Exercise for preventing falls in older people living in the community

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Published in:
Cochrane Database of Systematic Reviews

DOI:
10.1002/14651858.CD012424

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Exercise for preventing falls in older people living in the community.
Cochrane Database of Systematic Reviews 2016, Issue 11. Art. No.: CD012424.
DOI: 10.1002/14651858.CD012424.

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[Intervention Protocol]

Exercise for preventing falls in older people living in the community

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Editorial group: Cochrane Bone, Joint and Muscle Trauma Group.
Publication status and date: New, published in Issue 11, 2016.

Citation: Sherrington C, Tiedemann A, Fairhall NJ, Hopewell S, Michaleff ZA, Howard K, Clemson L, Lamb SE. Exercise for preventing falls in older people living in the community. *Cochrane Database of Systematic Reviews* 2016, Issue 11. Art. No.: CD012424. DOI: 10.1002/14651858.CD012424.

ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effects (benefits and harms) of exercise interventions for preventing falls in older people living in the community.

BACKGROUND

Description of the condition

About a third of community-dwelling people over 65 years of age fall each year (Campbell 1990; Tinetti 1988) and the rate of fall-related injuries increases with age (Peel 2002). Falls can have serious consequences such as fractures and head injuries (Peel 2002). Around 10% of falls result in a fracture (Campbell 1990; Tinetti 1988); fall-associated fractures in older people are a significant source of morbidity and mortality (Burns 2016). Although most fall-related injuries, such as bruising, lacerations and sprains, are less serious, they can still lead to pain, reduced function and substantial healthcare costs (Burns 2016).

Falls are associated with reduced quality of life (Stenhagen 2014) and can have psychological consequences: fear of falling and loss of confidence that can result in self-restricted activity levels leading to a reduction in physical function and social interactions (Yardley 2002). Paradoxically, this restriction of activities may increase the risk of further falls by contributing to deterioration in physical abilities. Both injurious and non-injurious falls can have these psychological and subsequent physical impacts.

Despite early attempts to achieve a consensus definition of 'a fall' (Anonymous 1987), many definitions still exist in the literature. It is particularly important for studies to use a clear, simple definition of a fall. An international researchers' consensus statement defines a fall as "an unexpected event in which the participant comes to rest on the ground, floor, or lower level" (Lamb 2005). The wording recommended when asking study participants is: "In the

past month, 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?" (Lamb 2005). 'Lower level' refers to a surface lower than the person's starting position so, for example, falling from a standing position to unintentionally sitting on a bed would be considered a fall.

In addition to the physical and psychological consequences for individuals and their families, falls can have important financial impacts on individuals, families and health and community care systems (Burns 2016). For example, falling is an independent predictor of admission to residential aged care facilities (Tinetti 1997).

Description of the intervention

Exercise is a physical activity that is planned, structured and repetitive and aims to improve or maintain physical fitness (Caspersen 1985). There is a wide range of possible types of exercise such as strengthening exercise, balance and co-ordination exercise and aerobic exercise. Exercise programmes often include one or more types of exercise. The Prevention of Falls Network Europe (ProFaNE) developed a taxonomy that classifies exercise type as primarily: i) gait, balance, and functional [task] training; ii) strength/resistance (including power); iii) flexibility; iv) three-dimensional (3D) exercise (e.g. Tai Chi, Qigong, dance); v) general physical activity; vi) endurance; and vii) other kind of exercises (Lamb 2011). Formal exercise programmes are delivered by a wide range of individuals ranging from health professionals (such as physiotherapists) and exercise professionals (such as trained fitness leaders) to trained volunteers. Exercise programmes may be supervised, unsupervised or involve a mixture of both.

This review will consider all types of exercise and all delivery methods.

Exercise can also be delivered as part of a multiple component intervention, where people also receive one or more other fall or fracture prevention intervention, such as home-hazard modification and vitamin D supplementation. The effects of multiple component interventions that include exercise will be assessed in Hopewell 2016.

