Fall Incidence as the Primary Outcome in Multiple Sclerosis Falls-Prevention Trials

Recommendation from the International MS Falls Prevention Research Network

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The aim of this article is to provide recommendations on behalf of the International MS Falls Prevention Research Network (IMSFPRN) for the primary outcome measure for multiple sclerosis (MS) falls-prevention interventions. The article will consider the definition of a fall, methods of measuring falls, and the elements of falls that should be recorded, as well as how these elements should be presented and analyzed. While this information can be used to inform the content of falls-prevention programs, the primary aim of the article is to make recommendations on how the outcome of these programs should be captured. Int J MS Care. 2014;16:178–184.

Falls are a common health concern in people with multiple sclerosis (MS), with more than 50% of people with MS suffering a fall in a 3-month period. Resulting injuries may range from mild sprains and strains to fractures and head injuries requiring hospitalization.^{1,2} The physical impact of a fall can cause functional limitations and have a significant effect on participation.³ The longer-term consequences of these fall-related injuries may include time off from work, inability to return to work, increased need for care including institutionalization, and even increased risk of death. Additionally, a fall can lead to concerns about falling⁴ that subsequently result in activity curtailment.^{5,6} Activity curtailment may lead to a reduction in social interaction or lack of physical activity leading to deconditioning and secondary health problems. Therefore, it

is essential to intervene to reduce falls and their adverse consequences.

The International MS Falls Prevention Research Network (IMSFPRN) is a multidisciplinary collaboration between researchers that aims to develop and implement multisite research protocols to advance knowledge on falls and falls prevention among people with MS.⁷ The objective of this article is to consider the IMSFPRN's choice and rationale for the primary outcome for MS falls-prevention interventions—reduction in the number of falls—and how this should be measured. We will discuss a number of factors including the definition of a fall, the methods of fall recording, the elements of falls that should be recorded, and how these elements are presented and analyzed. The ultimate goal of this article is to make recommendations regarding the primary outcome measure for falls-prevention research specific to individuals with MS.

The number of investigations focusing on falls prevention in people with MS is low compared with research on falls prevention in other populations such as older adults (for example, the Cochrane review by Gillespie et al.^{8,9} included 159 trials). Therefore, much can be learned from research into falls in older people and other populations. The Prevention of Falls Network Europe (ProFaNE) published a common outcome data set for falls management interventions in older people¹⁰ that served as a starting point for the IMSFPRN discus-

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sion. ProFaNE recommends that prospective falls diaries be used to record falls daily, with monthly returns. The group also recommends that data from the falls diaries be summarized as number of falls, number of fallers/nonfallers and frequent fallers, and annual fall rate per person. Additionally, it suggests that radiologic confirmation of a peripheral limb fracture be the primary measure of fall-related injury. However, because the pathology and demographics of people with MS differ from those of elderly fallers, and falls in MS are seemingly distinct from those observed in the elderly,¹¹ these recommendations may need to be modified to apply them to the investigations of falls prevention among people with MS.

Outcome Measures Used in Existing Falls Research in MS

When developing a recommendation for a specific primary outcome for a falls-prevention program, a range of options should be considered. These include fall risk, the number of people falling, total number of falls in a given period, rate of falls, and injurious falls. In the MS population, where relapses and fatigue are an issue, it may be useful to also capture the number of falls per day and to examine the pattern over a calendar month.

To date, a limited number of falls-prevention and fall risk reduction programs for people with MS have been investigated (Table 1).¹²⁻¹⁷ Owing in part to the varied nature of investigations, several different fall-related outcomes have been used. These include balance, dynamic mobility, balance confidence, adoption of falls-prevention strategies, composite measures of fall risk (ie, physiological profile assessment [PPA] of fall risk), retrospective recall of falls, and prospective falls diaries. The outcome measures used have a range of strengths and weaknesses. For example, the adoption by people with MS of falls-prevention strategies is a potentially positive outcome, and interventions have been shown to improve relevant knowledge and skills among people with MS.¹⁵ However, people who use fall risk reduction strategies still fall frequently,¹⁸ suggesting that the adoption of fall risk reduction strategies should not be the sole outcome for falls-prevention studies.

