Feasibility and Impact of an 8-Week Integrative Yoga Program in People with Moderate Multiple Sclerosis–Related Disability

A Pilot Study

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Background: *This pilot study determined the feasibility of a specifically designed 8-week yoga program for people with moderate multiple sclerosis (MS)–related disability. We explored the program’s effect on quality of life (QOL) and physical and mental performance.*

Methods: *We used a single-group design with repeated measurements at baseline, postintervention, and 8-week follow-up. Feasibility was examined through cost, recruitment, retention, attendance, and safety. Outcomes included the Multiple Sclerosis Quality of Life Inventory (MSQLI), 12-item Multiple Sclerosis Walking Scale (MSWS-12), Timed 25-Foot Walk test (T25FW), 6-Minute Walk Test (6MWT), Nine-Hole Peg Test (NHPT), Five-Times Sit-to-Stand Test (FTSTS), Multidirectional Reach Test (MDRT), maximum expiratory pressure, and Paced Auditory Serial Addition Test-3” (PASAT-3”).*

Results: *Fourteen participants completed the study. The program was feasible. There were significant main effects on the 36-item Short Form Health Status Survey Mental Component Summary (SF-36 MCS), Modified Fatigue Impact Scale (MFIS), Bladder Control Scale (BLCS), Perceived Deficits Questionnaire (PDQ), Mental Health Inventory (MHI), MSWS-12, T25FW, NHPT, PASAT-3”, 6MWT, FTSTS, and MDRT-Back. Improvements were found on the SF-36 MCS, MFIS, BLCS, PDQ, MHI, and MSWS-12 between baseline and postintervention. The effect on PDQ persisted at follow-up. Improvements were found on the T25FW, NHPT, 6MWT, FTSTS, and MDRT-Back between baseline and postintervention that persisted at follow-up. The PASAT-3” did not change between baseline and postintervention but did between postintervention and follow-up.*

Conclusions: *The yoga program was safe and feasible. Improvements in certain measures of QOL and performance were seen at postintervention and follow-up. Int J MS Care. 2017;19:30–39.*

Maximizing physical function and quality of life (QOL) is of paramount importance for the person with multiple sclerosis (MS). Disease progression, severity, and signs and symptoms

are unpredictable and vary between people.¹ People with MS may experience fatigue, asthenia, balance and mobility loss, depression, and decreased cognitive function.² The QOL is impaired in individuals with MS owing

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to these and other factors.^{2,3} This variation in signs and symptoms makes planning rehabilitation programs challenging. People with MS are responsive to exercise interventions,⁴ although programs that focus on a single modality (eg, strength training) may not have a broad effect on the wide range of impairments and disabilities that may result from MS. Similarly, programs that combine resistance and endurance exercises can have positive effects⁵ but may not fully address the complex physical and QOL issues. Because of the widespread impact of MS on physical performance and QOL, and the heterogeneity of disease manifestation and disability severity, modifiable interventions that affect a broad spectrum of health constructs must be explored.

Yoga as a Therapeutic Intervention

Yoga is an ancient mind-body practice that includes meditation, breathing practices, activities or postures, philosophy, cleansing practices, and deep relaxation.⁶ The most widely recognized forms of yoga include asanas (physical poses) and breathing exercises.⁷ There are many different yoga styles, including Iyengar, Svaroopa, Viniyoga, Kripalu, Kundalini, and Himalayan. In general, yoga is practiced to promote strength, endurance, flexibility, well-being, and a sense of calm and harmony.⁶ Physiologically, yoga produces the opposite of a sympathetic nervous system fight or flight response—that is, yoga promotes a parasympathetic sense of calm and relaxation.⁸ A growing body of literature indicates that yoga results in short-term physiological changes and that yoga participants may experience long-term benefits in physical status and emotional well-being.^{6,9,10} Yoga breathing practices, meditation, and postures decrease anxiety and depression and increase subjective well-being, cognitive function, balance, coordination, strength, and flexibility in healthy populations and in people with chronic diseases.⁹

