older. Most people with fibromyalgia are women (about 80 - 90 percent). However, men and children also can have the disorder. Most people are diagnosed during middle age.<sup>2</sup> A 2007 study found that 34% of fibromyalgia patients spend between \$100- \$1,000 per month above their insurance to see a healthcare professional. Prominent fibromyalgia researchers and specialists estimate the costs in the U.S. between \$12-14 billion each year and accounts for a loss of 1-2% of the nation's overall productivity.<sup>3</sup> On average, fibromyalgia patients have 25 healthcare visits and 11 prescriptions per year.<sup>4</sup>

The cause of fibromyalgia is unknown but it is likely a cause of genetics and triggering factors such as infections or physical or emotional trauma.<sup>1</sup> Researches believe repeated nerve stimulation causes an abnormal increase in neurotransmitters resulting in an overreaction to pain signals.<sup>1</sup> Fibromyalgia is a disorder that causes muscle pain and fatigue. Fibromyalgia patients have tender points throughout their body as well additional symptoms such as trouble sleeping, morning stiffness, headaches, and problems with thinking and memory.<sup>5</sup> Unfortunately, there is no gold standard treatment for fibromyalgia. Treatment options include pain relievers such as acetaminophen, ibuprofen, naproxen, and tramadol; antidepressants such as duloxetine, milnacipran, amitriptyline,

and fluoxetine; anti-epileptic drugs such as gabapentin and pregabalin; and alternative therapies such as stress reduction, acupuncture, massage, and exercise.<sup>1</sup> Often a multifaceted approach is taken, with multiple treatment modalities being used at once.

Currently there is no cure for fibromyalgia. While all of the treatment methods mentioned above have been shown to improve symptoms in some people with fibromyalgia, no treatment is effective for everyone. Yoga may be an effective alternative in reducing fibromyalgia-related symptoms in some women with fibromyalgia.

## **OBJECTIVE**

The objective of this selective EBM review is to determine whether or not yoga is effective in reducing fibromyalgia-related symptoms in women with fibromyalgia.

## **METHODS**

This review focused on adult women with fibromyalgia. The intervention studied was a yoga program. Carson et al. studied Yoga of Awareness against a wait-list control group.<sup>8</sup> Schmidt et al. compared Mindfulness-Based Stress Reduction (MBSR) in comparison to an active control intervention aimed at equating the non-specific features of MBSR as well as a wait-list control group.<sup>6</sup> Rudrud studied the effect of hatha yoga in a before-after study.<sup>7</sup> Though many outcomes were evaluated in each study, the outcome of focus for this review was reduction of fibromyalgia-related symptoms. Two of the studies were randomized control trials (RCT) and one of the studies was a before-after study. Each article was published in a peer-reviewed journal and all articles were published in English. Databases accessed included PubMed, AMED, and CINAHL Plus

and searches were done with the keywords “yoga” and “fibromyalgia”. Articles were selected by the author based on relevance and inclusion of patient oriented outcomes (POEMS). Inclusion criteria included recent studies that were RCTs or other experimental studies. Exclusion criteria included patients under the age of 18, male patients, or studies that focused on forms of exercise other than yoga. Statistical data analysis was reported using p-value, relative benefit increase (RBI), absolute benefit increase (ABI), and number needed to treat (NNT).

**TABLE 1:** Demographics and Characteristics of Included Studies

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Schmidt (2010) <sup>6</sup>	Double blind, placebo controlled RCT	177	18-70	-Women 18-70 years of age who currently has fibromyalgia, as defined by the American College of Rheumatology criteria -Command of the German language	-Life-threatening disease -Evidence of suppressed immune functioning -Participation in other clinical trials	32	Mindfulness-based stress reduction (MBSR)
Rudrud (2012) <sup>7</sup>	Before-after study	10	39-64	-Women age 39-64 who had physician-diagnosed FM based on the criteria established by the American College of Rheumatology -Did not practice yoga or other regular stretching routines for at least 1 month prior to study onset	-Participants did not have other health conditions that limited their ability to participate in yoga, such as chronic back pain from herniated or bulging discs, pregnancy, or hip or knee replacements	2	Hatha Yoga
Carson (2010) <sup>8</sup>	Double blind, placebo controlled RCT	53	≥21	-Be diagnosed with fibromyalgia by American College of Rheumatology criteria -Be on a stable regimen of pharmacologic and/or non-pharmacologic treatment for fibromyalgia > 3 months	-Currently engaged in intensive yoga practice (practice > 3 days/week) -Actively contemplating suicide -Physically disabled in a manner that precluded meaningful participation in the intervention	5	Yoga of Awareness