Fall Risk as an Outcome Measure

Three meta-analyses¹⁹⁻²¹ have focused on risk factors for falls in people with MS, and all have concluded that balance deficits, progressive MS, and mobility aid use are associated with and predict falls status. Despite the

Table 1. Outcomes used in falls-prevention intervention studies to date

Author, year	Brief study description	Outcomes
Cattaneo et al., ¹² 2007	RCT of balance interventions 1-motor and sensory balance rehab, 2-motor balance strategies rehab, 3-not aimed at balance	Fall frequency (self-report falls in past month) Berg Balance Scale Dynamic Gait Index Dizziness Handicap Inventory Activities-specific Balance Confidence Scale
Coote et al., ¹³ 2013	RCT of group or individual physiotherapy or yoga, physiotherapy focusing on exercises for strength and balance	Fall prevalence (self-report last 3 months) Berg Balance Scale 6-Minute Walk test Multiple Sclerosis Impact Scale-29 Modified Fatigue Impact Scale
Esnouf et al., ¹⁴ 2010	RCT of oddstock drop foot stimulator	Canadian Occupational Performance Measure Prospective falls diary during intervention period
Finlayson et al., ¹⁵ 2009	RCT of fall risk management program	Knowledge of fall risk factors Increased knowledge and skills to manage falls and falls risk
Nilsagård et al., ¹⁶ 2014	Single group pre/post exercise intervention focusing on Core Stability, Dual Tasking, and Sensory Conditions	Prospective falls over 7 weeks Berg Balance Scale 4 Square Step Test Sit-to-Stand Test Timed Up and Go (TUG) TUG Cognitive Functional Gait assessment MS Walking Scale-12 Activities-specific Balance Confidence Scale MS Impact Scale
Stephens et al., ¹⁷ 2001	RCT of Awareness Through Movement Intervention	Prospective falls diary during intervention Equiscale balance test Modified Clinical Test for Sensory Integration of Balance Activities-specific Balance Confidence Scale MS Self-Efficacy Scale

Abbreviations: MS, multiple sclerosis; RCT, randomized controlled trial.

commonality of conclusions, the ability of balance and mobility measures to predict future falls continues to be unclear. To date, the limited data from prospective studies have been inconsistent, and no studies have presented analyses of individual measures that can be considered excellent in predicting which MS patients will fall. For example, in the largest prospective study to date, the best model to explain falls included the PPA, Expanded Disability Status Scale (EDSS), and Ashworth scale, and had only fair to good predictive ability (sensitivity 70%, specificity 69%), maintaining the possibility of a significant number of false-negative values. Given the limited number of studies as well as lack of consensus in the findings, at this time it is not possible to definitively propose a measure of fall risk for people with MS that can be used as an outcome measure in falls-prevention studies. Additionally, there is evidence from the research on older adults that reducing fall risk does not necessarily lead to a reduction in the number of falls.^{8,22} Therefore, the IMSFPRN proposes that the primary outcome should be a reduction in falls rather than fall risk.

The Definition of a Fall

In the MS literature to date, a number of definitions of a fall have been used, and these are presented in Table 2.²³⁻³¹ In a systematic review of the literature on

Table 2. Definitions of falls in the multiple sclerosis literature to date

Definition
Unexpected event in which participant comes to rest on ground, floor, or lower level
Unexpected contact of any part of the body with the ground ²³⁻³⁰
Landing on the ground or at some other level, such as a chair or bed
Unexpected loss of balance resulting in whole-body contact with the ground
Any event that led to an unexpected contact with a support surface
An event in which the individual unintentionally comes to rest on the ground or a lower surface not as the result of a major intrinsic event (eg, stroke or heart attack) or an overwhelming extrinsic event (such as ice)
Unintentionally coming to the ground or some lower level and other than as a consequence of sustaining a violent blow, loss of consciousness, sudden onset of paralysis as in stroke or an epileptic seizure
A slip or trip in which you lost your balance and landed on the floor or ground or lower level