How the intervention might work

Many aspects of physical functioning deteriorate with increased age and inactivity. Impairments in muscle strength, balance control and gait are particularly strong risk factors for falls. For example, those with poor leg extensor strength were found to be 43% more likely to fall at home than their stronger counterparts (Menant 2016). Systematic reviews have found that those with gait problems have twice the odds of falling than those without (Deandrea 2010) and that measures of balance and mobility such as the Berg Balance Scale score, Timed Up and Go test, and five times sit-to-stand test can identify individuals at greater risk of future falls (Lusardi 2016).

Exercises that address these impairments are therefore likely to reduce the risk of falling. As Cochrane reviews have now found that exercise improves both strength (Liu 2009) and balance (Howe 2011) in older people, exercise is likely to have a fall prevention effect through its impact on these key fall risk factors. A Cochrane review found that exercise reduces the fear of falling (Kendrick 2014), which is also a strong predictor of falls.

Exercise is the most commonly tested single fall prevention intervention and has been found to prevent falls (Gillespie 2012). Exercise has been suggested to be a cost-effective fall-prevention strategy in economic evaluations accompanying randomised trials (Davis 2010).

Exercise interventions have been found to be effective when delivered in a group-based or individual home-based setting. The optimal features of successful fall prevention exercise programmes are not yet clear but programmes that are multi-component (e.g. target both strength and balance) (Gillespie 2012) and programmes that include balance training appear to be particularly effective (Sherrington 2011).

Different approaches to exercise will have advantages and disadvantages in terms of cost, 'enjoyability', accessibility and impacts on different body systems and outcomes. These advantages and disadvantages are likely to be different for different individuals and different settings.

Exercise has the potential to lead to adverse events such as cardiovascular episodes and musculoskeletal injuries if not carefully prescribed and undertaken (Thompson 2013). Exercise may also increase the risk of falls, particularly in higher risk individuals. For example, exercise interventions aiming to improve balance and ultimately lessen the risk of falling often involve a 'challenge' to balance that simultaneously puts the person at greater risk of falling (Sherrington 2011). The risk may be increased if an exercise participant becomes fatigued (due to deconditioning or as a result of co-morbidities or medications) or are not encouraged to use support when needed (Skelton 2001). Trials and reviews should therefore record and report adverse events.

As the majority of fractures in older people involve falls, exercise has the potential to prevent fractures. Systematic reviews by Gillespie 2012 and Robertson 2002 have suggested that exercise may prevent fractures and fall-related injuries.

Why it is important to do this review

An update of the effects of exercise interventions on falls is warranted given the number of new trials published, the increasing number of older people living in the community and the major long-term consequences associated with falls and fall-related injuries to both the individual and to society.

It is also important to understand to what extent interventions designed to prevent falls will also prevent fall-associated fractures.

Different exercise programmes may have different effects on falls and so careful analysis of the impact of different programmes is crucial. Additionally, looking for adverse effects associated with the different exercise programmes, such as exercise-related falls and muscle strains, is also important.

OBJECTIVES

To assess the effects (benefits and harms) of exercise interventions for preventing falls in older people living in the community.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials, either individual or cluster randomised, evaluating the effects of exercise interventions on the incidence of falls in older people living in the community. We will exclude trials that explicitly use methods of quasi-randomisation (e.g. allocation to groups by alternation or date of birth).

Types of participants

We will include trials if they specify an inclusion criterion of 60 years of age or over. Trials that include younger participants will be included if the mean age minus one standard deviation is more than 60 years. We propose to include trials where the majority of participants were living in the community, either at home or in places of residence that, on the whole, do not provide residential health-related care or rehabilitative services; for example, hostels (in Australia), retirement villages, or sheltered housing. Trials with mixed populations (community and higher dependency places of residence) will be eligible for inclusion if data are provided for subgroups based on setting or the numbers in higher dependency residences are very few and balanced in the comparison groups.

We propose to include trials recruiting participants in hospital if the majority were discharged to the community (where the majority of the intervention was delivered and falls were recorded).

