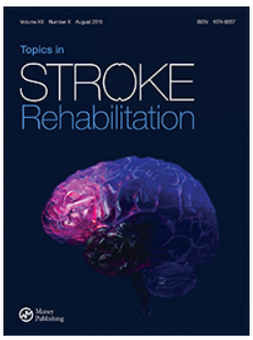

Topics in Stroke Rehabilitation

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/ytsr20

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To cite this article: Diego Longo, Guido Santini, Giulio Cherubini, Daniela Melchiorre, Francesco Ferrarello & Maria Angela Bagni (2022): The muscle shortening maneuver in individuals with stroke: a consideration-of-concept randomized pilot trial, Topics in Stroke Rehabilitation, DOI: 10.1080/10749357.2022.2145741

To link to this article: https://doi.org/10.1080/10749357.2022.2145741

Published online: 18 Nov 2022.

TOPICS IN STROKE REHABILITATION
https://doi.org/10.1080/10749357.2022.2145741

The muscle shortening maneuver in individuals with stroke: a consideration-of-concept randomized pilot trial

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ABSTRACT

Background and Purpose: The Muscle Shortening Maneuver (MSM) is derived from Feldman's λ model of motor control, and seems to induce a more balanced agonist- antagonist-muscular action. The hypothesized mechanism of action is a modulation of the Tonic Stretch Reflex Threshold (TSRT). We designed a pilot, randomized trial aimed to explore the mechanisms of action of the technique. An ancillary objective was to research the implementation of the MSM as a stroke rehabilitation intervention.

Methods: A sample of 10 participants with chronic stroke was enrolled and randomly assigned to MSM (*n*, 5) or conventional physical therapy (CPT) (*n*, 5) treatments. The TSRTs were assessed by the Montreal Spasticity Measure device. A selection of clinical and instrumental outcome measures was taken to investigate function and activity levels. Data were collected at baseline, end-of-treatment, and one month after the end-of-treatment.

Results: No adverse events were observed. In both between- and within-group post-treatment assessments, in the affected ankle the MSM group showed decreased TSRTs of the plantar flexor, increased strength of the dorsiflexor and active range of motion; also, the time needed to perform the Timed Up and Go test decreased. No changes were evident across assessments in the CPT group.

Discussion and Conclusions: The MSM seems able to modulate the TSRTs in individuals with stroke. Although with the limitations due to the pilot design, the variation in participants' responses appear to be promising. Many methodological issues have to be clarified and specified conceiving the progression toward a confirmatory trial.

ARTICLE HISTORY
Received 10 May 2022
Accepted 05 November 2022

KEYWORDS
Stroke; spasticity; motor control; muscle shortening maneuver; tonic stretch reflex threshold; plantar flexors muscles; rehabilitation

Introduction

Physical therapy plays a key role in stroke rehabilitation, and many approaches and techniques have been implemented.[1] The physical and neurophysiological principles of movement control has guided the development of a variety of physical therapy interventions such as, for example, the neurodevelopmental approach, motor learning, constraint-induced movement therapy, functional electrical stimulation, and robotics.[2] The effectiveness of treatment strategies is debated. Although none has demonstrated greater efficiency than any others in the recovery of function and mobility,[1] some interventions (e.g. intensive repetitive task-oriented and task-specific training) promote recovery after stroke.[2,3]

The Muscle Shortening Maneuver (MSM), a physical therapy approach, was introduced by Grimaldi et al.[4] in the eighties and is derived from Feldman's λ model of motor control.[5] According to the model, the nervous system is able to modify the equilibrium state of the neuromuscular system by changing its parameters, thus controlling movement.[6] Motoneuronal recruitment depends on the actual muscle length when the latter exceeds a threshold length, λ. Parameter λ, the lower muscle length or joint angle at which motoneuronal recruitment occurs, is therefore considered the point of origin for the positional frame of reference for the generation of active muscle forces.[7,8] Unexpected changes in external load condition (e.g. a spring-like assisting or opposing load)

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cause rapid adaptations of the positional frames of reference of opposing agonist and antagonist motoneurons,[9] affecting their recruitment.

The dynamic stretch reflex threshold (DSRT) is influenced by stretch speed while the tonic stretch reflex threshold (TSRT) represents the specific value of the DSRT at zero velocity, and is equivalent to the parameter λ. Dynamic and tonic stretch reflex thresholds are expressed in relation to the configuration of the joints, within a body frame of reference.[10] The TSRT is regulated by the central nervous system throughout the biomechanical joint range to produce muscle activation. In order to obtain complete muscle relaxation at rest, the TSRT is regulated to lie outside the biomechanical joint range. However, in the spastic state, the TSRT may lie within the biomechanical range at rest, and this results in joint configurations in which muscles may or may not exhibit spasticity[8,11] .

MSM is noninvasive and free of side effects[5,12–16] and is locally used in clinical practice.[17] The treatment approach consists of two essential simultaneously applied elements: a muscle shortening and a solicitation in traction. A physical therapist applies a series of fast accelerations by means of an elastic element (e.g. a flexible rod) firmly attached to a skeletal segment (e.g. the foot) in the presence of forces acting in the opposite direction (added mass), thus producing a tensile stress. MSM provokes a dynamic muscle lengthening associated with sudden shortening of the agonist and antagonist muscles. Alternating pull and release, the elastic element, produces muscle lengthening followed by sudden shortening. Regardless of the primary target of the intervention, both the agonist and antagonist muscles (e.g. ankle dorsi- and plantarflexor) are stimulated with simultaneous assisting and opposing loads. The fast acceleration, acting in opposite directions, produces tissue tensile stress. Tissue deformation stimulates the muscle spindles, with an enrollment of motor units and an attempt to produce muscle tension. However, the development of tension is prevented by the sudden shortening of the muscle due to the therapeutic maneuver. The ambiguous perceptual stimuli are thought to evoke informational confusion, thus leading the central nervous system to the development of new tonic TSRTs and a subsequent improvement in active muscle recruitment.[4] Studies of MSM reported positive effects on muscle strength and joint excursion when administered in orthopedic conditions[5,12,13] and central nervous system diseases.[14–16] In addition to this, an increase of electromyographic activity (EMG) was observed in a case of peripheral nerve injury.[18]

