Age and Ageing 2006; **35:** 5–10
doi:10.1093/ageing/afi218
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SYSTEMATIC REVIEW

Systematic review of definitions and methods of measuring falls in randomised controlled fall prevention trials

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Abstract

Objective: to review systematically the range of case definitions and methods used to measure falls in randomised controlled trials.
Design/methods: a Cochrane review of fall prevention interventions was used to identify fall definitions in published trials. Secondary searches of various databases were used to identify additional methodological or theoretical papers. Two independent reviewers undertook data extraction, with adjudication by a third reviewer in cases of disagreement.
Settings: community-dwelling and institutionalised older persons.
Results: 90 publications met the predefined inclusion criteria. Of these, 44 provided no definition of the term fall. In the remainder, there were substantial variations in the definition and methods of measuring falls. Reporting periods ranged from 1 week to 4 years with only 41% using prospective data collection methods.
Conclusion: the standard of reporting falls in published trials is poor and significantly impedes comparison between studies. The review has been used to inform an international consensus exercise to make recommendations for a core set of outcome measures for fall prevention trials.

Keywords: *systematic review, methodology, fall-related outcomes, fall prevention trials, elderly*

Introduction

The prevention of falls in older people is a public health target in many countries around the world. A large and rapidly increasing number of randomised controlled trials of falls prevention have been published [1–90], which have contributed significantly to identifying effective and cost-effective interventions [**91**]. However, trials are a time-consuming and resource-intensive endeavour. It is essential that as much as possible is learnt from the many trials being undertaken, in the shortest possible time span. Systematic literature reviews and meta-analysis have proven effective in this respect. Although trials have a common target of fall prevention, the definition of a fall, the method of identifying when a fall has occurred, the details recorded, and the method of analysis appear to vary. This lack of standardisation represents a serious methodological pitfall for the evaluation and interpretation of prevention strategies and a more homogeneous methodology has been repeatedly requested [**92**, **93**].

A first step to standardise the definition, measurement and analysis of falls is to summarise the methodology used in controlled studies. Therefore we conducted a systematic review of the measurement methods used in randomised controlled trials that report falls as a study endpoint.

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Methods

Search strategy

Literature searches were an exact replication of those used in the Cochrane Review of interventions to prevent falls in older people [**91**] (with permission). Studies published until January 2005 were included if they were randomised controlled trials recruiting in community or institutional settings.

Data sources

The Cochrane musculoskeletal group specialised register, Cochrane Central Register of controlled trials, MEDLINE, EMBASE, CINHAL, and reference lists of identified articles were searched. No language restrictions were applied. Further trials were identified by contact with researchers. More details of the search and methodology are provided elsewhere (http://www2.warwick.ac.uk/fac/med/healthcom/emergencycare/research/profane/addendum_to_consensus.pdf page 15).

Data extraction

The definitions and method of recording falls were extracted by two independent reviewers (E.J., K.H.) using a database designed to support standardised extraction [**94**]. Disagreement was resolved by third party adjudication (S.L.). Falls definitions were analysed for clarity in the description of the event and for the sources of variation between definitions (such as the inclusion or exclusion of falls due to certain medical events). Methods of collecting and recording data were categorised into prospective, retrospective or record searching.

Results

Fall definitions

Ninety papers met the review inclusion criteria [1–90].Of these, 44 did not provide a definition of a fall. There was no single definition that stood out as a gold standard. The most frequent citations were the definitions of the Kellogg working group ($n = 8$) [**95**] and FICSIT collaboration ($n = 9$) [**96**]. However, some papers referencing these definitions had made amendments to or changed the original [23, 37, 46, 48, 57, 67, 68, 77, 80, 81, 88]. All other definitions ($n = 28$) differed from each other or were unreferenced.

Most definitions used a combination of topographical, biomechanical and behavioural components to describe a fall. A homogeneous component of definitions was that an individual must come to rest at a lower level, but the description of the level varied. Some studies counted a fall only if it resulted in body contact with the ground or floor. Other definitions also included furniture and wall contact. From a behavioural perspective, falls were defined variously as unintentional, inadvertent, involuntary, or accidental. Another significant and important source of variation was whether falls that were attributable to acute medical events such as syncope and seizures should be included or excluded. Falls resulting from environmental hazards or overwhelming external force and disease-related symptoms were also inconsistently included or excluded. Where studies felt a need to include or exclude falls of specific causes, there were between five and eight criteria in addition to the biomechanical and topographical criteria used to define the fall [29, 34, **95**]. In contrast, some definitions explicitly included all falls related to diseases or unknown causes [27].