We will exclude studies that test exercise interventions for preventing falls in people affected by particular clinical conditions such as stroke, Parkinson's disease, multiple sclerosis and dementia. Several of these topic areas are covered by other Cochrane reviews (Canning 2015; Verheyden 2013). We acknowledge that some individuals with these (and other) health conditions may be included in studies of the general community but will only exclude studies in which all participants have a particular condition.

Types of interventions

This review will include all exercise interventions tested in trials that measure falls in older people. The intention is to include trials where exercise is a single intervention as opposed to a component of a broader intervention. We will include trials where an additional low-contact intervention (e.g. information on fall prevention) was given to one or both groups if we judge that the main purpose of the study was to investigate the role of exercise.

Based on the ProFaNE taxonomy (Lamb 2011), we will group exercises in the following main categories: i) gait, balance, and functional training; ii) strength/resistance training; iii) flexibility; iv) three-dimensional (3D) exercise; iv) general physical activity; v) endurance; vi) other kind of exercises. We will also form another category for exercise programmes that include more than one of the above categories. The descriptions of interventions used in individual trials will be examined and the intervention categorised accordingly. For example, some forms of yoga may be categorised as flexibility exercise and others as 3D exercise. We will compare each of these types of exercise with control comprising either 'usual care' (i.e. no change in usual activities) or a control intervention (i.e. an intervention that is not thought to reduce falls, such as general health education, social visits or very gentle exercise not expected to impact on falls).

Thus for our first umbrella comparison of exercise versus control, we will make the following comparisons:

i) gait, balance, co-ordination and functional task training versus control;

ii) strengthening exercises (including resistance and power training) versus control;

iii) flexibility training versus control;

iii) three-dimensional (3D) exercise (including Tai Chi, Qigong and dance) versus control;

iv) general physical activity versus control;

v) endurance training versus control;

vi) other kinds of exercises versus control;

vii) exercise programmes including more than one of the above categories versus control.

We also plan to compare the following:

a) different types of exercise based on the above categories;

b) different intensities (higher versus lower intensity) of the same type of exercise;

c) different modes of delivery (e.g. group versus individual) of the same type of exercise.

Exercise programme uptake, duration, frequency, intensity and individual- or group-based delivery, level of supervision, adverse events and additional information or support given to participants are expected to vary in the included trials; these characteristics will be noted and reported in our review.

Types of outcome measures

Primary outcomes

- Rate of falls (falls per person-years).

Secondary outcomes

- Number of people who experienced one or more falls (risk of falling).
- Number of people who experienced one or more fall-related fractures.
- Number of people who experienced one or more falls that required medical attention.
- Number of people who experienced one or more adverse effects of intervention.

The rate of falls has been chosen as the single primary outcome for ease of interpretation of the results of the review. Furthermore the rate of falls is likely to be more sensitive to change than the proportion of fallers, especially in samples with high fall rates. As falls are count data, dichotomisation to falling versus not falling represents a loss of information. Therefore many trials use the rate of falls as their primary outcome and use negative binomial regression to compare the rates between intervention and control groups as recommended in Robertson 2005.
We will record and report intervention adherence data where available for use in the interpretation of trial and review findings.
We will extract cost and cost-effectiveness data, where available.

Timing of outcome measurement

We will make assessments at short-term (less than 18 months) and long-term (18 months or longer) follow-up. For studies with less than 18 months of follow-up, we will use the longest duration reported.

Search methods for identification of studies

Electronic searches

Our search will extend the searches performed up to February 2012 in Gillespie 2012. We will search the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (February 2012 to present), the Cochrane Central Register of Controlled Trials (CENTRAL) (Cochrane Register of Studies Online) (2012 Issue 3 to current issue), MEDLINE (March 2012 to present), Embase (March 2012 to present), the Cumulative Index to Nursing and Allied Health Literature (CINAHL) (February 2012 to present) and the Physiotherapy Evidence Database (PEDro) (2012 to present), using tailored search strategies. We will not apply any language restrictions.
In MEDLINE, we will combine subject-specific search terms with the sensitivity- and precision-maximising version of the Cochrane Highly Sensitive Search Strategy for identifying randomised trials (Lefebvre 2011). The search strategies for CENTRAL, MEDLINE, Embase, CINAHL and PEDro are shown in Appendix 1.
We will also search the World Health Organisation International Clinical Trials Registry Platform (WHO ICTRP) and ClinicalTrials.gov for ongoing and recently completed trials.

