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A group-delivered self-management program reduces spasticity in people with multiple sclerosis: A randomized, controlled pilot trial

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Cinda L Hugos, Dennis Bourdette, Yiyi Chen, Zunqiu Chen and Michelle Cameron

Abstract

Background: Spasticity affects more than 80% of people with multiple sclerosis (MS), affecting activity, participation, and quality of life. Based on an international guideline, an MS spasticity group education and stretching program, MS Spasticity: Take Control (STC), has been developed.

Objective: The objective of this paper is to determine whether STC with home stretching is associated with greater changes in spasticity than usual care (UC), consisting of an illustrated stretching booklet and home stretching but without group instruction or support, in people with MS.

Methods: Ambulatory MS patients with self-reported spasticity interfering with daily activities were randomized to STC or UC. Individuals completed questionnaires regarding MS, spasticity, walking, fatigue and mood, and physical measures of spasticity and walking.

Results: Thirty-eight of 40 participants completed both assessments. Mean total score and scores on two subscales of the MS Spasticity Scale-88 improved more with STC than with UC ($p < 0.03$). There was no significant change in the Modified Ashworth Scale in either group. Mean scores on the Modified Fatigue Impact Scale, the Beck Depression Inventory-II, and the physical component of the Multiple Sclerosis Impact Scale-29 showed statistically and clinically significant improvements in the STC group only.

Conclusions: Participation in STC improved self-reported impact of spasticity more than UC and provided encouraging improvements in other measures.

***Keywords*:** Spasticity, fatigue, rehabilitation, multiple sclerosis, exercise

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Introduction

Multiple sclerosis (MS) is a common disabling disease of the central nervous system affecting approximately 400,000 Americans and 2.5 million people worldwide.[1] Spasticity occurs in 60%–80% of people with MS (PwMS) and contributes to MS disability with gait disorders, falls, fatigue, spasms, and pain potentially hastening the time to wheelchair dependence. Increased disability and dependency may lead to social isolation and depression, cardiovascular disease, muscle fibrosis, and joint contracture with secondary skin breakdown, infection, and death.[2–4] In 2003, an international guideline for spasticity management in MS was published.[3,4] Based on this guideline, a small-group self-management program, MS Spasticity: Take Control (STC), was developed. This program has an educational digital video disc (DVD), a lower-extremity stretching DVD, and facilitator and participant manuals. We conducted a randomized, controlled pilot trial with 40 participants to evaluate the acceptance, feasibility, and initial efficacy of the STC program.

Materials and methods

Study design

This was a single-center, single-blind, parallel, two-arm, randomized, controlled trial with 1:1 allocation comparing STC with usual care (UC) for lower-extremity spasticity in PwMS. STC includes two two-hour weekly group sessions followed by home stretching. UC used an illustrated booklet with home

Correspondence to:
Cinda L Hugos
Portland VA Medical Center, 3710 US Veterans Hospital Road, Mail code 27, Portland OR, 97239, USA.
hugosc@ohsu.edu

Cinda L Hugos,
VA Portland Health Care System (HCS), USA Oregon Health & Science University, USA

Dennis Bourdette,
VA Portland Health Care System (HCS), USA Oregon Health & Science University, USA

Yiyi Chen,
Oregon Health & Science University, USA

Zunqiu Chen,
Oregon Health & Science University, USA

Michelle Cameron,
VA Portland Health Care System (HCS), USA Oregon Health & Science University, USA

stretching instructions but no in-person instruction or group support. Primary outcomes were assessed for both groups following four weeks of home exercise.

Study participants

This study was approved by the joint Veterans Administration Portland Health Care System (VAPORHCS) and Oregon Health & Science University (OHSU) Institutional Review Board, registered with clinicaltrials.gov #NCT02170779, and all participants signed and received a copy of the written informed consent. Inclusion criteria were (1) physician-confirmed diagnosis of MS,[5] (2) age 18 or older, (3) able to provide informed consent and comply with study procedures, (4) able to walk 25 feet independently with or without assistive devices, (5) fluent in written and spoken English as program materials are not provided in other languages, (6) self-reported lower-extremity spasticity interfering with daily activities, and (7) willing to not change medications during the study. Exclusion criteria were (1) other medical or mental conditions that would interfere with participation.

Location and facilitators. Participants were recruited from the VAPORHCS and OHSU MS clinics and the surrounding community. Baseline and follow-up measures were completed by research assistants blinded to group assignment. STC was facilitated by a licensed physical therapist (CH) with assistance from the study coordinator.

Procedures

Participants consented and completed all physical assessments in person. A link was then emailed to participants to complete study questionnaires electronically later the same day at home or on a library computer at the study site. The statistician (YC) provided randomization in blocks of two with the first individual randomly assigned to STC or UC and the second individual assigned to the other arm. Those randomized to STC came to two two-hour classes one week apart. Those randomized to UC were mailed the stretching booklet and exercise diary with instructions to stretch daily and record all exercise. Four weeks later, all participants were sent a link to complete the study questionnaires electronically prior to completing the physical outcome measures in person. Participants were kept blind to active or control intervention assignment by being informed we were comparing different MS-specific materials for effects on MS and symptoms of MS to determine which worked best. All study visits and STC classes were held in accessible conference rooms with free parking. All participants received $100 for time and travel for each study visit attended.