Yoga for People with MS

In people with MS, yoga was among the six most popular forms of complementary and alternative medicine used for symptom management.¹¹ A recent meta-analysis concluded that yoga was more effective than usual care in improving mood and perceived fatigue but not muscle function, cognitive function, or health-related QOL in people with MS.¹² Yoga was no more effective than the interventions with which it was compared.¹² An overarching limitation of the literature is the lack of well-described, reproducible yoga inter-

vention models. In general, yoga activities vary widely between types and between instructors within types. More importantly, there is a lack of programs tailored to the needs of people with MS that are scalable to accommodate differing levels and types of disability. Recognizing this limitation, we created a standardized, integrative yoga program for people with moderate MS-related disability through a modified Delphi process.¹³ Delphi panel participants included people with MS, certified yoga instructors with experience teaching people with MS, and health-care professionals and researchers with experience and expertise in MS care or yoga. This resulted in a comprehensive program specifically designed to address the needs of people with moderate MS-related disability. Details of this process have been presented elsewhere.¹⁴ The program was designed with scalable difficulty to meet the heterogeneous capabilities of a sample of people with moderate MS-related disability while maximizing program standardization. The first objective of this study was to examine the feasibility of the specifically designed yoga program in people with moderate MS-related disability. The second objective was to examine the immediate and lasting effects of the program on function, activity, and participation.

Methods

Design

We conducted a single-group pilot study, approved by the Rutgers University–Newark institutional review board, to assess the safety, feasibility, and effects of a specifically designed yoga program on QOL, physical performance, and mental performance in people with moderate MS-related disability. Repeated measures were obtained at three time points: baseline, after 8 weeks of yoga classes (postintervention), and again 8 weeks later (follow-up). Weekly home practice tracking forms were completed throughout the study.

Participants

Participants were recruited from the Southern New Jersey/Philadelphia area through National Multiple Sclerosis Society newsletters, newspaper ads, and flyers sent to area neurologists and MS support groups. Respondents were screened by telephone to determine eligibility and availability for study dates. Individuals deemed potentially eligible then completed the Self-report of Multiple Sclerosis Disease Severity (SR-MSDS).¹⁵ The inclusion criteria were age 18 to 64 years, ability to ambulate without the assistance of another person for

a minimum of 25 feet, ability to communicate in English, and a neurologist-confirmed diagnosis of any subtype of MS with moderate disability as evidenced by a score of 3 to 6 on the SR-MSDS.¹⁵ The SR-MSDS is based primarily on Expanded Disability Status Scale (EDSS) score descriptions, including elements of the Patient-Determined Disease Steps scale, and was used in a large-scale population study of people with MS.¹⁵ Although psychometric data were not stated, Kobelt et al.¹⁵ reported good correlations between SR-MSDS and EDSS scores, where each of the scores from 3 through 6 on the SR-MSDS are similar to the respective scores of 3 through 6 on the EDSS. Participants did not need to be yoga naive but must have had no yoga experience in the 6 months before recruitment. The exclusion criteria were MS exacerbation in the previous 8 weeks or other serious medical conditions that would impair ability to participate in the study. Before enrollment, participants provided an authorization for participation letter from their physician. All the participants signed informed consent forms.

The Yoga Intervention

Before participant recruitment, the investigators created a manualized yoga program¹⁶ using a modified Delphi process (available at <http://shp.rutgers.edu/documents/yoga.pdf>). The twice-weekly 90-minute yoga sessions included yoga philosophy, breathing practices (pranayama), postures (asanas), meditation, and deep relaxation. In total, 16 classes were provided. All the

participants were encouraged to attend all the classes. The class content, summarized in Table 1, was progressed over 8 weeks. Preplanned variations of asanas were implemented to meet the capabilities of participants. Participants were provided with instructions for home practice that was to be performed on the days that class did not meet. Before participant enrollment, certified and experienced yoga instructors underwent 6 hours of training in the yoga protocol by research team members. Each class was staffed by three individuals: two yoga instructors and one study team member (ETC, DK, or SGF). The student to staff ratio at yoga classes was approximately 5:1. Each class segment was led by one yoga instructor. The second yoga instructor and the study team member assisted by providing props (ie, yoga blocks and blankets) and facilitating transfers to and from the floor as needed. Our experience with the classes suggests that this level of supervision is necessary to facilitate performance and ensure participant safety.

