

# Whom to Target for Falls-Prevention Trials

## Recommendations from the International MS Falls Prevention Research Network

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*Effective falls-prevention approaches for people with multiple sclerosis (MS) are needed. A significant challenge in studying falls-prevention programs for people with MS is deciding whom to include in trials. This article presents and discusses potential criteria for selecting participants for trials of falls-prevention interventions in MS. This narrative review reports on the inaugural meeting of the International MS Falls Prevention Research Network (IMSFPRN), which was held in March 2014 in Kingston, Ontario, Canada. Criteria considered were age, assistive device use, cognition, and fall history. The IMSFPRN reached consensus agreement to recommend that participants of all ages with varying levels of cognitive ability who are able to ambulate with or without assistance and who have a history of falling should be included in their future falls-prevention trials. *Int J MS Care.* 2014;16:203–207.*

**M**ultiple sclerosis (MS) is a chronic neurologic disease that may cause impairments in cognition, muscle strength, muscle tone, sensation, coordination, balance, and gait, all of which are associated with an increased risk of falls.<sup>1-7</sup> A number of studies also demonstrate that people with MS fall frequently<sup>1,3,5,6,8-12</sup> and fall significantly more often than healthy people of the same age and gender.<sup>11,13</sup> Over 50% of people with MS fall in a 3- to 6-month period, and around 30% to 50% fall multiple times.<sup>3,5-7,9,10</sup> People with MS also often sustain fall-related injuries.<sup>6,8,11,14</sup> Falls in people with MS are also associated with reduced balance confidence,<sup>15</sup> social isolation, and reduced participation in occupational and leisure activities.<sup>16,17</sup> Although the cross-sectional data do

not clarify the direction of these associations, it is theorized that falling likely contributes to reduced balance confidence, socialization, and participation in activities. Given the high frequency of falls in people with MS and the significant impact of these falls on people's lives, effective falls-prevention approaches are needed.

### Methods

The International MS Falls Prevention Research Network (IMSFPRN) was established to help meet the need to develop and evaluate falls-prevention approaches for people with MS. The IMSFPRN held its inaugural meeting in March 2014 in Kingston, Ontario, Canada, to develop a falls-prevention intervention research protocol that could be executed at multiple sites. This meeting was attended by a multidisciplinary group of MS researchers, providers, patients, and representatives from MS support organizations and professional organizations. Different members of the group focused on and presented different specific aspects of trial design for discussion by all members of the group, and each aspect was discussed until consensus was reached. This article, which is derived from the meeting, focuses specifically on whom to include in future trials of MS falls-prevention interventions.

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We agreed that to be most useful, falls-prevention studies in MS should include people at risk for falls, as they would be most likely to benefit from effective falls prevention. Although fall risk is multifactorial, with approximately 40 factors having been found to be associated with falls in people with MS,<sup>7</sup> and over 400 fall risk factors having been identified in older adults, the population in whom falls have been most thoroughly studied,<sup>18</sup> at the inaugural IMSFPRN meeting we focused on only four potential fall risk factors: age, mobility aid use, cognition, and fall history. These four factors were selected by the group members presenting on this topic by a combination of literature review, their own research, and clinical experience. A more systematic approach to selecting factors to focus on was not taken because the MS falls literature is in its infancy and the risk factors identified for falls in people with MS vary between studies and between meta-analyses. This article summarizes the discussion of the IMSFPRN meeting regarding whom to include in future MS falls-prevention trials and clarifies why the Network agreed that age, use of a mobility aid, and cognition should not be inclusion or exclusion criteria but that participants for such future falls-prevention trials in MS should be selected on the basis of having a history of prior falls.

## Results

### People of All Ages Should Be Included in Studies of Falls Prevention in MS

Although some studies suggest that fall risk in people with MS varies with age, the literature on this possible association is not consistent. We therefore recommend that people of all ages be included in studies of falls prevention in MS. In the general population, most studies indicate that older adults are at increased risk for falls,<sup>19</sup> suggesting that one could consider limiting inclusion in studies of falls prevention in MS only to older adults with MS. This decision could enrich the study population for fall risk. It has been proposed that the combined effects of advancing age and disease status could also place older adults with MS at greater risk for falls.<sup>20</sup> The expected association between falls and age has led some MS researchers to examine falls specifically in middle-aged and older adults with MS,<sup>8</sup> and cross-sectional reports examining individuals with MS over a wide age range have found that fallers tend to be older than nonfallers.<sup>1</sup> However, prospective investigations have not found that older adults with MS are at greater

