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Home-based, square-stepping exercise program among older adults with multiple sclerosis: results of a feasibility randomized controlled study

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ABSTRACT

There is very little known about exercise rehabilitation approaches for older adults with multiple sclerosis (MS), yet this growing segment of the MS population experiences declines in cognition and mobility associated with disease progression and aging. We conducted a RCT examining the feasibility of a 12-week, home-based Square-Stepping Exercise (SSE) program in older adults with MS. Older adults with MS ($N = 26$) with mild-to-moderate levels of disability were recruited and randomized into the intervention (i.e., SSE) or a minimal activity, attention-control conditions. Participants in the SSE condition received a mat for home-based practice of the step patterns, an instruction manual, and a logbook along with a pedometer for monitoring compliance. Both conditions received weekly Skype™ calls and had biweekly meetings with an exercise trainer. Feasibility was assessed based on process, resource, management and scientific outcomes. Regarding scientific outcomes, participants in both conditions completed in-lab assessments before and after the 12-week period. Twenty-five participants completed the study (96%) and the total cost of the study was $13,387.00 USD. Pedometer data demonstrated good compliance with the SSE intervention condition. Effect sizes calculated for all treatment outcomes ranged from small-to-moderate for both mobility and cognitive variables between the intervention and attention-control conditions, thereby providing preliminary evidence that participation in the SSE program may improve cognition and mobility function. The results support the feasibility, acceptability, and possible efficacy of a home-based SSE intervention for older adults with MS.

1. Introduction

There are increasing numbers of adults with multiple sclerosis (MS) who are now aging into older adulthood. This is reflected by the shifting age demography of persons with MS whereby there is an expanding prevalence of older adults living with MS [1]. Aging with MS as a disabling disease presents a number of consequences, and older adults with MS present with poor health status and functioning, cognitive and ambulatory difficulty, and dependence for activities of daily living [2–7]. There is further evidence of a faster rate of disability progression among older adults with MS [8], yet there are no approved disease-modifying therapies (DMTs) for adults with MS beyond 65 years of age. This is mostly due to the paucity of research studies including this age group in trials. Nevertheless, some evidence indicates that DMTs have no or very modest effect for slowing disability in this demographic of persons with MS [9].

Researchers and clinicians have become interested in exercise training as an approach for managing the consequences of aging and MS. This is largely based on evidence for benefits of exercise in MS [10] and older adults in the general population [11] separately, but there have been a few interventions focusing on the beneficial effects of exercise for older adults with MS [12]. We further note that the rates of participation in physical activity and exercise are exceedingly low in older adults with this MS [13,14] and that this population does not meet current recommendations of physical activity necessary for accruing health benefits. Several factors may interfere with physical activity and exercise participation in older adults with MS, including increasing age, perception that exercise is too difficult, cost of exercise

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Table 1
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

* 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.

programs and lack of low-cost and accessible recreational facilities [15]. Such observations must be accounted for in the design of exercise training programs for older adults that are consistent with recommendations regarding exercise for persons with MS [16].

We recently described and proposed a methodological protocol paper involving a feasibility study of the square-stepping exercise (SSE) in older adults with MS [17]. The SSE program was originally developed by Japanese researchers and focused on improving functional fitness (e.g., lower limb muscle strength, walking ability, balance, reduce the risk of falls) and enhancing cognition in older adults of the general population [18]. To this end, we opted for the SSE intervention for its potential benefit to improve clinical aspects in older adults with MS. The SSE-MS project is a 12-week, home-based, exercise training program developed to be an easy-to-do and fun exercise with the potential to improve mobility and cognition in individuals with MS in the older adulthood. The present manuscript reports results (i.e., outcomes) regarding the process, resource, management, and scientific feasibility metrics on the feasibility of SSE-MS Project in adults with MS aged 60 years and older. The results were reported in accordance with current recommendations and guidelines for feasibility trials [19].

2. Methods

2.1. Ethical approval

This feasibility study was a randomized controlled trial (RCT) conducted between October 2016 and September 2017. The study protocol was approved by a university institutional review board (IRB) and all participants signed an informed consent document before data collection.

2.2. Participant recruitment and eligibility

Participants were recruited from the Midwest region of United States using (i) the North American Research Committee on Multiple Sclerosis (NARCOMS), (ii) a database of people with MS who had previously participated in studies conducted by researchers in the Exercise Neuroscience Research Laboratory, (iii) interactions with potential participants during MS events and MS-specific support groups, (iv) advertisement on the research laboratory's website, and (v) advertisement in local newspapers. Participant recruitment was an ongoing process over the course of the study.

Recruitment flyers and newspaper advertisements provided detailed eligibility criteria, and included contact information (i.e., telephone and email) for the researchers. Inclusion criteria for the study included: (a) 60 years and older; (b) clinically definitive diagnosis of MS; (c) relapse-free for the past 30 days; (d) ability to walk with or without an assistive device (e.g., cane); (e) willing and able to participate in the 12-week home-based intervention; (f) non-exerciser (operationalized as 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 [20], (h) signed medical release form; and (i) scoring ≥13 points in the Telephone Interview for Cognitive Status, indicating no more than mild cognitive impairment [21]. Participants who did not meet those criteria were excluded from study participation. We sought a sample size exceeding 12 participants per group, as it is believed to be acceptable for pilot and feasibility studies involving RCT study designs [22]. We did not conduct a formal sample size calculation, as this was a feasibility study.

2.3. Procedure

Participants who successfully enrolled in the study were scheduled for a visit to the Exercise Neuroscience Research Laboratory. This visit started with a review and provision of a written informed consent document. Participants then undertook baseline assessments (e.g., functional mobility, walking speed and endurance, cognitive assessments) and were randomized using concealed allocation into the intervention condition or the attention control condition. This involved (a) a research staff member not involved in the study pre-preparing opaque sealed envelopes with slips of paper containing group allocation and storing these in a randomization container and (b) another research staff member involved in the study choosing an envelope. This determined group allocation. Because of the feasibility pilot nature of the study, outcome assessors were not blind to group allocation. The intervention was delivered over a 12-week period and we further collected outcome assessments both during (e.g., communication and safety) and after (e.g., treatment effect). All participants received $250 as incentive for participation. Participation included two in-laboratory assessment (i.e., pre- and post-intervention), six site visits/encounters