

Feasibility study design and methods for a home-based, square-stepping exercise program among older adults with multiple sclerosis: The SSE-MS project



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ABSTRACT

We propose a randomized controlled trial (RCT) examining the feasibility of square-stepping exercise (SSE) delivered as a home-based program for older adults with multiple sclerosis (MS). We will assess feasibility in the four domains of process, resources, management and scientific outcomes. The trial will recruit older adults (aged 60 years and older) with mild-to-moderate MS-related disability who will be randomized into intervention or attention control conditions. Participants will complete assessments before and after completion of the conditions delivered over a 12-week period. Participants in the intervention group will have biweekly meetings with an exercise trainer in the Exercise Neuroscience Research Laboratory and receive verbal and visual instruction on step patterns for the SSE program. Participants will receive a mat for home-based practice of the step patterns, an instruction manual, and a logbook and pedometer for monitoring compliance. Compliance will be further monitored through weekly scheduled Skype calls. This feasibility study will inform future phase II and III RCTs that determine the actual efficacy and effectiveness of a home-based exercise program for older adults with MS.

1. Introduction

Multiple sclerosis (MS) is a lifelong, unpredictable and often disabling disease of the central nervous system [1,2]. Of the half-million adults living with MS in the U.S., an estimated 30% are between the age of 55–64 years and approximately 15% are 65 years of age or older [3]. Other epidemiologic reports have suggested that those aged 65 years and older represent nearly 10% of the persons living with MS [4,5]. One study conducted in Manitoba, Canada, indicates a shift in the peak prevalence of MS among older age groups [6]. The peak prevalence of MS occurred at 35–39 years of age, with no documented cases beyond an age of 64 years, in 1984. By 2004, the peak prevalence was at 55–59 years of age, with cases of MS documented beyond 80 years of age [6]. This reflects both the aging of the general population and increased longevity among persons with MS.

The growing demographic of older adults living with MS will present both clinical and public health challenges for managing the consequences of aging with MS as a chronic disease. Older adults with MS experiences age-related declines in physical and psychological functioning that appear to be compounded by the disease and its progression [4,7]. Older adults with MS frequently report poor health status

and functioning, cognitive and ambulatory difficulty, and dependence for activities of daily living [8–13]. The continued loss of mobility, possibility of burdening family members, and relocation are common concerns raised by those aging with MS [14]. We reported that a sample of older adults with MS (mean age of 60 years) had a physical function profile consistent with the normative value of 70-year old, community dwelling adults [15]; this indicate the possibility of accelerated aging in persons with MS. This was confirmed in a follow-up study of age- and sex-matched older adults with and without MS [16]. As the population of persons with MS ages, it is important and necessary to implement integrative preventive and geriatric care for MS management that focuses on wellness, functional rehabilitation, and maximizing quality of life in the older MS cohort [17]. This is particularly important as there is limited evidence for the efficacy of disease modifying drugs in persons over 60 years of age, and the existing evidence indicates no beneficial effect [18], thereby underscoring the importance of developing rehabilitation approaches that can improve outcomes in older adults with MS.

The focus on healthy lifestyle behaviors, such as exercise, may potentially be a powerful approach for managing the consequences of aging with MS [17]. There is compelling evidence for the benefits of

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exercise in young and middle-aged persons with MS [19–21], but there is a paucity of research in older adults with MS [22,23]. Exercise training in persons with MS further has been mostly conducted in highly supervised and controlled settings (e.g., laboratories), and has not been guided by feasibility study designs for optimizing the delivery of effective exercise interventions into the MS population [24]. This combination likely explains poor uptake of physical activity participation for health benefits, particularly among older adults with MS [25]. Indeed, older adults with MS engage in alarmingly reduced levels of moderate-to-vigorous physical activity [25], and this is seemingly associated with accessibility and acceptability barriers of center-based exercise environments.

Previous research studies on physical activity and its benefits in persons with MS have not undergone initial and systematic feasibility testing [26]. This is a limitation as it potentially weakens translation, and may hinder effectiveness achievement of studies related to long-term adherence. Differences between feasibility and pilot studies relates to the fact that pilot study is considered a smaller version of a large-scale randomized controlled trial (RCT), where the main purpose involves investigating if all components of the study work together and yielded evidence of efficacy. On the other hand, feasibility studies primarily aim to reveal whether the study is practical; to identify and establish the important parameters of the design of the main study; and to address potential threats to the validity of the outcomes of the study. To this end, feasibility studies allow researchers to gather valuable information on process, resources, management, and scientific metrics and inform the design and credibility of subsequent stages of research [27–30].