Searching other resources

We will check reference lists of other systematic reviews as well as contacting researchers in the field to assist in the identification of ongoing and recently completed trials.

Data collection and analysis

Selection of studies

Pairs of review authors (CS, AT, NJF, ZAM) will screen the title, abstract and descriptors of identified studies for possible inclusion. From the full text, two review authors (CS, AT, NJF, ZAM) will independently assess potentially eligible trials for inclusion and resolve any disagreement through discussion. We will contact authors for additional information if necessary.

Data extraction and management

Pairs of review authors will independently extract data using a pretested data extraction form (based on the one used in Gillespie 2012). We will extract data from both newly included trials and those included in Gillespie 2012. For the latter trials, however, we will only extract information and data for additional outcomes that were not collected previously for Gillespie 2012. Disagreement will be resolved by consensus or third party adjudication. Review authors will not be blinded to authors and sources. They will not assess their own trials.
We will use the standardised data extraction form to record the following items.

- General information: review author's name; date of data extraction; study ID; first author of study; author's contact address (if available); citation of paper; and trial objectives.
- Trial details: trial design; location; setting; sample size; inclusion and exclusion criteria; comparability of groups; length of follow-up; stratification; stopping rules; and funding source.
- 'Risk of bias' assessment: sequence generation; allocation concealment; blinding (participants, personnel, outcome assessors); incomplete outcome data; selective outcome reporting; and other bias (recall bias).
- Characteristics of participants: age; gender; ethnicity; the number randomised, analysed and lost to follow-up; and dropouts in each arm (with reasons).

- Interventions: experimental and control interventions; timing of intervention; uptake of intervention, whether studies assessed adherence (compliance) with interventions and associated data; and additional co-interventions (such as motivational strategies) .
- Outcomes measured: rate of falls; number of people experiencing one or more falls; number of people sustaining one or more fall-related fractures; number of people who experienced one or more falls requiring medical attention; and number of people who experienced adverse effects of the interventions.
- Other details: cost and cost-effectiveness information.

We will retrieve data from both full-text and abstract reports of studies. Where these sources do not provide sufficient information, we will contact study authors for additional details.

Assessment of risk of bias in included studies

Pairs of two review authors (CS, AT, NJF, ZAM, SH, SEL) will independently assess risk of bias using Cochrane's 'Risk of bias' tool as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Review authors will not be blinded to authors and sources. Review authors will not assess their own trials. Disagreement will be resolved by consensus or third party adjudication (CS, SEL).

As outlined in Appendix 2, we will assess the following domains: random sequence generation (selection bias); allocation concealment (selection bias); blinding of participants and personnel (performance bias); blinding of outcome assessment (detection bias, for each outcome separately); incomplete outcome data (attrition bias); and selective outcome reporting bias. We will also assess bias in the recall of falls due to less reliable methods of ascertainment (Hannan 2010). Regarding risk of bias, we will rate this as either low, high or unclear for each domain.

Measures of treatment effect

We will report the treatment effects for rate of falls as rate ratios (RaRs) with 95% confidence intervals (CIs). For the number of fallers, number of participants sustaining fall-related fractures and number of participants experiencing falls that required medical attention, we will report risk ratios (RRs) and 95% CIs.

