

Effects of a DVD-delivered exercise intervention on physical function in older adults with multiple sclerosis: A pilot randomized controlled trial

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Abstract

Background: Older adults with multiple sclerosis (MS) exhibit disease-related impairments such as compromised strength, balance, mobility, coordination, and quality of life (QOL). Exercise training as an intervention to reverse these conditions in older adults with MS is limited.

Objective: The objective of this pilot trial was to examine the effects of a DVD exercise intervention targeting flexibility, strength, and balance in older adults with MS in order to generate effect sizes to power a larger trial.

Methods: Participants were randomly assigned to a six-month DVD exercise intervention ($n = 24$) or a healthy aging DVD control condition ($n = 24$). Measures of physical function, physical activity, sedentary behavior, QOL and program satisfaction were assessed at baseline and at follow-up.

Results: The DVD exercise intervention was well received with no adverse events. Effects sizes ranged from small to modest reflecting improved function, increased physical activity, decreased sitting time, and improved QOL in the intervention condition compared to the control condition.

Conclusion: This pilot randomized controlled trial suggests that older adults with MS are receptive to an exercise program via DVD, and the program results in modest but potentially important improvements in function and physical activity.

Keywords: Multiple sclerosis, quality of life, outcome measurement

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Introduction

One of the hallmarks of aging successfully is the ability to maintain physical function and independence.¹ The older adult population in the United States (US) is expected to more than double to 92 million by 2060² with advanced age accompanied by poor health, declines in functional performance,³ and increased disability.⁴ Conditions associated with aging can be further accelerated by the onset and/or progression of chronic disabling diseases, such as multiple sclerosis (MS). The worldwide prevalence of MS, a progressive neurodegenerative disease that affects the central nervous system,⁵ is estimated to be 2.3 million individuals with more than 400,000 cases in the US alone.⁶ Importantly, 32% of these individuals are between the ages of 55 and 64, 14% are 65 or older,⁷ and they exhibit MS-related impairments

that are reflective of the aging process, including compromised strength, balance, mobility, coordination, and quality of life (QOL).⁸ These impairments are hastened by physical inactivity⁹ and reversed by exercise training. To date, research examining exercise training as an intervention for these outcomes in older adults with MS is limited.¹⁰

Exercise training as a behavioral intervention has been reliably and consistently shown to offer a protective effect on functional limitations and disability in MS.^{11,12} Although exercise training interventions have been successfully applied in individuals with MS,^{13,14} these interventions have rarely been designed and tested in the older MS population. A further concern is that the nature of most exercise interventions for individuals with MS, and for

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otherwise healthy adults, are often center based (i.e. medical settings, universities) and group based (i.e. supervised). Such interventions may prove challenging for older adults with MS given issues of travel, accessibility, resources, disease status, and cost. Identifying innovative, low-cost, and broad-reaching exercise training interventions designed to improve physical function performance in older adults with MS is an important public health goal.

One potential approach may be targeted exercise training delivered via commercial media, such as a digital video disk (DVD). A recent National Institutes of Health (NIH)-funded study examined the efficacy of a progressive, home-based, DVD-delivered exercise program focusing on improving flexibility, toning, and balance (*FlexToBa*) in low-active community-dwelling older adults.¹⁵ Participants randomized to the exercise DVD condition showed significant and clinically relevant improvements on the Short Physical Performance Battery (SPPB),¹⁶ as well as on measures of strength and upper and lower extremity flexibility. The intervention was safe and well tolerated, with participants reporting high levels of satisfaction with the program. Finally, participants in the exercise DVD condition maintained clinically significant gains compared to the control condition in a six-month follow-up report.¹⁷

The objective of this pilot randomized controlled trial (RCT) was to examine the effects of an exercise training DVD on mobility, strength, flexibility, physical activity, and QOL in older adults with MS and to generate effect sizes to power a larger trial. Additionally, we were interested in the extent to which the exercise DVD increased self-reported physical activity and reduced the time spent in sedentary activities (i.e. sitting behavior).