The potential for physical injury caused by a fall was another source of variation.

Only two of the 90 articles analysed the consequences of using different fall definitions on the outcome [4, 67]. Both reported that the variation in case definition influenced study results.

Methods of collecting falls data

There was considerable heterogeneity in reporting systems and the time period over which information was collected (Table 1). Three main methods of collecting falls data were found: (i) retrospective reporting systems using telephone interview, face-to-face interview or postal questionnaire ($n = 24$, 27%); (ii) prospective reporting systems using postcards, calendars and diaries ($n = 38$, 42%); (iii) routine surveillance systems or abstraction from health care records ($n = 16$, 18%). In 12 of the papers (13%), no or insufficient information on data collection was given.

For retrospective studies, recall periods ranged from 1 week to 4 years. Prospective registration systems requested immediate return of the data, or return on specified time points ranging from 1 week to 6 months. The primary system was often backed up by secondary data capture mechanism. Only three articles [25, 85, 88] documented the adherence to the primary fall reporting system, indicating an insufficient response rate of 48–83%.

Methods of summarising data

Tables 2 and 3 detail the methods used to summarise falls data. The most frequently reported summary statistic was the number of participants sustaining a fall (i.e. number of fallers) (70%). The number of falls (i.e. incidence of falls) was reported in 61% of studies. Fall rates, expressed either as the number of falls per person or with an additional time denominator, were low (28%). Some papers further classified events or persons as recurrent fallers, and by the injury that resulted. Injury classifications were inconsistent. A few studies reported fall-free survival (i.e. time to a first fall) (18%) or fall rates adjusted by the level of physical activity using a questionnaire [50]. Other summaries included the number of falls in different locations (e.g. indoor and outdoor). Study endpoints included aspects such as the number of general practitioner (GP) visits or the number of fractures sustained without explicit attribution to a documented fall.

Discussion

Fall definition

A first step in any epidemiological investigation is to develop a clear case definition. In the reviewed articles no single definition of fall was used as a designated standard. Although unsystematic and lacking explicit rationale, researchers have often tried to match their fall definition

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Table 1. Documentation methods of collecting falls data (n = 90)

Primary collection method	Frequency n (%)	Description
Prospective registration—calendar [2,6,7,10,14,16,22,25,26,37,48,56,57,59,64,67,77,84,90]	19 (21)	Additional use of postcard [26], recall—face-to-face interview [25] and telephone interview [25,77,84,90]. Returned at fall occurrence [26], fortnightly [22], monthly [6,7,10,16,25,48,56,57,59,67,77], or after 6 months [14]. Follow-up was written [14,26], face-to-face interview [14], telephone interview [6,16,22,26,48,56,57,59], at fall occurrence [22,26,48,59], monthly [6,16,56,67], 3 months [26], 6 months [14], or 12 months [14]
Prospective registration—patient diary [24,29,31,33,51,61,72,75]	8 (9)	Additional use of recall—postal questionnaire [33], GP records [33,72], hospital databases [33,73], reminder—verbal [24] and reminder—telephone calls [31], telephone call at occurrence [72] . Returned weekly [29] or fortnightly [24]. Follow-up was written [24,33], face-to-face interview [31], telephone interview [24,31,41] at 3 months [31] or 6 months [31,33]
Prospective registration—postcard [4,17,18,38,55,68,70,74,76,87,88]	11 (12)	Additional use of telephone calls to report falls [38,68,70,74,88]. Includes slips/trips [76]. Returned at fall occurrence [4,17] weekly [55], every 2 weeks [87], or monthly [18,38,68,70,74,76,88]. Follow-up was telephone interview [4,17,18,38,55] or face-to-face interview [7,17] at monthly [4,18] or 6 month [17] intervals
Recall—face-to-face interview [1,8,21,23,28,47,50,65,69,73,82]	11 (12)	Additional use of weekly telephone calls or monthly fall diaries [47]. Interval recall was 1–2 weeks [47,50], 1 month [69], 6 weeks [23], 3 months [1,28], 4 months [21], 3–6 months [73] 6–12 weeks [82]. Recall at the end of the study was 36 months [8] or 48 months [65]. Controls were telephone interviewed [21,50]
Recall—postal questionnaire [12,13,34,45,62,66,85]	7 (8)	Interval recall was 1 month [85], 2 months [34], 4 months [12], 6 months [62], or 12 months [13,66]. Additional use of diary [12]. Hospital discharge files [66], nurse-administered files [85]. Follow-up was at 12 months [13,66], 18 months [62], 24 months [13,66] or 36 months [62] using face-to-face interview [62] or telephone interview [34]
Recall—telephone[9,20,32,43,44,51]	6 (7)	Interval recall was 4 weeks [9], monthly [20,43,51], or 2 months [32]. Recall at the end of the study was 12 months [44]. Follow-up at 12 months [20,43] or 24 months [20]. Face-to-face interview at 12 months follow-up [9] or to two participants with no telephone [32].
Nursing home fall records [3,5,27,39,42,46,49,53,78,81,89]	11 (12)	Additional use of: medical records [46], individual resident chart/incidence report forms [81]
Hospital fall or health care records [19,35,54,79,80]	5 (6)	Follow-up at 3 and 6 months [54].
Unclear or not mentioned [11,15,30,36,40,52,58,60,63,71,83,86]	12 (13)	