## **OUTCOMES MEASURED**

Reduction of fibromyalgia-related symptoms were measured using the Fibromyalgia Impact Questionnaire Revised (FIQR), Patient Global Impression of Change (PGIC), Total Myalgic Score (TMS), Timed Chair Raise, Sensory Integration for Balance Test (SCBT), Chronic Pain Acceptance Questionnaire (CPAQ), Coping Strategies Questionnaire (CSQ), Vanderbilt Multidimensional Pain Coping Inventory (VMPCI), daily diaries assessing pain, fatigue, distress, vigor, acceptance, and relaxation, and a p-value  $<0.05$  in the study by Carson et al<sup>8</sup>; The Quality of Life Profile for the Chronically Ill (PLC) and a p-value  $>0.05$  in the study by Schmidt et al<sup>6</sup>; and FIQR, weekly journal reports regarding health status, and tender point evaluation in the study by Rudrud.<sup>7</sup>

## **RESULTS**

Three studies explored the efficacy of yoga in reducing fibromyalgia-related symptoms with results presented as continuous data. Two studies were randomized control trials and one study was a before-after study. One RCT compared yoga with an active control intervention and a wait-list control group while the other RCT compared yoga with only a wait-list control group. Safety and adverse events were not discussed in any of the three studies due to the innocuous nature of yoga practice. Experienced instructors were used in all three studies and modifications were offered throughout yoga practice in order to accommodate the health limitations of participants.

In the study by Carson et al. patients were randomly assigned to either the experimental Yoga of Awareness group or the control group. Patients, clinicians and



study workers were all kept blind to treatment. All patients were analyzed in the groups to which they were randomized using intention-to-treat analysis. ITT methods were followed for all primary outcome analyses, using the last-observation-carried-forward method. In order to analyze the results of this study, the author of this review converted continuous data to dichotomous data. This data was converted from the PGIC measure of overall improvement on fibromyalgia symptoms. The study states that “4.5% in the yoga condition vs. 0.0% in the control reported being “very much better”, 9.1% in the yoga condition vs. 0.0% in the control were “much better”, 77.3 in the yoga condition vs. 19.2% in the control were “a little better”, 4.5% in the yoga condition vs. 38.5% in the control reported “no change”, 4.5% in the yoga condition vs. 34.6% in the control were “a little worse”, and 0.0% in the yoga condition vs. 7.7% in the control were “much worse”.” The author chose to define efficacy as “very much better”, “much better”, or “a little better” and converted the continuous data to dichotomous data based on this premise. Based on this data the relative benefit increase (RBI) was 373%, the absolute benefit increase (ABI) was 71.7% and the numbers needed to treat (NNT) was 2 meaning that you need to treat two patients in order for one patient to benefit. The p-values for the six diary outcomes – pain, fatigue, emotional distress, vigor, success at acceptance, and relaxation coping strategies – were all substantially less than 0.05, ranging from 0.0001 to 0.0005. From these numbers it is clear that Yoga of Awareness improved a wide range of fibromyalgia symptoms and functional deficits, including pain, fatigue, stiffness, poor sleep, depression, poor memory, anxiety, tenderness, poor balance, environmental sensitivity, vigor, and limited strength.<sup>8</sup>

In the study by Schmidt et al. patients were randomly assigned to the experimental MBSR group, the active control “relaxation” group, or the control group. Patients, clinicians, and study workers were kept blind to treatment; however, the study physicians reported that patients occasionally volunteered information regarding allocation, and estimated this to occur in approximately 20% of the sample. All patients were analyzed in the groups to which they were randomized using intention-to-treat analysis. ITT analysis was done using regression-based single imputation procedure by the software SOLAS 2.0. Continuous data was converted to dichotomous data in order to better analyze the findings of the study. The researchers determined a 14% change in the FIQ as a minimal clinically important difference. Based on this, they determined that symptoms improved by 22% for the wait list and by 30% for the mindfulness group. Based on the data provided in the article the RBI was 36%, the ABI was 8% and the NNT was 13, meaning that you need to treat 13 patients for 1 patient to benefit. Statistical analyses showed that there were no significant differences between any treatment and control groups. The p-value for MBSR as compared to the active control group was 0.20 and the p-value for the wait list control group compared to both active treatments was 0.70. Based on this analysis Mindfulness-Based Stress Reduction cannot be recommended as an effective treatment for women with fibromyalgia.<sup>6</sup>