We therefore designed a consideration-of-concept controlled pilot, randomized trial.[19] Our primary objective was to assess the potential mechanisms of action of the technique, thus investigating the hypothesis that MSM could influence the modulation of the TSRTs. An ancillary objective was to investigate the implementation of a protocol exploring the MSM as a rehabilitation technique to improve body functions and activities in individuals with limitations due to chronic stroke, particularly its safety, usefulness of the outcome measures, and variation in participants' responses.

Methods

The reporting of this study conforms to the CONSORT extension for pilot and feasibility studies[20] and the Recommendation for Reporting the Results of Pilot Studies.[21] The study was approved by the local ethics committee (CEA 14900 spe). Eligible subjects signed an informed consent form containing information on characteristics, modalities, and timing of the study, and on personal data management. Participation was on a voluntary basis; no compensation was offered. The pilot trial protocol can be accessed from the corresponding author on reasonable request.

Study design

A convenience sample of 10 participants was enrolled by a physical therapist investigator. The recruiter randomly assigned participants to MSM or comparison groups (ratio, 1:1). A numbered sequence of opaque and sealed envelopes containing the assignment number was set by a health professional not involved in the recruitment.

Individuals affected by chronic stroke and admitted to the outpatient rehabilitation clinics Turati Foundation (Pistoia, Italy), MAiC Foundation (Pistoia, Italy), and Longo physical therapy studio (Florence, Italy) were invited to

participate. To be included individuals had to be 18 years or older, affected by chronic (>1 year from event) ischemic stroke, with ankle plantar flexor spasticity measured by Modified Ashworth Scale (MAS, score 1–3)[22] and able to reach the facilities involved in the study. Exclusion criteria were the presence of severe cognitive deficits (Mini-mental state examination ≤18), bone deformity and/or pain in the affected ankle joint, pregnancy, botulinum toxin therapy within the previous 5 months, and any comorbidity or disability that would preclude participation in the treatment program. Participants wearing an ankle-foot orthosis (AFO) were not allowed to use it during the study procedure.

MSM treatment

In the MSM session, the individual lay supine on a physical therapy bed, with the foot protruding from the edge. Layers of foam rubber were placed below the knee to reduce tension in the calf muscles. A bandage was applied to the distal third of the leg and the whole foot. A flexible rod (harmonic steel rod covered with foam and neoprene; length, cm 60; width, cm 6; thickness, cm 0.5) was fixed with adhesive tape to the plantar surface along the transverse axis of the participant's foot, protruding about 5 cm from the rear edge of the heel. Small iron parallelepiped weights (weight, kg 1.2 or 3; width, cm 6; thickness, cm 0.5 or 1) could be applied to increase the elastic return of the harmonic steel (e.g. in case of reduced joint excursion of the ankle due to spasticity). The therapist, sitting by the bed, performed the MSM by pulling and releasing with his hand the end of the rod. Dorsal and plantar flexion movements were rhythmically performed (Hertz, 2) for 15 minutes (Figure 1). The participant was requested to relax, avoid any voluntary movement, and let the therapist move the foot. The rod and the bandage were then removed.

The MSM treatment was administered by a trained physical therapy undergraduate student (GS) under supervision. Training and supervision were provided by the first author, a physical therapist with 10 years of clinical experience in neurological rehabilitation and expertise in MSM administration. Three sessions of 1-h specific MSM training were provided to the student by the senior physical therapist. Four MSM intervention sessions were provided. The treatment was administered individually, face-to-face, once a week for four consecutive weeks in an outpatient clinic. Each session had a duration of 40 minutes, including time to apply/remove the bandage and intervention

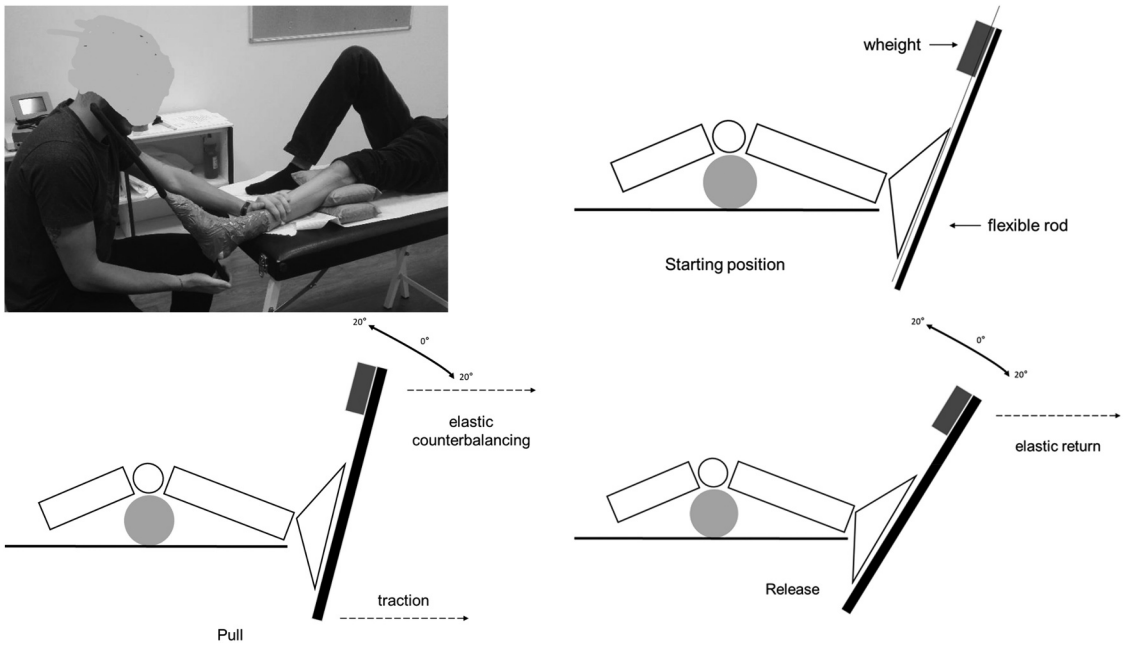

Figure 1. Administering the Muscle Shortening Maneuver. Picture and schematic representation.