Materials and methods

Study design and participants

We used a two-arm, assessor-blinded, six-month RCT design. Participants were randomized to either the *FlexToBa* DVD exercise condition or to a *Healthy Aging*[®] DVD attentional control condition. Randomization was conducted using a password-protected database, and the sample was stratified by sex and age across condition. Participant flow through the trial is shown in Figure 1. Values for key baseline characteristics are shown in Table 1.

Recruitment and eligibility criteria

We recruited participants from a mailing list of individuals with MS in Illinois, a database of previous research volunteers, and a research advertisement posted on the website of the Greater Illinois chapter of the National Multiple Sclerosis Society (NMSS). These efforts targeted people with MS 50 years of age and older living within a 50-mile radius of Champaign-Urbana, Illinois. The advertisements informed potential participants of a free, programmatic home-based exercise program designed to improve flexibility, strength, balance, and mobility in older adults with MS. It is important to note that all content of the *FlexToBa* DVD, as well as the accompanying handbook, focuses on older adults rather than older adults with a particular chronic disease, thereby reducing any stigma that may be attached to such a program. The inclusion criteria for participation were: (a) definite diagnosis of MS that was confirmed in writing by the patient's neurologist; (b) relapse free in the last 30 days; (c) ambulatory with minimal assistance (i.e. able to walk independently or with a cane); (d) capable of engaging in systematic exercise without exacerbating any existing condition; (e) clearance for participation in physical activity by personal physician; and (f) Expanded Disability Status Scale (EDSS)¹⁸ score of less than 6.5 (i.e. constant bilateral assistance). The EDSS cut-off was selected for concerns with participant safety (i.e. falls). Participants completed a university institutional review board-approved informed consent on entry into the study.

Interventions

The exercise and attentional control DVD interventions have been described in detail elsewhere.^{15,19,20} Briefly, the *FlexToBa* intervention condition was composed of three DVDs, two resistance bands (one light and one moderate intensity), a yoga mat, and a *FlexToBa* handbook. The first DVD provided an introduction to the program, exercise progressions, and safety principles. The remaining two disks consisted of six progressive exercise sessions with each session containing two sets of 11 to 12 different exercises focusing on balance, strength, and flexibility. Participants were encouraged to exercise with the *FlexToBa* DVDs three times per week on non-consecutive days and to progress to the next session every four weeks. The exercises were modeled by a trained exercise leader accompanied by three age-appropriate models who had completed a similar, onsite exercise training program prior to DVD production. Modifications of each exercise were modeled for those who required an easier task and for those preferring a more challenging version of the activity. All participants received an exercise