Feasibility

Feasibility was explored with budget utilization, recruitment rates, retention rates, attendance rates, and safety (via reporting of adverse events).

Outcome Measures

The QOL was measured using the Multiple Sclerosis Quality of Life Inventory,¹⁷ a battery of ten scales covering multiple dimensions. The scales and their range of values are listed in Table 2. Walking ability was measured using three outcomes: the 12-item Multiple Sclerosis Walking Scale-12 (MSWS-12), the Timed 25-Foot Walk (T25-FWT), and the 6-Minute Walk Test (6MWT).

Table 1. Yoga program specifically designed for people with MS: overview of class content

Content	Time allotted (approximate), min	Brief description
Yoga philosophy	10	Talks on key aspects of yoga, including Yoga Sutras, the Chakra system, Yamas, Niyamas, and others. Topics varied by class.
Pranayama	10	Breathing activities initially included diaphragmatic breathing and were progressed to include other techniques, such as alternate nostril breathing, Ujjayi, and Dirga.
Asana	50	The early weeks included warm-up activities and easier postures in sitting or lying; over the weeks, the asana series was progressed to include a greater variety of postures, some of which were performed in standing (with chair or wall support if needed), such as Standing Overhead Stretch, Warrior I and II, and Standing Downward Dog.
Relaxation	10	Included rest in Shavasana pose and facilitation of relaxation through techniques such as Tense & Release, Sweeping 21 Breaths, and 61-Point Relaxation. Some repetition of relaxation techniques over the weeks.
Meditation	10	Instructor-guided meditation using different techniques, such as Mindfulness, Chakra Visualization, Compassion, Mantra, and Contemplative Walking. Some repetition of meditation techniques over the weeks.

Abbreviation: MS, multiple sclerosis.

Note: The complete 8-week yoga class manual for people with moderate disability due to MS is available online at <http://shp.rutgers.edu/documents/yoga.pdf>.

Table 2. Scales included in the Multiple Sclerosis Quality of Life Inventory

Self-report tool	Score range	Best possible score
36-item Short Form Health Status Survey		
Physical Composite Score	0–100	100
Mental Composite Score	0–100	100
Modified Fatigue Impact Scale	0–84	0
MOS Pain Effects Scale	6–30	6
Sexual Satisfaction Scale	4–24	4
Bladder Control Scale	0–22	0
Bowel Control Scale	0–26	0
Impact of Visual Impairment Scale	0–15	0
Perceived Deficits Questionnaire	0–80	0
Mental Health Inventory	0–100	100
MOS Modified Social Support Survey	0–100	100

Abbreviation: MOS, Medical Outcomes Study.

rosis Walking Scale (MSWS-12), the Timed 25-Foot Walk test (T25FW), and the 6-Minute Walk Test (6MWT). The MSWS-12 is a 12-item questionnaire that measures a person's perception of how MS affects his or her walking ability. The MSWS-12 was developed for use with people with MS and is a valid and reliable measure of walking ability.^{18,19} The range of values is 0 to 100, with 100 indicating the most negative effect on walking ability. The T25FW measures how many seconds it takes to walk 25 feet (7.62 m) from a standing start with instructions to walk at a fast but safe speed. The T25FW is a widely used, valid, and reliable measure to detect change in walking ability in people with MS.²⁰ The 6MWT is a submaximal test of walking endurance that measures the total distance walked in 6 minutes. In the 6MWT, participants are instructed to walk as quickly, but safely, as possible. The 6MWT has high interrater, intrarater, and test-retest reliability in people with MS.^{21,22}

The Nine-Hole Peg Test (NHPT) (dominant [NHPT-Dom] and nondominant [NHPT-Non] sides) was used to measure upper-extremity function. The NHPT is a valid and reliable measure of upper-extremity function in people with MS.^{23,24} Functional lower-extremity strength was examined using the Five Times Sit-to-Stand Test (FTSTS). The FTSTS measured how many seconds a person requires to stand and sit from a chair five times as quickly as possible. There is little evidence of psychometric properties of the FTSTS in people with MS; however, this outcome was selected because it is a quick test of general lower-

extremity strength with good reliability and validity in other neurologic populations.²⁵ Balance was measured using the Multidirectional Reach Test (MDRT), which examines the limits of stability (ie, how far the person can voluntarily shift their center of gravity) to the front, back, left, and right while maintaining a stable base of support.²⁶ As with the FTSTS, there is little evidence of psychometric properties of the MDRT in people with MS; however, the MDRT was selected as a balance test that would be sensitive to the type of balance training that might occur during the yoga intervention.