Interventions

Experimental intervention. STC was delivered in two two-hour facilitator-led group sessions one week apart. The first session of STC consisted of participant introductions, viewing, and discussing a 28-minute DVD featuring education from MS professionals and poignant stories by PwMS, viewing and discussing a 20-minute lower-extremity stretching DVD with stretches for eight body areas with different positioning choices, introduction of the exercise diary to be completed after the second session, and preparation for the group stretching session the following week. In the second session of STC, participants practiced all the stretches under guidance of the facilitators. The goal of the second session was to try all the exercises offered and find at least one for each body area for a daily 15-minute stretching routine. Participants were instructed to record their stretching and other exercise participation for the next four weeks in their diaries and return for the final assessment visit. Facilitator and participant manuals were used to guide the spasticity management program and provide reference material for home use and the stretching exercises (Table 1).

Control intervention/UC. Participants in the UC group did not attend the two class visits but instead were mailed the National MS Society (NMSS) booklet *Stretching for people with MS: An illustrated manual* and the same exercise diary given to the STC group with instructions to stretch daily and record all exercise for the same four weeks as the STC group and return for the final assessment visit.[6] We called this ''usual care'' because the NMSS has provided this free booklet to people with MS who ask about appropriate exercise for more than 25 years.

Outcome measures

Outcome measures were questionnaires administered electronically and physical measures collected in person. For all the questionnaires, lower scores are better (i.e. less impact of MS). The first four are MS-specific scales developed for MS and validated in MS.

The **MS Spasticity Scale-88 (MSSS-88)** measures patient experience and perception of the impact of spasticity in MS with day-to-day symptoms and during functional activities over the previous two weeks. It has 88 questions to quantify spasticity for a total score and in eight clinically relevant and

Table 1. Contents of MS Spasticity: Take Control program.

MS Spasticity: Take Control Educational DVD 28 minutes	MS Spasticity: Take Control of Lower Extremity Stretching DVD 20 minutes	Manuals
• Recognizing spasticity and triggers of spasticity • Treatment: ○ Stretching ○ Other exercises ○ Medications ○ Botox ○ Intrathecal baclofen pump ○ Complementary and Alternative Methods ■ Relaxation ■ Massage ■ Meditation ■ Yoga • Take Control of MS Spasticity and MS	• Eight body areas: ○ Whole body elongation ○ Trunk rotation ○ Inner thighs ○ Hip flexors/extensors ○ Hamstrings ○ Quadriceps ○ Upper calves ○ Lower calves • Positions: ○ Lying: ■ Elongate ■ Trunk rotation ■ Inner thighs ■ Hip flexors/extensors ■ Hamstrings ■ Quadriceps ○ Sitting: ■ Trunk rotation ■ Inner thighs ■ Hamstrings ■ Quadriceps ■ Upper calves ■ Lower calves ○ Standing: ■ Hamstrings ■ Quadriceps ■ Upper calves ■ Lower calves • Instructions: ○ Intensity: ■ To feel a ‘‘gentle pull but no pain’’ ■ Initially 2–3/10 on Numeric Rating Scale for pain (NRSp) ■ Progress to 4–6/10 on NRSp with practice ○ Velocity: ■ ‘‘Proceed slowly until you feel a gentle pull, then hold as instructed’’ ○ Repetitions: ■ ‘‘At least once per day,’’ specifically at least one repetition one time per day ○ Duration: ■ 30–60 seconds ○ Frequency: ■ Daily	• Participant manuals: ○ 70 pages ○ All video information in writing ○ Learning objectives ○ Glossary of terms ○ Space for notes and personal reflections ○ Photos of all stretches ○ Written instructions with all stretches • Facilitator manuals: ○ 82 pages ○ All of the material in the participant manuals ○ Program format ○ Agenda for each session ○ List of materials for each session ○ Information on small group management

MS: multiple sclerosis; DVD: digital video disc.

stand-alone subscales: muscle stiffness, pain and discomfort, muscle spasms, activities of daily living, walking, body movements, emotional health, and social functioning.[7]

The **Multiple Sclerosis Walking Scale-12 (MSWS-12)** measures the impact of MS on walking ability over the previous two weeks.[8]

The **Modified Fatigue Impact Scale (MFIS)** captures the frequency of fatigue-related issues over the previous four weeks, providing a total score and scores for three subscales: physical, cognitive, and psychosocial.[9,10]

The **MS Impact Scale (MSIS-29)** asks about the impact of MS on day-to-day physical and psychological health over the past two weeks.[11]

The **Beck Depression Inventory II (BDI-II)** measures depressive symptoms experienced over the past two weeks.[12] The BDI-II is widely used and validated in MS.