administration. The locations were the outpatient rehabilitation clinics of the Turati (cases, 3) and MAiC (cases, 1) foundations, and the Longo physical therapy studio (cases, 1).

Comparator treatment, conventional physical therapy

Conventional physical therapy (CPT) was chosen as comparator treatment. The content of CPT was a combination of functional training in basic activities of daily living, balance and postural exercises, task training, mobilization and stretching, and individual and family/caregiver education. It represents the current standard of outpatient physical therapy care for individuals with stroke provided by the local health authority. Equipment for ambulation training (e.g. parallel bars), balance training (e.g. balance boards, foam pads), and exercise (e.g. resistance bands and weights) were utilized. CPT was provided by two senior physical therapists with more than 10 years of clinical experience in neurological rehabilitation and expertise in stroke recovery. The intervention was tailored according to clinical condition and was administered individually, face-to-face. Ten sessions were provided in four weeks (three sessions in week 1 and 2, two sessions in week 3 and 4) in the outpatient rehabilitation clinics of the Turati (cases, 1) and MAiC (cases, 4) foundations; each session had a duration of 60 minutes.

Variables and outcomes measures

Data were extracted using a standard data recording spreadsheet, including characteristics of the participants and stroke-related issues (age, gender, side affected, years from the event, use of assistive devices); adherence rate, and adverse events were recorded.

To investigate variation of TSRT values (i.e. our specific feasibility primary objective) and sensitivity of the threshold to the stretching speed (μ) of the affected plantar flexor, we used the Montreal Spasticity Measure Device (MSMD).[10,23] The measure involves the use of a two-channel surface EMG system and an electro-goniometer which provide data to a computer. Software computes the TSRT in real time.[10,23,24] The MSMD showed good inter-rater reliability when evaluating stroke-related plantar-flexor spasticity, with an intraclass correlation coefficient ($ICC_{2,1}$) of 0.85[10]. Evaluation of stroke-related elbow flexor spasticity by TSRT displayed fair-to-good reliability (intra-rater, $ICCs_{2,1}$ 0.46–0.68; intrarater, $ICCs_{2,1}$ 0.53–0.68, $ICC_{1,1}$ 0.65), a 95% minimal detectable change of 32.4 degrees, and low sensitivity to change (standardized effect size, 0.40)[24,25]

The evaluation procedure was consistent with that used in previous studies.[10,24] Briefly, a series of 20 passive stretches of the plantar-flexor muscles were performed by the assessor, at various speeds. The data points obtained represented the DSRT angles evoked by stretching the calf muscles at different speeds. The software then performed off-line linear regression to find the TSRT angle at 0 speed. The same software computed the μ value, defined as the inverse of the slope of the linear regression line (Figure 2). The initial ankle angle corresponded to maximum dorsiflexion (high joint angle); therefore, greater TSRT's values indicate greater level of spasticity.

To explore the eventual impact of the treatments on body functions and activity levels in individuals with limitations due to stroke (i.e. an ancillary feasibility objective), a selection of clinical and instrumental outcome measures was taken with exploratory aims. Strength of the dorsiflexor (ankle dorsiflexion item of the Motricity Index (MI)[26]; electronic hand-held dynamometry, newtons[27]) and passive and active range of motion[28] (PROM and AROM; electronic goniometry, from maximum dorsiflexion to maximum plantarflexion and vice versa, AROM applying a minimal manual resistance) of the affected ankle were recorded. Spasticity was measured by means of the MSMD and the MAS.[22] The Barthel Index (BI)[29] was used to assess the level of independence in basic activities of daily living; the Minimal Detectable Change (MDC) estimated in individuals with chronic stroke is 4.02 points.[30] Finally, the Timed Up and Go test (TUG)[31] was used as a measure of walking ability; the MDC estimated in individuals with chronic stroke is 2.9 seconds.[31]

Data were collected by the first author in the Department of Experimental and Clinical Medicine, Physiological Sciences section, University of Florence, Italy, at baseline (T0), at