Maximal expiratory pressure (MEP) was measured using a respiratory pressure meter (MicroRPM; Micro Direct Inc, Lewiston, ME) and the manufacturer's standardized procedures. The MEP is an indirect measure of expiratory muscle strength that has been correlated with EDSS scores²⁷ and MS disease duration.²⁸ Cognitive performance (ie, attention and concentration) was assessed using the Paced Auditory Serial Addition Test-3" (PASAT-3"). Along with the T25FW and the NHPT, the PASAT-3" is a component of the Multiple Sclerosis Functional Composite.²⁹ Although all three components were collected, the Multiple Sclerosis Functional Composite was not calculated because the component tests were not conducted in the standardized sequence described in the instruction manual.³⁰ Testing sessions also included blood sample collection for analysis of circulating immune and neuroendocrine biomarkers and gene expression; however, they are not reported herein but will be reported in a future article.

Data Collection

Data collection involved several of the authors (ETC, DK, SGF, MS, and KL) and other trained study staff. Data were collected using a standardized station setup, with participants moving from one station to the next after completing the activities at a given station. Blood samples were collected first. After that, stations alternated between surveys and physical performance tests. The 6MWT was performed last.

Statistical Analyses

Data were analyzed using a statistical software program (IBM SPSS Statistics for Windows, version 21.0; IBM Corp, Armonk, NY). Descriptive statistics were used for demographic data, attendance, and adherence. Outcome data were analyzed to determine whether they were normally distributed. Normally distributed

outcome data (36-item Short Form Health Status Survey [SF-36] Physical Composite Score [PCS], SF-36 Mental Composite Score [MCS], Pain Effects Scale [PES], Bladder Control Scale [BLCS], Bowel Control Scale [BWCS], Perceived Deficits Questionnaire [PDQ], Modified Social Support Survey (MSSS), MSWS-12, NHPT-Dom, PASAT-3", MDRT-Front, and MDRT-Right) were analyzed using a one-factor repeated-measures analysis of variance. In cases in which sphericity was violated, the more conservative Greenhouse-Geisser-corrected degrees of freedom method was used (NHPT-Non, 6MWT, and MEP). Nonnormally distributed data were analyzed using Friedman's test (MFIS, Sexual Satisfaction Scale [SSS], Impact of Visual Impairment Scale [IVIS], Mental Health Inventory [MHI], T25FW, FTSTS, MDRT-Back, and MDRT-Left). Planned pairwise comparisons (paired-samples *t* tests for parametric data and Wilcoxon signed rank tests for nonparametric data) were conducted to analyze differences among the baseline, postintervention, and follow-up measurements using a Bonferroni correction for multiple comparisons to reduce the likelihood of type I error.

Results

Feasibility: Costs, Recruitment, Retention, Attendance, and Safety

This pilot study was feasible and safe for people with moderate disability due to MS. Execution of this pilot study cost approximately \$20,000. Briefly, the costs were associated with recruitment ads, yoga studio rental, yoga equipment, and stipends for the participants, personnel (yoga instructors and study staff), and data collection equipment (eg, disposable components for MEP tests). Other equip-

ment, such as the respiratory pressure meter, was already owned by the authors. We estimated that an additional \$2000 would have been needed to purchase all the necessary equipment. Costs associated with biomarker analysis and gene expression are not included in this budget.

Recruitment, conducted over 2 months and targeted to an area within 30 miles of the study site, yielded an adequate number of participants for this pilot study. Figure 1 summarizes recruitment, screening, enrollment, and study completion. One participant withdrew during the first week of yoga classes because of an unrelated health problem. Fourteen participants (all women) completed the intervention and testing at all three time points. Twenty adverse events were reported during the study, but all were determined to be minor or transient (Table 3). It was common for participants to require individual attention during yoga classes, such as assistance with modifications of postures. Overall, attendance at yoga classes was 89% (mean, 14.2 of 16 classes) for the 14 people who completed the study. The class size ranged from 9 to 14 participants, with a mean class size of 12.5 participants. During the yoga intervention period, home practice (reported by 14 participants) was performed a mean (SD) of 2.4 (1.4) times per week. During follow-up, home practice (reported by 13 participants) was performed a mean (SD) of 2.0 (1.4) times per week.