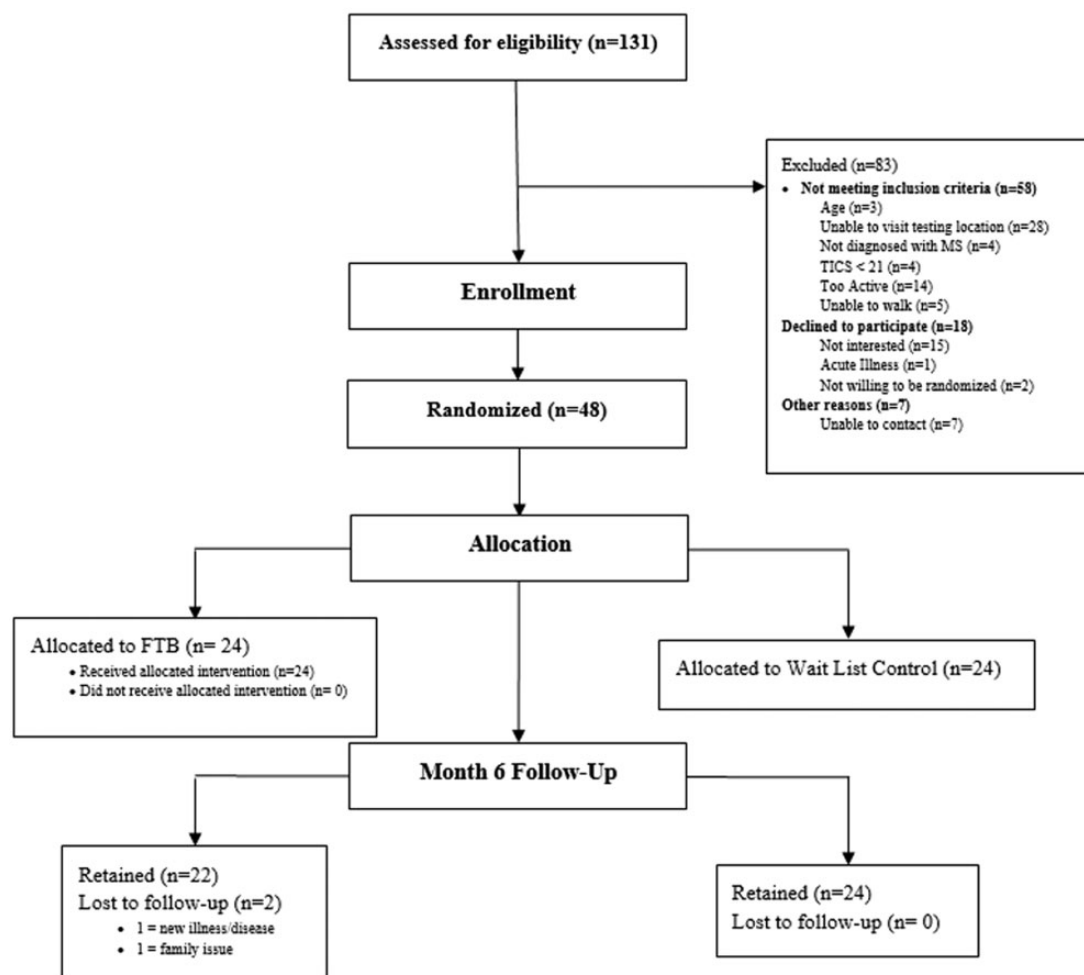


Figure 1. Flow of participants through the trial.
 FTB: *FlexToBa*; TICS: Telephone Interview of Cognitive Status.

prescription designed to aid them in progressing through the program gradually and safely. For the first two weeks of each month, participants were instructed to complete one to two sets of eight to 10 repetitions at a rating of perceived exertion²¹ (RPE) of 10–12 (i.e. fairly light). For the last two weeks of the month, the prescription advised participants to complete two sets of 10–12 repetitions at an RPE of 13–15 (i.e. somewhat hard). All participants were provided with two resistance bands to be used for the strengthening exercises. They began all exercises with the thinner, lower resistance band, and advanced to the thicker band when they could successfully complete two full sets of a particular exercise with the thinner band.

Participants were provided with daily exercise logs to complete and return by mail on a monthly basis.

These logs were used to provide individualized graphical and written feedback of their progress in the trial. All *FlexToBa* participants received a short biweekly support telephone call with an exercise “tip of the day” for the first two months and a monthly call thereafter.

Participants in the attention and social-contact control condition received a copy of the commercially available Dr Andrew Weil *Healthy Aging*[®] DVD and were asked to watch the 85-minute documentary in its entirety and to continue with their normal day-to-day lives. Participants received telephone calls on the same schedule as the treatment condition in which healthy aging topics were discussed and a health “tip of the day” was provided. After completion of the program, the control participants received the *FlexToBa* DVDs and equipment.

Table 1. Baseline characteristics of intervention and control conditions.

	<i>FlexToBa</i> (N = 24)	Control (N = 24)
Sex (%)		
Male	25 (n = 6)	25 (n = 6)
Female	75 (n = 18)	75 (n = 18)
Age (years)	59.62 ± 1.43	59.78 ± 1.50
MS duration (years)	18.10 ± 9.42	19.85 ± 9.42
MS type (%)		
Relapsing–remitting	66.7 (n = 16)	66.7 (n = 16)
Secondary Progressive	12.5 (n = 3)	8.3 (n = 2)
Primary progressive	4.2 (n = 1)	0 (n = 0)
Unknown	4.2 (n = 1)	8.3 (n = 2)
Not reported	12.5 (n = 3)	16.7 (n = 4)
Use of assistive device (%)	25	50

FlexToBa: Flexibility, Toning, and Balance.