2. Specific aims

We propose a randomized controlled trial (RCT) examining primarily the feasibility and secondarily the efficacy of a home-based, exercise regimen square-stepping exercise (SSE) for improving mobility, balance and cognition in older adults with MS. The SSE was developed with a focus on preventative care (i.e., improving mobility and cognitive function, and fall prevention) and enjoyment [31]. SSE involves lower extremity leg movements as an exercise modality, while requiring cognitive function by including elements of recall memory, executive function, visuospatial function, and analogy. This study focuses on feasibility-based assessments of processes (e.g., rates of recruitment, adherence, and retention), resources (e.g., time, space, monetary cost and equipment requirements per stage of the research), management (e.g., research preparation, researcher capacity, and expertise strengths and weakness), and science (e.g., safety, burden, participant feedback and efficacy/outcomes) metrics of the SSE program delivered over a 12-week period using a home-based model. The information yielded by such a feasibility study will be critical for designing larger-scale studies that can establish actual efficacy and effectiveness of the SSE program in older adults with MS. The primary aim of this study is to examine the feasibility of the RCT plan and secondarily its effect on chosen outcomes (i.e., efficacy). The first is a component that differentiates feasibility from pilot studies [30]. The strength of this study is the focus upon the metrics of feasibility and secondarily upon the results of the RCT. Collectively the present manuscript provides valuable information for others attempting to design and undertake feasibility studies prior conducting them on a large scale.

3. Methods

3.1. Ethical approval

Ethical approval will be obtained from the Institutional Review Board of the University of Illinois at Urbana-Champaign, USA.

3.2. Participants characteristics

Inclusion criteria include: (a) clinically definitive diagnosis of MS; (b) age 60 years or older; (c) relapse-free for the past 30 days; (d) ability to walk with or without assistive device (i.e., cane); (e) willing and able to participate in a 12-week home-based exercise regimen using hybrid approach; (f) non-exercisers (operationalized to be not engaging in structured exercise 2 + days/week); (g) asymptomatic (i.e., one or fewer affirmatives on the Physical Activity Readiness Questionnaire (PAR-Q)) or physician approval for undertaking exercise training for those with 2 or more affirmatives on the PAR-Q [32]. More than 1 affirmative on the PAR-Q indicates that the participant is at more than a minimal risk for exercise-related complications and therefore physician approval will be required prior to enrolling such participants in this study; and (h) scoring ≥ 13 points in the Telephone Interview for Cognitive Status, indicating no more than mild cognitive impairment. Participants who do not meet those criteria will be excluded from study participation. Of note, we will assess disability level using the Expanded Disability Status Scale (EDSS) [33] for all participants included in the study. We will further collect demographic (i.e., age, sex, marital status, years of education, income, race) and clinical (i.e., years of disease, type of MS, co-morbidities and medication) data on the participants.

3.3. Recruitment and enrollment

Participants will be recruited through advertisements in local newspapers (100-mile radius around the University of Illinois campus), referrals from local neurology practices, posts on the Greater Illinois chapter of the National Multiple Sclerosis Society (NMSS) website, targeted recruitment through the North American Research Committee on Multiple Sclerosis (NARCOMS), and other similar outlets. We will further use our database from previous studies to recruit individuals aged 60 years and older. Potential participants will be screened by telephone to determine eligibility status. Those who qualify will be scheduled for a visit to the Exercise Neuroscience Research Laboratory (ENRL) to sign the informed consent document (ICD) and undertake baseline assessments (i.e., efficacy/outcome assessments). Following baseline assessments, participants will be randomly allocated using a concealed method (i.e., opaque envelopes) into the exercise intervention (i.e., SSE) or attention control (i.e., stretching and toning) conditions. This eliminates the potential bias that would occur by randomizing after seeing baseline data. <http://www.sciencedirect.com/science/article/pii/S1551714415301336> Fig. 1 reflects participant flow through the program from recruitment to completion of the program.