Table 3. Reported minor and transient adverse events

Event or complaint	Related to testing	Related to yoga	Unrelated to testing or yoga	Pre-existing
Transient eye pain and vertigo		X		
Transient tingling in hip and thigh; minor knee pain		X		X
Leg spasms and low back pain		X		X
"Heaviness" in leg			X	X
Thigh pain			X	
Soreness in thumb and wrist			X	
Low back pain and spasm		X		
Tooth extraction with residual mouth pain			X	
Fall while doing home practice; face soreness		X		
Shoulder pain		X		
Swollen lymph nodes			X	
Neck, shoulder, and back pain		X		X
Hip pain		X		X
Headache		X		
Ganglion cyst (wrist)			X	
Tooth pain			X	
Soreness in arms, back, and legs	X			
Headache and gastrointestinal problems; fatigue			X	
Aches and pains in all joints			X	
Transient phlebitis at blood collection site	X			

Participants

The age range of the 14 people who completed the study was 34 to 64 years (mean [SD], 53.5 [8.3] years). Thirteen participants had relapsing-remitting MS, and one had primary progressive MS. Number of years since MS diagnosis ranged from 2 to 26 (mean [SD], 13.9 [7.6]). Disease severity (SR-MSDS score) ranged from 3 to 6 (median, 5; interquartile range, 2).

Outcomes

The results are summarized in Table 4. Measurement of all of the outcomes used in this study took approxi-

mately 90 minutes per participant. Approximately half of the time was used to complete surveys, and the other half was used for physical performance tests and rest periods.

Self-report Measures

There were significant main effects on the SF-36 MCS, MFIS, BLCS, PDQ, MHI, and MSWS-12. Pairwise comparisons showed that the effects on the SF-36, MFIS, BLCS, PDQ, MHI, and MSWS-12 were found between baseline and postintervention. The effect on PDQ persisted at follow-up, but all others returned to baseline values.

Physical Performance Measures

There were significant main effects on the T25FW, NHPT-Dom, NHPT-Non, PASAT-3", 6MWT, FTSTS, and MDRT-Back. Pairwise comparisons showed that the effects on the T25FW, NHPT-Dom, NHPT-Non, 6MWT, FTSTS, and MDRT-Back were found between baseline and postintervention and persisted at follow-up. The pairwise comparison showed that the PASAT-3" did not change between baseline and postintervention but did between postintervention and follow-up.

Discussion

Eight weeks of yoga had a positive effect on physical performance, mental function, and QOL in people with moderate MS-related disability, and statistically significant improvement was noted in several variables. Many of the improvements observed at postintervention carried over to follow-up. In general, improvements were more persistent at follow-up for performance-based outcomes than for self-reported outcomes. The continuation of home practice after completion of the intervention likely contributed to the carryover seen at follow-up; however, the analyses used could not support the inclusion of home practice as a covariate, thus constituting a limitation of this study. Alternatively, perhaps the postintervention improvements contributed to ongoing levels of increased physical activity and QOL that then served to maintain the improvements. It is possible that the broad effects on QOL and physical performance measures found are related to the integrative nature of the intervention—that is, the program included elements specifically designed to address outlook and attitude, autonomic regulation, mental focus, and stress reduction in addition to neuromusculoskeletal function. However, with the absence of a control group, it is not possible to