Outcomes

The primary outcomes were physical function performance, physical activity, and QOL assessed at baseline and following the six-month DVD intervention. All physical function assessments were completed in an independent laboratory by trained and blinded personnel who were uninvolved in the delivery of the intervention, recruitment of participants, and allocation into conditions. Participants were paid \$50 for completion of all testing and questionnaires.

The SPPB¹⁶ assesses balance, gait speed, and lower extremity strength and has been reliably associated with nursing home admission and mortality, as well as mobility and disability up to four years later in older community-dwelling adults.²² Balance was assessed by asking participants to maintain upright posture for up to 10 seconds per test while standing with their feet in side-by-side, semi-tandem, and tandem positions. Gait speed was assessed by measuring the time taken by a participant to walk a four-meter course at a normal pace. Lower extremity strength was assessed by a chair stand test in which participants were instructed to sit in and fully rise from a chair five times as quickly as possible, without using their arms for support. Performance scores for each SPPB individual test and a summary score aggregating the individual tests were calculated as per standard SPPB protocol. Each of the three performance measures was assigned a categorical score ranging from 0, inability to complete a test, to 4, the highest level of performance. A summary score ranging from 0 to 12 was then calculated by aggregating walking speed, chair stand, and balance scores.

In addition to the SPPB, we measured upper body strength and endurance with a 30-second arm curl test, upper body flexibility with the Back Scratch Test, and lower body flexibility with the Sit And Reach Test, which are components of the Senior Fitness Test.²³ Grip strength was assessed using a hand-held dynamometer. An additional balance measure, the one leg stand, was administered.²⁴ Physical activity was measured with the Godin Leisure-Time Exercise Questionnaire (GLTEQ)²⁵ and sitting time was assessed with the Sitting Time Questionnaire.²⁶ QOL was assessed with the Multiple Sclerosis Impact Scale (MSIS)²⁷ and the Satisfaction with Life Scale.²⁸ Finally, participants in the *FlexToBa* condition completed a program evaluation post-intervention to gauge participant satisfaction with the program. A full description of all measures can be found in Wójcicki et al.²⁰

Data analysis

A series of analyses of covariance (ANCOVAs) were conducted with treatment condition as the between-subjects factor, and sex, age, and baseline values of the outcome measures as covariates. Finally, we calculated effect sizes (Cohen's *d*)²⁹ for the adjusted mean differences between treatment conditions. Mean values, standard errors, *p* values, and Cohen's *d* effect sizes are shown in Tables 2–4.

Results

Participant retention, satisfaction, and adverse events

We randomized 48 participants to the two conditions (*FlexToBa* = 24; control = 24) with 25% of each

Table 2. Intervention effects on functional performance.