Twenty-four older adults with MS will be recruited to participate in this study (i.e., 12 in the SSE condition and 12 in the attention control group) [34]. The sample size was not determined from a formal power analysis, as the primary purpose of this study is to examine feasibility of conducting the exercise program rather than examining its efficacy per se. The sample size of 12 per condition is based on three arguments about pilot trials, namely (a) the focus on feasibility, (b) gains in precision about the mean and variance after 12 individuals are very small, and (c) regulatory considerations. We further recognize that there may be 20% drop out based on previous research [35], and that gathering information on drop out is important for the design of a future trial. Accordingly, the information gathered from this feasibility trial (i.e., effect sizes and drop-out rates) will help inform sample size estimates for a future phase II trial. Because of the higher incidence of MS between male and female (i.e., 2:1 ratio), we expect a higher number of females than males to enroll in the study.

3.4. Feasibility metrics

This study will assess outcomes based on process, resources, management and scientific metrics of feasibility. These metrics are

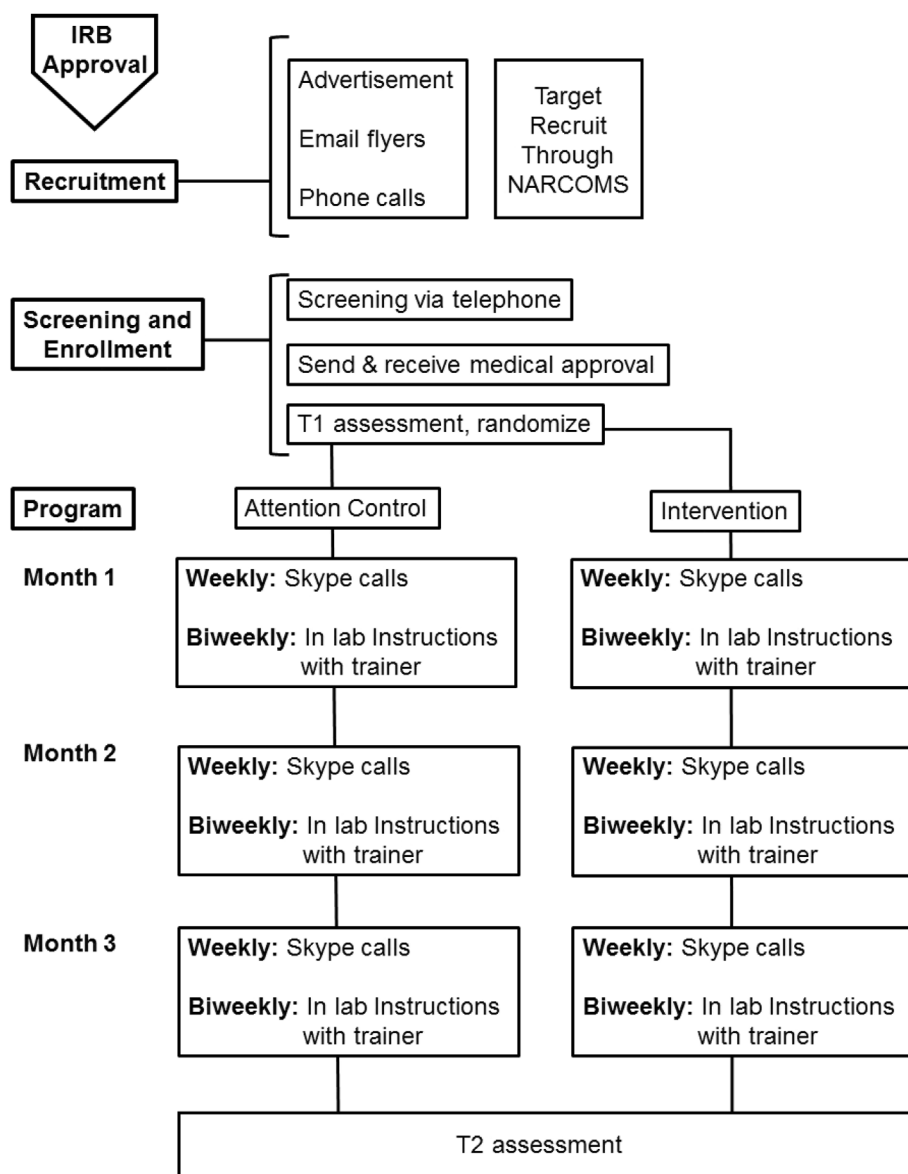


Fig. 1. Flowchart of recruitment through completion of the program.

summarized in Table 1 along with the methods for collecting and assessing relevant data, and the importance of each feasibility metric to the development of future trials.

