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Multifactorial and multiple component interventions for preventing falls in older people living in the community (Protocol)

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TABLE OF CONTENTS

[Intervention Protocol]

Multifactorial and multiple component interventions for preventing falls in older people living in the community

Sally Hopewell[1], Olubusola Adedire[1], Bethan J Copsey[2], Catherine Sherrington[3], Lindy M Clemson[4], Jacqueline CT Close[5], Sarah E Lamb[2]

[1]Oxford Clinical Trials Research Unit, University of Oxford, Oxford, UK. [2]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford, Oxford, UK. [3]Musculoskeletal Division, The George Institute for Global Health, Sydney Medical School, University of Sydney, Sydney, Australia. [4]Faculty of Health Sciences, University of Sydney, Lidcombe, Australia. [5]Falls, Balance and Injury Research Centre, Neuroscience Research Australia, Randwick, Australia

Contact address: Sally Hopewell, Oxford Clinical Trials Research Unit, University of Oxford, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Windmill Road, Oxford, Oxfordshire, OX3 7LD, UK. sally.hopewell@csm.ox.ac.uk.

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

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

BACKGROUND

Description of the condition

Falls and fall-related injuries are common and a serious problem in older people. People over 65 years of age have the highest risk of falling, with around a one-third of older people living in the community falling at least once per year (Campbell 1990; NICE 2013). The rate of fall-related injuries also increases with age (Peel 2002). Most fall-related injuries are minor, such as bruising, abrasions, lacerations, strains and sprains, but can still cause significant pain and discomfort. However, some falls can have serious long-term consequences, including fall-related fractures and head injuries (Peel 2002). Around 10% of falls result in a fracture (Campbell 1990; Tinetti 1988), and fall-associated fractures in older people are a significant source of morbidity and mortality (Scuffham 2003).

Despite early attempts to achieve a consensus definition of 'a fall' (Kellogg 1987), many definitions still exist in the literature. It is particularly important to have a clear, simple definition for studies in which older people record their own falls as their concept of a fall may differ from that of researchers or healthcare professionals (Zecevic 2006). An international consensus statement defined a fall as "an unexpected event in which the participant comes to rest on the ground, floor or lower level" (Lamb 2005). The recommended wording when asking individuals about falls 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).

Epidemiological studies of varying quality have identified a number of risk factors for falling in community-dwelling older people (Deandrea 2010). These risk factors can be broadly categorised as either intrinsic or extrinsic. Intrinsic fall-related risk factors include advanced age, history of previous falls, muscle weakness, gait and balance problems, poor vision, and chronic diseases such as arthritis, diabetes, stroke, Parkinson's, dementia and incontinence. Extrinsic fall-related risk factors include environmental factors such as lack of hand rails, poor lighting, slippery or uneven surfaces, use of walking aids and poor footwear (Todd 2004). It is estimated that around 15% of falls result from a major external event that would cause most people to fall. A similar percentage of falls result from a single identifiable event such as syncope (fainting). However, most result from multiple interacting factors (e.g. a person has balance problems, poor vision and slips on an uneven surface which results in a fall) (Campbell 2006). Generally, the more risk factors a person has, the greater their chances are of having a fall. Falls can have major psychological consequences, such as a fear of falling and loss of confidence, which can result in self-restricted activity levels and may lead in turn to a reduction in physical function and social interactions (Yardley 2002). There is evidence that exercise interventions in older people living in the community probably reduce fear of falling to a limited extent immediately after the intervention (without increasing the risk or frequency of falls). However, there is insufficient evidence to determine whether this reduces fear beyond the end of the intervention (Kendrick 2014). Falling also puts a strain on the family and is an independent predictor of admission to a nursing home (Tinetti 1997).

Description of the intervention

Many interventions and programmes of interventions for preventing falls have been established and evaluated. These are often based on known modifiable risk factors for falling and some interventions specifically target people at high risk of falling, such as those with a history of falling. Most fall prevention interventions can be classified according to the taxonomy developed by the Prevention of Falls Network Europe (ProFANE) (Lamb 2007; Lamb 2011). Drawing on this, with some modifications that primarily reflect categorisation in Gillespie 2012, the main intervention categories we will use in this review plus examples of individual interventions are shown below.