The rate of falls is the total number of falls per unit of person-time that falls were monitored (e.g. falls per person-year). The RaR compares the rate of falls in any two groups during each trial. We will use a RaR (for example, incidence RaR or hazard ratio for all falls) with 95% CI if these were reported in the paper. If both adjusted and unadjusted RaRs were reported, we will use the unadjusted estimate unless the adjustment was for clustering. If a RaR was not reported but appropriate raw data are available, we will use Excel to calculate a RaR and 95% CI. We will use the reported rate of falls (falls per person-year) in each group and the total number of falls for participants contributing data, or we will calculate the rate of falls in each group from the total number of falls and the actual total length of time falls were monitored (person-years) for participants contributing data. In cases where data were only available for people who had completed the study, or where the trial authors had stated there were no losses to follow-up, we will assume that these participants had been followed up for the maximum possible period.

For number of fallers, a dichotomous outcome, we will use RR as the treatment effect. The RR compares the number of people who fell once or more (fallers) between groups. We will use a reported estimate of risk (hazard ratio for first fall, risk ratio (relative risk), or odds ratio) and 95% CI if available. If both adjusted and unadjusted estimates were reported we will use the unadjusted estimate, unless the adjustment was for clustering. If an odds ratio was reported, or an effect estimate and 95% CI was not, and appropriate data were available, we will calculate a RR and 95% CI using the 'csi' command in Stata. For the calculations we will use the number of participants contributing data in each group if this is known; if not reported we will use the number randomised to each group. The same approach will be used for the number of people sustaining fractures, the number of people experiencing falls requiring medical attention and the number of people experiencing adverse events.

Unit of analysis issues

For trials which were cluster-randomised, for example by medical practice, we will perform adjustments for clustering, as described in Higgins 2011, if this was not done in the published report. We will use an intra-class correlation coefficient (ICC) of 0.01 as reported in Smeeth 2002. We will ignore the possibility of a clustering effect in trials randomising by household.

For trials with multiple arms, we will include multiple pair-wise comparisons (intervention versus control) in analyses but in order to avoid the same group of participants being included twice, we will 'split' the control group by distributing the number of control group participants to each analysis in proportion to the number of participants in each intervention group.

Dealing with missing data

Some missing data is inevitable in studies of older people given the increased risk of ill health and death and the length of delivery of the intervention in fall prevention trials. We will attempt to contact study investigators for any key missing or unclear data or information on their trial. Sensitivity analyses will be undertaken excluding trials with more than 20% loss to follow-up and trials where a 'per protocol' analysis was used: i.e. those who did not complete exercise programmes were excluded from the analysis.

Assessment of heterogeneity

The decision about whether or not to combine the results of individual studies will depend on an assessment of clinical and methodological heterogeneity. If studies are considered sufficiently homogeneous in their study design, we will carry out meta-analyses and assess the statistical heterogeneity. Statistical heterogeneity of treatment effects between trials will be assessed by visual inspection of the graphs and using the Chi² test (with a significance level at $P < 0.10$) and the I^2 statistic. We will base our interpretation of the I^2 results on that suggested by Higgins 2011: 0% to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 50% to 90% may represent substantial heterogeneity; and 75% to 100% may represent very substantial ('considerable') heterogeneity.

Assessment of reporting biases

To explore the possibility of publication and other reporting biases, we will construct funnel plots for analyses that contain more than 10 data points.

Data synthesis

We will group similar exercise interventions using the fall prevention classification system (taxonomy) developed by the Prevention of Falls Network Europe (ProFaNE) (Lamb 2011). Full details are available in the ProFaNE Taxonomy Manual.

When considered appropriate, we will pool results of comparable studies using both fixed-effect and random-effects models. The choice of the model to report will be guided by careful consideration of the extent of heterogeneity and whether it can be explained, in addition to other factors, such as the number and size of included studies. Ninety-five per cent CIs will be used throughout. We will consider not pooling data where there is considerable heterogeneity ($I^2 \geq 75\%$) that cannot be explained by the diversity of methodological or clinical features among trials. Where it is inappropriate to pool data, we will still present trial data in the analyses or tables for illustrative purposes and will report these in the text.

When considered appropriate, we will pool data using the generic inverse variance method in Review Manager 5 (RevMan 5.3). This method enables pooling of the adjusted and unadjusted treatment effect estimates (rate ratios or risk ratios) reported in the individual studies or which can be calculated from data presented in the published article (*see* Measures of treatment effect). The generic inverse variance option in Review Manager 5 requires entering the natural logarithm of the rate ratio or risk ratio and its standard error for each trial; we will calculate these in Excel.

