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ADSTEP: Preliminary Investigation of a Multicomponent Walking Aid Program in People With Multiple Sclerosis

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Abstract

Objective: To evaluate the effect of the Assistive Device Selection, Training and Education Program (ADSTEP) on falls and walking and sitting activity in people with multiple sclerosis (PwMS).

Design: Randomized controlled trial.

Setting: Veterans affairs medical center.

Participants: PwMS (N=40) using a walking aid at baseline who had fallen in the previous year.

Interventions: Participants were randomly assigned to ADSTEP or control. ADSTEP had 6 weekly, 40-minute, 1-on-1 sessions with a physical therapist, starting with walking aid selection and fitting, followed by task-oriented progressive gait training. Control was usual medical care with the option of ADSTEP after the study.

Main Outcome Measures: The following were assessed at baseline, intervention completion, and 3 months later: falls, timed Up and Go, timed 25-foot walk, 2-minute walk, Four Square Step Test, International Physical Activity Questionnaire, Quebec User Evaluation of Satisfaction with Assistive Technologies, Multiple Sclerosis Walking Scale-12, Activities-Specific Balance Confidence Scale, and Multiple Sclerosis Impact Scale-29. Effect on these outcomes was estimated by a 2-by-2 repeated measures general linear model.

Results: Fewer ADSTEP than control participants fell ($\chi^2=3.96$, $P<.05$. number needed to treat =3.3). Time spent sitting changed significantly differently with ADSTEP than with control from baseline to intervention completion ($F=11.16$, $P=.002$. ADSTEP: reduced 87.00 ± 194.89 min/d; control: increased 103.50 ± 142.21 min/d; $d=0.88$) and to 3-month follow-up ($F=9.25$, $P=.004$. ADSTEP: reduced 75.79 ± 171.57 min/d; control: increased 84.50 ± 149.23 min/d; $d=0.79$).

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ADSTEP yielded a moderate effect on time spent walking compared to control at 3-month follow-up ($P>.05$. ADSTEP $117.53\pm148.40\text{min/d}$; control $46.43\pm58.55\text{min/d}$; $d=0.63$).

Conclusions: ADSTEP prevents falls, reduces sitting, and may increase walking in PwMS.

Keywords

Accidental falls; Multiple sclerosis; Physical activity; Randomized controlled trial; Rehabilitation; Walking

Multiple sclerosis (MS) affects approximately 400,000 people in the United States and over 2.5 million people worldwide.¹ Impaired walking and frequent falls are among the most ubiquitous symptoms in people with MS (PwMS).¹⁻⁵ The most consistently reported risk factors for falls in PwMS are having progressive MS or having MS for longer, impaired balance, slower walking, and use of a mobility aid. Around 50% to 60% of PwMS fall over 3 months and 30% to 40% fall twice or more in this time frame.⁶⁻⁹ Falls and impaired walking reduce safety, independence, physical activity, and quality of life in PwMS.

Many PwMS use walking aids (eg, canes, crutches, walkers) to improve their walking safety, ability, and participation.¹⁰ Unfortunately, PwMS who use walking aids fall more often than those who do not,^{8,9} and they attribute many of their falls to the walking aid.¹¹ This suggests that walking aids as currently used are not optimally effective and may even, at times, cause falls rather than prevent them.

Despite the physical and psychological benefits of physical activity,¹²⁻¹⁴ PwMS, particularly those who use walking aids, are less active than healthy adults¹⁵⁻¹⁷ and less active than current guidelines recommend.¹⁸ Those with progressive MS are the least active.¹⁷ Unfortunately, more physical activity can be associated with more falls, possibly because of increased standing and walking.¹⁹ There is a critical need for interventions that improve both safety and physical activity in PwMS who use walking aids.^{20,21}

The associations between walking aid use, falls, and physical activity in PwMS are complex. Improper walking aid selection and fitting, coupled with lack of targeted training, are modifiable risk factors that likely contribute to these associations.^{8,9} Therefore, the primary investigator for this trial (MHC), a neurologist and physical therapist who treats patients with MS, and the treating physical therapist for this trial (EZ), who specializes in neurological rehabilitation, developed Assistive Device Selection, Training and Education Program (ADSTEP), a standardized multicomponent walking aid selection and training program. We know of no published guidelines or studies on walking aid programs in any patient population, therefore ADSTEP is based on our understanding of effective approaches for motor training and functional restoration in people with central nervous system injury practical within most health care systems in the United States.