Table 4. Summary of results over time on self-report and performance outcomes

Outcome measure	Group scores, mean (SD)			Within-group effect <i>P</i> value	Pairwise comparisons <i>P</i> values ^a		
	Baseline	Post-intervention	Follow-up		Baseline to post-intervention	Post-intervention to follow-up	Baseline to follow-up
MSQLI							
SF-36 PCS ^b	36.5 (5.8)	35.9 (8.0)	36.5 (6.4)	.902	>.99	>.99	>.99
SF-36 MCS ^b	46.1 (9.6)	56.3 (7.7)	49.5 (9.2)	.001 ^c	.002 ^c	.049 ^c	.446
MFIS ^d	46.4 (9.0)	37.5 (12.2)	40.8 (10.7)	.009 ^c	.010 ^c	.872	.131
PES ^b	14.5 (5.8)	12.4 (3.8)	13.6 (4.7)	.097	.125	>.99	.46
SSS ^d	12.8 (6.7)	11.0 (6.4)	10.0 (6.4)	.457	.53	.37	.26
BLCS ^b	6.5 (6.4)	3.4 (2.9)	4.3 (3.8)	.023 ^c	.028 ^c	.314	.068
BWCS ^b	5.9 (4.4)	3.8 (3.3)	3.9 (3.1)	.088	.27	>.99	.353
IVIS ^d	2.3 (2.0)	1.4 (1.7)	1.5 (2.3)	.222	.12	>.99	.77
PDQ ^b	38.9 (15.0)	33.2 (13.0)	24.9 (12.0)	.024 ^c	.02 ^c	.37	.07 ^c
MHI ^d	67.9 (15.5)	78.8 (11.6)	75.9 (10.6)	.001 ^c	.003 ^c	.47	.054
MSSS ^b	67.1 (18.3)	71.4 (22.0)	70.5 (18.8)	.596	.65	>.99	>.99
MSWS-12 ^b	56.1 (20.7)	43.5 (23.5)	51.3 (25.1)	.038 ^c	.028 ^c	.555	.807
T25WT, s ^d	8.4 (3.4)	7.3 (2.9)	7.5 (3.1)	.000 ^c	.006 ^c	>.99	.003 ^c
NHPT-Dominant hand, s ^b	25.1 (3.0)	23.0 (3.8)	22.5 (3.5)	.002 ^c	.041 ^c	>.99	.009 ^c
NHPT-Nondominant hand, s ^e	25.7 (3.8)	24.1 (4.5)	23.2 (4.5)	.027 ^c	.41	.19	.036 ^c
PASAT-3", % correct ^b	65.1 (21.9)	69.3 (23.3)	74.5 (16.6)	.012 ^c	.579	.014 ^d	.27
6MWT, m ^e	245.5 (94.5)	269.9 (97.3)	270.3 (103.7)	.028 ^c	.024 ^c	.929	.039 ^c
FTSTS ^d	18.0 (3.9)	13.1 (4.1)	12.9 (2.9)	.000 ^c	.009 ^c	.929	.009 ^c
MDRT-Front, cm ^b	25.2 (5.2)	27.3 (5.0)	27.1 (5.3)	.163	.45	>.99	.10
MDRT-Back, cm ^d	14.5 (7.0)	20.4 (9.3)	18.1 (3.9)	.027 ^c	.02 ^c	.76	.02 ^c
MDRT-Right, cm ^b	25.2 (5.2)	27.3 (5.0)	27.1 (5.3)	.228	.80	>.99	.53
MDRT-Left, cm ^d	17.2 (5.8)	18.5 (5.0)	19.2 (4.3)	.405	.70	.79	.26
MEP, cm H ₂ O ^e	76.21 (5.16)	75.76 (4.68)	75.93 (7.35)	.983	>.99	>.99	>.99

Abbreviations: BLCS, Bladder Control Scale; BWCS, Bowel Control Scale; FTSTS, Five Times Sit-to-Stand Test; IVIS, Impact of Vision Impairment Scale; MDRT, Multidirectional Reach Test; MEP, maximal expiratory pressure; MFIS, Modified Fatigue Impact Scale; MHI, Mental Health Inventory; MSQLI, Multiple Sclerosis Quality of Life Inventory; MSSS, Modified Social Support Survey; MSWS-12, 12-item Multiple Sclerosis Walking Scale; NHPT, Nine-Hole Peg Test; PASAT-3", Paced Auditory Serial Addition Test-3"; PDQ, Perceived Deficits Questionnaire; PES, Medical Outcomes Study Pain Effects Scale; SF-36 MCS, 36-item Short Form Health Status Survey Mental Component Scale; SF-36 PCS, 36-item Short Form Health Status Survey Physical Component Scale; SSS, Sexual Satisfaction Survey; T25FW, Timed 25-Foot Walk Test; 6MWT, 6-Minute Walk Test.