3.5. Outcome assessments

The scientific outcomes will be administered to all participants before randomization and following 12-week intervention. All measures have been validated in persons with MS and will be administered using standard procedures. The primary outcomes will be mobility and cognition. The Timed 25-foot walk (T25FW) [36,37], the Six-minute Walk (6 MW) [38,39] and the Timed Up and Go (TUG) [40–42] will represent standard performance measures of mobility disability along with the Short Physical Performance Battery (SPPB) [15], which consists of measures of balance (i.e., side-by-side stand, semi-tandem stand, tandem stand), gait speed (i.e., first gait speed test, second gait speed test), and lower-limb power strength (i.e., single chair stand, repeated chair stands). The Brief International Cognitive Assessment MS (BICAMS), which includes the oral version of the Symbol Digit Modalities Test (SDMT), Brief Visuospatial Memory Test (BVMT), and the California Verbal Learning Test (CVLT) will represent cognitive endpoints [43]. All aforementioned outcomes will be assessed pre- and post-

intervention period (i.e., 12 weeks) by trained researchers, with several year experience in rehabilitation studies, in a laboratory setting. There will be no randomization of test order, but rather all participants will follow the same order (i.e., neurological examination, cognitive tests, T25FW, TUG, SPPB, 6 MW) for baseline and follow-up as a control of order effects.

3.6. Randomization

Eligible participants who sign the ICD and undertake the baseline assessment will be randomly assigned 1:1 into the exercise (i.e., SSE) intervention or attention control conditions. A research staff not involved with the study will be responsible to randomly put inside of opaque envelopes and sealed them, slips of paper containing allocation on a 1:1 basis into either the intervention or attention control conditions. Enveloped will them be stored together in a randomization container. Following the baseline assessment, participants will be taken to one of the rooms in the ENRL and will be asked to draw one of the pre-prepared envelopes displayed over a table, so him/her can be allocated to one of the two possible groups (i.e., SSE intervention or attention control). This procedure has been previously used in other trials [44].

Table 1
Feasibility Metrics; proposed methodology and importance to future research in MS.

Metric	SSEMS will monitor and assess	How this will be monitored and assessed	Importance to future Phase II and III studies
Process; assesses participant recruitment and retention.	a. Recruitment and refusal rates b. Retention, attrition and adherence rates	a. We will use phone and electronic mail recruitment and record all contact with potential participants and refusal reasons (through an online refusal feedback form, email and over the phone). b. We will record all participants' flow through the recruitment, enrollment and intervention sections of the study. We will record adherence with the intervention via log book, weekly phone calls, and step count as measured throughout SSE sessions at home.	a. To provide information on optimal recruitment method expected recruitment, and refusal reasons. b. To provide target areas for optimizing participant retention and intervention adherence.
Resources; assesses communication and monetary requirements of the study.	c. Communication with participants. d. Communication needs of participants and staff. e. Monetary costs of research	c. We will utilize a password protected database to monitor contact with all potential and enrolled participants. d. We will establish and record all problems and communication alterations, including communication need of participant and SSE trainere. We will establish and record all monetary costs for the study; for both the intervention and attention control participants.	c. To establish communication frequency and highlight communication problems. d. To establish communication needs and anticipated communication problems. e. To establish monetary cost to conduct the research and establish areas for cost saving.
Management; assesses data management and safety reporting during the study.	f. IRB approval procedures. g. Staff preparation and report time for participant communication. h. Time and accuracy in data collection/entry. i. Reporting and handling of adverse events (AE), serious adverse events (SAE) and clinical emergencies.	f. We will document communications between University IRB and staff, and time from submission of IRB application to approval. g. We will document all preparation, call time, attempted call time and report-taking time for each participant during the intervention; including the biweekly meetings and weekly phone calls. h. We will check for data completeness, and record time to collect, enter and check data. i. We will record our use and handling of standard university protocol for reporting of all AEs, SAEs and clinical emergencies.	f. To detail staff time requirements. g. To detail staff time requirements and highlight considerations for alterations. h. To detail what safety procedures should be implemented
Scientific; assesses the safety, burden and treatment effect of the study.	j. AEs, SAEs and clinical emergencies. k. Participants experience, burden, and compliance during the intervention. l. Treatment effect.	j. We will follow standard university protocol to record all AEs, SAEs and clinical emergencies. The SSE trainer will also ask participants about AEs and SAEs and other medical concerns during the weekly phone calls and biweekly visits to the lab and will take notes of that. k. We will record participant feedback on the intervention via logbook-sheet available in the participants' binder. Participants will be asked to complete information in a specific sheet after each SSE session regarding level of perceived effort, enjoyment, feelings, and levels of perceived physical and mental fatigue. l. We will determine effect size and clinical meaningfulness of any change in mobility and cognition outcomes.	i. To determine the safety and feasibility of the intervention and highlight considerations for alterations. j. To determine acceptability and highlight considerations for alterations. Determining compliance will further allow correct conclusions to be drawn from the results. k. To determine data for power calculations and anticipated clinical impact.