ADSTEP consists of 6 weekly, 40-minute, 1-on-1 sessions with a physical therapist, consistent with standard physical therapy referrals and approval in the United States. The program starts with device selection and fitting. People often obtain their walking aids from a store, a friend or relative, based on availability, direct-to-consumer advertising, or information from untrained personnel, with no or very limited input from health care

providers.^{22–24} Consequently, they are likely to have the wrong device and for the device to fit poorly, potential increasing the risk for falls. ADSTEP then proceeds with task-oriented gait training with the walking aid, adapted from Carr and Shepherd's motor relearning program for stroke,²⁵ which focuses on improving motor control and relearning daily activities within the context of functional tasks. The training involves repeated guided practice of the task in typical and progressively more challenging circumstances. This takes advantage of the fact that even when people with central nervous system disorders have cognitive and motor impairments, they can still learn motor tasks and improve with training.^{26–29} Task-oriented training has been shown to improve walking, mobility, and balance in people with various neurological conditions including MS.^{28,29}

ADSTEP differs from usual medical care, in that a PwMS who uses a walking aid may or may not be referred to physical therapy. If they do receive physical therapy, there is little evidence to guide the number or duration of sessions, or whether the sessions should include strengthening, stretching, balance exercises, spasticity management, gait training, and/or other interventions. ADSTEP utilizes skills within the scope and practice of physical therapy but is consistently 6 40-minutes sessions all focused on walking aid selection, fitting, and task-oriented gait training.

To date, we are not aware of any published studies primarily evaluating the effects of a walking aid selection and training program on falls and physical activity in PwMS. We therefore performed a pilot, randomized controlled trial to compare the effects of ADSTEP to usual medical care on falls, physical activity (walking and sitting), timed mobility tests, and patient-reported outcomes in PwMS using a walking aid at baseline. We hypothesized that, compared to usual medical care, ADSTEP would prevent falls, increase physical activity, and improve timed mobility tests and patient-reported outcomes.

Methods

Study population

Participants were recruited from the outpatient MS clinic at the Veterans Affairs Portland Health Care System and the surrounding community. Eighty-four people were screened and 40 met inclusion criteria and enrolled. Participants were randomly allocated after baseline measures, in blocks of 4, to the 2 conditions by the study statistician (fig 1). All personnel involved in outcome assessments were blinded to allocation. The Veterans Affairs Portland Health Care System institutional review board approved the study. All participants signed informed consent prior to participation. This trial was registered on clinicaltrials.gov ().

Inclusion criteria were: confirmed MS of any type, self-reported current intermittent or constant use of unilateral or bilateral assistance for walking, over age 18, able to walk at least 25 feet, no relapse in prior 30 days, and self-reported history of 1 or more falls in the previous year. Falling in the previous year was required because this is a strong predictor of future falls.³⁰ Exclusion criteria were: reporting receiving more than 1 hour of walking aid training within the previous 3 years, and serious conditions that would preclude reliable study participation (eg, dementia, deafness, and blindness). Functional magnetic resonance imaging (MRI) was performed in a subset of participants (manuscript in preparation),

therefore participants had to be right-handed, weigh under 350 pounds, and not have MRI contraindications.

Interventions

Active condition: ADSTEP—Participants randomized to ADSTEP were scheduled for the 6 sessions with a single physical therapist to begin within 2 weeks of baseline measures. Sessions were scheduled for the same day and time each week, although timing could be adjusted to fit the participant's needs. ADSTEP took place in a small rehabilitation gym and nearby hallways and outdoor locations.

The first session started with observation and assessment of walking with the current walking aid(s), including safety, comfort, acceptability, and functionality for expected tasks and environments. Then the therapist offered trials with other devices, including canes, crutches, and a front-wheeled walker. The therapist and subject mutually agreed upon the appropriate aid (new or old) and the therapist adjusted this aid according to standard principles, including the elbow being flexed 20 to 30 degrees when holding the aid and, for crutches, the axillary pad being about 3" below the axilla.^{24,31,32} If the selected aid differed from the participant's current aid, they were given the new aid to keep.