^aAnalysis using paired-samples *t* tests or Wilcoxon signed rank tests with Bonferroni corrections for multiple comparisons.

^bAnalysis using one-factor repeated-measures analysis of variance.

^cStatistically significant value ($P < .05$).

^dAnalysis using Friedman's test.

^eAnalysis using one-factor repeated-measures analysis of variance with Greenhouse-Geisser-corrected degrees of freedom.

differentiate specific effects of yoga intervention from the effects of being involved in a group activity.

Of the outcomes that improved significantly, clinically meaningful within-group mean changes were seen only in leg strength (FTSTS)³¹ (4.9-second improvement from baseline to postintervention; 5.1-second improvement from baseline to follow-up). The mean within-group changes for the MFIS, T25FW, 6MWT,

and MSWS-12 did not surpass reported minimal detectable change values for those tests.^{4,20,32,33} Minimal detectable change values for other outcomes that showed statistically significant change (PASAT-3", MDRT-Back, SF-36 MCS, BLCS, PDQ, and MHI) have not been reported, so we are unable to determine whether those changes were clinically meaningful. As the yoga practice gradually increased in difficulty and the physical capabil-

ities of the participants to perform it seemed to improve over time, it is possible that a longer intervention would result in larger effects.

The outcomes that did not improve were the SF-36 PCS, PES, SSS, BWCS, IVIS, MSSS, and MEP. It was surprising that the SF-36 PCS did not improve because many physical performance tests improved. It was not surprising that the SSS, BWCS, IVIS, and MSSS did not improve because the yoga program did not directly target these QOL domains. Although the program included breathing exercises (pranayama), the dosage and the specific pranayamas did not have an effect on MEP. The MDRT improved only in the backward direction. This may be because there was more potential for gain in that direction compared with the front or sides. Several asanas involved trunk extension and balancing, which likely contributed to the improvement in the MDRT-Back.

A recent systematic review and meta-analysis of seven randomized controlled trials of yoga for people with MS found evidence for short-term benefits of yoga compared with usual care for fatigue and mood but not for health-related QOL, mobility, or cognitive function.¹² Compared with non-yogic exercise programs, yoga was not superior in any of these domains. Cramer et al.¹² reported that none of the trials reviewed³⁴⁻⁴¹ were robust against methodological bias. Furthermore, the forms of yoga and dosing varied across studies, and sufficient detail to reproduce the programs was generally absent. This lack of standardization is common in yoga research and is a reason that this pilot study included careful development of a manualized yoga protocol.

Keeping in mind the methodological limitations mentioned previously herein, several studies have reported benefits from yoga on various self-report and performance measures in individuals with MS. Trials that measured balance in people with MS after yoga reported improvements.^{34,35,38,42} Those studies used the Berg Balance Scale. Although we did not use the Berg Balance Scale, we found improvements in the MDRT-Back, indicative of improved balance. Walking endurance improved statistically but did not achieve a clinically significant improvement in the present trial. Findings related to walking endurance in other studies are conflicting, with two studies reporting improvement in the 2-minute walk test distance^{34,35} and two reporting no change in 6MWT distance.^{37,38} The present finding of improved walking speed (T25FW) was consis-

tent with the findings of Guner and Inanici,⁴² whereas Ahmadi et al.^{34,35} reported no change in walking speed after yoga. The present pilot study found improved fatigue (postintervention) after yoga. Other studies have reported conflicting findings on indices of fatigue, with four reporting improved fatigue after yoga^{34,35,37,39} and two reporting no improvement.^{38,41} The present findings of improved QOL are in agreement with reports by Ahmadi et al.,^{34,35} Doulati et al.,³⁶ and Garrett et al.,³⁷ whereas Hogan et al.³⁸ reported no improvement in QOL after yoga intervention. We did not find a change in pain as measured by the PES, whereas Doulati et al.³⁶ reported improved pain after 12 weeks of yoga.