From Finlayson et al.³¹ Reprinted with permission.

falls in older people, Hauer et al.³² found that the lack of definition in some studies and the range of definitions in others precluded comparison between studies. This review led to the definition proposed by ProFaNE,¹⁰ which recommends that a fall be defined as “an unexpected event in which the participants come to rest on the ground, floor, or lower level.” This definition has been used verbatim by several MS studies to date, and variations of it by others. The advantage of this definition is that it is straightforward and minimizes subjective judgment by the researcher and/or participants. Consequently, the IMSFPRN proposes to adopt this definition.

Presentation of Data on Falls

One possible successful outcome of a falls-prevention intervention is a reduction in the number of people falling; a second is a reduction in the number of falls that each person has. Therefore, the IMSFPRN is interested not only in whether someone fell during a defined period, but also in how many times they fell. Within the MS population, an individual's number of falls is very important given the high percentage of recurrent fallers.²¹ In analyzing falls data, the absolute numbers for each variable may be recorded, which subsequently may be used to classify each participant's fall status (for example, as a “faller” or “frequent faller”). Lamb et al.¹⁰ recommend that both the number of falls and the number of fallers be presented, as well as the number of frequent fallers. However, they fail to specify the number of falls a person must have in order to be defined as a “frequent faller.” Studies of people with MS to date have defined fall status using a number of different metrics. For example, in prospective studies Gunn et al.³³ used the criterion of having two or more falls to be classified as a faller, Nilsagård et al.²³ considered a faller as anyone having one or more falls, while Hoang et al.³⁴ used the criterion of three or more falls to define frequent fallers. Interestingly, overall the results of these investigations highlight similar fall risk factors. As it only takes one fall to cause injury or related consequences, we propose that a faller be defined as anyone who records one or more falls during the observation period. We also propose that a multiple or frequent faller be defined as anyone reporting two or more falls during that period.

The time frame in which falls occur is important and adds to the information on the type and severity of the problem; for example, three falls in 1 month is a potentially different problem than three falls in 1 year. In

order to address this, and the issue of defining frequent fallers, the computation of “fall rate” is recommended in the literature on the elderly.¹⁰ This is calculated as the number of falls per person per year and has been used as the primary outcome in a number of Cochrane reviews of the literature on the elderly and stroke-related falls.^{9,35,36} Falls per person per year can be computed from any time period of diary recording, allowing comparison across studies with different reporting periods. We therefore propose that MS falls-prevention intervention studies use the number of falls per person per year as the primary outcome, with the number of falls, number of fallers, and frequent fallers as additional outcome variables. The length of time for recording falls will be considered in a later section.

Fall Recording—Retrospective versus Prospective

Several studies of falls in people with MS have highlighted discrepancies between reported/recorded fall prevalence using retrospective recall and fall incidence using prospective falls diaries. In a study of 76 community-dwelling people with MS in Sweden,²³ the reported/recorded retrospective fall prevalence was 36%, while the reported/recorded prospective fall incidence for the same cohort was 63%. Similarly, in a UK sample of 148 people with MS,³³ 57% of the sample retrospectively reported falls, while 70.3% recorded falls prospectively using diaries. These studies are further supported by the findings of Dibble et al.,³⁷ who reported that 63% of their sample underestimated the number of falls they had recorded during a 12-month period. These are not unexpected findings considering the high prevalence of cognitive dysfunction in people with MS.³⁸ Therefore, the IMSFPRN recommends that future research with the aim of reducing falls in people with MS should prospectively record falls using falls diaries.