Subgroup analysis and investigation of heterogeneity

If there are sufficient trials we will use subgroup analyses to compare effects within the categories of exercise outlined above. We will carry out subgroup analyses that compare effects in trials of a) higher versus lower falls risk at enrolment (i.e. trials with participants selected for inclusion based on history of falling or other specific risk factors for falling versus trials with unselected participants), b) individual versus group-based exercise and c) exercise delivered by people with different qualifications (e.g. health professionals versus trained fitness leaders).

We will use the test for subgroup differences available in RevMan 5.3 to determine whether there is evidence for a difference in treatment effect between subgroups.

Sensitivity analysis

We will carry out sensitivity analyses to explore the possible impact of risk of bias on statistically significant pooled estimates of treatment effect. We will remove trials from pooled analyses if they are assessed as high risk of bias in one or more key domains: random sequence generation (selection bias), allocation concealment (selection bias), blinding of outcome assessors (detection bias) and incomplete outcome data (attrition bias) (*see* Table 8.7.a; Higgins 2011).

We will examine the impact on the results of the choice of statistical model for pooling (fixed-effect versus random-effects) and cluster versus individual randomised trials.

Assessing the quality of the evidence and 'Summary of findings' tables

We will use the GRADE approach to assess the quality of evidence related to the primary and secondary outcomes listed in the Types of outcome measures (Schünemann 2011). The quality rating 'high' is reserved for a body of evidence based on randomised controlled trials. We may downgrade the quality rating to 'moderate', 'low' or 'very low' depending on the presence and extent of five factors: study limitations; inconsistency of effect; imprecision; indirectness; or publication bias. Where there is sufficient evidence, we will prepare 'Summary of findings' tables featuring the primary outcome and secondary outcomes for the different comparisons described in the Types of interventions.

ACKNOWLEDGEMENTS

We are grateful to Helen Handoll, Dawn Skelton and Janet Wale for helpful comments on drafts of this protocol. We thank Joanne Elliott for her assistance with developing the search strategy and Lindsey Elstub for editorial support. We are also grateful to the review authors, particularly Lesley Gillespie and Clare Robertson, of Gillespie 2012 for the development of methods and procedures.

This project was supported by the National Institute for Health Research via Cochrane Infrastructure funding to the Cochrane Bone, Joint and Muscle Trauma Group. The views and opinions

expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search strategies

CENTRAL (CRS Online)

#1 MESH DESCRIPTOR Accidental Falls
#2 (falls or faller*):TI,AB,KY
#3 #1 OR #2
#4 MESH DESCRIPTOR Aged EXPLODE ALL TREES
#5 (senior*1 or elder* or old* or aged or ag?ing or postmenopausal or community dwelling):TI,AB,KY
#6 #4 OR #5
#7 #3 AND #6

MEDLINE (Ovid Interface)

1 Accidental Falls/
2 (falls or faller$1).tw.
3 or/1-2
4 exp Aged/
5 (senior*1 or elder* or old* or aged or ag?ing or postmenopausal or community dwelling).tw.
6 or/4-5
7 3 and 6
8 Randomized controlled trial.pt.
9 Controlled clinical trial.pt.
10 randomized.ab.
11 placebo.ab.
12 Clinical trials as topic/
13 randomly.ab.
14 trial.ti.
15 8 or 9 or 10 or 11 or 12 or 13 or 14
16 exp Animals/ not Humans/
17 15 not 16
19 7 and 17

Embase (Ovid Interface)