3.7. Exercise intervention group

Participants in the exercise condition (i.e., SSE) will be involved in a 12-week period of exercise using a hybrid of biweekly, in-person supervised instruction followed by ongoing home-based practice (i.e., 2–5 days/week) with weekly Skype monitoring. The SSE itself will be performed on a thin mat of 250 × 100 cm, partitioned into 40 smaller squares (25 cm per side). SSE provides sequences of stepping patterns (200 total ranging in difficulty from beginners through advanced) wherein participants learn and practice specific stepping routines by progressively stepping along the mat length direction (250 cm), avoiding treading on the lines of the squares. Importantly, participants presenting with difficulties in terms of step width or length when moving their feet will be allowed to treading the lines. Further, if the proposed step pattern places participant at an increased risk of falling, the pattern will be replaced. Participants will start with basic step patterns that focus on walking-like movement (i.e., beginner level 1) and will gradually progress to more complex step patterns requiring forward, lateral, diagonal and backwards movements (i.e., advanced

level 3). Refer to [Table 2](#) and [Fig. 2](#) for more details on progression and levels of step pattern. The number of step patterns and difficulty will progress biweekly based on observed mastery of the step patterns from the previous 2-week period. Over the course of the intervention, participants will have a total of 6 encounters (one every two weeks) with the exercise trainer to be familiarized with and receive verbal and visual instructions about the step patterns. Participants will then practice the sequence of step patterns designated for the two-week period at home until the next meeting. The meetings between participant and exercise trainer will be individualized and will take place at the ENRL. During the meetings, the exercise trainer will demonstrate to the participant a set of step patterns by performing the patterns from one end of the mat to the other by stepping in the squares. Following demonstration, participants will be asked to repeat each of the stepping patterns 5 times. Researchers have observed that pattern recognition and memorization is normally achieved after 4–5 repetitions [45]. After familiarization and learning the stepping pattern, participants will then receive a visual diagram of the patterns demonstrated and practiced during the meeting to take home for exercising (i.e., SSE practices). The

Table 2
Progression of the arms of the SSE-MS program.