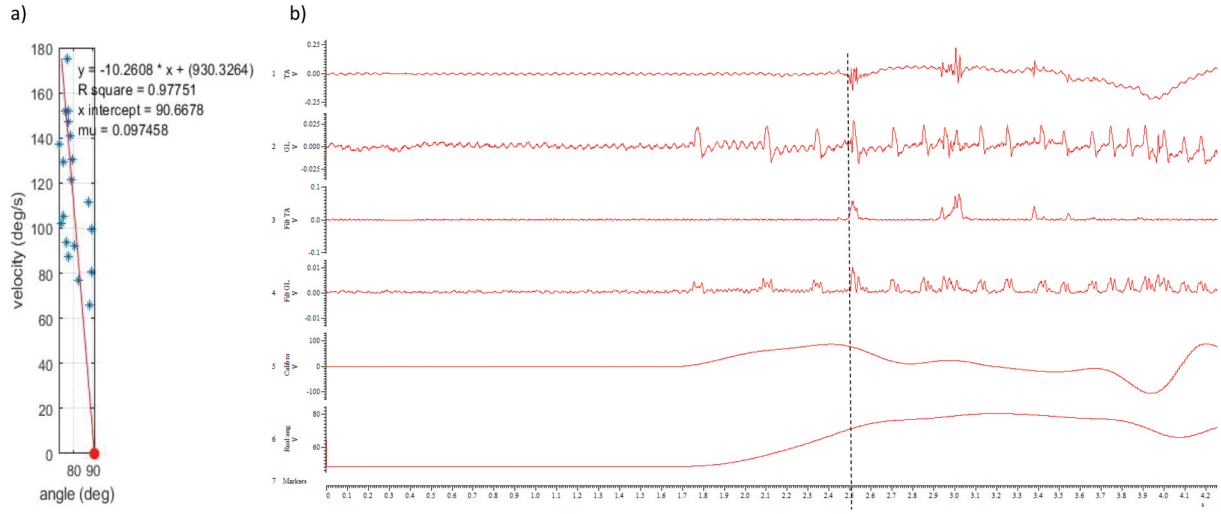

Figure 2. (a) Graphical representation of a Tonic Stretch Reflex Threshold (TSRT) obtained by linear regression. Blue points represent Dynamic Stretch Reflex Threshold (DSRT) measurements, the intersection of the line with the x-axis is the angular value of the TSRT. (b) Detection of a DSRT using the MSMD. TA = EMG activity of the tibialis anterior; GL = EMG activity of the lateral gastrocnemius; Filt = filtered; Calibra = calibrated rate of stretch; Real Ang = angle.

the end of the treatment (T1), and one month after the end of treatment (T2).

Statistical analysis

Data were analyzed by an independent investigator (FF). Sample characteristics were analyzed using descriptive statistics. Given the sample size, nonparametric tests were selected. The Fisher's exact test and the Mann-Whitney U were used to detect differences in categorical and ordinal variables, respectively. Differences between groups in continuous outcome measures were examined using the Mann-Whitney U; score variations were calculated subtracting pretraining values from the corresponding post-training values. Effect size was computed according to the formula $\eta^2 = Z^2/n$. A η^2 value ≥ .60 indicates a large effect.[32] The Friedman test was utilized to assess within-group variations across the assessments; in case of significant results, post-hoc analysis was conducted by the Dunn test, with Bonferroni correction. In case of significant differences in between- or within- comparisons, the Hodges-Lehmann estimator was used to estimate the 95% confidence intervals (CI) of the median of the differences. We further analyzed data on TUG and BI by plotting change scores and the range of random measurement error (i.e. the interval spanning between the $\pm MDC_{95}$ values) and computing the proportions (95% Confidence Interval-CI) of individuals showing an improvement in performance equal to or greater than the absolute MDC_{95} value.

The significant level was set at $p \leq .05$. Analyses were performed with IBM SPSS Statistics software for Windows (version 20.0; IBM Corp, Armonk, NY).

Results

Participants were recruited and enrolled in June–October 2019. The last follow-up was performed in January 2020. The participants (male, 6) were 24–78 years old (median, 52 year). Of them, seven had the left side affected and all scored >18 at the MMSE. At baseline, one participant in the MSM group was using a cane and one participant in each group used an AFO. The treatment was administered 4–32 years after the event (median, 7). Demographic, clinical, and baseline data are presented in Table 1. We found no significant

Table 1. Baseline data.

ID	Group	Sex	Age[a]	Affected side	Years from stroke event	Walking assistive device	AFO	TSRT[b]	μ	MAS	DF strenght[c]	MI-ad	BI	TUG[d]	AROM DF[b]	PROM DF[b]
1	MSM	M	49	Left	32	Yes	No	67,75	−0,0200	3	77	14	95	12,74	−16,5	10
2	MSM	M	46	Left	5	No	No	95,16	0,0500	3	18	14	100	13,31	4,0	7
3	MSM	M	24	Right	8	No	Yes	90,66	0,0900	3	68	14	95	13,02	−10,0	−5
4	MSM	F	55	Left	5	No	No	99,34	0,1700	3	52	14	60	28,94	−17,0	−15
5	MSM	M	78	Right	29	No	No	83,95	0,0700	3	25	14	70	30,72	−36,0	−20
6	CPT	F	46	Right	5	No	No	113,26	0,1200	1	9	14	80	29,05	−10,0	0
7	CPT	F	58	Left	8	No	No	80,36	0,0500	2	38	14	95	14,06	−16,0	−4
8	CPT	F	66	Left	10	No	No	99,09	0,1800	3	23	14	75	16,50	−12,0	6
9	CPT	M	39	Left	6	No	Yes	75,31	0,0800	2	75	14	100	12,90	1,0	8
10	CPT	M	60	Left	4	No	No	77,56	0,1900	3	33	14	80	28,08	−30,0	−28
Between-group *p*		.524[e]	.675 [f]	1.000 [e]	.396 [f]	1.000	1.000	.917 [f]	.209 [f]	.053 [f]	.465 [f]	1.000 [f]	.831 [f]	.754 [f]	.675 [f]	.917 [f]

a = years; b = degrees; c = Newtons; d = seconds; e = Fisher's exact test; f = Mann-Whitney U; μ = sensitivity of the threshold to the stretching speed. Abbreviations: AROM = active range of motion; BI = Barthel Index; CPT = conventional physical therapy; DF = dorsiflexion; MAS = Modified Ashworth Scale; MI-ad = ankle dorsiflexion item of the Motricity Index; MSM = muscle shortening maneuver; PROM = passive range of motion; TSRT = tonic stretch reflex threshold; TUG = Timed Up and Go test.

