Yoga intervention for adults with mild-to-moderate asthma: a pilot study

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Background: Preliminary studies investigating yoga and breath work for treating asthma have been promising. Several randomized controlled trials have shown a benefit from yoga postures and breathing vs control, but the control in these cases involved no intervention other than usual care. This study advances the field by providing an active control.

Objective: To determine the effectiveness and feasibility of a yoga and breath work intervention for improving clinical indices and quality of life in adults with mild-to-moderate asthma.

Methods: A randomized, controlled, double-masked clinical trial was conducted between October 1, 2001, and March 31, 2003. Random assignment was made to either a 4-week yoga intervention that included postures and breath work or a stretching control condition. Outcome measures were evaluated at 4, 8, 12, and 16 weeks and included the Mini Asthma Quality of Life Questionnaire, rescue inhaler use, spirometry, symptom diaries, and health care utilization.

Results: Sixty-two participants were randomized to the intervention and control groups, and 45 completed the final follow-up measures. Intention-to-treat analysis was performed. Significant within-group differences in postbronchodilator forced expiratory volume in 1 second and morning symptom scores were apparent in both groups at 4 and 16 weeks; however, no significant differences between groups were observed on any outcome measures.

Conclusions: Iyengar yoga conferred no appreciable benefit in mild-to-moderate asthma. Circumstances under which yoga is of benefit in asthma management, if any, remain to be determined.

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INTRODUCTION

Yoga, a 5,000-year-old practice of postures, breathing exercises, and meditation,[1] is a widely used complementary and alternative therapy for asthma.[2] Anecdotal evidence favors yoga's effectiveness as adjunctive treatment for asthma,[3] supported by physiologically based theories of mechanisms of action. Yogic practices promote relaxation, reduce sympathetic activity[4–6] and reactivity, and improve pulmonary ventilation by relaxation of voluntary inspiratory and expiratory muscles.[7,8]

Previous studies[9–14] have shown the efficacy of certain components of yoga on asthma; however, this work is limited in its methods, compounded by the use of small sample sizes and circumscribed populations.[13] Interpretation of the previous literature is further complicated by the variety of yogic interventions used and, in most studies, the lack of an active control condition, raising the prospect of placebo[15] or Hawthorne[16] effects.

Reported herein are the results of a randomized, double-masked controlled clinical trial that investigated the effects of adjuvant yoga therapy on quality of life, medication use, clinical markers, symptoms, and health care utilization in adults with mild-to-moderate asthma. In addition, the study sought to demonstrate the feasibility of (1) using a sham active control condition and (2) implementing a yoga intervention in the context of standard care and daily living for individuals with asthma.

METHODS

Research Design and Participant Selection

This double-masked randomized controlled trial was conducted between October 1, 2001, and March 31, 2003, at the Yale-Griffin Prevention Research Center. A total of 62 participants were recruited through newspaper advertisements, postings in pulmonary clinics and the community at large, and direct mailings to patients of pulmonary clinics and primary care centers. Inclusion criteria consisted of (1) age of 18 years or older; (2) an established diagnosis of mild-to-moderate asthma for at least 6 months (meeting the American Thoracic Society[17] spirometry criteria for mild-to-moderate asthma, which requires either a forced expiratory volume in 1 second [FEV_1]/forced vital capacity [FVC] below the lower limit of normal with a significant response to a bronchodilator [a ≥12% increase and a ≥200-mL absolute increase in FEV_1 15 minutes after the administration of 2 puffs of a short-acting β-agonist] or peak expiratory flow rate [PEFR] variability >20%); (3) taking at least 1 of the following: inhaled β-agonists, methylxanthines, anticholinergics, inhaled corticosteroids, leukotriene inhibitors or receptor antagonists, or mast cell–stabilizing agents for at least 6 months; and (4) stable medication dosing for the past month. Participants were excluded if they (1) smoked currently (or in the past year) or had a smoking history of greater than 5 pack-years

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(the more stringent criterion of 5 pack-years instead of the standard 10 pack-years was used because asthmatic patients who smoked longer may have irreversible obstruction and may not be as likely to respond to yoga); (2) had a concomitant lung disease; (3) had only exercise-induced asthma; (4) practiced yoga in the past 3 years; (5) were pregnant; (6) had a chronic medical condition that required treatment with oral corticosteroids in the past month; (7) had a medical condition that contraindicated exercise; or (8) had an unstable medical condition. Participants from all ethnic and minority groups were equally eligible for study participation.