1 Falling/
2 (falls or fallers).tw.
3 or/1-2
4 exp Aged/
5 (senior*1 or elder* or old* or aged or ag?ing or postmenopausal or community dwelling).tw.
6 or/4-5
7 3 and 6
8 exp Randomized Controlled Trial/ or exp Single Blind Procedure/ or exp Double Blind Procedure/ or Crossover Procedure/
9 (random* or RCT or placebo or allocat* or crossover* or 'cross over' or trial or (doubl* adj1 blind*) or (singl* adj1 blind*)).ti,ab.
10 8 or 9
11 (exp Animal/ or animal.hw. or Nonhuman/) not (exp Human/ or Human cell/ or (human or humans).ti.)
12 10 not 11
13 7 and 12

CINAHL (Ebsco)

S1 (MH "Accidental Falls")
S2 TI (falls or faller*) OR AB (falls or faller*)
S3 S1 OR S2
S4 (MH "Aged+")
S5 TI (senior* or elder* or old* or aged or ag?ing or postmenopausal or community dwelling) OR AB (senior* or elder* or old* or aged or ag?ing or postmenopausal or community dwelling)
S6 S4 OR S5
S7 S3 AND S6
S8 PT Clinical Trial
S9 (MH "Clinical Trials+")
S10 TI clinical trial* OR AB clinical trial*
S11 TI ((single blind* or double blind*)) OR AB ((single blind* or double blind*))
S12 TI random* OR AB random*
S13 S8 OR S9 OR S10 OR S11 OR S12
S14 S7 AND S13

PEDro

Advanced search option selected
Abstract and Title: Fall*
Method: Clinical trial
Sub discipline: gerontology
New record added since: (date of last review entered here)

Appendix 2. 'Risk of bias' assessment tool

Domain	Criteria for judging risk of bias
Random sequence generation relating to selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence	• Judgement of 'low risk' if the trial authors described a random component in the sequence generation, e.g. referring to a random number table; using a computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots; minimisation. • Judgement of 'high risk' if the trial used a systematic non-random method, e.g. date of admission; odd or even date of birth; case record number; clinician judgement; participant preference; patient risk factor score or test results; availability of intervention. • Judgement of 'unclear risk' if there is insufficient information about the sequence generation process to permit judgement of 'low risk' or 'high risk'.
Allocation concealment relating to selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment	• Judgement of 'low risk' in studies using: ○ individual randomisation if the trial described allocation concealment as by central allocation (telephone, internet-based or pharmacy-controlled randomisation); sequentially-numbered identical drug containers; sequentially-

(*Continued*)

	numbered, opaque, sealed envelopes; ○ cluster randomisation if allocation of all cluster units performed at the start of the study and individual participant recruitment was completed prior to assignment of the cluster, and the same participants were followed up over time or individual participants were recruited after cluster assignment, but recruitment carried out by a person unaware of group allocation and participant characteristics (e.g. fall history) or individual participants in intervention and control arms were invited by mail questionnaire with identical information. • Judgement of 'high risk' in studies using: ○ individual randomisation if investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, e.g. using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes unsealed, non-opaque, or not sequentially numbered; alternation or rotation; date of birth; case record number; or any other explicitly unconcealed procedure; ○ cluster-randomisation if individual participant recruitment was undertaken after group allocation by a person who was unblinded and may have had knowledge of participant characteristics. • Judgement of 'unclear risk' if insufficient information to permit judgement of 'low risk' or 'high risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement, e.g. if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.
Blinding of participants and personnel relating to performance bias due to knowledge of the allocated interventions by participants and personnel carrying out the interventions	• Judgement of 'low risk' if blinding of participants and personnel implementing the interventions was ensured, and unlikely that the blinding could have been broken but the review authors judge that the outcomes (falls and fractures) are unlikely to be influenced by lack of blinding. • Judgement of 'high risk' if participants or intervention delivery personnel, or both, were not blinded to group allocation (e.g. exercise intervention), and the outcomes (falls and fractures) are likely to be influenced by lack of blinding. • Judgement of 'unclear risk' if there is insufficient information to make a judgement of 'low risk' or 'high risk'.
Blinding of outcome assessment relating to detection bias due to knowledge of the allocated interventions by outcome assessors	• Falls, fallers, medical attention and adverse events: ○ judgement of 'low risk' if outcomes were recorded/confirmed in all allocated groups using the same method and the personnel recording/confirming outcomes were blind to group allocation; ○ judgement of 'high risk' if outcomes were not recorded/confirmed in all allocated groups using the same

