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ORIGINAL RESEARCH

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±194.89min/d; control: increased 103.50±142.21min/d; $d=0.88$) and to 3-month follow-up (F=9.25, $P=.004$. ADSTEP: reduced 75.79±171.57min/d; control: increased 84.50±149.23min/d; $d=0.79$). ADSTEP yielded a moderate effect on time spent walking compared to control at 3-month follow-up ($P>.05$. ADSTEP 117.53±148.40min/d; control 46.43±58.55min/d; $d=0.63$).

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

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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

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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 adults[15-17] 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.

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**

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 (NCT02408718).

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