- Exercises (supervised or unsupervised, or both): including gait, balance and functional training; strength/resistance exercises; flexibility exercises; 3D training (e.g. Tai Chi); general physical activity; endurance training or others.
- Medication (drug target): including vitamin D and calcium supplementation.
- Medication (review): including medication withdrawal, dose reduction or increase, substitution or provision.
- Surgery: including cataract extraction, pacemaker provision, podiatric surgery or others.
- Management of urinary incontinence (e.g. assisted toileting, bladder retraining).
- Fluid or nutrition therapy where the basic objective was to restore the volume and composition of the body fluids to normal with respect to water-electrolyte balance (fluid therapy) or to improve the health status of the individual by adjusting the quantities, qualities and methods of nutrient intake (nutrition therapy).
- Psychological intervention, either individual or in a group: including cognitive (behavioural) interventions.
- Environment/assistive technology: furnishings and adaptations to homes and other premises; aids for personal mobility (e.g. walking aids); aids for communication and signalling (e.g. alarm systems); body-worn aids for personal care and protection (e.g. anti-slip devices for shoes).
- Environment/assistive technology: aids for communication (e.g. eyeglasses, hearing aids). This includes vision assessment.
- Social environment: including staff ratio, staff training, service model change, telephone support, caregiver training, homecare services or others.
- Knowledge/education interventions: including written material, videos and lectures (above the information that is given more generally).

Fall prevention interventions may comprise single component interventions from one of the above categories alone (e.g. balance training) or involve combinations of two or more component interventions from the same category (e.g. exercise) or from different categories (e.g. exercise and medication (drug target)). Delivery of interventions with more than one component intervention from different categories can broadly be divided into the following two main groups.

- Multifactorial interventions where the component interventions are based on individual assessment of risk.
- Multiple component interventions where the same component interventions are provided to all people (Gillespie 2012; Lamb 2005).

We have provided further descriptions of these two groups of interventions below.

Multifactorial interventions are interventions that involve an assessment of an individual to determine the presence of two or more modifiable risk factors for falling, which is then followed by specific interventions targeted to those risk factors (Lamb 2011). Importantly, not all people receive the same combination of interventions. For example, based on an individual's risk profile, one person may receive supervised exercise and home-hazard modification whereas another may receive home-hazard modification and medication modification. The manner in which multifactorial interventions are delivered varies. In some instances, the assessment and linked interventions are by the same provider. In other

instances, one provider may undertake the assessment, but linked interventions are provided through referral to other providers or other routes.

Multiple component interventions are those where people receive a fixed combination of two or more fall prevention interventions from the different categories shown above (Lamb 2011). For example, all people at risk of falling will receive the same combination of component interventions, such as supervised exercise, education and home-hazard modification. Provision is regardless of their underlying risk factor profile, which is not usually assessed as part of the intervention (Gillespie 2012). Hence there is no formal tailoring to the exact risk factor profile of an individual.

How the intervention might work

Fall prevention interventions aim to minimise known modifiable risk factors for falling, and thereby, prevent falls and associated injuries (Todd 2004).

The hypothesis underlying multifactorial interventions is that health providers assess a range of modifiable risk factors for falling and, along with the linked interventions that follow, provide a much more tailored and potentially effective intervention. This assumes a cumulative and reasonably linear association between the number of risk factors and the probability of falling (Tinetti 2003). It assumes all risk factors contribute in a similar way and that increasing the numbers of risk factors assessed reduces the chances of falling, but this assumption may not be true (Gates 2008). Gillespie 2012 found some evidence that multifactorial interventions may reduce the rate of falls (i.e. the total number of falls per unit of person time that falls were monitored), but not the risk of falling (i.e. the number of people who fell once or more). Of note is the wide variation in the risk factors assessed, and both the type and format of matched interventions described in published interventions. Multifactorial interventions are the recommended approach for falls prevention in the UK (NICE 2013) and recommended as a primary treatment strategy in the guideline for prevention of falls published by the American Geriatrics Society, the British Geriatrics Society and the Australian Commission on Safety and Quality in Healthcare (ACSQH 2009; American Geriatrics Society 2011). Implementation of multifactorial interventions is a challenge because of the time involved, skills demand, sometimes the need for coordinated efforts for assessment and intervention delivery (involving multiple health professionals), and associated cost implications (Vieira 2016).