Falls Diaries—Duration and Return Rate

Falls diaries can provide valuable information regarding the occurrence of falls. If designed correctly, they also can provide data on various other aspects of the falls, including the context (time of day, activity at the time, location, etc.), the causes (legs giving way, slip, trip, loss of balance, etc.), and consequences of the fall (injury, activity curtailment, care, etc.). When incorporating a falls diary into a falls intervention, care should be taken to balance the burden on the participant with maximizing data collection.

In order to inform the design of falls diaries, we reviewed those diaries used by four MS research groups to date.^{4,33,34,39} All used daily reporting with different formats for recording falls. Three used a 1-month-view calendar with space to write the number of falls beneath each date,^{4,34,39} while the other group used a format with one page per day.³³ For all four groups, diaries were presented to the participants in a pack or binder at the start of the trial, and the investigators suggested that these constituted an important visual reminder to record falls. Diaries were generally returned by mail on a monthly basis, although one group used a biweekly time frame for returns.³³ One group using monthly returns used biweekly phone reminders to optimize the accuracy of falls recording,³⁹ and all followed up by phone or e-mail if the diaries were not returned within 7 to 10 days of the expected date.

The reporting period and frequency of returning diaries is a balance between burden and inconvenience to participants and loss of accuracy of data due to memory problems. For instance, if monthly returns are used, the participants may have forgotten to record for several weeks before it is noticed that a diary is missing, and recall over many weeks to subsequently complete the diary may result in inaccuracies. Biweekly returns may be more accurate in terms of numbers of falls but result in increased postal charges and place extra demands on the participant. Owing to the prevalence of cognitive dysfunction in people with MS, we suggest that biweekly phone reminders be used, and that diaries be returned on a monthly basis, with a further phone reminder if the diary is not received within 7 days of the expected date. A sample falls diary is included in Supplementary Appendix 1, which is published in the online version of this article at ijmsc.org. While this diary is based on the best available information at this time, it does require validation.

Given the young age of people with MS who fall,²¹ and their potential familiarity with technology, the use of other forms of reporting and reminders such as text alerts, mobile phone applications, or other fall-sensing devices should be evaluated. To date few studies have been published evaluating these technological approaches in people with MS.

It is not clear for what time frame the falls diaries should be kept, such as 3 months, 6 months, or 12 months. The reporting period needs to be long enough to capture falls before intervention and a change in falls

after intervention, but short enough to avoid excessive interruption of everyday life. Fall rates in people with MS have been shown to be significantly higher than those observed in older people.⁴⁰ For example, in one study,⁴¹ fall rate for the total sample (N = 148) was estimated at 18.4 falls per person per year. When calculated for fallers only (70% of the total sample, n = 104), the fall rate equated to 26.2 falls per person per year (or 2.15 falls per person per month). Based on these data, it is suggested that 3 months is long enough to capture falls frequency before intervention. However, the reporting period should also consider the mechanism of the intervention; for example, interventions targeting behavior change may require a longer time to have an observable impact. Longer-term follow-up after the post-intervention phase should also be considered in order to evaluate the long-term effect of the intervention on fall rate.

Recording the Causes, Context, and Consequences of Falls

The causes, context, and consequences of falls are also frequently included in falls diaries, with researchers either asking about the most recent fall as an example or asking for details of each fall that occurs. The accuracy of self-reports of causes of falls is not known. As some participants have up to 63 falls in a 3-month period,⁴¹ the recording of causes and context for each fall may be overly burdensome. Once again, the balance between the data set and participant burden comes into play. While extensive detailed information on these factors might be important in studies intended to gather a wide range of information to inform intervention development and report predictors of falls, it may be less important in intervention studies where rates of falling are the primary outcome.