risk for falls,<sup>6,10</sup> and a recent large meta-analysis (n = 537) of prospective falls data found that in the cohorts studied, younger adults with MS were more likely than older adults to fall over a 3-month period.<sup>12</sup> The authors proposed that younger adults may have been at greater risk for falls because they were more active. They also suggested that older adults with MS may have learned strategies to better manage their fall risk. To our knowledge, there are no published data on falls in individuals with juvenile MS. The complex interactions between age at onset, disability, and disease progression in people with MS further complicate any conclusion regarding age and fall risk in MS. Based on the extant literature, which reports conflicting findings regarding the association of age and falls in people with MS, the IMSFPRN recommends including people of all ages in studies of falls prevention in MS to allow for further study of the impact of age on falls prevention, risk, and incidence in this population.

### People Who Do and Do Not Use Mobility Aids Should Be Included in Studies of Falls Prevention in MS

The use of mobility aids is the factor most consistently found to be associated with fall status in studies of people with MS, and researchers could therefore consider limiting studies of falls prevention in people with MS to those who use a mobility aid. However, the IMSFPRN recommends including people who do and do not use mobility aids because fall risk is high in both groups. Mobility aid use has been found to be related to fall status in both cross-sectional<sup>1,3,21,22</sup> and prospective investigations<sup>10</sup> of falls in MS. Mobility aids are generally considered to be canes, walkers, and walking sticks or poles but not orthoses (eg, ankle-foot orthoses). Some have also considered seated wheeled mobility devices (eg, wheelchairs, scooters) as mobility aids. Although use of a mobility aid may simply be a proxy for disability and mobility status, it is likely that the association between use of an aid and falls is more complex. Finlayson and colleagues<sup>21</sup> demonstrated that individuals with MS who use multiple mobility aids (eg, cane, walker, wheelchair, etc.) are more likely to have fallen than those who do not use multiple aids. Those with multiple aids may have difficulty determining which aid is appropriate to use at which time, increasing their risk for falls. Coote and colleagues<sup>22</sup> also found that falls were not evenly distributed across mobility aid users, with those who

used bilateral support having a greater likelihood of a fall than those who did not use an aid. Individuals with gait impairment who did not use an aid were the most likely to be recurrent fallers (more than one fall). A large meta-analysis of prospective fall data<sup>12</sup> also recently revealed that Expanded Disability Status Scale scores of 4.0 and 6.0, the transitional points in MS relating to onset of gait impairment and use of unilateral support, respectively, were significantly associated with increased fall risk. It is possible that these transitional stages of mobility limitation progression are key times for falls-prevention interventions.

Overall, current evidence indicates that, although use of a mobility aid is associated with elevated fall risk, falls are relatively common across the mobility spectrum, possibly with distinct risk factors across the range of mobility function. Therefore, at this time the IMSFPRN recommends evaluating falls-prevention programs in MS in people who do and do not use mobility aids.

### **People with Varied Levels of Cognitive Ability Should Be Included in Studies of Falls Prevention in MS**

Although traditionally falls are believed to stem from mobility limitations, increasing evidence indicates that impaired cognition is also a risk factor for falls in people with MS. However, our current understanding of these relationships is too limited for the IMSFPRN to recommend that cognitive function be an inclusion or exclusion criterion for studies of falls prevention in MS. We recommend that falls-prevention programs be tailored to take into account the diverse levels of cognitive function of people with MS. It is known that MS is associated with a wide range of cognitive problems.<sup>23</sup> Several cognitive domains including verbal memory<sup>24</sup> and cognitive processing speed<sup>25</sup> are associated with the frequency of prior falls, and executive function has been associated with the frequency of future falls.<sup>26</sup> There are also data linking the interaction between impairments of cognition and walking to fall risk in people with MS,<sup>27</sup> although others have not found this association.<sup>6</sup> The mechanisms underlying the link between cognition and falls in people with MS are not well understood. It is possible that impaired cognition contributes to poor selection of movements to respond to balance perturbations or rapid changes in the environment and poor judgment contributes to poor mobility aid choices for specific tasks and environments.