Week	Intervention				Control			
	Frequency (days/week)	Duration (minutes)	Number of Step Patterns	Level of Step Patterns	Frequency (days/week)	Duration (minutes)	Stretching Exercises	Sets/time for each exercise
1*	2	10–15	4	B1; B1; B1; B2	2	10	H & N	1/30 s
2	2	10–15	+ 4	B1; B1, B2, B2	2	10	W1 + S	1/30 s
3*	3	15–20	+ 4	B2; B2; B2; B2; I1	3	15	W1-2 + SR	2/20 s
4	3	15–20	+ 4	B2; B2; I1; I1; I1	3	15	W1-3 + E	2/20 s
5*	3	15–20	+ 4	I1; I1; I1; I1; I2	3	15	W1-4 + FE	2/20 s
6	4	20–25	+ 4	I1; I1; I1; I2; I2; I2	4	20	W1-5 + Ha	2/20 s
7*	4	20–25	+ 4	I2; I2; I2; I2; I2; I3	4	20	W1-6 + W	3/20 s
8	4	20–25	+ 4	I2; I2; I2; I3; I3; I3	4	20	W1-7 + T	3/20 s
9*	5	25–30	+ 4	I3; I3; I3; I3; I3; I3; A1	5	25	W1-8 + Hi	3/20 s
10	5	25–30	+ 4	I3; I3; I3; I3; A1; A1; A1	5	25	W1-9 + A	4/20 s
11*	5	25–30	+ 4	A1; A1; A1; A1; A1; A1; A2; A2	5	30	W1-10 + FoE	4/20 s
12	5	25–30	+ 4	A1; A2; A2; A2; A2; A2; A3; A3	5	30	W11	4/20 s

Note: * Meeting with SSE/Stretching trainer; B1 = Beginner one; B2 = Beginner two; I1 = Intermediate one; I2 = Intermediate two; I3 = Intermediate three; A1 = Advanced one; A2 = Advanced two; A3 = Advanced three; H = Head; N = Neck; W1, 11 = Week one to eleven; S = Shoulder; SR = Shoulder Range; E = Elbow; FE = Forearm Exercises; Ha = Hand; W = Wrist; T = Trunk; Hi = Hip; A = Ankle; FoE = Foot Exercise.