Potential participants were screened using a semistructured telephone interview. Participants who met initial screening criteria underwent a clinical screening visit, which also served as a baseline evaluation and the beginning of a 1-week run-in period. At the end of the run-in period, participants completed the baseline measurements. In the interest of maintaining small class sizes for the intervention, participants were divided into 5 consecutive cohorts. In each cohort, participants were randomly assigned on the basis of software-generated (SAS version 8.2; SAS Institute Inc, Cary, NC) blocked random assignment to a yoga intervention group or a stretching control group. At enrollment, each participant was assigned an identification number, which was later coded to his or her allocation. All allocations were maintained in sealed envelopes that were unavailable to outcomes assessors to maintain masking. In addition, all participants were told that they were receiving "complementary care body conditioning" for asthma management, and Sanskrit words, including *yoga, asana, pranayama,* and *dhyana,* were not used with participants. All participants continued to receive conventional medical care for their asthma symptoms. The study was approved by the Yale Human Investigations Committee and the Griffin Hospital Institutional Review Board. Informed consent was obtained from participants before randomization.

Treatment Intervention

Participants assigned to the yoga intervention participated in twice-weekly 90-minute yoga sessions for 4 weeks. Classes were led by an experienced Iyengar yoga instructor. Iyengar yoga was chosen as the intervention because of its accessibility to beginners and because instruction is well-standardized, in contrast to several other schools of yoga. In each class, participants were taught generally accepted principles of Iyengar yoga, including 15 asanas (postures), pranayama (breathing), and dhyana (meditation). The yoga instructor gave individually tailored advice to improve each participant's technique. Participants were instructed in specific pranayama techniques, and during each asana, participants were reminded to use these techniques. Each class concluded with instruction in relaxation techniques and meditation. Participants were provided printed materials and audiocassettes that explained the techniques learned during the yoga sessions, and they were encouraged to practice at home. At the conclusion of the 4 weeks of training sessions, participants were asked to continue with a home practice for 20 minutes per day, 3 times a week, for an additional 3 months.

Control Intervention

Participants assigned to the control condition underwent a sham intervention of basic muscle stretching exercises. Girodo et al[18] previously demonstrated that muscular and general aerobic conditioning did not produce observable rehabilitative effects in asthmatic participants, indicating that physical activity is an appropriate sham intervention for asthma. Classes lasted 1 hour and met the same number of times as the yoga classes. Classes were led by a certified exercise physiologist or by graduate students in exercise physiology. Instruction consisted of stretches based on published guidelines from the American College of Sports Medicine.[19] None of the exercises used any of the postures or breathing techniques taught in yoga. Control participants were given printed materials and audiocassettes of the stretching exercises and were told to continue these exercises for 20 minutes per day, 3 times a week, for 3 months after completing the training sessions.

Outcome Measures

The primary outcome measures were frequency of rescue inhaler use, measured as the average number of puffs per day, and quality of life, measured using the Mini Asthma Quality of Life Questionnaire (MiniAQLQ). The MiniAQLQ is a validated quality-of-life scale that measures 4 domains of quality of life: symptoms, activity limitation, emotional function, and environmental stimuli. The overall score is recorded as the average of 15 questions scored on a scale from 1 to 7, where higher scores reflect better quality of life. Secondary outcome measures included prebronchodilator and postbronchodilator FEV_1, PEFR variability, baseline medication use, asthma symptom score, health care utilization, and compliance with the assigned intervention.

Outcomes were evaluated at baseline, at the end of the training sessions, and then monthly for 3 months by an investigator masked to treatment assignment. At the assessments, completed diary cards (filled out at home during the previous week) were collected, and blank cards were furnished. Prebronchodilator and postbronchodilator FEV_1 were measured, and participants answered the MiniAQLQ and a brief questionnaire on asthma medication use and health care utilization, with additional questions about compliance with the assigned intervention and validation of the participants' masking at follow-up. Finally, the PEFR measurement technique was observed, and participants were retrained as necessary.

Data Analysis and Sample Size

An a priori sample size (n = 66) was calculated for 90% power[20] at a 2-tailed $\alpha = .05$ and an attrition rate of 20% to detect a difference in MiniAQLQ scores and for 80% power at a 2-tailed $\alpha = .05$ and an attrition rate of 20% to detect a difference in rescue inhaler use. Data analysis was conducted using a statistical software program (SAS version 8.2). A

2-tailed $P \leq .05$ was considered statistically significant. Continuous variables were analyzed using the Mann-Whitney *U* test or the 2-sample *t* test, depending on the distribution of the data. Categorical variables were analyzed using χ^2 analysis or the Fisher exact test. Multivariable linear regression was used to evaluate trends. Paired *t* testing was performed to evaluate changes in MiniAQLQ scores, rescue inhaler use, and secondary outcomes from baseline.