Task-oriented training with the walking aid followed. Tasks were progressed as specified in the ADSTEP manual and after achieving safe performance of prior tasks beginning with indoor walking on smooth even surfaces, such as vinyl, and progressing to carpet and transitions between surfaces. Turning was then added and progressed, from large open spaces to navigating obstacles such as doors and chairs, to turning in tight spaces. Stair climbing followed and was progressed from holding a handrail with the therapist managing the walking aid to the participant navigating the stairs while holding the walking aid themselves. Outdoor walking was then added and followed similar progression, from sidewalks to grass, gravel and inclines; turning wide then tight; climbing curbs and steps with and then without handrails. Dual-task activities, such as walking with head turns, carrying an object, counting aloud and while conversing, were added as participants mastered single task activities.

Control condition: usual medical care—Participants randomized to the control condition did not participate in ADSTEP during the study. They continued to receive usual medical care and completed the same outcome measures at the same time points as the active intervention group. They were allowed to receive any prescribed therapy and were allowed to change their walking aid and were offered ADSTEP following study participation.

Outcomes

Participant characteristics—Demographics, MS-related disability, and falls in the prior year were self-reported prior to randomization.³³

Falls—Falls were counted prospectively during the intervention period and for the following 3 months using self-report calendars, the gold standard for assessing fall

frequency.^{34,35} Each calendar page covered 1 month. The definition of a fall, “A fall is an unexpected event in which you come to rest on the ground, floor, or lower level,”^{36(p.1619)} was explained at enrollment and was on each calendar page. Calendars were mailed back monthly. If a calendar was not received within 1 week of the due date, participants were contacted. Falls were analyzed categorically (no falls, 1 fall, or recurrent [>1] falls) and by total number.

Physical activity—Physical activity was assessed with the International Physical Activity Questionnaire short form (IPAQsf) at baseline, intervention completion, and 3 months later.³⁷ The IPAQsf consists of 7 questions assessing physical activity and inactivity over the prior 7 days, including time spent sitting, time spent walking, and physical activity intensity. The IPAQsf has been used and validated in PwMS.^{12,38,39}

Timed mobility performance—Timed mobility performance was measured at baseline, intervention completion, and 3 months later with the timed Up and Go (TUG),⁴⁰ the timed 25-foot walk (T25W),⁴¹ the 2-minute walk test (2MWT),⁴² and the Four Square Step Test (FSST).⁴³ These measures are timed with a stopwatch and have good reliability and validity in PwMS.^{44–47}

Patient-reported outcomes—Patient reported outcomes (PROs) were evaluated with questionnaires at baseline, intervention completion, and 3 months later. Specifically, walking aid satisfaction was assessed with the questions related to device satisfaction on the Quebec User Evaluation of Satisfaction With Assistive Technologies (QUEST) 2.0.⁴⁸ The 4 unused questions relate to device maintenance. The effect of MS on walking was assessed with the Multiple Sclerosis Walking Scale-12 (MSWS-12).^{49,50} Balance confidence was assessed with the Activities-Specific Balance Confidence Scale (ABC).^{6,51,52} The effect of MS on day-to-day life was assessed with the Multiple Sclerosis Impact Scale-29 (MSIS-29).^{53,54} These measures have good reliability and validity in PwMS and the MSWS-12, ABC and MSIS-29 are recommended outcome measures for exercise studies in MS.⁵⁰