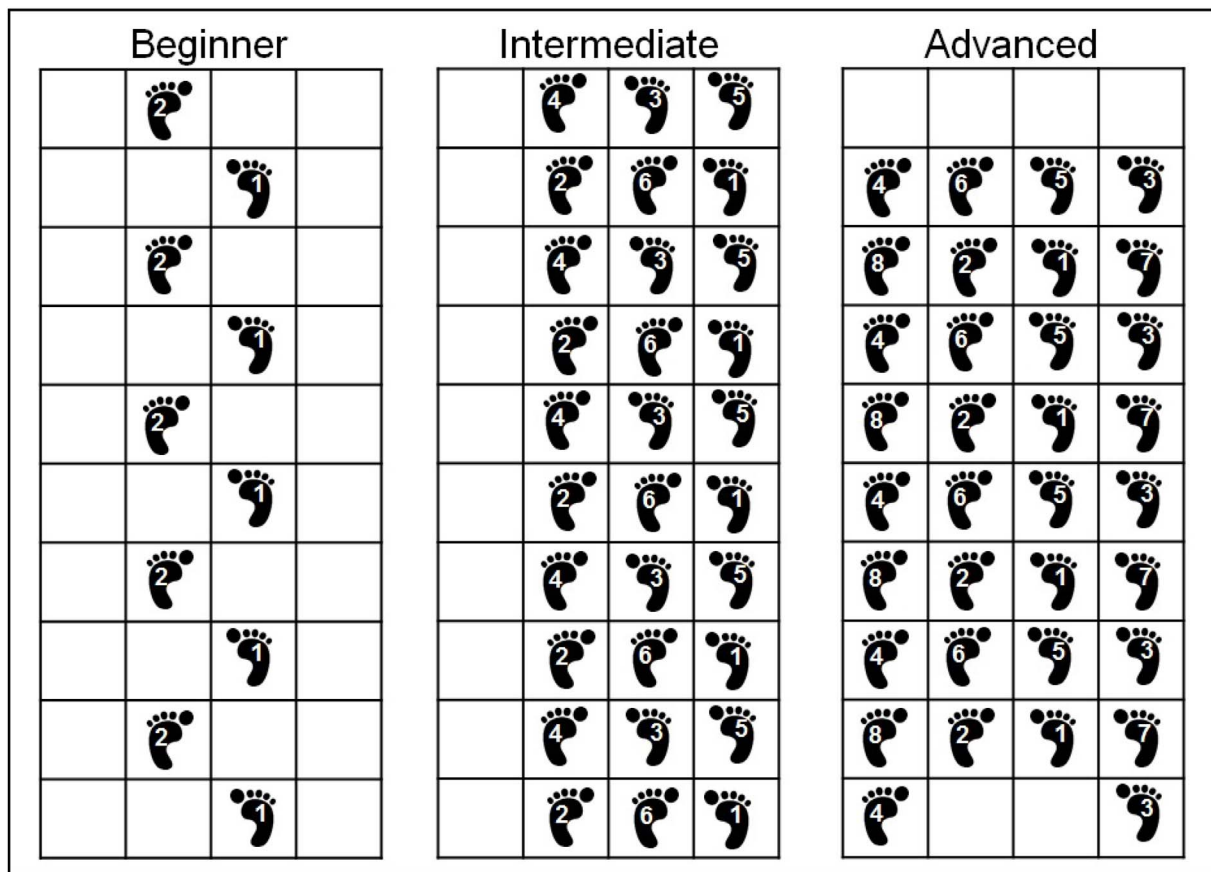


Fig. 2. Examples of the three different levels of patterns available in the square-stepping exercise program.

program will start with 2 times per week with 15-minute sessions and will progress to 5 times per week with 30-minute sessions (Table 2). Of note, the program is based on the FITT (Frequency, Intensity, Time and Type) principle vastly used in exercise programs. Thereby, the progression from 2 to 5 days per week and 10–15 min to 25–30 min will happen systematically rather than participants' choice. Participants will be provided with a mat, a logbook, and a pedometer (i.e., Yamax SW-

200). There is evidence of the accuracy of the Yamax SW-200 pedometers in providing steps information in persons with MS [46]. We further pilot tested the devices on this setting and had 99.8% accuracy in detecting steps. Participants will be asked to wear the pedometer during all SSE home-sessions and to record the date, start and end time, and the number of steps at the end of each session in a logbook. This procedure will be used to monitor compliance with the program.

Participants will be taught on how to use the device during the lab instruction/training on the mat tasks. This will provide an idea on the step requirement for each session and then compare this information in the lab with the home-based data for compliance. At the end of each session, participants will also be asked to answer and report to five different scales related to: level of perceived exertion, feeling, enjoyment, physical and mental fatigue. All this information will be retrieved during the biweekly meetings. This will be also used to track compliance. By the time of the next meeting, researchers will retrieve the logbook, and will ask participants to demonstrate they mastered the patterns/sequences before providing new sequences. Participants will demonstrate mastery of the sequences by successfully completing twice each of the stepping patterns exercised at home. The new step sequences will add to the ones learned in the previous meeting and will progress in difficulty over the 12-week period. Weekly skype calls will be scheduled with participants as an additional way to ensure compliance and also to answer possible questions participants may have at the moment.

3.8. Control group

Participants in the control group will be involved in a 12-week period using the same hybrid of biweekly, in-person supervised instruction followed by ongoing home-based practice (i.e., 2–5 days/week) with weekly Skype monitoring. The stimulus will be a light intensity stretching and toning program based on the illustrated manual for people with MS developed by the National Multiple Sclerosis Society. This stimulus is common in RCTs of exercise training in older adults and serves as an attention-control condition. Participants will receive graphical instructions on the designated stretching exercises. The intervention will progressively include more exercises and sets over the course of 12-week period, and will include both upper and lower body exercises. The inclusion of more exercises and sets are important and are designed for maintaining interest and adherence with the control group. The stretching program for the control group will follow the similar frequency and duration as the intervention group. Compliance for this the control group will be monitored through the weekly skype calls and through the five scales that are completed at the end of each home-based session.

4. Data analysis

All data will be entered into and analyzed using SPSS version 22.0 (SPSS Inc. Armonk, NY: IBM Corp.). Data will be first examined for normality violations, outliers, errors, and pattern of missing values. Missing data will be replaced using the expectation-maximization approach, after the missing completely at random test are confirmed [47,48]. The feasibility metrics will be initially examined using percentage and frequency analysis and descriptive statistics. Data on the effect of the intervention on scientific outcomes of efficacy will be examined in two ways: (a) descriptive statistics (e.g., mean, standard deviation, median, interquartile range) and (b) Condition \times Time mixed-factor ANOVA. Condition will be a between-subjects factor and time will be a within-subjects factor. Of note, covariates will not be included and statistical analysis will serve primarily for the observation of eta-squared values rather than statistical significance. Effect sizes associated with F -statistics will be expressed as eta-squared (η^2). Effect sizes based on a difference in mean scores over time between groups will be expressed as Cohen's d . The η^2 values for the interaction-term from the ANOVAs will serve as the effect sizes for future power analyses. The partial eta-squared estimate for the interaction term from the ANOVA will inform power analyses for future large studies, and the intra-correlation coefficient for test-retest reliability for the control group will inform the reliability estimate for the power analyses.