Qualitative Inquiry

As the study progressed, it became apparent that recruitment and retention were substantial challenges (Table 1 and Fig 1). To determine possible reasons for these difficulties, group interviews were held after the study ended with people who met the inclusion criteria but who did not participate in the study. A research associate moderated the group, and standard qualitative methods[21] were used to collect and analyze data. Participants were asked what would influence their participation in the study, the best means for recruitment, and their opinions on recruitment advertising content and the appeal of the interventions offered.

RESULTS

Quantitative Results

Sixty-two participants were randomized to the intervention and control groups, and 45 completed the final follow-up measures at week 16 (Fig 1). Of the individuals who identified themselves as potential candidates, many did not meet the study eligibility criteria. Fifty-one ineligible participants were past smokers and could not meet the stringent criterion of a smoking history of less than 5 pack-years. There were no adverse events associated with either intervention. The results reported herein, excluding compliance and attendance, are based on the intention-to-treat principle.

Participants were aged 18 to 76 years, with a mean age of 51 years. The intervention and control groups did not differ significantly regarding pertinent demographic characteristics (Table 2). At baseline, the intervention and control groups significantly differed regarding FEV_1/FVC ($P = .02$) and FEV between 25% and 75% ($P = .03$). Morning PEFR values between groups had a marginally significant difference ($P = .052$). Although not all baseline values were significantly different, the intervention group consistently exhibited more disability for all spirometry measurements and asthma severity assessments than controls.

Compliance was evaluated as the number of times that body-conditioning exercises were performed during the 2 weeks before evaluation. Attendance was measured as the total number of classes attended. Mean treatment compliance and class attendance did not differ significantly between treatment groups. Compliance rates declined for both groups as the study progressed, with a statistically significant decline in compliance from week 4 (the first time compliance was evaluated) in the intervention group to 12 weeks ($P = .02$) and 16 weeks ($P = .003$) of follow-up. Compliance and rescue inhaler use were directly related in the intervention group ($P = .004$) (data not shown) but not in the control group.

Quality of life did not differ significantly between treatment groups at any point. However, body-conditioning exercises had a significant increase in effect at 16 weeks regarding overall quality of life ($P = .04$) (Table 3). Neither treatment had any effect on the frequency of rescue inhaler use, and neither did the groups differ significantly regarding use (Table 4).

There were no differences between treatment groups or significant changes from baseline in either group at 4 or 16 weeks of follow-up in any secondary outcomes, including FEV_1, postbronchodilator FEV_1, FVC, FEV_1/FVC, or FEV between 25% and 75%. There was an improvement at 4 and 16 weeks in postbronchodilator FEV_1 from baseline in the intervention ($P = .001$ and $P < .001$) and control ($P < .001$ for both) groups, although there was no linear trend. In addition, there was an improvement in morning asthma symptoms in the intervention and control group at 4 weeks ($P = .03$) and 16 weeks ($P < .001$).

Qualitative Results

Nine people participated in group interviews, which were conducted with the sole intention of improving recruitment and retention in future studies. When participants were asked what would affect their participation in an asthma study, many felt that logistics were an important factor, including location, transportation, time of day, and overall time commitment. Many participants thought that the present study was too demanding. Compensation was noted as a contributing factor for interest in a study, but it was not considered the primary motivator by most respondents. Asthma severity was noted several times as a reason for joining a study. Many participants stated that if their asthma were worse, they would be more likely to inquire about a trial.

No major common themes stood out when participants were asked where recruitment materials should be placed. Advertising with brightly colored flyers, direct mail, and advertisements in newspapers, on the radio, and on cable television were all mentioned. When asked how the recruit-

Table 1. Expected Enrollment

Enrollment	No. of participants
No. eligible in target population	17,632 (7.9% of the total population in the Naugatuck River Valley and New Haven, CT)*
No. of expected responses	882 (5% of the eligible population)
No. of actual responses	215
Recruitment target No.	66
Actual No. recruited	62
Actual No. retained	45

*7.9% is the overall prevalence of asthma in adults in Connecticut (Connecticut Department of Public Health. Asthma in Connecticut. Available at: http://www.dph.state.ct.us/Publications/BCH/EEOH/AsthmaRpt.pdf).