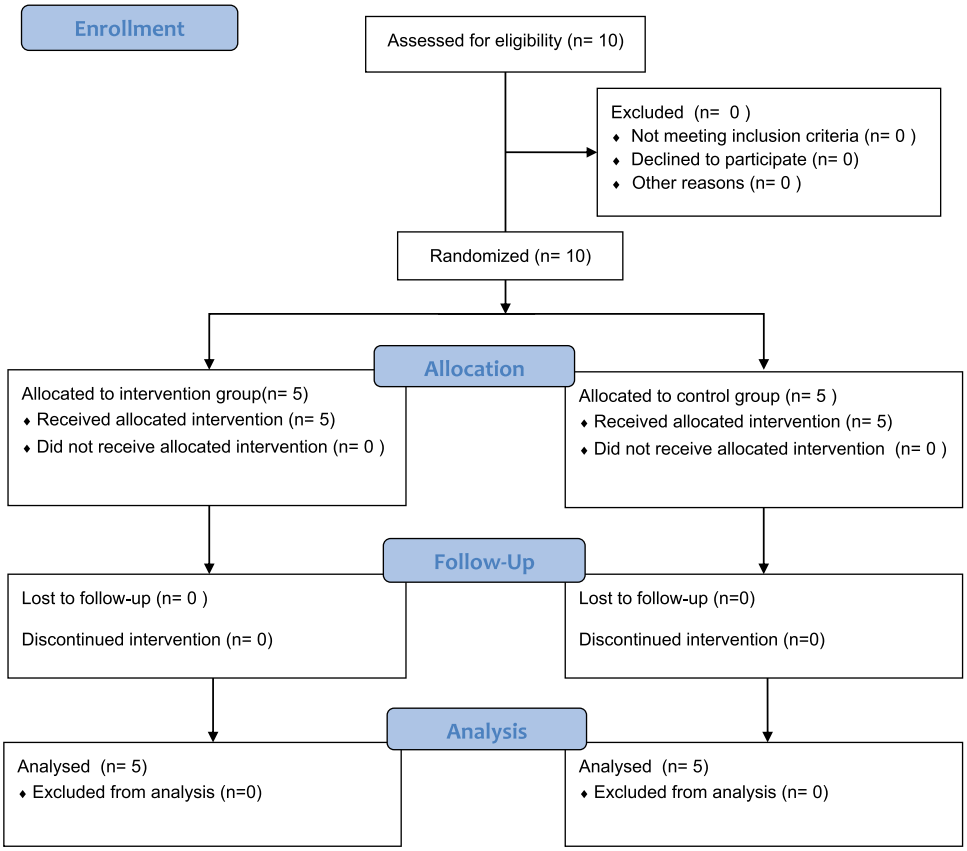

Figure 3. CONSORT flowchart diagram.

difference between groups at baseline (Table 1). All participants completed the study and had complete data (Figure 3). There were no adverse events observed or reported, and no protocol deviations. No change in the use of assistive devices (i.e. cane or AFO) was detected.

In post-treatment between-group comparisons there were differences based on change scores, with large effect sizes (Table 2). In both T1 and T2 assessments, compared to the CPT, the MSM group showed decrease of the TSRTs and of the time needed to perform the TUG test, and

Table 2. Pre-post-treatment between group comparisons.

Variable	CPT (n = 5)	MSM (n = 5)	η^2	p	CPT (n = 5)	MSM (n = 5)	η^2	p
	T1				**T2**			
MAS	2 (1; 3)	3 (1; 3)	0.001	0.910	2 (1; 3)	3 1; 3)	0.001	0.910
MI-ad	14 (14; 14)	19 (14; 25)	0.375	0.053	14 (14; 14)	19 (14; 25)	0.375	0.053
	T1 minus T0				T2 minus T0			
TSRT[a]	−0.73 (−2.21; 0.71)	−12.12 (−13.58; −3.94)	0.682	0.009	−0.23 (−1.49; 1.24)	−11. 08 (−15.39; −4.01)	0.682	0.009
μ	0 (−0.01; 0.02)	−0.03 (−0.08; 0.07)	0.028	0.599	0 (−0.01; 0.03)	−0.03 (−0.12; 0.04)	0.054	0.463
DF strength[b]	2 (−2; 5)	27 (5; 53)	0.632	0.012	5 (0; 6)	29 (14; 66)	0.686	0.009
BI	0 (0; 5)	0 (0; 15)	0.002	0.881	0 (0; 20)	0 (0; 15)	0.002	0.881
TUG[c]	−0.45 (−1.10; 1.8)	−3.38 (−4.94; −1.82)	0.682	0.009	0.97 (0.71; 1.26)	−3.94 (−13.62; −1.72)	0.682	0.009
AROM DF[a]	4 (1; 5)	18 (6; 20)	0.686	0.009	4 (−12; 6)	20.5 (7; 27)	0.682	0.009
PROM DF[a]	4 (1; 8)	14 (1; 29)	0.323	0.072	4 (1; 8)	15 (2; 30)	0.317	0.075

a = degrees; b = Newtons; c = seconds; μ = sensitivity of the threshold to the stretching speed. Data are median (minimum; maximum). Abbreviations: AROM = active range of motion; BI = Barthel Index; CPT = conventional physical therapy; DF = dorsiflexion; MAS = Modified Ashworth Scale; MI-ad = ankle dorsiflexion item of the Motricity Index; MSM = muscle shortening maneuver; PROM = passive range of motion; T0 = baseline; T1 = end-of-treatment; T2 = one month after end-of-treatment;TSRT = tonic stretch reflex threshold; TUG = Timed Up and Go test.

Table 3. Pre-post- treatment within group comparisons.