	<i>FlexToBa</i> (mean \pm SE)	Control (mean \pm SE)	<i>p</i> values	<i>d</i>
SPPB				
Pre-	8.52 \pm 0.52	8.35 \pm 0.52	0.51	
Post- ^a	8.95 \pm 0.60	8.47 \pm 0.60	0.49	
Post-adjusted ^b	8.85 \pm 0.29	8.57 \pm 0.29	0.51	0.21
Sit and Reach				
Pre-	-0.45 \pm 0.84	-0.48 \pm 0.84	0.80	
Post- ^a	0.62 \pm 0.95	0.44 \pm 0.95	0.68	
Post-adjusted ^b	0.61 \pm 0.57	0.27 \pm 0.57	0.68	0.13
Back Scratch				
Pre-	-4.52 \pm 1.30	-5.28 \pm 1.30	0.38	
Post- ^a	-4.19 \pm 1.06	-6.29 \pm 1.06	0.16	
Post-adjusted ^b	-4.50 \pm 0.54	-6.02 \pm 0.54	0.05	0.63
Arm Curl				
Pre-	11.57 \pm 0.62	12.19 \pm 0.62	0.51	
Post- ^a	12.71 \pm 0.77	12.71 \pm 0.77	0.74	
Post-adjusted ^b	12.83 \pm 0.74	13.60 \pm 0.74	0.47	-0.22
Grip Strength (Right Handed)				
Pre-	63.33 \pm 3.43	61.62 \pm 3.43	0.75	
Post- ^a	67.14 \pm 3.15	64.45 \pm 3.15	0.69	
Post-adjusted ^b	66.46 \pm 1.62	65.13 \pm 1.62	0.56	0.18
Grip Strength (Left Handed)				
Pre-	59.81 \pm 3.00	59.57 \pm 3.00	0.80	
Post- ^a	63.50 \pm 2.77	61.38 \pm 1.77	0.52	
Post-adjusted ^b	63.41 \pm 1.85	61.46 \pm 1.85	0.46	0.23
One-leg Stand (Right Leg)				
Pre-	4.72 \pm 1.80	10.12 \pm 1.80	0.06	
Post- ^a	7.90 \pm 2.29	7.89 \pm 2.29	0.03	
Post-adjusted ^b	10.21 \pm 1.78	5.83 \pm 1.76	0.08	0.57
One-leg Stand (Left Leg)				
Pre-	5.40 \pm 2.18	9.60 \pm 2.18	0.59	
Post- ^a	6.71 \pm 2.31	10.19 \pm 2.30	0.73	
Post-adjusted ^b	8.50 \pm 1.37	8.40 \pm 1.37	0.96	0.01

FlexToBa: Flexibility, Toning, and Balance; SE: standard error; SPPB: Short Physical Performance Battery.
^aAdjusted for sex, age. ^bAdjusted for sex, age, baseline value. Sit and Reach and Back Scratch units are in inches, grip strength in pounds, and one-leg stand in seconds.

condition male and 75% female participants. The mean age of the sample was 59.7 years (\pm 5.5) with 77.1% married, 31% employed full/part time, and 56.3% having a bachelor's degree or higher. Of the 41 participants who reported the type of MS, 72% reported relapsing-remitting MS and the average duration of disease (time since diagnosis) was 19.0 years (\pm 9.4). Of the 48 participants randomized to this pilot trial, 46 were retained at six months (\sim 96%; see Figure 1). Program evaluations were returned by 23 (\sim 96%) of the *FlexToBa* participants who reported being "satisfied" or "completely satisfied" with the overall program (87%), quality

of the DVD program (87%), quality of the written materials (95%), instructions from the exercise leader (100%), and appropriateness of the modified exercises (87%). There were no adverse events reported across the six-month intervention period.

Physical function outcomes

The two conditions did not significantly differ at program end in physical function, although the majority of the differences were in the hypothesized direction with small to moderate effect sizes favoring the *FlexToBa* condition (see Table 2). For example, the intervention condition had more favorable SPPB

Table 3. Treatment effects on physical activity and sedentary behavior.

	<i>FlexToBa</i> (mean ± SE)	Control (mean ± SE)	<i>p</i> values	<i>d</i>
Total leisure activity				
Pre-	8.47 ± 1.86	6.85 ± 1.82	0.40	
Post- ^a	21.54 ± 3.03	12.61 ± 2.86	0.06	
Post-adjusted ^b	20.96 ± 2.69	13.22 ± 2.63	0.05	0.61
Moderate/Vigorous activity				
Pre-	2.72 ± 1.44	2.72 ± 1.41	0.98	
Post- ^a	10.62 ± 2.29	4.66 ± 2.24	0.02	
Post-adjusted ^b	10.66 ± 1.79	4.63 ± 1.72	0.02	0.73
Sitting time (weekdays)				
Pre-	659.67 ± 52.17	677.92 ± 51.02	0.86	
Post- ^a	618.66 ± 65.61	790.41 ± 64.17	0.15	
Post-adjusted ^b	621.16 ± 64.93	788.02 ± 63.50	0.07	0.54
Sitting time (weekend)				
Pre-	676.27 ± 71.11	713.78 ± 69.55	0.94	
Post- ^a	663.24 ± 78.81	743.89 ± 77.08	0.69	
Post-adjusted ^b	673.43 ± 70.06	734.68 ± 68.52	0.54	0.18

FlexToBa: Flexibility, Toning, and Balance; SE: standard error. ^aAdjusted for sex, age. ^bAdjusted for sex, age, baseline value. Sitting time units are total minutes for weekdays and weekends.