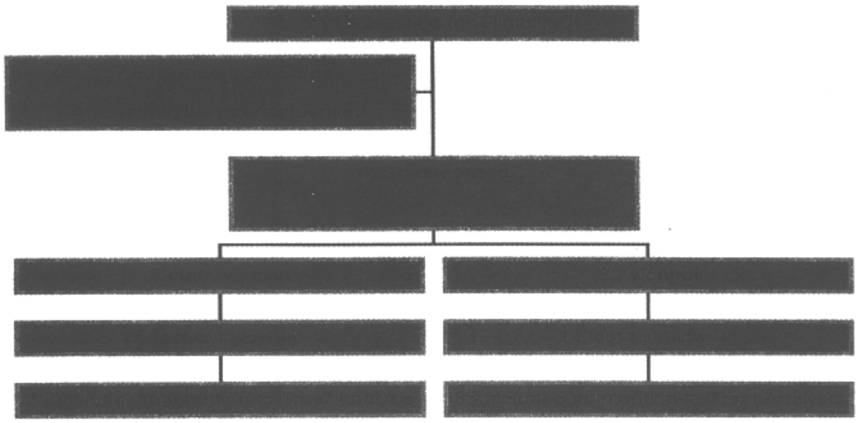

Figure 1. Participant flowchart.

ment materials could be more effective, participants indicated that the benefits of the study should be emphasized, fewer words should be used, and an attention-grabber was needed.

DISCUSSION

This study successfully demonstrated the feasibility of conducting a randomized, sham active control, double-masked trial of yoga for adults with mild-to-moderate asthma. Significant improvements in postbronchodilator FEV_1 and symptom scores were observed in the yoga and control groups at 4 and 16 weeks. Previous studies[10,11,13] also investigating yoga for asthma determined similar results (although not significant) for symptom score and respiratory function, but such results were only apparent in the yoga group. Within-group improvement in both arms suggests that the interventions may have been too similar and as such exerted similar favorable effects. Alternatively, the sham intervention may have a benefit of its own. It is also possible that the active

Table 2. Demographics and Baseline Values

	Intervention group (n = 29)	Control group (n = 33)	*P* value*
Sex, No. (%)			
M	5 (17)	11 (33)	
F	24 (83)	22 (67)	.15
Age, mean (SE), y	52.3 (2.59)	49.9 (2.48)	.50
Race, No. (%)			
White	27 (93)	25 (76)	
African American	1 (3)	5 (15)	
Hispanic	1 (3)	3 (9)	.17
Height, mean (SE), in.	64.87 (0.67)	65.01 (0.71)	.88
Weight, mean (SE), lb	164.3 (8.68)	172.8 (7.22)	.45
MiniAQLQ mean (SE), total score	4.82 (0.19)	4.80 (0.20)	.26
Rescue inhaler use, mean (SE), times per day	1.13 (0.40)	0.79 (0.20)	.44
PEFR, mean (SE)			
Morning	329.05 (21.50)	405.78 (31.21)	.052
Evening	331.71 (17.92)	391.12 (26.19)	.07
FEV_1, mean (SE)	2.05 (0.12)	2.69 (0.16)	.13
Postbronchodilator FEV_1, mean (SE)	2.32 (0.15)	2.60 (0.17)	.22
FVC, mean (SE)	3.07 (0.14)	3.23 (0.20)	.51
FEV_1/FVC, mean (SE)	0.67 (0.02)	0.74 (0.02)	.02
FEV_{25-75}, mean (SE)	1.46 (0.18)	2.10 (0.21)	.03
Asthma symptom score, mean (SE)			
Morning	1.90 (0.20)	0.40 (0.11)	.61
Evening	1.76 (0.16)	0.45 (0.09)	.73
Physician visits			.25

Abbreviations: FEV_1, forced expiratory volume in 1 second; FEV_{25-75}, FEV between 25% and 75%; FVC, forced vital capacity; MiniAQLQ, Mini Asthma Quality of Life Questionnaire; PEFR, peak expiratory flow rate.

*P value obtained from χ^2 analysis, Fisher exact test, or t test.