The physical measures, also widely used and validated in MS, were the following.

The **Modified Ashworth Scale (MAS)** rates spasticity at each major joint of each limb based on the response to passive quick stretch applied by the rater.[13–16]

Timed Up and Go (TUG) is the time it takes to rise from a chair, walk 10 feet, turn around, and walk back to the chair, turn around, and sit down. The better of two trials was used.[17,18]

Timed 25 Foot Walk (T25FW) is the time it takes to walk 25 feet. Two trials were averaged.[19,20]

2-Minute Walk Test (2MW) is the distance that a patient can quickly walk on a flat, hard surface in a period of two minutes with or without resting.[21,22]

All participants kept an exercise diary for the four weeks of home practice and completed a knowledge test about spasticity following either intervention.

Statistical analysis

Descriptive statistical analysis was conducted for all endpoints and patient characteristics by group and as a whole. Because of the small sample size, it is not easy to determine whether the endpoints or the changes of the endpoints approximately follow a normal distribution. Therefore, we used non-parametric tests throughout the study for robustness of the testing result. We used the signed test to evaluate whether the changes following the interventions were significant within each group, and used the Wilcoxon rank sum test to compare whether the changes were significantly different between the two groups. We used McNemar's test to determine whether participants within each group changed stretching activity from baseline to follow-up. Also, because of the small sample size, we lack the power to reliably conduct multiple regression modeling to control for the potential baseline differences for this pilot study. All testing results that had a p value less than 0.05 were considered statistically significant. SAS 9.4 (Cary, NC) was used for all data analysis.

Results

Between December 2015 and April 2016, 40 individuals were randomized and 38 completed both baseline and follow-up measurements for analysis (Figure 1). Baseline measurements did not differ between groups except more people in the STC group than in the UC group were taking MS disease-modifying medications (13 (68.4%) and five (26.3%), respectively) (Table 2). Mean MSSS-88 total scores improved more in the STC group than in the UC group between baseline and follow-up (STC −27.8, UC −3.7, $p < 0.03$) and on the pain and discomfort subscale (STC −3.9, UC +0.3, $p < 0.02$) and muscle spasms subscale (STC −5.0, UC −0.5, $p < 0.03$) (Figures 2 and 3 and Table 3). Other MSSS-88 subscales improved more in the STC group than in the UC group but these differences did not achieve statistical significance (Figure 3 and Table 3). Changes in MAS, MSWS-12, and the physical performance measures did not differ significantly between groups (Table 3). STC participants improved significantly in fatigue on the MFIS ($p = 0.03$), depression on the BDI-II ($p = 0.004$), physical function on the MSIS-29 physical component subscale ($p = 0.002$), and knowledge about spasticity on a written test ($p < 0.04$) but these changes were not significantly differently from those of the UC participants ($p > 0.05$) (Table 3). Nineteen participants reported no walking limitations with Expanded Disability Status Scale (EDSS) score < 4.5 (>500 meters without aid or rest (UC: 2.0 $n = 2$, 4.0 $n = 7$; STC 4.0 $n = 10$)). The other 19 individuals had walking limitations with EDSS of 4.5–6.5 with 13 of those needing an aid for walking (unilateral: UC $n = 1$, STC $n = 2$; bilateral UC $n = 6$ and STC $n = 4$). Thirteen people in the STC group were stretching at baseline. At the end of the study all 19 participants in the STC group were stretching ($p = 0.023$). Eight people were

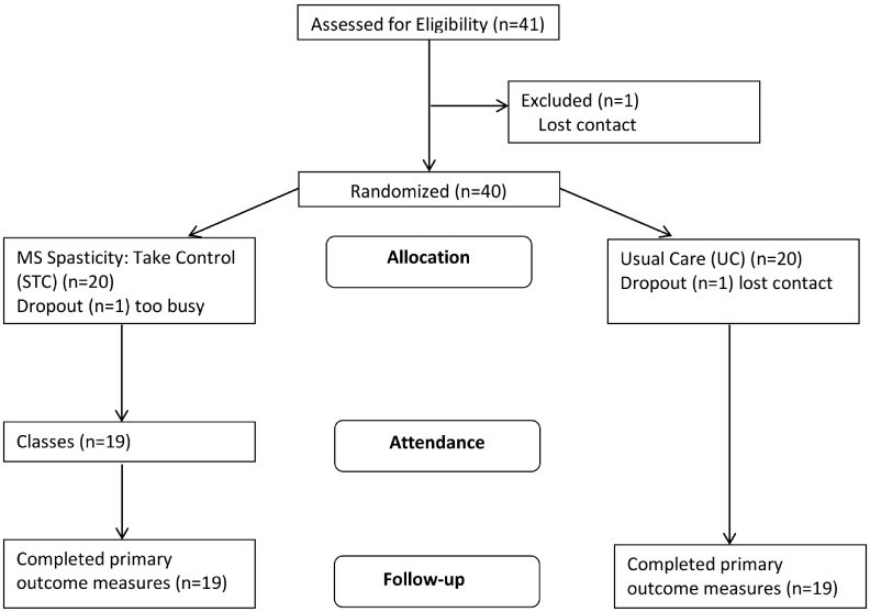

Figure 1. Consort diagram.