### **Studies of Falls Prevention in MS Should Focus on People Who Have Fallen**

In order to focus falls-prevention interventions on those at greatest risk for future falls, since prior falls have consistently been associated with risk for future falls in people with MS, the IMSFPRN recommends that studies of falls prevention in MS focus on those who have fallen before. We discussed whether falls-prevention studies should focus on those who have fallen already, as a secondary prevention intervention to minimize further falls, or whether studies should focus on those who have not yet fallen but have risk factors for falls, as a primary prevention intervention. We know that those with a history of falls are highly likely to fall again. Cameron and colleagues found that simply asking about falls history had 89% sensitivity for future falls and was the best predictor from a range of clinical scales in determining those who would fall in the next 6 months.<sup>28</sup> Similarly, Gunn and colleagues<sup>6</sup> found that those who had reported falls previously had 10.62 increased odds of falling again. Clearly, people with MS with a history of falls should be included in falls-prevention intervention studies.

Whether people with MS who have not fallen should also be included in falls-prevention studies is not clear. MS itself is a risk factor for falls. As stated previously, over 50% of people with MS fall in a 3- to 6-month period, but identifying who is at greatest risk for falls is difficult. Several clinical measures have been investigated as predictors of falls in older people. The joint American Geriatric Society/British Geriatric Society guidelines<sup>29</sup> suggest that the Get Up and Go Test, the Timed Up and Go (TUG) test, the Berg Balance Scale (BBS), and the Performance Oriented Mobility Assessment (POMA) should be part of a multifactorial fall risk assessment for older adults. These measures have not consistently predicted falls in prospective studies of falls in people with MS. A number of studies have suggested that various measures, including the Activities-specific Balance Confidence (ABC) scale, the Dynamic Gait Index (DGI), the BBS,<sup>30</sup> and the Physiologic Profile Assessment (PPA),<sup>6</sup> can be used to identify fallers with MS, but none have clearly sufficient sensitivity and specificity to be clinically useful. Thus, while preventing future falls in nonfallers is a worthwhile aim, at present there is insufficient data to suggest the measures that could be used to identify those in need of intervention. This remains a priority for researchers in the area of falls

in people with MS. The IMSFPRN recommends that falls-prevention intervention studies in MS focus on people who have fallen in the past.

## Implications of Inclusion Recommendations

Based on current literature on falls in ambulatory people with MS and the Network's collective expert opinion, the IMSFPRN recommends broad inclusion criteria for falls-prevention studies in MS. Studies should include subjects of all ages who have fallen in the past, who do and do not use assistive mobility devices and who have sufficient cognitive capacity to participate effectively in the identified intervention(s). It is important to note that these recommendations are not the result of a rigorous systematic review or meta-analysis, but rather are heavily influenced by the Network's expert opinion and knowledge of the falls research in the MS community. These recommendations are seen as an initial step in an organized international effort to minimize falls in people with MS. As the evidence for fall risk factors expands and we learn more about the responses to falls-prevention interventions, these criteria will require review and modification.

## Practice Points

- Because the association between aging and falls is not clear in the MS literature, people of all ages should be included in MS falls-prevention trials.
- Because mobility aid use has a complex interaction with falling in individuals with MS, and falls are experienced by people who do and do not use mobility aids, the use of an aid should not be an inclusion or exclusion criterion for falls-prevention trials.
- Cognitive impairment has been linked to falls in the MS community. Although falls-prevention programs should be tailored to cognitive ability, cognitive ability should not be an inclusion or exclusion criterion for falls-prevention trials in people with MS.
- Because a history of a fall in the past year is one of the strongest predictors of future falls in individuals with MS, MS falls-prevention trials should target those with a history of falling.

It is also noted that these inclusion criteria will lead to a diverse heterogeneous sample. Potential disadvantages of this heterogeneity include requiring larger sample sizes to detect effects and tailoring of interventions to meet needs of those with differing abilities. This will likely preclude a one-size-fits-all rehabilitation approach, but given the variety and combinations of symptoms and fall risk factors for people with MS, a one-size-fits-all approach is probably not appropriate. However, the advantage of these recommended inclusion criteria is that they will optimize generalizability and maximize the number of people with MS who can participate and potentially benefit from the studied falls-prevention interventions.

## Conclusion

People with MS are at high risk for falls and adverse consequences of falls. Designing ideal falls-prevention studies and identifying who should be included in them is complex. At this time the IMSFPRN recommends that falls-prevention studies include subjects of all ages who have fallen in the past, who do and do not use assistive mobility devices, and who have sufficient cognitive capacity to participate effectively in the identified intervention(s). □

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