Variable	CPT Group (n = 5)			p	MSM Group (n = 5)			p
	T0	T1	T2		T0	T1	T2	
TSRT[a]	80.36 (75.31; 113.26)	79.92 (76.02; 111.05)	78.94 (75.98; 114.50)	0.819	90.66 (67.75; 99.34)	78.14 (63.81; 88.48)	75.27 (63.74; 88.26)	0.015
μ	0.12 (0.05; 0.19)	0.11 (0.05; 0.21)	0.12 (0.06; 0.22)	0.607	0.07 (−0.02; 0.17)	0.06 (0.002; 0.140)	0.03 (0.004; 0.110)	0.692
MAS	2 (1; 3)	2 (1; 3)	2 (1; 3)	1	3 (3;3)	3 (1;3)	3 (1;3)	0.135
DF strength[b]	33 (9; 75)	31(11; 80)	34 (15; 81)	0.076	52 (18;77)	73 (37;104)	84 (43;115)	0.007
MI-ad	14 (14; 14)	14 (14; 14)	14 (14; 14)	1	14 (14;14)	19 (14;25)	19 (14;25)	0.050
BI	80 (75; 100)	80 (80; 100)	95 (80; 100)	0.368	95 (60;100)	95 (70;100)	95 (70;100)	0.368
TUG[c]	16.50 (12.90; 29.05)	18.30 (11.80; 29.30)	17.47 (13.63; 30.31)	0.247	13.31 (12.74; 30.72)	10.92 (9.25; 27.34)	11.02 (9.10; 26.78)	0.015
AROM DF[a]	−12 (−30; 1)	−9 (−25; 3)	−11 (−24; 3)	0.069	−16.5 (−36.5; 4)	3 (−18; 10)	7 (−9; 11)	0.007
PROM DF[a]	0 (−28; 8)	1 (−20; 13)	1 (−20; 11)	0.012	−5 (−20; 10)	9 (7; 17)	10 (9; 17)	0.008

a = degrees; b = Newtons; c = seconds; μ = sensitivity of the threshold to the stretching speed. Data are median (minimum; maximum). Abbreviations: AROM = active range of motion; BI = Barthel Index; CPT = conventional physical therapy; DF = dorsiflexion; MAS = Modified Ashworth Scale; MI-ad = ankle dorsiflexion item of the Motricity Index; MSM = muscle shortening maneuver; PROM = passive range of motion; T0 = baseline; T1 = end-of-treatment; T2 = one month after end-of-treatment;TSRT = tonic stretch reflex threshold; TUG = Timed Up and Go test.

increase in strength of the dorsiflexor muscles (dynamometry) and AROM (Table 2). The estimate of the 95% CI of the median of the differences is presented in Table 3. One participant per group (20%, 95%CI 4–62) showed improvement in the BI score greater than the MDC_{95} value at T1 and T2. Three and 4 out of 5 participants in the MSM group (60%,95% CI 23–88 and 80%, 95% CI 38–96, respectively) showed an improvement in the TUG performance greater than the MDC_{95} value at T1 and T2, respectively (Figure 4).

In within-group comparisons, Friedman tests showed some differences between the assessments. Changes in TSRTs, TUG, strength of the dorsiflexors (dynamometry), AROM and PROM reached statistical significance in the MSM group (Table 3). Differences were confirmed by post-hoc pairwise analysis; compared to baseline, T2 TSRT, TUG, dorsiflexor dynamometry, AROM, and PROM were improved (Table 4. The PROM improvement detected in the CPT group (Table 3) was not confirmed by post-hoc pairwise analysis, showing p values ≥ .050 between observations.

Discussion

Being the base of well-designed randomized controlled trials, pilot studies are important for the research process aimed to develop interventions for individuals with disability.[19] The pilot design that we implemented was appropriate for the objectives we set, namely to assess the potential mechanisms of action of an intervention and the implementation of a protocol exploring a rehabilitation technique[11].