Table 4. Intervention effects on quality of life outcomes.

	<i>FlexToBa</i> (mean ± SE)	Control (mean ± SE)	<i>p</i> values	<i>d</i>
SWLS				
Pre-	21.52 ± 1.61	22.54 ± 1.58	0.77	
Post- ^a	23.01 ± 1.74	20.99 ± 1.70	0.07	
Post-adjusted ^b	23.43 ± 1.14	20.58 ± 1.11	0.08	0.53
MSIS (physical subdomain)				
Pre-	44.76 ± 3.63	47.66 ± 3.55	0.78	
Post- ^a	47.88 ± 3.67	42.55 ± 3.59	0.19	
Post-adjusted ^b	49.28 ± 1.73	46.28 ± 1.69	0.23	0.36
MSIS (psychological subdomain)				
Pre-	18.89 ± 1.65	21.14 ± 1.62	0.17	
Post- ^a	19.91 ± 1.55	21.00 ± 1.52	0.47	
Post-adjusted ^b	20.72 ± 1.04	20.32 ± 1.02	0.73	0.10

FlexToBa: Flexibility, Toning, and Balance; SE: standard error; SWLS: Satisfaction with Life Scale; MSIS: Multiple Sclerosis Impact Scale. ^aAdjusted for sex, age. ^bAdjusted for sex, age, baseline value.

scores ($d=0.21$) than the control condition, better lower ($d=0.13$) and upper body flexibility ($d=0.63$), greater grip strength for the right ($d=0.18$) and left hands ($d=0.23$), better balance for the right-leg stand ($d=0.57$) but not the left ($d=0.01$). The absolute adjusted difference between the SPPB scores (0.28) approximated the lower-bound threshold for a small clinically meaningful difference (i.e. 0.30).

Physical activity, sitting behavior and QOL outcomes

Participants in the *FlexToBa* condition reported significantly ($p < 0.05$) greater total leisure time physical activity ($d=0.61$) and greater moderate to vigorous leisure time physical activity ($d=0.73$) than the control condition (see Table 3). Additionally, the intervention condition reported less time spent in sitting activities during weekdays

($d = -0.54$) and to a lesser extent on weekends ($d = -0.18$) than the control condition. Participants in the exercise training condition reported greater satisfaction with life ($d = .53$) and higher scores on the physical ($d = 0.36$) and psychological ($d = 0.10$) subscales of the MSIS (see Table 4).

Discussion

The development and testing of programs that promote exercise and health in later life has been identified as an important public health goal.³⁰ Such programs should be accessible for large numbers of older adults and target physical capabilities that are predictive of disability, institutionalization, and mortality.^{15,31} Such physical outcomes include strength, mobility, flexibility, and balance, and those outcomes are particularly compromised in individuals with MS. Herein, we tested the feasibility and safety of delivering a program by DVD targeting flexibility, strength, and balance activities in older adults with MS.

Overall, the *FlexToBa* intervention was well received by this sample who reported high levels of satisfaction with all aspects of the program. In addition, we believe the program to be safe as no adverse events were reported during the six-month period. It is conceivable that participants may have incurred musculoskeletal injuries due to exercising and reported these to their primary care physician. However, during support calls, participants were asked whether they had any concerns or questions about the program. Although not a direct assessment, this was certainly an opportunity to report any injuries sustained while exercising. There were very few statistically significant differences between the two treatment conditions, and this is not unexpected considering the pilot nature of this RCT and small sample size. However, effect sizes are suggestive of generally small-to-moderate effects favoring the *FlexToBa* condition in terms of improved physical function, physical activity levels, and QOL, and these effects can be used to power a future efficacy trial in older adults with MS. Although findings from pilot trials are inconclusive, we are encouraged by the findings reported herein, given that compromised mobility and functional impairment are highly prevalent in individuals with MS.³² Of particular note, we delivered the intervention to older individuals with MS, an understudied segment of this population that is likely to have even greater decrements in function due to an acceleration of the aging process brought about by disease progression. This acceleration in functional impairment in all probability makes participation in center-based exercise training programs

extremely difficult. The *FlexToBa* program was specifically developed for older adults as a progressive, low-cost intervention that can be tailored to individual capabilities, conducted at home, and has broad reach and high potential for dissemination.¹⁵ With the generation of effect sizes, the next step should be to demonstrate the efficacy of this intervention in a larger sample of older adults with MS.