Table 2. Baseline characteristics.

Variable	Control	STC
Age years, mean (SD)	53.4 (12.8)	52.8 (12.3)
(low, high)	(30, 79)	(39, 70)
Time since diagnosis years, mean (SD)	15.7 (10.5)	15.1 (8.1)
(low, high)	(1, 36)	(2, 28)
EDSS, mean (SD)	4.9 (1.5)	4.8 (1.1)
(low, high)	(2, 6.5)	(4, 6.5)
Female, *n* (%)	16 (84)	13 (68)
Caucasian/Hispanic/Latino, *n* (%)	18 (95)	18 (95)
Military service, *n* (%)	2 (10.5)	2 (10.5)
Education: BS or above, *n* (%)	10 (53)	10 (53)
Unemployed, *n* (%)	15 (79)	15 (79)
DMT, *n* (%)	5 (26.3)	13 (68.4)
Relapsing–remitting, *n* (%)	8 (42.1)	10 (52.6)
Secondary progressive, *n* (%)	4 (21.1)	6 (31.6)
Primary progressive, *n* (%)	7 (36.8)	3 (15.8)

STC: MS Spasticity: Take Control; EDSS: Expanded Disability Status Scale; BS: bachelor of science; DMT: disease-modifying therapy.

stretching at baseline in the UC group. At the end, 18/19 individuals in the UC group were stretching ($p = 0.002$) (Table 3).

Discussion

Participation in STC, a group MS-spasticity education and lower-extremity stretching program followed by independent home stretching for four weeks, was associated with less impact of spasticity overall and less spasticity-related pain and discomfort and muscle spasms than UC participation using written instructions for independent stretching without in-person instruction or group support. STC participation was also associated with less impact of fatigue, reduced depression, and reduced impact of physical components of MS following the intervention while UC

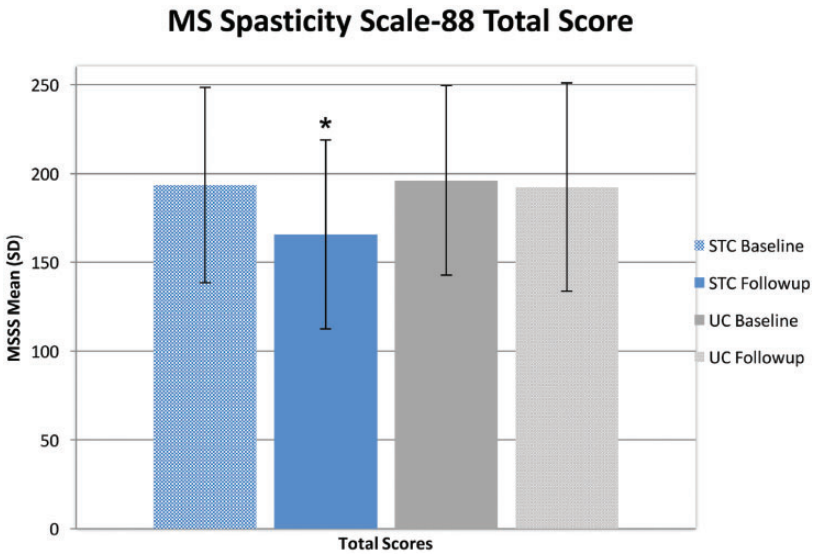

Figure 2. MS Spasticity Scale (MSSS) total score.
*Improvement in STC is significantly greater than in UC.
STC: MS Spasticity: Take Control; UC: usual care.