Table 3. Mini Asthma Quality of Life Questionnaire Total Score Changes From Baseline

	Change, mean (SE)	
	Intervention group	Control group
Week 4	0.17 (0.14)	0.36 (0.22)
Week 16	0.57 (0.37)	0.35 (0.16)

control implemented in the study compensated for placebo and Hawthorne effects and thus revealed the ineffectiveness of yoga not evident in previous uncontrolled trials.

Unlike previous studies,[10,12,13,22] the present study found no statistically significant differences between the yoga and control groups on any outcome measures, including the primary outcome measures—total asthma-related quality-of-life score and rescue inhaler use. Manocha et al[22] and Bowler et al,[9] although using different quality-of-life scales, did not report significant differences between intervention and control groups; however, they observed positive trends in the "mood" subscale of the quality-of-life measure and identified positive overall quality-of-life trends, respectively. Previous studies[9,11] in yogic breathing techniques were successful in producing a significant effect and positive trends[10] in rescue inhaler use; however, our study did not achieve such results, possibly because the yoga intervention did not focus solely on breathing techniques. Vedanthan et al,[13] who studied an intervention similar to the present study, observed reduced rescue inhaler use in the yoga group, although it was not significantly different from that in the control group.

It is possible that the lack of statistically significant differences between the yoga and control groups on all outcome measures is attributable to the inadequate sample size attained. As seen in Table 1, the number of interested inquirers fell far short of expectations, and the required sample size was not reached. Qualitative data indicate that severity of asthma, the study's limited budget, and the time commitment required of participants may have affected recruitment numbers. In addition to recruitment challenges, this study experienced a higher-than-anticipated attrition rate, a result of which is an underpowered study. If there was a therapeutic effect, it may not have been apparent with the data available.

A significant decline in compliance with the intervention was evident in both groups, possibly owing to the time commitment required of participants or the lack of interest in the yoga or stretching exercises. Rescue inhaler use increased with compliance in the intervention group. Such an effect is difficult to interpret, but it may be associated with the increased disability apparent in the intervention group at baseline. This difference in disability at baseline between groups, despite randomization, may also have obscured a possible therapeutic between-group effect; therefore, differences at baseline affect the ability to make a true comparison after intervention.

Table 4. Rescue Inhaler Use Changes From Baseline

	Change, mean (SE)	
	Intervention group	Control group
Week 4	−0.06 (0.16)	−0.47 (0.41)
Week 16	−0.31 (0.40)	0.45 (0.22)

This study was subject to several limitations. Although participants were asked before enrollment whether they had practiced yoga previously, they were not asked about their experience with asthma education or self-management or self-relaxation. If participants practiced self-relaxation techniques before enrollment, an improvement might not be expected in either group. Also, the total study period for participants was limited to 4 months. The effect of yoga may not be seen until after that period, or it may increase or decrease with prolonged practice. Further studies into the effects of yoga over time may be indicated. In addition, it is not known whether all components of yoga have an effect on asthma. A multiarmed study may be able to separate the effects of yoga's individual components.

A major strength of this study is in the design of its control condition. Previous studies of yoga for asthma have designed their control groups to undergo no intervention other than usual care,[12–14] not accounting for the possible placebo effect that the intervention group may experience from participating in the trial, and also precluding participant masking. In this trial, all control participants underwent a plausible sham intervention of stretching exercises. By keeping control participants actively involved in an intervention, benefits specifically due to yoga could be distinguished from placebo effects. None were observed, suggesting that the benefits of yoga previously cited in uncontrolled trials were, in fact, due to the placebo effect.

The feasibility and efficacy of yoga as an adjuvant therapy for asthma were evaluated. The challenges faced during the implementation of this study suggest that incorporating yoga into the lifestyle of a person with asthma does not happen easily. The time commitment and schedule hypothesized to offer benefit was not something that many participants could adhere to, as evidenced by class attendance logs and compliance journals. Also, yoga can be more costly than conventional medications during the initial period of instruction; however, once learned, yoga can be practiced at home with no associated costs. Insurance coverage for yoga instruction is variable,[23–25] and without reimbursement, patients may be reluctant to absorb the cost of yoga therapy. It is difficult to claim that a yoga regimen would be feasible adjuvant treatment for asthma in the general population, children, or those with more severe disease.

In conclusion, this study finds no evidence of benefit specifically attributable to Iyengar yoga in mild-to-moderate asthma; however, these results do not preclude a possible benefit of yoga in specific patient populations, in patients with greater severity of disease, or by practicing a different school of yoga. Any circumstances under which yoga confers such benefit remain to be elucidated.

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