Our study sample had an overall unadjusted baseline SPPB score of 8.7, and this is reflective of being at risk for subsequent disability. Our findings suggest a modest effect of the intervention for increasing the SPPB score by ~ 0.30 , a small, clinically meaningful difference.³³ If, in future research efforts, the *FlexToBa* program can demonstrate small gains in function or, alternatively, the prevention of further impairment and the onset of disability, this would be of considerable public health and clinical importance. Preserving sufficient function to prevent the onset of disability and retain an adequate level of independence would make an important difference to the QOL in those with MS. Interestingly, there were small improvements in the control condition in the SPPB score. In the initial efficacy trial testing the intervention in older adults, the intervention condition increased SPPB scores, whereas SPPB scores declined in the control condition.¹⁵ We speculate that the commercial *Healthy Aging*© DVD that was used in this study as an attention control comparator may actually have had positive health benefits and may have a more potent effect in those individuals with more significant health problems than with generally healthy older adults. Thus, we recommend that subsequent larger scale exercise trials using the *FlexToBa* program in clinical populations give careful consideration to the selection of a control condition. However, it will be important to control for attention and social contact, as done in the present study, factors that are rarely considered in exercise trials in MS.

It is well documented that individuals with MS are less physically active than their healthy counterparts³⁴ and identifying innovative strategies to increase this important lifestyle behavior is vital. Given the mobility limitations that are a result of disease progression, people with MS are not afforded the array of activity choices that healthy adults enjoy. Thus, it will be necessary to embrace new technologies to deliver physical activity directly and to promote active lifestyles. For example, using an Internet-based behavior-change intervention supplemented by Web-based video coaching sessions, Motl and colleagues³⁵ were able to increase

physical activity in a sample of individuals with relapsing–remitting MS. Such interventions, if replicable on a large scale, have the potential for broad reach and dissemination. The *FlexToBa* intervention offers similar potential, particularly for older adults with MS, but specifically targets those elements of physical function that are compromised with disease progression. Additionally, this DVD intervention has sufficient progressions for six months of exercise, reducing the potential for boredom that is associated with the majority of commercial exercise DVDs, which are typically 30–50 minutes in length with limited content and progression. The *FlexToBa* DVD was developed within a social cognitive theory framework³⁶ and embeds strategies to enhance self-efficacy and increase motivation, thus enhancing adherence to the program. Finally, as noted earlier, in both the MS sample and the older, healthy adult sample reported by McAuley et al.,¹⁵ it was evident that this intervention is safe, enjoyable, and very well received. Such factors bode well for continued activity.

We acknowledge a number of limitations in the present study. The sample is small with insufficient power to find statistically significant differences between groups. However, the study was designed as a pilot RCT to determine whether this intervention was suitable for older adults with MS and to generate effect sizes to power a larger trial. The intervention itself is relatively short in duration (i.e. six months) and whether any improvements in function are maintained or built on in the future with continued use of the program remains to be determined. We are optimistic in this regard, given that Wójcicki et al.¹⁷ reported maintenance of six-month gains at 12-months post-baseline.

In summary, we found modest improvements in flexibility, strength, and balance and in physical activity and QOL favoring a DVD-delivered exercise training intervention. The intervention is a low-cost, well-received approach to delivering targeted exercise to older adults with MS. We note that this is one of the first attempts to intervene with a segment of the MS population whose decrements in physical function are likely accelerated by the aging process. Finally, given the pilot RCT design, it will be important to replicate these findings in a larger, sufficiently powered trial.

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Conflict of interest

None declared.

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