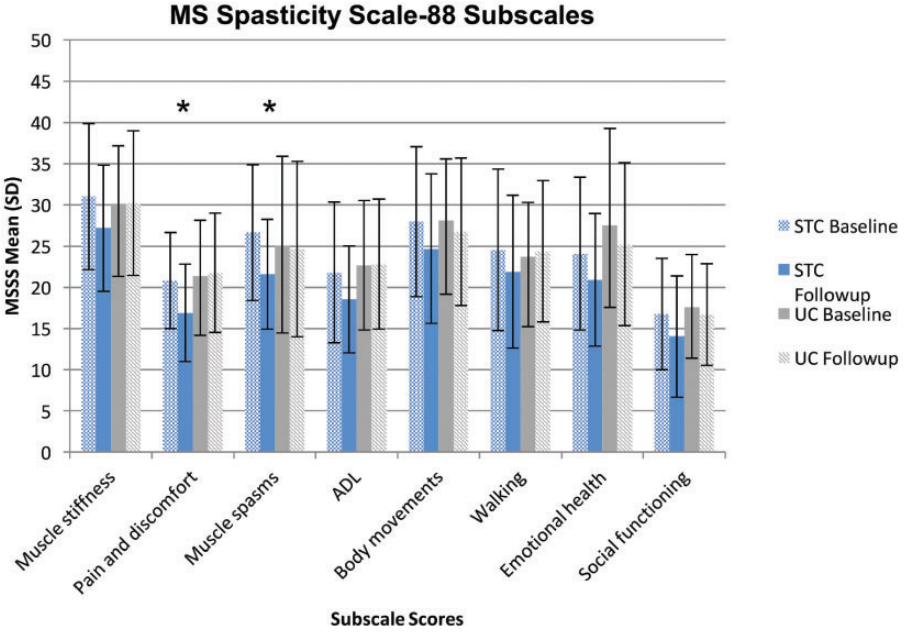

Figure 3. MS Spasticity Scale (MSSS) subscale scores.
*Improvement in STC is significantly greater than in UC.
STC: MS Spasticity: Take Control; UC: usual care.

participation was not. Neither STC nor UC participation was associated with statistically significant changes in objectively measured spasticity (MAS) or objectively measured walking tests (TUG, T25FW, 2MW). These findings suggest STC may have beneficial effects on the subjective impact of MS-related lower-extremity spasticity.

The improvements in the impact of spasticity found in this study compared to placebo are similar to those found with cannabis products and in other exercise studies. One study comparing extract of cannabis to placebo found improvements in their cannabis-treated group in all MSSS-88 subscales except the activities of daily living subscale and significant

Table 3. Results.

	Baseline median	Baseline mean	SD	Follow-up median	Follow-up mean	SD	Median diff	*p* value
MSWS								
STC	85.4	77.5	26.9	70.8	72.6	27	–2.1	0.24
UC	89.6	83.3	25	93.8	82.2	31	–2.1	0.24
STC vs UC								0.84
MSSS Total Score								
STC	189	193.5	55	164	165.7	53	–29	0.019
UC	195	196.1	53.5	188	192.4	59	4	0.82
STC vs UC								0.023
MSSS Muscle Stiffness 1								
STC	30	31	8.8	26	27.2	7.6	–3	0.24
UC	29	30.1	7.1	30	30.2	8.8	0	0.8
STC vs UC								0.156
MSSS Pain and Discomfort 2								
STC	21	20.8	5.8	16	16.9	5.9	–3	0.001
UC	22	21.4	6.7	21	21.7	7.2	0	0.99
STC vs UC								0.012
MSSS Muscle Spasms 3								
STC	27	26.6	8.2	21	21.6	6.7	–4	0.013
UC	22	25.1	10.8	23	24.6	11	0	0.99
STC vs UC								0.024
MSSS Activities of Daily Living 4								
STC	22	21.8	8.6	18	18.5	6.5	–2	0.144
UC	22	22.7	7.9	21	22.8	7.9	0	0.99
STC vs UC								0.065
MSSS Body Movements 5								
STC	30	28	9.1	26	24.7	9.1	–4	0.144
UC	25	28.1	7.5	29	26.7	8.9	–2	0.332
STC vs UC								0.266
MSSS Walking 6								
STC	23	24.5	9.8	21	21.9	9.3	–3	0.167
UC	22	23.7	6.5	22	24.4	8.6	2	0.815
STC vs UC								0.074
MSSS Emotional Health 7								
STC	22	24.1	9.3	18	20.9	8	–2	0.332
UC	25	27.5	11.8	23	25.2	9.9	–2	0.144
STC vs UC								0.965
MSSS Social Functioning 8								
STC	17	16.7	6.8	11	14.1	7.4	–2	0.119
UC	17	17.6	6.4	17	16.7	6.2	–1	0.455
STC vs UC								0.311
MSIS Physical								
STC	53	52.3	15.9	42	45.6	17	–8	0.002
UC	55	54.8	17.6	53	52.4	19	–2	0.629
STC vs UC								0.144

(continued)

Table 3. Continued

	Baseline median	Baseline mean	SD	Follow-up median	Follow-up mean	SD	Median diff	*p* value
MSIS Psychological								
STC	20	19.8	6.5	15	18.2	7.6	−2	0.302
UC	22	22	9.3	20	20.6	7.6	−1	0.455
STC vs UC								0.953
MFIS								
STC	48	48	16	42	41.1	19	−8	0.031
UC	45	48.5	14.9	45	43.5	21	−2	0.629
STC vs UC								0.492
BDI-II								
STC	15	13.7	9.1	9	9	7.5	−3	0.004
UC	13	13.7	8	13	11.5	8	0	0.99
STC vs UC								0.11
MAS								
STC	10	12.1	10.1	9	10.8	9.5	−1	0.332
UC	15	12.6	9.8	12	10.8	9.3	−1	0.077
STC vs UC								0.915
T25FW								
STC	5.6	7.9	7.1	5.9	7.6	7	−0.2	0.648
UC	7.2	9.6	10.4	7.8	9.4	10	−0.2	0.481
STC vs UC								0.738
TUG								
STC	10.5	12	8.7	8.3	11.3	9.7	−0.2	0.167
UC	11.4	16	13.4	12.5	14	14	−1.3	0.481
STC vs UC								0.773
2MW								
STC	455	433.3	152	470	462.8	151	33.6	0.064
UC	390	370.8	157	397.5	412.5	159	11.7	0.096
STC vs UC								0.638
Knowledge								
STC	16	16.7	1.48	18	17.4	1.9	1	0.035
UC	16	15.7	1.53	16	16.1	1.5	1	0.455
STC vs UC								0.493