Of the falls diaries we reviewed, all but one recorded the context (location, time of day, activity being performed at the time, etc.) and the perceived cause (slip, trip, knee gave way, etc.) of falls. A change in falls context may be a positive outcome for an intervention trial. A person with activity curtailment who rarely left the house and whose pre-intervention falls were all indoors might consider it more positive if their falls happened outside of the home during social or recreational activities, suggesting a possible reduction of their activity curtailment. Therefore, while it is not a priority, the IMSFPRN recommends that the context be considered for

recording. The context may allow for individualization of any intervention.

Similarly, a change in the cause of falls might also indicate improvement; for example, a person who falls because of their knees giving way may not experience that after intervention if quadriceps-strengthening exercises are a key component of the intervention. It is probably unreasonable to burden participants with recording these for each fall, but it may be feasible to record the perceived cause of falls for two falls in each month.

The consequences of falls, in terms of injuries or health-care use, are an element of falls that is essential to record. Estimates of injurious falls for people with MS vary. The literature clearly indicates that falls in people with MS are more injurious than those in people without MS. For instance, the ProFaNE group¹⁰ proposes that injurious falls be recorded as the “number of radiologically confirmed peripheral fracture events per person year.” Several studies have suggested that the fracture rate among people with MS is considerably greater than in the general population. A Danish study⁴² comparing people with MS to the National Hospital Discharge register found incidence rate ratios of 3.36 (tibia), 6.66 (femur), and 3.20 (hip) for fractures in people with MS. A study of 721 veterans with MS reported that 2.8% of them had an injurious fall coded in their medical

PracticePoints

- The International MS Falls Prevention Research Network (IMSFPRN) proposes that the primary outcome measure of a falls-prevention program should be a reduction in the number of falls, rather than fall risk.
- A simple, easy-to-understand definition of a fall should be used. The IMSFPRN proposes to use the Prevention of Falls Network Europe (ProFaNE) definition: “an unexpected event in which the participants come to rest on the ground, floor, or lower level.”
- Prospective falls diaries should be used as a measurement tool to record the number of falls each day for a minimum of 3 months. Longer lengths of recording may be required depending on the content of the falls-prevention intervention.
- Falls diaries should also be used to record information on the consequences, circumstances, and perceived causes of a fall.

record, compared with 1.5% of veterans without MS.¹ A British study comparing people with MS to the UK General Practice Register⁴³ found a threefold increased risk of hip fracture, confirming that fractures due to falls are important to record and report. However, falls of a much lesser severity can also result in considerable costs to the person and to the health-care system. It appears that these less injurious falls may be more common than severe injuries. For instance, in a phone survey of the North American Research Committee on Multiple Sclerosis database,⁴⁴ 23% reported seeking medical attention for a fall, while another survey of community-dwelling people with MS revealed that 58% of falls were found to be medically injurious.² Additionally, given that many falls are not reported to health-care professionals in both the MS² and elderly⁴⁵ populations, recording medical attention for falls may not be an accurate representation of injurious falls. For that reason, the IMSFPRN proposes that falls diaries contain all self-reported injuries in addition to health-care use information. We also recommend that specific training in the completion of the falls diary for all study participants be implemented at the start of the trial, with the biweekly phone calls used to verify that information is being recorded accurately.

Conclusions and Recommendations

The IMSFPRN recommends that a reduction in falls should be the primary outcome of falls-prevention programs. Consistent with recommendations from ProFaNE,¹⁰ a fall should be defined as “an unexpected event in which the participants come to rest on the ground, floor, or lower level.” At this time, the IMSFPRN recommends using prospective falls diaries to record the number of falls each day. Participants should be reminded by phone every 2 weeks to complete the diaries, which should be returned on a monthly basis with a further reminder if not received within 7 days of the expected date. The length of reporting may depend on the nature of the intervention but should be at least 3 months. Falls data should be presented as the rate of falls per person per unit time, in addition to the total number of falls and the number of fallers. Information on the consequences of each fall—that is, self-reported injury and health-care use—should also be recorded and reported. The IMSFPRN recommends that information on the causes and context of falls should be captured for the first two falls in each month. □

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