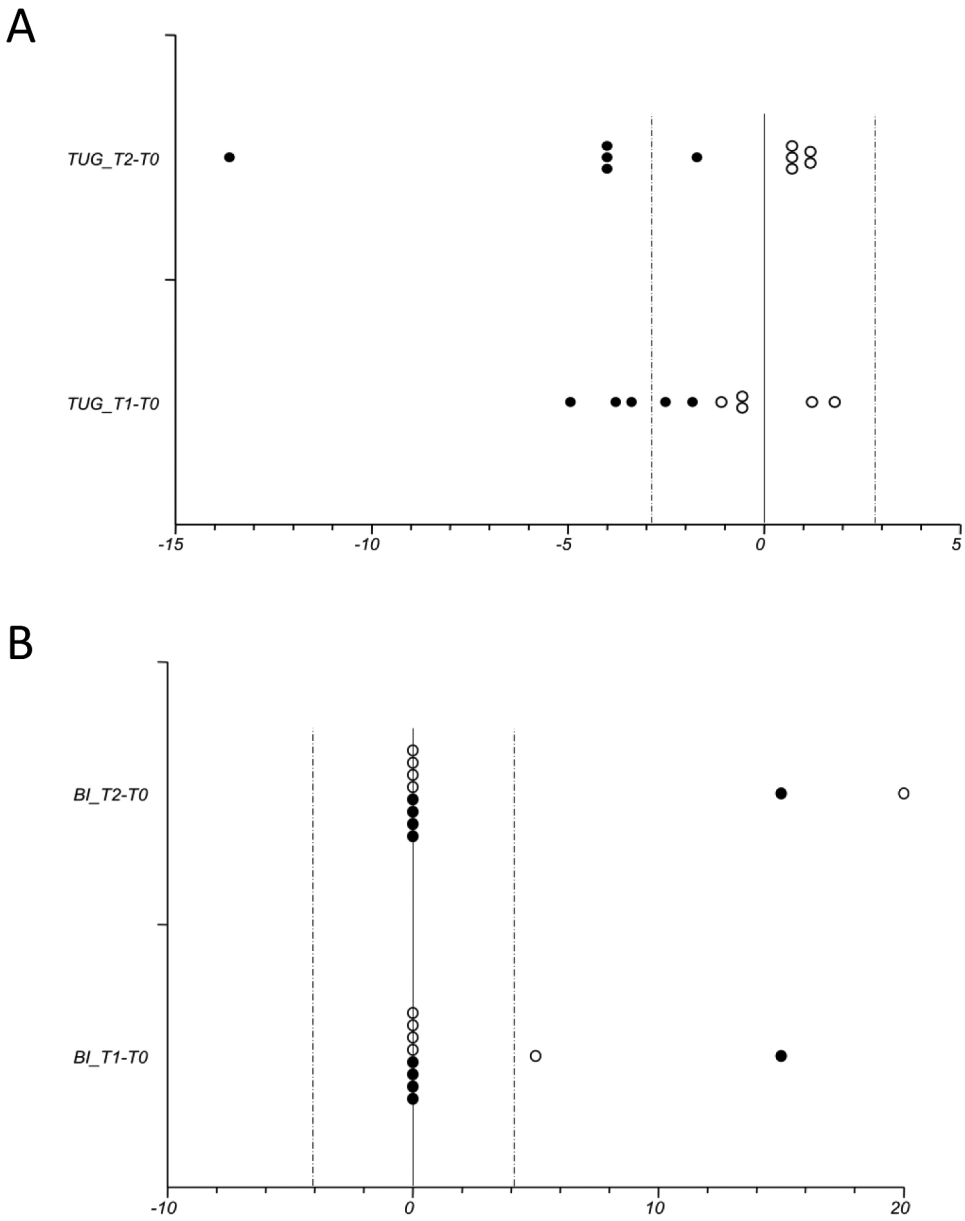

Figure 4. Individual TUG and BI change scores Legend. White dots represent participants in the conventional physical therapy group; black dots represent participants in the muscle shortening maneuver group; the vertical lines indicate a difference of 0 and the ±MDC95 values. (a) TUG = Timed Up and Go test; values in the x axis are seconds. (b) BI = Barthel Index; values in the x axis are points.

Although not significantly, participants in the MSM group showed at baseline higher MAS scores, suggesting higher levels of spasticity; however, the observation was not confirmed by the TSRT measurement. According to the results, TSRT values decreased in the MSM group, whereas the sensitivity of the threshold to stretching speed (i.e. the μ value) was unchanged. The variation of the TSRT values observed by the MSMD measure is consistent with the hypothesized mechanisms of action of MSM, a modulation of the TSRTs.[4,13,15,16] It is plausible that the observed clinical variations in joint range of motion and muscle strength are linked to the decrease of the plantar-flexor TSRT, thus suggesting a potential effect of MSM on the neuromuscular spindles of the plantar-flexor muscles of the affected ankle and related motor control. The MSM is oriented to the body structure level and the observed effect (i.e. a more balanced agonist-antagonist muscular action), if confirmed, would suggest behavioral restitution rather than compensation.[33] New agonist/antagonist activation

Table 4. Significant post-hoc test results. MSM group.

MSM POST HOC[a]		
Between group		*p*
T1 minus T0	**Median of the differences (95%CI)[b]**	
TSRT[c]	−10.91 (−12.85 to −3.50)	.009
DF strength[d]	25 (4 to 51)	.012
TUG[e]	−3.32 (−5.18 to −1.40)	.009
AROM DF[a]	14 (4 to 17)	.009
T2 minus T0	**Median of the differences (95%CI)[b]**	
TSRT[a]	−11.31 (−14.96 to −4.68)	.009
DF strength[b]	24 (12 to 62)	.009
TUG[c]	−4.91 (−14.35 to −2.98)	.009
AROM DF[a]	18 (5 to 23)	.009
Within group		
T2-T0	**Median of the differences (95%CI)[b]**	
TSRT[c]	−11.08 (−15.39 to −4.01)	.013
DF strength[d]	40 (14 to 66)	.005
TUG[e]	−3.96 (−13.62 to −1.72)	.013
AROM DF[c]	21 (7 to 27)	.005
PROM DF[c]	16 (2 to 30)	.008

a = only significant results; b = Hodges-Lehmann estimator; c = degrees; d = Newtons; e = seconds . Abbreviations: AROM = active range of motion; DF = dorsiflexion; MSM = muscle shortening maneuver; PROM = passive range of motion; T0 = baseline; T1 = end-of-treatment; T2 = one month after end-of-treatment;TSRT = tonic stretch reflex threshold; TUG = Timed Up and Go test.

patterns have been observed in elbow muscles in response to load changes[9].

Characterizing stretch reflex behavior in terms of the TSRT angle provides a more reliable assessment of spasticity than current clinical scales. With some caveats, the Tardieu scale spasticity rating resembles the TSRT measure. Therefore, the Tardieu scale determines the "catch angle" at which muscle resistance is felt during slow and fast stretches (i.e. similar to TSRT and DSRT, respectively). However, the Tardieu scale relies on a subjective perception of muscle resistance, and does not distinguish between passive and active components. By using EMG data, the extracted stretch reflex features (TSRT and changes in parameter λ) are not affected by mechanical factors (e.g. applied force, intrinsic muscle resistance), or by the underlying neurophysiology. The MSMD can also be used during passive and active muscle stretching to assess the patient's ability to modulate TSRT, a potential biomarker of exercise recovery.[34] TSRT characteristics discriminate between neurological deficits of muscle tone.[25] In our sample, we observed hypersensitivity to velocity of plantar-flexor muscle stretch, with μ values almost similar to those observed in elbow muscles of individuals with chronic stroke (mean, 0.10 deg/s).[35] We noticed that one subject in the MSM group presented negative or very close to 0 μ values, which usually characterize Parkinson disease rigidity.[35] As he was the participant with the longest disease duration (over 30 years), fibrosis and small retractions could have interfered the sensitivity to stretch. It would be recommended to consider the MSMD parameters (TSRT and μ) when planning and analyzing trials of stroke rehabilitation interventions including participants with spasticity.