5. Discussion

There are several novel aspects of this study protocol. The feasibility study design will allow for the research team to gather information on the process, resources, management and scientific feasibility of our approach. This comprehensive assessment will provide formative data for a well-designed, future RCT of home-based exercise in older adults with MS. The feasibility data gathered in the SSE-MS program will guide future efforts in this area by determining optimal recruitment strategies, integrity of the study protocol, appropriateness of outcome assessments, and considerations for methodology alterations. This is essential for subsequent research on exercise programs with limited supervision or non-supervised exercise in MS. Other innovative aspects of the program include: the examination of an exercise intervention that has not been applied/tested in persons with MS, and the examination of a home-based exercise intervention that has not been applied/tested in persons with MS and targeting older adults with MS, a cohort that has received minimal research attention in exercise intervention trials. The SSE program is further innovative in that involves the application of an exercise training stimulus that requires simultaneously physical (i.e., lower limb) and cognitive activation that has long-term, home-based rehabilitation potential.

The present study has the potential to have a positive impact on prevalent negative aspects of the disease (i.e., walking ability, mobility disability, and cognition). This is important as there are data suggesting that disease-modifying agents might have no association with disability progression in older adults with MS [18], and investigators have advocated for alternative approaches for slowing or reversing mobility disability [49,50]. Parallel, this study may have a positive impact among those who care for persons with MS, in the sense that if successful, SSE may be an alternative, easy and affordable exercise program that can be integrated within rehabilitation therapies for slowing, preventing, or reversing the progression of mobility and cognitive disability in this population. Therefore, the study may have the potential to significantly advance the management of progressive mobility and cognitive impairment, ubiquitous to MS course, using exercise as therapeutic approach in older adults with MS.

6. Limitations

The proposed study is not without limitation. Although clear instructions on how to proceed/perform the SSE practice at home will be provided, participants may deviate to best accommodate their needs. For example, participants are instructed to try to memorize the step pattern first and then practice; however, some participants may find it easy to perform the step pattern while looking at the visual graphic provided during a certain amount of time before try it without. We are further checking compliance by asking participants to wear a pedometer as a measure of step count. Because some persons with MS have problems with memory and multitasking, it is possible that some may forget to wear the pedometer during the SSE home practice. Although our devices pointed for 99.8% accuracy in detecting steps during pilot testing, small changes in pedometers positions in the body may compromise such metric and may pose additional limitation. However, we are including weekly Skype calls with participants as a way to limit this issue. This will remind participants to wear the device and about the volume of practice for the week, and will include a logbook tracking progress. A short conversation regarding participant's perceptions of the practice will also take place during the weekly skype conversations. This conversation will allow us to understand for example, participant's level of motivation, challenges, and strategies used to put the program in practice at home. Additionally, our inclusion/exclusion criteria will limit the generalizability of our findings. We have chosen to recruit only older individuals with MS (i.e., 60 years and over) that are able to walk with or without a cane. Thus, older adults who use a walker/roller for locomotion will be excluded for safety. To this end, the suitability of the

SSE program for older adults with severe MS-related disability will not be determined nor its suitability for individuals younger than 60 years old.

7. Conclusions

The proposed study has the potential to help older adults with MS experience the benefits of exercise regimen, including improvements in cognition, mobility and functioning. This is because step patterns become more difficult to remember as participants advances in the program and also because the number of steps required to performed a pattern increases and require the participants to move in different directions. We believe that the hybrid design of the SSE program will contribute to advancements of research designs in the area of home-based exercise interventions among older adults with MS. The SSE program using a home-based approach, once refined and tested for effectiveness, has the potential to reach a large number of older adults with MS and can be delivered with limited personnel involvement; which may translate to an easy to deliver and low cost type of intervention. Collectively, this could translate into higher rates of physical activity/exercise participation in this population.

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