(*Continued*)

	method or the personnel recording/confirming outcomes were NOT blind to group allocation; ○ judgement of 'unclear' if there is insufficient information to make a judgement of 'low risk' or 'high risk'. • Fractures: ○ judgement of 'low risk' if fractures were recorded/ confirmed in all allocated groups using the same method and fractures were confirmed by the results of radiological examination or from primary care case records and the personnel recording/confirming fractures were blind to group allocation; ○ judgement of 'high risk' if fractures were not recorded/ confirmed in all allocated groups using the same method or the only evidence for fractures was from self reports from participants or carers; ○ judgement of 'unclear risk' if there is insufficient information to make a judgement of 'low risk' or 'high risk'.
Incomplete outcome data relating to attrition bias due to amount, nature or handling of incomplete outcome data	• Judgement of 'low risk' if there are no missing outcome data, or less than 20% of outcome data are missing and losses are balanced in numbers across intervention groups with similar reasons for missing data across groups or missing data have been imputed using appropriate methods. • Judgement of 'high risk' if greater than 20% of outcome data missing, or reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups, or 'as-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation or potentially inappropriate application of simple imputation. • Judgement of 'unclear risk' if there is insufficient information to make a judgement of 'low risk' or 'high risk'.
Selective outcome reporting relating to bias due to the selective reporting or non-reporting of findings	• Judgement of 'low risk' if the study protocol is available and all prespecified study outcomes are reported in the prespecified way or the study protocol is unavailable but it is clear the published report includes all expected outcomes. • Judgement of 'high risk' if not all prespecified study outcomes are reported, or one or more primary outcomes are reported in ways which were not prespecified, or one or more outcomes are reported incompletely or the study fails to include results for a key outcome that would be expected to be reported. • Judgement of 'unclear risk' if there is insufficient information to make a judgement of 'low risk' or 'high risk'.
Method of ascertaining falls relating to bias in the recall of falls due to unreliable methods of ascertainment	• Judgement of 'low risk' if the study used some form of concurrent collection of data about falling, e.g. participants given postcards to fill in daily and mail back monthly, calendar to mark monthly, or more frequent, follow-up by the researchers. • Judgement of 'high risk' if ascertainment relied on

(*Continued*)

	participant recall at longer intervals than 1 month during the study or at its conclusion. • Judgement of 'unclear risk' if there was retrospective recall over a short period only, or if the trial authors did not describe details of ascertainment, i.e. insufficient information was provided to allow a judgement of 'low risk' or 'high risk'.

We adapted this from Table 8.5.a 'The Cochrane Collaboration's tool for assessing risk of bias' and Table 8.5.d 'Criteria for judging risk of bias in the 'Risk of bias' assessment tool' (Higgins 2011).

CONTRIBUTIONS OF AUTHORS

All authors have contributed to the development of this protocol. Catherine Sherrington is the guarantor of the protocol for this review.

DECLARATIONS OF INTEREST

Several authors (CS, AT, NF, SH, KH and SL) are currently running trials of fall prevention interventions. These trials are all funded by national grant agencies. Review authors will not assess their own trials for risk of bias.

CS, AT and NF have previously published a non-Cochrane systematic review of exercise interventions for falls prevention (Sherrington 2011) and along with ZM, have recently submitted an updated version of this review for publication.

NOTES

This review will provide updated evidence for one of the intervention categories (exercise) covered in the Cochrane review 'Interventions for preventing falls in older people living in the community' (Gillespie 2012). Some of the wording in several sections of this protocol, such as Background/Description of the condition, is taken from Gillespie 2012. This reflects shared authorship of the two publications but also attempts to maintain a continuity with the Gillespie 2012 review, as well as links between our review and other proposed reviews that will cover other intervention categories such as multifactorial and multiple component interventions (Hopewell 2016).