with the chosen intervention or target population. In half of the studies reviewed the notion of a fall is taken for granted and no definition is provided whatsoever. Whilst in everyday life it may seem self-evident what constitutes a fall, for research purposes this is not satisfactory and a clear definition of the target event is required.

In some studies when explicit definitions were used, extensive exclusions of what did not constitute a fall were also given, leading to highly selected study populations and fall observations [29]. Such falls would be difficult to classify retrospectively, and the results may be difficult to generalise.

In most of the reviewed articles, falls resulting from acute medical events and/or external force were explicitly excluded. Falls resulting from external force, such as a collision, occur in younger adults or vigorous elderly persons and are perceived as an accident as opposed to the effect of motor deficits that could be reversed by intervention. This logic appears flawed. Excluding falls because they are not believed to be amenable to the intervention should not be necessary. A randomised design should distribute such confounders equally into each arm of the trial. Defining away the 'unavoidable' falls permits trial sizes to be smaller as the effect size is bigger, but at the expense of introducing definitional artefact and potential for observer or researcher bias. Overall the review reveals that, in general, it was a subjective decision by researchers as to which medical conditions or environmental hazards were included.

One example of the impact of the chosen fall definition is the intervention study of Wolf *et al.* [67]. In this case the effect of a Tai Chi Chuan intervention was studied. The choice of the fall definition including 'near falls' led to a significant result whereas the exclusion of near falls would have led to a less favourable result. This demonstrates the need to standardise the topographical component of the fall definition.

The wording 'involuntary', 'unintentional', 'unexpected', 'inadvertent', 'unplanned', or 'sudden' describes an external perspective not always experienced or verbalised by fallers. People who fall may use different wording, e.g. stumbling, slipping or tripping [**98**]. This clearly is an understudied area.

No publication contained information on how participants or proxies were instructed or trained. It remained unclear whether the documentation of falls used in studies was based on the given definition and only a few studies described an active process of an expert confirmation of fall reports as a mandatory second step [4, 77, 81, 88]. Buchner *et al.* [4] reported that only a few falls which had been reported by participants were rejected by a blinded review committee.

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Table 2. Fall outcome measurement (n = 90)

Number of falls: documented in 58 studies (63%)
Number of falls [2,3,5–8,10,12–16,19,20,25–27,29,31,33–37,39–41,45,48,50,51,54,55,57–60,62,64,67,69–71,74,75,76,78–80,81,83–86], number of multiple fallers [80,81], medical care falls[9,26,33,39,47,48,59], fracture falls [19,20,26,45,47,48], number of injury falls [6,9,11,19,26,27,35,39,46–48,51,57–59,79–81], number of treatable injurious falls [84], requiring hospital admission [26,33,39,43,55], resulting in A&E attendance [33,39,55], number of excessive falls [3], number of any event (including falls) [9]

Number of fallers: documented in 71 studies (80%)
Number of fallers, including percentage of fallers [1–4,6,9,11–14,16–21,23,24,25,26, 27–37,40–45,47,49–51,53,55,59,61,63–66,68,70,71,73,74,77,78,80,81,86–88,90], fallers in last 3 months [89], number of non-fallers [20], sustaining medical care [16,26,59,61,66], sustaining fracture falls [1,26,29,37,41,49,52,53,65], sustaining injury (including serious injury) [12,16,26,29,41,50,55,59,61,63,66,68,81], sustaining adverse effects [3,10,24,31,39,59], fall-related hip fracture/fracture of radius or ankle [52], number sustaining one fall [20,80], number sustaining two or more falls [6,9,11,19,26,27,35,39,46,47,48,51,57,58,59,68, 70,74,75,78,80,81], sustaining three or more falls [12,25,37,81], sustaining fall resulting in A&E attendance [15] or hospital admission [25,26,57], sustaining 'balance' falls [34], number sustaining non-accidental falls [34], sustaining fall resulting in laceration [29], sustaining fall with skin injury/other fall-related injuries [53]