Statistical analyses

All outcome analyses were based on intent to treat. Means and standard deviations were calculated at each time point. Assumption of normality was evaluated using Q-Q plots and equality of variance was analyzed with Levene’s test. Welch’s unequal variance t-test was used for all variables with significant Levene’s test results. A 2-by-2 repeated measures general linear model was used to estimate the effect of ADSTEP. Group and time were the factors. Seven participants in the ADSTEP group and none in the control changed walking aids during this study ($t=-3.20$, $P=.005$). Therefore, a categorical variable of device change (YES/NO) was included as a covariate in the general linear models. Alpha was set a priori at $P .05$ for all tests. Post hoc analysis with Bonferroni correction was used to explore significant main effects and interactions. Cohen’s d effect sizes (d) were calculated to compare outcomes between groups and were interpreted as weak (<0.50), moderate ($0.50-0.79$), or strong (>0.80).⁵⁵ Falls in the groups were compared categorically using chi-square tests and these results were used to derive number needed to treat (NNT). Those who did not fall were categorized as nonfallers. Those who fell once or more were categorized as fallers,

and those who fell more than once were categorized as recurrent fallers. Statistical analyses were performed with SPSS version 23.^a

Results

Participant characteristics

Forty participants were randomized, 20 to each group. Nineteen of the ADSTEP group completed all 6 ADSTEP sessions and 1 completed 5 sessions. All participants completed all outcome visits and all collected data were included in analyses.

Participants were well matched in their demographics, fall history, and outcome measures at baseline (tables 1, 2, and fig 2).

Falls

There was a significant association between group (ADSTEP vs control) and falling over the study period (table 3) with significantly fewer fallers in the ADSTEP group than in the control group ($\chi^2=3.96$, $P<.05$, NNT=3.3). There were also fewer recurrent fallers in the ADSTEP group than in the control group but this did not meet statistical significance ($\chi^2=5.24$, $P=.07$, NNT=5). There was no significant difference between groups in the mean total number of falls.

Physical activity

Based on IPAQsf responses, the ADSTEP group reported a significantly different change in average number of minutes/days spent sitting compared to the control group from baseline to intervention completion ($F=11.16$, $P=.002$. ADSTEP: reduced sitting by 87.00 ± 194.89 min/d; control: increased sitting by 103.50 ± 142.21 min/d; $d=0.88$) (fig 2A) and from baseline to the 3-month follow-up ($F=9.25$, $P=.004$. ADSTEP: reduced sitting by 75.79 ± 171.57 min/d; control: increased sitting by 84.50 ± 149.23 min/d; $d=0.79$) (fig 2A). There were no significant differences in vigorous activity, moderate activity, or walking activity as captured by the IPAQsf between groups at any time point or in changes over time between groups (ie, interaction effects). The ADSTEP group also reported more time spent walking than the control group at the 3-month follow-up, with a moderate effect size but this difference did not meet statistical significance (ADSTEP: 117.53 ± 148.40 min/d; control: 46.43 ± 58.55 min/d; $P>.05$, $d=0.63$) (fig 2B).

Timed mobility performance

There were no significant differences between groups at any time point or in changes over time between groups (ie, interaction effects) for any of the timed mobility tests including the TUG, the T25W, the 2MWT, and the FSST, and all effect sizes were weak (see table 3).

PROs

There were no significant differences between groups at any time point or in changes over time between groups (ie, interaction effects) for the QUEST, the MSWS-12, the ABC, or the

^a.SPSS, version 23; IBM.

MSIS-29. However, all of these outcomes showed moderate effect sizes for improvements in the ADSTEP group compared to the control at intervention completion, with the strongest effect for walking aid satisfaction (QUEST) and balance confidence (ABC) (d for QUEST=0.70, ABC=0.72, MSWS-12=0.60, MSIS-29=0.54). The effect size for the ABC also approached moderate at the 3-month follow-up (d =0.49) (see table 2).

Discussion

This pilot study is the first to provide evidence that the multicomponent walking aid program, ADSTEP (consisting of walking aid selection, fitting, and task-oriented training) prevents falls and improves physical activity behavior, including less sitting time and possibly more walking time, compared to usual medical care. Statistically significantly fewer people in the training group fell and, based on statistically significant interactions with moderate to strong effect sizes, the ADSTEP group reduced the amount of time they spent sitting while the control group increased the amount of time they spent sitting. In addition, although not statistically significant, based on a moderate effect size, the ADSTEP group also likely spent more time walking.