Weekly stretching (McNemar's test)

	Baseline		Post		
	0	1–4	0	1–4	*p* value
STC	6 (31.58%)	13 (68.42%)	0	19 (100%)	0.0233
UC	12 (63.16%)	7 (36.84%)	1 (5.56%)	17 (94.44%)	0.002
	STC (no change)	STC (change)	UC (no change)	UC (change)	
STC vs UC	13 (68.42%)	6 (31.58%)	8 (44.44%)	10 (55.56%)	0.1412

MS: multiple sclerosis; MSWS: Multiple Sclerosis Walking Scale; STC: MS Spasticity: Take Control; UC: usual care; MSSS: MS Spasticity Scale; MSIS: MS Impact Scale; MFIS: Modified Fatigue Impact Scale; BDI-II: Beck Depression Inventory II; MAS: Modified Ashworth Scale; T25FW: Timed 25 foot walk; TUG: Timed Up and Go; 2MW: Two-Minute Walk.

differences in three subscales: muscle stiffness, muscle spasms, and body movement.[23] Another study found significant differences on three subscales (pain and discomfort, muscle spasms, and emotional health) in patients treated with cannabinoid oromucosal spray compared to untreated individuals.[24] A study of whole-body vibration combined with exercise found significant differences only on the pain and discomfort and the muscle spasms subscales of the MSSS-88.[25] Intermittent transcranial theta burst stimulation (iTBS) combined with exercise produced significant improvement in MSSS-88 total score compared with sham iTBS with exercise therapy and iTBS alone.[26] Four weeks of unloaded leg cycling was associated with significant improvement in the MSSS-88 total score and the pain and discomfort subscale immediately after exercise and one and four weeks later and on the walking subscale only at one week after exercise.[27]

The statistically significant improvements in the STC group in self-reported impact of fatigue, as reflected by scores on the MFIS: Depression, as reflected by scores on the BDI-II, and physical components of MS, as reflected by scores on the physical component subscale of the MSIS-29, found in this study are also interesting. The 6.9-point improvement in the MFIS score in the STC group (from 48 to 41.1) is very close to the seven-point change generally considered clinically significant.[10,28–31] The 4.7-point improvement in BDI-II score in the STC group (from 13.7 to 9) reflects a change from ''mild depression'' to ''minimal depression.''[12] And the 6.7-point improvement on the physical component subscale of the MSIS-29 in the STC group (from 52.3 to 45.6) is very close to the seven to eight points generally accepted as the minimal clinically important difference.[32,33]

Self-reported walking ability, as reflected by scores on the MSWS-12, and functional walking, as reflected by scores on the TUG, improved in the STC group but did not reach statistical significance compared to baseline scores or to the UC group. However, the −14.6 points or 17% improvement in MSWS-12 and −2.2 seconds or 21% improvement in TUG are both clinically significant. Also of interest is the UC group worsening by 10% on the TUG (+1.1 seconds) and 5% on the MSWS-12 (+4.2 points). Our −14.6-point improvement on the MSWS-12 exceeds patient- and therapist-reported clinically meaningful changes of −10.4 and −11.4 points, respectively.[34] Our 21% improvement in the TUG is the same as another study that reported 21% improvement is needed to show genuine improvement on the TUG in individuals with EDSS $\leq$4.[17]

Participation in either the STC or UC interventions encouraged individuals to continue to stretch or to start stretching as would be hoped in a research study asking participants to stretch and then record daily stretching. More people in STC were stretching at the beginning of the study than in UC but by the end, all participants were stretching except one in UC. Even with the high participation in stretching by the UC group, the STC group demonstrated more encouraging results, possibly due to the specific instruction and group support. What remains to be seen is if participants will continue to stretch indefinitely, as recommended clinically given the ongoing and unrelenting nature of spasticity in MS, and if benefits can be sustained or extended in those who do so. Stretching may be safer and have fewer side effects than medications and may augment effects of medications.[35]