Fall rates: documented in 44 studies (49%)
Mean number of falls per participant/person [3,4,16,17,22,25,29,37,38,42,43,45,49,52,64], median number of falls [12,25,37,55], mean number of injury fall [38,68], falls/person/100 months [84], injurious falls/person/100 months [84], rate per 1,000 person years[2,26,32], fall rate per 100 person-years [20,41,48,57], injurious falls per 100 person-years [41,46,48,57], falls per person-week [3,37,59], falls per 100 patient-days [63], falls per 1000 days [27], falls per 1,000 resident weeks [53], falls per 1,000 occupied bed days [79], fall-related injuries per 10,000 occupied bed days [79], fall-related skin injuries/fractures/other injuries per 1,000 resident weeks [53], non-vertebral fracture rate per 1,000 patient years [52], fall/person who falls/slip/person who slips/trip/person who trips rate per 100 person-months [56], falls per person-month [19,82], fall rate per person-year [6,7,16,31,68,74,78,81], cumulative fall incidence percentage of fallers [14], injurious falls/person/year [81], serious injurious falls/10 person/year [81], fall incidence of first fall/month/person [47], mean number of falls per group [39], rate of medical care falls [57], rate of reduction of falls [32], falls rate adjusted for physical activity [50]

Location and characteristics of fall: documented in 8 studies (9%)
Number sustaining a fall indoors [34], number falling at home/away from home [16], fall rate of falls sustained outside/indoors [14,57], number sustaining fall outdoors [20], fall rate of falls indoors involving environmental hazard [57], location of fall [22,35], time/activity/footwear/perceived cause of fall [22], number of falls from bed [58], number of falls occurring elsewhere (ambulation/transfer) [58]

Time to event: documented in 17 studies (19%)
Time to first fall [2,4,16,18,25–27,31,35,42,47,55,56,59,74,86], time to fall for sub-samples of function [87], time to first slip or trip [56], time to one or more falls [67], time to one or more injurious falls [67], time trend for falls over time (quartiles) [2]

Unattributed events: documented in 19 studies (21%)
Number of GP visits/number of hospital visits/number of hospital admissions [12], number requiring hospitalisation [14,43], number requiring hospital admission unrelated to falls [43], number of admission days [8,14,53], number admitted to institutions for more than 6 months [8], mean length of stay in institutions [8], number of bed-days [14,66], number of days with restricted activity [66], hospitalisation rates [49], frequency of hospitalisations [53], number of fall prevention changes made [51], type of fall prevention change made [51], impact of degree of disability on fall outcome [65], number of syncope events [29], combined falls and syncope [29], number of injuries [33], number sustaining hip fracture [2,55], fracture rate (percentage) [73,78], number sustaining spinal fracture [20], number needed to treat [18,27], number of bed-days with a fall or fall-related problem [33], number of any event or other events resulting in injury or medical treatment [9], cumulative incidence of first fracture [14], cumulative incidence of medical consultations[14]

A comprehensive, non-exclusive fall definition is to be preferred and is recommended for future research. Definitions need to be simple, and understood reliably by lay people, who document their own falls. This could be supplemented by a further subclassification of falls by time, location, activity, etc., when further documented by staff. This is in concordance with a recently published consensus statement that recommends a fall to be defined as 'an unexpected event in which the participant comes to rest on the ground, floor, or lower level'. Including the lay perspective participants should be asked: '. . . have you had any fall including a slip or trip in which you lost your balance and landed on the floor or ground or lower level?' [**98**].

Fall reports

The method used to report falls also remains problematic and highly variable.

Only one study investigated adherence to the reporting system, documenting poor results [30]. There are some conflicting reports on the accuracy of different data collection methods [**98–101**]. Routine health care records are limited by their quality and availability in different settings. In the community they are of little use since they record less than 20% of the fall events reported by patients [**100**]. Prospective registration systems are superior, but the issue of under- or over-reporting still remains unsettled [**102**]. The recall period is a substantial source of variation in the number of falls reported. Fall diaries can lead to a substantial increase in reported falls compared to report without a diary—a classic Hawthorne effect [**103**, **104**]. The validity of reporting systems was not referenced in any study and only some studies gave references of a former use in previous intervention studies or common data sets.