Previous studies of fall prevention interventions in MS have primarily examined the effects of exercise and/or education.^{21,56–62} Exercise generally improves strength and balance, and education increases fall prevention knowledge but neither consistently reduces fall risk or, more importantly, prevents falls.^{6,21,56–58,60,61} A 2015 systematic review of studies of interventions to reduce falls and improve balance in adults with MS surprisingly found that few studies specifically examined the effect on future falls and, that the strength and balance improvements may not be sufficient to affect falls.⁵⁸ In contrast to earlier studies, ADSTEP focuses on improving walking with a walking aid, a single strong modifiable risk factor for falls in PwMS.^{8,63} Specifically and exclusively addressing walking with a walking aid likely helped achieve the task-specific outcomes of safer walking and less sitting, seen in this trial.

Although the effect of ADSTEP on other physical activity outcomes did not meet statistical significance, this study was not powered to detect significant effects on these outcomes. Based on the observed effect sizes, post hoc power calculations indicate a study with 120 PwMS would yield statistically significant effects on falls as well as time spent walking and sitting. In addition, physical activity measurement was limited to self-report when objective measurement of free-living physical activity that could be obtained with body-worn accelerometers would be more accurate and thus more likely to yield statistically significant findings.⁶⁴ It is also important that in this trial, falling and sitting were reduced and walking possibly increased while in other studies, more physical activity, with more exposure to fall hazards, has been associated with more falls.¹⁹

In contrast to the effect of ADSTEP on falls and sitting time, ADSTEP did not appear to affect timed mobility or PROs. We believe that mobility was not accelerated because, although being able to walk faster is associated with improved functional outcomes, faster walking can also come at the cost of decreased safety.^{65–67} Therefore, ADSTEP emphasized walking safety and ability but not speed, yielding effects consistent with this emphasis. Studies of people receiving the medication dalfampridine, an intervention that increases gait

speed, actually reported more falls in the intervention group, which again, has been attributed to increased exposure.⁶⁸ Our study did not include a timed dual task measure, such as the dual task TUG.⁶⁹ This may have been more likely to show acceleration because ADSTEP includes dual task training and because fall risk is strongly correlated with dual task speed in PwMS and in other populations.^{70,71} The lack of significant effects on the PROs may also be attributed to the specificity of the effect of ADSTEP, and the small sample size.

This study has a number of strengths. It was a randomized controlled trial with objective outcome assessments performed by assessors blinded to allocation with excellent adherence and minimal missing data. Falls were prospectively assessed, the current gold standard, rather than retrospectively recalled or a fall proxy of balance or fall risk.^{58,59} The clinical effect of this outcome alone could be substantial, with a NNT of 3.3 to prevent one person falling and 5 to prevent recurrent falls, and the possibility that ADSTEP may also increase physical activity.

Study limitations

This study also has several limitations. The sample was small, limiting power to draw definitive conclusions about many outcomes. Potential participants were excluded if they reported receiving more than 1 hour of walking aid training within the previous 3 years but were not excluded for having received other forms of physical therapy, which may have confounded our results. Physical activity was assessed with a self-report measure, the IPAQsf, rather than an objective measure such as a body-worn accelerometer.^{64,72} Furthermore, we did not capture the effect of this program on functional activities as could be captured with the functional mobility assessment questionnaire.⁷³ In addition, although a multicomponent multisession program can address a range of important issues, combining components in 1 program prevents evaluation of the individual or incremental contributions of components or sessions. The control condition did not control for 1-on-1 contact, and this study was carried out at a single site with a single physical therapist providing the intervention, limiting generalizability.

Conclusions

This pilot study suggests that, compared to usual medical care, a multicomponent walking aid program, ADSTEP (consisting of walking aid selection, fitting, and task-oriented training), is associated with preventing falls, reducing sitting time, and possibly increasing walking time in PwMS. This study supports the need for a fully powered, multisite trial to definitively determine the effect of ADSTEP on falls and physical activity in PwMS.