The present study has several strengths. This is the first formal standardized program based on the MS spasticity guideline. The STC program includes all the recommendations of a systematic review on the effects of stretching in spasticity (body positioning, intensity, velocity, repetitions, duration, dose, and frequency).[36] We used the robust MSSS-88 to measure the impact of spasticity during daily activities from the patient perspective.[7] The MSSS-88 was developed in response to criticisms of the Ashworth scale and the MAS, the most commonly used spasticity assessments, that rely on the examiner's subjective measuring and rating of the patient's spasticity and capture only one component of spasticity, the resistance of tissue to passive movement from an applied quick stretch.[15] Our MSSS-88 results compare favorably to studies of cannabis or exercise therapy for MS-related spasticity. The comparison to UC controlled for non-specific effects of socialization and attention associated with participating in a research study. Our use of computer-based assessments minimized missing data. Study drop-outs were minimal (5%) and equal between groups. Adverse events were minimal with only one being study related and none severe. We used a variety of outcome measures with self-reported outcomes, the commonly used examiner-assessed MAS, and objectively measured physical performance. The outcome assessors were blind to group assignment. While the sample was small and limited to one metropolitan area, it is likely representative of people with MS and spasticity: half had unrestricted walking and the other half had walking limitations, participants were mostly women older than 50 years, most had a diagnosis of MS for more than 15 years, and most were unemployed. Advantages of the STC

program include: stretching for spasticity is a familiar and logical recommendation for spasticity based on empirical evidence and years of medical practice, and group delivery is generally less expensive than one-on-one physical therapy; requires no special equipment, can be continued at home indefinitely without assistance or other support, and, while standardized, can still be customized for individual needs with the different exercises provided.

This study also has limitations. Our sample, while likely representative of PwMS and adequate for a pilot study, is very small, limiting generalizability. Many of our participants reported stretching at the beginning of the study, which may have limited potential for improvement, but the instruction may have encouraged participants to change their stretching regimens. The program also needs to be delivered in other locations to determine if benefits in this study can be reproduced. MS and spasticity last a lifetime so follow-up beyond four weeks is warranted to gather information about ongoing participation in stretching and other exercise and adverse events and to evaluate sustainability or extension of benefits seen in the present investigation.

Although this study has limitations, it is important to understand that STC, while derived from evidence and similar to other self-management programs in wide distribution and used for many conditions, needs high-quality evidence to support widespread dissemination. Daily stretching requires time and effort by PwMS and they deserve to know if it is truly beneficial. The study presented here provides an early step in evaluating this new program's effectiveness and suggests participation in STC decreased the impact of spasticity on activities and the daily lives of people living with MS and spasticity. A larger trial with longer follow-up and careful monitoring of stretching and other exercise participation and adverse events is needed to fully assess potential benefit of this program.

Conclusion

This small study suggests that the STC education and stretching program decreases the impact of spasticity on daily activity participation and produces clinically important changes in PwMS and spasticity. STC should be subjected to a fully powered, randomized, controlled trial, with impact of spasticity from the patient's perspective as the primary outcome, to determine its effectiveness and, therefore, value in PwMS. Having a proven program to help manage MS-related spasticity is important to optimize health-related quality of life for PwMS.

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Conflicts of interest

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References

1. Ramagopalan SV and Sadovnick AD. Epidemiology of multiple sclerosis. *Neurol Clin* 2011; 29: 207–217.
2. Rizzo MA, Hadjimichael OC, Preiningerova J, et al. Prevalence and treatment of spasticity reported by multiple sclerosis patients. *Mult Scler* 2004; 10: 589–595.
3. Multiple Sclerosis Council for Clinical Practice Guidelines. (2003) *Spasticity management in multiple sclerosis: Evidence-based management strategies for spasticity treatment in multiple sclerosis*. Washington, DC: Paralyzed Veterans of America, 2003.
4. Haselkorn JK and Loomis S. Multiple sclerosis and spasticity. *Phys Med Rehabil Clin N Am* 2005; 16: 467–481.
5. Polman CH, Reingold SC, Banwell B, et al. Diagnostic criteria for multiple sclerosis: 2010 revisions to the McDonald criteria. *Ann Neurol* 2011; 69: 292–302.
6. Gibson B. *Stretching for people with MS: An illustrated manual*. National Multiple Sclerosis Society, 2011.
7. Hobart JC, Riazi A, Thompson AJ, et al. Getting the measure of spasticity in multiple sclerosis: The Multiple Sclerosis Spasticity Scale (MSSS-88). *Brain* 2006; 129: 224–234.
8. Hobart JC, Riazi A, Lamping DL, et al. Measuring the impact of MS on walking ability: The 12-Item MS Walking Scale (MSWS-12). *Neurology* 2003; 60: 31–36.