The choice of quantitative instrumental outcome measures was satisfactory. The TSRT could be considered a quantitative motor control-based spasticity measure,[25] therefore very suitable to investigate the eventual effect of the MSM in future studies. Well-trained assessors can lower the burden for the participant. Electronic goniometers, hand-held dynamometers, and chronometers are reliable and easy to use. Clinical measures such as the BI, MAS, and MI should be used as independent variables, to select and characterize the sample. As recommended, demographic and stroke information and core measures (i.e. National Institute of Health Stroke Scale, Fugl–Meyer, 10-m walk test, EuroQOL-5D, and simplified modified Rankin Scale) should be considered in future studies.[36] In the present study, the intervention was aimed at improving the motor control of the affected ankle, eventually enhancing the gait pattern. A reliable gait quality assessment tool such as an optoelectronic analysis[37] or at least an observational gait analysis[38] should be contemplated in the design of a future study.

In the contest of our study, statistical testing was not intended to demonstrate that one treatment would be more effective than the other, and was conducted as part of the pilot evaluation of participant responses. As already mentioned, CPT represents the routine therapy that would have been eventually administered. Between group analysis showed decreased TSRTs and time needed to perform the TUG test, and increased strength of the dorsiflexors and AROM in the MSM group. It should be considered that there was a difference in the amount of attention provided (i.e. 2.5 h MSM vs 10 h CPT, 4 sessions vs 10) and MSM is a physically inactive treatment (i.e. the participant lies on the bed). The improvements were observed many years after the event, when the condition is considered almost unchangeable. Due to the MSM characteristics, reconditioning, a factor that may be involved with results in trials recruiting individuals at the chronic stage,[19,39] cannot be called into question. Effect sizes were large[31] and the medians of the differences, although consistent, have to be interpreted with caution, due to wide 95%CIs. We also recognize that using change values can overestimate differences between groups and therefore effect sizes. In our study, we observed TSRT values slightly higher than those reported by Blanchette et al. (2016).[10] TSRT MDC_{95} has been reported for elbow flexor of individuals with sub-acute stroke,[35] thus we are not able to compare our findings. Increments in strength of the dorsiflexor and ankle range of motion positively affect mobility in individuals affected by stroke,[32,40] and this is reflected in the improved TUG test performance. Participants in the MSM group mostly had an improvement in the TUG test greater than the absolute MDC_{95} value (Table 3, Figure 4), whereas one individual per group achieved a similar result at the BI.

Within-group analysis showed significant variations in TSRTs, TUG, strength of the dorsiflexors (MI and dynamometry), AROM and PROM in the MSM group, and PROM in the CPT group. However, in post-hoc analysis, variations of MI in the MSM group and PROM in the CPT group were not confirmed. Post-hoc analysis also showed that the improvements were significant one month after the end of treatment, at T2 follow-up. These findings are in contrast to those reported in previous studies on the MSM. Although they were conducted on a variety of clinical conditions and had various endpoints, outcomes were significantly favorable at the end-of-the-intervention assessment.[5,12–15] It should be noted that in the present study the variables showing improvement were measured by reliable quantitative instrumental measures.

Our findings encourage the progression toward a stage 2 trial. Keeping in mind a next study, and to appropriately register the trial, we need to consider a variety of methodological issues.[39,41] Aspects such as recruitment strategy, participant stratification, blinding, stage of recovery, spasticity level, type and location of stroke interfere with function and functional level, and should be contemplated designing a trial. Also what participants do in between sessions should be accounted for (e.g. steps/day). Including individuals presenting cognitive and communication disorders and comorbidity may increase the generalizability of results.[42] The MSM was applied to improve motor weakness and ankle joint excursion in children with hemiplegia due to cerebral palsy by means of a prototype device.[16] The technology was subsequently developed and simplified, and the updated equipment used to improve ankle mobility in a patient with incomplete peroneal nerve injury.[18] Exhaustive standardized MSM intervention protocols and training programs for therapist and assessors, would increase the research quality and the reliability of the technique.[41]

Particularly challenging are decisions on MSM dosing and control intervention. In previous studies reporting on MSM, no harm or adverse events were evident. As our aim was exploratory and safety was our first concern, we chose the low dosing as a starting point. The comparator treatment that we used, although easily available and adequate for a pilot, would not be acceptable for an effectiveness study.[19,39] An interesting control intervention could be Transcutaneous Electrical Nerve Stimulation (TENS), which has been recognized as effective in reducing spasticity in participants with chronic stroke,[43] with the underlying hypothesis that the treatment may have an effect on TSRT modulation.[44] Meta-analyses published on the topic rely on findings based on the MAS measure.[43,45,46] Thus, it would be interesting to compare MSM and TENS using

the MSMD measure. Both interventions could be delivered in the existing health-care settings, with a relatively low burden (i.e. twice a week, 45 minute sessions) for participants. Involving eligible individuals in study design could increase the relevance of the trial and its outcomes.[39,47]

In conclusion, the findings seem to confirm the hypothesis that the mechanisms of action of MSM consist in the modulation of TSRTs. Despite the limitations due to the pilot design, the variation in participants' responses appear to be promising. Many methodological issues have to be clarified and specified in progressing the methodology toward a stage 2 trial.

Acknowledgments

The authors of this study acknowledge their gratitude to Mindy Levin Full Professor, School of Physical and Occupational Therapy, McGill University, Montreal (CAN), for her constant support and especially for making her great knowledge of the theoretical basis of motor control and their applications available to us in carrying out this clinical study.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

The authors did not receive support from any organization for the submitted work.

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