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List of abbreviations:

2MWT	2-minute walk test
ABC	Activities-Specific Balance Confidence Scale
ADSTEP	Assistive Device Selection, Training and Education Program
FSST	Four Square Step Test
IPAQsf	International Physical Activity Questionnaire, short form
MRI	magnetic resonance imaging
MS	multiple sclerosis
MSIS-29	Multiple Sclerosis Impact Scale-29
MSWS-12	Multiple Sclerosis Walking Scale-12
NNT	number needed to treat
PRO	patient-reported outcome
PwMS	people with multiple sclerosis
QUEST	Quebec User Evaluation of Satisfaction With Assistive Technologies
T25W	timed 25-foot walk
TUG	timed Up and Go

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Fig 1.

CONSORT diagram for the clinical investigation. *Inclusion criteria not met: no use of assistive device for walking (n=4), no falls in the past year (n=4), unconfirmed diagnosis of MS (n=1), received gait training within the last 3 years (n=1), making a change to medications (n=1), contraindications to MRI (n=6).

Fig 2. Average amount of (A) time spent sitting and (B) time spent walking per day at baseline, intervention completion, and 3 months later, based on IPAQsf responses. Error bars represent standard deviation.

Table 1

Baseline participant demographics and number of falls reported retrospectively for the previous year, by group assignment

Characteristic	ADSTEP (n = 20)	Control (n = 20)
Age (y), mean $\pm$ SD	56.0 $\pm$ 9	54.8 $\pm$ 1.4
Sex, men/women	6/1	7/1
Race, African American/Caucasian	1/1	3/1
EDSS (self-report), median $\pm$ SE	6.0 $\pm$ 0	6.0 $\pm$ 0
Falls previous year, mean $\pm$ SD	12.4 $\pm$ 2.1	12.1 $\pm$ 14

Table 2

Timed mobility performance and patient-reported outcomes at baseline, intervention completion, and 3 months later

Measure	Timepoint	Test	ADSTEP (n = 20)	Control (n = 20)	Cohen's d
Timed mobility performance	Baseline	TUG (s)	16.9±10.7	17.3±8.5	0.05
		T25WT (s)	10.2±6.9	10.4±7.6	0.03
		2MWT (min)	94.1±35.9	95.2±33.8	0.01
		FSST (s)	31.1±33.0	37.4±33.2	0.20
	Intervention completion	TUG (s)	18.0±13.6	17.3±7.5	0.06
		T25WT (s)	10.0±7.9	9.2±3.9	0.13
		2MWT (min)	100.3±36.1	100.4±35.0	0.00
		FSST (s)	35.7±43.4	28.3±19.3	0.22
Patient-reported outcomes	3 months later	TUG (s)	19.4±18.6	17.0±7.5	0.18
		T25WT (s)	10.2±8.6	9.6±4.5	0.10
		2MWT (min)	97.5±39.3	99.2±35.1	0.05
		FSST (s)	32.6±39	32.2±27.8	0.01
	Baseline	QUEST 2.0	4.3±0.9	4.3±0.6	0.05
		MSWS-12	47.8±8.5	47.0±8.8	0.10
		MSIS-29	81.6±15.3	82.8±23.3	0.06
		ABC	55.8±15.4	51.5±17.4	0.27
Intervention completion	Intervention completion	QUEST 2.0	4.7±0.3	4.4±0.6	0.70
		MSWS-12	44.1±8.7	49.1±8.5	0.60
		MSIS-29	76.9±16.5	87.4±23.2	0.54
		ABC	59.3±15.9	47.6±17.3	0.72
	3 months later	QUEST 2.0	4.6±0.5	4.4±0.7	0.38
		MSWS-12	48.5±6.5	49.7±7.7	0.17
		MSIS-29	79.7±17.3	86.9±25.3	0.34
		ABC	57.6±16.0	50.0±15.8	0.49

NOTE. Values are mean ±SD or as otherwise indicated. None of the changes over time or differences between groups were statistically significant. Lower scores on the MSWS-12 and MSIS-29 are better. Higher scores on the ABC and QUEST 2.0 are better.

Table 3

Fall status over the entire reporting period (intervention plus the following 3 months) for the ADSTEP group and the control group

Characteristic	ADSTEP (n = 20)	Control (n = 20)	Total
No fall (non-fallers)	10	4	14
1 or more falls (fallers)	10	16	26
2 or more falls (recurrent fallers)	10	14	24