9. Multiple Sclerosis Council for Clinical Practice Guidelines. (1998) *Fatigue and multiple sclerosis: Evidence-based management strategies for fatigue in multiple sclerosis*. Washington, DC: Paralyzed Veterans of America, 1998.
10. Hugos CL, Copperman LF, Fuller BE, et al. Clinical trial of a formal group fatigue program in multiple sclerosis. *Mult Scler* 2010; 16: 724–732.
11. Hobart J, Lamping D, Fitzpatrick R, et al. The Multiple Sclerosis Impact Scale (MSIS-29): A new patient-based outcome measure. *Brain* 2001; 124: 962–973.
12. Beck A, Steer R and Brown G. *BDI-II Beck Depression Inventory*. 2nd ed. San Antonio, TX: Harcourt Brace & Company, 1996.
13. Bohannon RW and Smith MB. Interrater reliability of a modified Ashworth scale of muscle spasticity. *Phys Ther* 1987; 67: 206–207.
14. Pandyan AD, Johnson GR, Price CI, et al. A review of the properties and limitations of the Ashworth and modified Ashworth Scales as measures of spasticity. *Clin Rehabil* 1999; 13: 373–383.
15. Malhotra S, Pandyan AD, Day CR, et al. Spasticity, an impairment that is poorly defined and poorly measured. *Clin Rehabil* 2009; 23: 651–658.
16. Fleuren JF, Voerman GE, Erren-Wolters CV, et al. Stop using the Ashworth Scale for the assessment of spasticity. *J Neurol Neurosurg Psychiatry* 2010; 81: 46–52.
17. Nilsagard Y, Lundholm C, Gunnarsson L, et al. Clinical relevance using timed walk tests and 'timed up and go' testing in persons with multiple sclerosis. *Physiother Res Int* 2007; 12: 105–114.
18. Podsiadlo D and Richardson S. The timed ''Up & Go'': A test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc* 1991; 39: 142–148.
19. Schwid SR, Goodman AD, Mattson DH, et al. The measurement of ambulatory impairment in multiple sclerosis. *Neurology* 1997; 49: 1419–1424.
20. Fischer J, Jak A, Kniker J, et al. *Multiple sclerosis functional composite (MSFC): Administration and scoring manual*. National Multiple Sclerosis Society, 2001.
21. Gijbels D, Eijnde BO and Feys P. Comparison of the 2- and 6-minute walk test in multiple sclerosis. *Mult Scler* 2011; 17: 1269–1272.
22. Bethoux F and Bennett S. Evaluating walking in patients with multiple sclerosis. *Int J MS Care* 2011; 13: 4–14.
23. Zajicek JP, Hobart JC, Slade A, et al. Multiple sclerosis and extract of cannabis: Results of the MUSEC trial. *J Neurol Neurosurg Psychiatry* 2012; 83: 1125–1132.
24. Henze T, von Mackensen S, Lehrieder G, et al. Linguistic and psychometric validation of the MSSS-88 questionnaire for patients with multiple sclerosis and spasticity in Germany. *Health Qual Life Outcomes* 2014; 12: 119.
25. Schyns F, Paul L, Finlay K, et al. Vibration therapy in multiple sclerosis: A pilot study exploring its effects on tone, muscle force, sensation and functional performance. *Clin Rehabil* 2009; 23: 771-781.
26. Mori F, Ljoka C, Magni E, et al. Transcranial magnetic stimulation primes the effects of exercise therapy in multiple sclerosis. *J Neurol* 2011; 258: 1281–1287.
27. Sosnoff J, Motl RW, Snook EM, et al. Effect of a 4-week period of unloaded leg cycling exercise on spasticity in multiple sclerosis. *NeuroRehabilitation* 2009; 24: 327–331.
28. Putzki N, Yaldizli O, Tettenborn B, et al. Multiple sclerosis associated fatigue during natalizumab treatment. *J Neurol Sci* 2009; 285: 109–113.
29. Ziemssen T, Hoffman J, Apfel R, et al. Effects of glatiramer acetate on fatigue and days of absence from work in first-time treated relapsing–remitting multiple sclerosis. *Health Qual Life Outcomes* 2008; 6: 67.
30. Metz LM, Patten SB, Archibald CJ, et al. The effect of immunomodulatory treatment on multiple sclerosis fatigue. *J Neurol Neurosurg Psychiatry* 2004; 75: 1045–1047.
31. Rammohan KW, Rosenberg JH, Lynn DJ, et al. Efficacy and safety of modafinil (Provigil) for the treatment of fatigue in multiple sclerosis: A two centre phase 2 study. *J Neurol Neurosurg Psychiatry* 2002; 72: 179–183.
32. Phillips GA, Wyrwich KW, Guo S, et al. Responder definition of the Multiple Sclerosis Impact Scale physical impact subscale for patients with physical worsening. *Mult Scler* 2014; 20: 1753–1760.
33. Costelloe L, O'Rourke K, Kearney H, et al. The patient knows best: Significant change in the physical component of the Multiple Sclerosis Impact Scale (MSIS-29 physical). *J Neurol Neurosurg Psychiatry* 2007; 78: 841–844.
34. Baert I, Freeman J, Smedal T, et al. Responsiveness and clinically meaningful improvement, according to disability level, of five walking measures after rehabilitation in multiple sclerosis: A European multicenter study. *Neurorehabil Neural Repair* 2014; 28: 621–631.
35. Brar SP, Smith MB, Nelson LM, et al. Evaluation of treatment protocols on minimal to moderate spasticity in multiple sclerosis. *Arch Phys Med Rehabil* 1991; 72: 186–189.
36. Bovend'Eerdt TJ, Newman M, Barker K, et al. The effects of stretching in spasticity: A systematic review. *Arch Phys Med Rehabil* 2008; 89: 1395–1406.