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Table 3. Most frequent methods of summarising fall outcomes

Data reported (n = 90)	Frequency (%)
Number of participants sustaining a fall	62 (70%)
Sustaining medical care falls	7 (8%)
Sustaining fracture falls	9 (10%)
Sustaining injury falls (including serious injury)	13 (15%)
Sustaining two or more falls	22 (25%)
Number of falls	54 (61%)
Injurious falls	18 (20%)
Medical care falls	7 (8%)
Falls leading to a fracture	6 (7%)
Requiring hospital admission	5 (6%)
Fall rates	
Mean number of falls per participant	15 (17%)
Non-specified falls/per person/[time denominator variable]	25 (28%)
Time to event: time to first fall	16 (18%)

Methods of fall documentation used in five or more studies.

Three systems of prospective reporting have been used in the reviewed articles: calendar, diary and postcard. The accuracy of each reporting system is difficult to determine [**101**]. More work is needed to establish methodological rigour. Even the difference between prospective and retrospective systems is difficult to clarify since both approaches were frequently used in the same study. Prospective systems often have a back-up retrospective recall (e.g. by a telephone call), thus introducing retrospective recall error into the data [**105**], sufficient to introduce significant deviation in outcome [**102**].

Fall prevention studies need a long follow-up [**91**, **99**, **106**] for sufficient events to occur, and to ensure longer term effects of interventions can be detected. However, to maximise accuracy the recall period over which participants report the absence or presence of a fall event must be short. The implication is that studies will require intensive follow-up over long periods. The cited consensus expert meeting recommended prospective daily recording and adequate surveillance of documentation and ascertainment of details of falls at least once a month [**98**].

Fall documentation

The way the data were summarised differed across articles. Although statistical analysis was not the target of this review we observed that the choice of summarising the primary outcome corresponded to different statistical procedures. This exacerbates the problems of evaluating and comparing different interventions for fall prevention [**93**]. For example, time to event data are perhaps best approached using Cox's proportional hazard modelling, whilst binomial event data are analysed using logistic regression. Defining falls in terms of resource use was common, but is not recommended for international comparison, where access and provision of services may vary substantially.

For better comparability of study results, a core set of fall outcome measures including number of falls, fallers, fall rate and time to first fall (as a safety measure) to summarise fall data along with a standardised statistical analysis indicating the absolute risk difference between groups will improve reporting standards for future intervention trials [**98**].

Limitations of the study

This study has some limitations since only randomised controlled studies were included. We are aware that by such preselection available information may have been neglected, especially in terms of descriptive epidemiological studies. However, such an approach covers most relevant, high-quality intervention studies and documents the current understanding and methodological practice in this research field.

To conclude, in this systematic review a substantial heterogeneity in fall definitions, the way falls are documented and analysed was identified. We need to standardise methods in fall prevention if advances are to be made. Based on this review, recommendations for the use and standardisation of these and additional methodological aspects related to fall prevention have been developed in an expert consensus conference by the ProFaNE group [**98**].

Key points

- A large variation in parameters was found indicating a substantial lack of standardisation in the use and application of terminology and documentation methods concerning falls.
- A comprehensive, non-exclusive fall definition is recommended for future research. Definitions need to be simple, and understood reliably by lay people, who document their own falls.
- Prospective daily recording of falls, surveillance of documentation and ascertainment of details of falls are recommended.
- For better comparability of study results, a core set of fall outcome measures is recommended.

Acknowledgements

The authors wish to thank Lesley Gillespie from the Cochrane Working group of fall prevention for cooperation in identifying previously published fall prevention trials. The authors are participants of a thematic network (PROFANE-Network) which is funded by the European Commission (QLRT-2001-02705) (Key Action #6; the ageing population and their disabilities; Quality of Life and Management of Living Resources Program). The content of the manuscript does not represent the opinion of the European Community and the Community is not responsible for any use that might be made of the information presented in the text.

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PLEASE NOTE: The very long list of references supporting this review has meant that only the most important are listed here and are represented by bold type throughout the text. References 1–90 are available on the journal website (http://www.ageing.oxfordjournals.org/).

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Received 2 February 2005; accepted in revised form 4 October 2005

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