Despite inconsistencies in findings in trials published to date, yoga seems to be beneficial on several domains of QOL and physical function. Further study of this intervention with well-designed randomized controlled trials will clarify the effectiveness of yoga in addressing problems with body function, activity, and participation experienced by those with MS. To estimate sample sizes for a future randomized controlled trial comparing this intervention with a control, we computed and averaged effect sizes of several physical performance measures (6MWT, T25FW, NHPT-Dom, FTSTS, and MDRT-Back) that were responsive to the intervention and persisted at follow-up. A conservative sample size estimate was then generated with room in the model for one potential covariate (eg, EDSS score) and for some variance to be attributable to unforeseen confounders. Based on these assumptions, at 95% power, a sample size of 32 (16 per group) would be required.

Although recruitment efforts achieved an adequate number of participants for this pilot study, alternative recruitment strategies or multiple study locations and times would likely be needed to achieve a larger sample for a randomized controlled trial.

This was a pilot study with no comparison group, so cause-and-effect conclusions cannot be made. A limitation of this study is that disease severity was measured using a self-report tool rather than a clinical one. The SR-MSDS was selected owing to time and budget restrictions. A future study should include clinical measurement of MS disease severity in lieu of, or in addition to, a self-report measure. Furthermore, because 78% of respondents to recruitment efforts were either unavailable or ineligible, it is unclear whether the present sample is representative of those with moderate MS-related disability.

The present findings should be interpreted with caution owing to the exploratory nature of this study, the small sample size, and the inclusion of many outcome measures. Furthermore, symptoms associated with MS may fluctuate from day to day, which may have affected the magnitudes of the measured outcomes. There is the possibility that improvements in performance-based tests may have been related to a practice effect. In particular, the PASAT-3" is known to have a strong practice effect,²⁴ which may explain the improvements seen in the PASAT-3" between postintervention and follow-up despite the lack of change between the baseline and postintervention tests. Other limitations include a possible Hawthorne effect if the participants' performance was affected by a desire to impress the investigators. Owing to the nature of the study (one group with regularly scheduled classes), an observable rapport and camaraderie developed between study participants. This alone may have had some positive impact, especially on outcomes that were self-reported. Three of the authors who assisted with yoga classes also participated in data collection; thus, data collection was not blinded, which may have introduced a source of bias. The yoga program in this study was 8 weeks long, after which home practice was continued by most participants. The home practice was not controlled by the study team to the extent that classes were. Other yoga studies for people with MS have incorporated yoga for periods ranging from 8 weeks to 6 months, with class frequencies ranging from once a week to three times per week.³⁴⁻⁴² This variation in dosing creates heterogeneity, limiting useful comparisons of results between studies.

Because of the variance in yoga approaches and class content in the general community, we purposefully manualized the curriculum for individuals with moderate disability due to MS. Although the full manual is

publicly available, we have not yet solicited feedback on its utility. Yoga instructors who use the protocol should have adequate experience in working with individuals who may require physical assistance. The ratio (5:1) of participants to instructors might prove impractical on a larger scale due to the costs. However, we are aware that many yoga classes for people with MS are generally taught with just one teacher experienced with this population and no assistant or helper. The yoga program used in this study may not be suitable for individuals with lesser or greater amounts of MS-related disability. Finally, the present findings are not generalizable to other forms or dosages of yoga that might be used with this population. All but one participant who completed the study had the relapsing-remitting form of MS; thus, we cannot generalize these findings to individuals with other forms of MS.

Conclusion

Our experience with and the results of this pilot study suggest that yoga is a safe and effective intervention for individuals with moderate MS-related disability when adequate supervision and safety measures are used. An 8-week, specifically designed yoga program had a positive effect on several QOL and physical performance outcomes. Further research is needed to study the effectiveness of this program compared with controls or other interventions and to determine whether this specifically developed yoga program is superior to a nonspecific yoga program or a program derived from specific yogic traditions. Investigation of optimal dosing, as well as use of supplemental materials (eg, DVDs) or online classes to facilitate home practice, may also be useful to maximize potential benefits. □

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PracticePoints

- This specifically designed yoga program was safe and feasible for people with moderate MS-related disability who were appropriately supervised.
- The results of this pilot study suggest that a specifically designed yoga program may have a positive effect on certain aspects of physical function and quality of life for people with moderate MS-related disability.

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