The study by Rudrud was not a controlled trial. Data gathered regarding patients’ fibromyalgia-related symptoms before beginning the hatha yoga program and after completing the program was analyzed using paired t-tests which was used to compare initial FIQ to post-intervention FIQ and Wilcoxon’s signed-rank tests to compare pre- and post-intervention tender point evaluations. Using these methods, researchers found a

28% reduction in FIQ scores and 70% of patients reported decline in pain on tender point evaluation. Qualitative analysis of patient journals also reflected these changes. Based on these analyses hatha yoga was effective in reducing fibromyalgia-related symptoms.<sup>7</sup>

**TABLE 2:** Treatment effects

<b>Study</b>	<b>RBI</b>	<b>ABI</b>	<b>NNT</b>
<b>Carson et al</b>	373%	71.7%	2
<b>Schmidt et al</b>	36%	8%	13
<b>Rudrud</b>	N/A	N/A	N/A

## DISCUSSION

This systematic review demonstrates possible relief from fibromyalgia symptoms by using yoga therapy in place of or in addition to standard fibromyalgia treatment options. Two of the three studies showed some improvement in fibromyalgia symptoms; however, the limitations of these studies raises questions about the true efficacy of yoga as an intervention for relief of fibromyalgia symptoms.

Lack of post-intervention follow-up was a limitation of all three studies. Due to this deficit, it is unclear if a short period of yoga practice can produce lasting symptom reduction or if it is necessary for fibromyalgia patients to continue with long-term yoga practice in order to maintain some relief from symptoms. Additionally, all three studies relied heavily on self-reported data from participants which may have resulted in bias. However, since there is no objective measure of fibromyalgia symptoms, this limitation is unavoidable.

In the study of Yoga of Awareness by Carson et al. yoga was found to benefit fibromyalgia patients conclusions may be limited due to a small sample size, absence of follow-up, and over-reliance on self-reported data as mentioned above.<sup>8</sup>

In the study of MBSR by Schmidt et al. outcomes, especially self-report questionnaires, may have been biased due to excessive patient burden. Earlier similar studies found improved patient outcomes after completing MBSR in contrast to this study, which did not. Patients were asked to report symptoms frequently and were asked to participate in multiple methods of measuring symptoms. This in addition to common symptoms of fibromyalgia such as fatigue and lack of energy may have excessively burdened patients, negating any benefit that may have been achieved through MBSR.

Earlier studies using MBSR were not blind so patients actively chose MBSR, which may have caused patients to be more motivated.<sup>6</sup>

In the study of hatha yoga by Rudrud, authenticity of findings was limited by the lack of a randomized control group and the very small sample size did not allow for comprehensive analysis. Finally, the lack of standardization of the yoga practice did not allow for further investigation into which components were most beneficial to participants.<sup>7</sup>

While yoga may be an effective therapy for fibromyalgia, particularly in combination with other therapies, access may be problematic for patients. Yoga is not covered by a patient's insurance, so regular yoga practice may place additional financial burden on patients. For patients living in rural areas, access to a yoga studio with a qualified instructor is likely to be limited. It is unclear from these studies if home practice alone, without the assistance of an instructor, would be beneficial in reducing patients' fibromyalgia symptoms.

## **CONCLUSION**

The studies reviewed in order to answer the question "is yoga effective in reducing fibromyalgia-related symptoms in women with fibromyalgia" show conflicting evidence in support of the hypothesis. Results of two studies show clear benefit to women with fibromyalgia, while the third study found no benefit and as a result recommended against this treatment modality. While, at this time, we cannot conclude that yoga is effective in reducing fibromyalgia-related symptoms, it is certainly a low-risk treatment option that may prove to be appealing to those dealing with this incurable

disease. Future studies are necessary before routinely recommending yoga as an effective treatment for reducing symptoms of fibromyalgia. Future studies should include a control group as well as a sample size large enough to generalize findings. It is also essential to minimize participant burden as much as possible, due to the already debilitating nature of this disease.

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