Multiple component interventions also aim to reduce several components of fall risk rather than dealing with single risk factors. However, there is no assessment and individual tailoring of the intervention to risk factors. There is some evidence that multiple component interventions may reduce the rate of falls and risk of falling in older people living in the community. However, additional evidence is needed to determine which are the most effective combinations of component interventions (Gillespie 2012). It might be simpler and cheaper not to undertake complex assessments, but to focus on interventions for the most common risk factors and provide these to all, regardless of exact risk status.

Why it is important to do this review

There is some evidence for the effectiveness of multifactorial interventions and multiple component interventions to prevent falls in older people living in the community based on the findings of a Cochrane review (Gillespie 2012). An update of the effects of these interventions 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 (including disability and reduced quality of life) to both the individual and to society. In the UK, the National Health Service (NHS) is estimated to spend around GBP 2.3 billion each year on fall-related injuries in people over the age of 65 (NICE 2013). Evidence is needed on which interventions are most effective in reducing falls and fall-related injuries; the results of which will be of major importance to healthcare professionals, policy makers, consumers, researchers and others with an interest in this topic.

OBJECTIVES

To assess the effects (benefits and harms) of multifactorial interventions and multiple component 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, that evaluate the effects of multifactorial interventions and multiple component 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 studies of interventions to prevent falls if they specify an inclusion criterion of participants aged 60 years or over. Also, we will include studies that include younger participants if

the mean age minus one standard deviation (SD) is more than 60 years. We will include studies where most participants who are recruited are 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. Studies with mixed populations (community and higher dependency places of residence) will be eligible for inclusion provided separate data are available for those participants living in the community or the numbers in higher dependency residences are very few and balanced in the comparison groups. We will include studies that recruit participants in hospital if most participants are discharged to the community (where most of the intervention is delivered and falls are recorded).

We will exclude studies that test interventions for preventing falls in people after stroke and with Parkinson's disease as these topic areas are covered by other Cochrane reviews (Canning 2015; Verheyden 2013).

Types of interventions

This Cochrane review will focus on any multifactorial intervention or multiple component intervention designed to reduce falls in older people (i.e. designed to minimise exposure to, or the effect of, any risk factor for falling). We will consider these two groups of interventions separately.

We define a multifactorial intervention as one in which interventions from two or more main categories of intervention can be given to participants, but the interventions are linked to each individual's risk profile (usually assessed using a formal process). Importantly, not all participants in a programme receive the same combination of interventions. We will distinguish between multifactorial interventions where treatments were actively provided to address identified risk factors and those where the intervention consisted mainly of referral to other services or the provision of information to increase knowledge (e.g. increase the person's awareness about their risk factors to enable them to take decisions). For example.

- Each individual receives an assessment of known risk factors for falling (fall risk assessment) and then receives an intervention to match their risk profile (i.e. one person may receive supervised exercise and home-hazard modification whereas another may receive home-hazard modification and medication modification).

We define a multiple component intervention as one in which interventions from two or more main categories of intervention are given to all participants of the falls prevention programme. Combinations of interventions and an assessment of relating to another category (e.g. assessment of environment/dwelling units) are also defined as multiple component interventions. For example, all participants of the fall prevention programme receive the following.

- Supervised exercise and medication (vitamin D and calcium supplementation).
- Supervised exercise and environmental assessment of their home.

We have based these definitions on those developed by the Prevention of Falls Network Europe (ProFaNE) (Lamb 2005).

We will include studies where the intervention is compared with 'usual care' (i.e. no change in usual activities), an attention control intervention (i.e. an intervention that is not thought to reduce falls; e.g. general health education or social visits) or exercise as a single active falls prevention intervention. We will analyse studies where the control group is usual care or an attention control intervention separately to those with exercise as an 'active' control.

We will not include comparisons of different multifactorial interventions or different multiple component interventions, comparisons of any multifactorial versus multiple component interventions, or comparisons where the control is a single active intervention apart from exercise.

Types of outcome measures

We will include studies that report data related to the rate and number of falls during follow-up (fallers). Prospective daily calendars returned monthly for at least one year from randomisation are the preferred method for recording falls (Lamb 2005). However, we will also include studies where falls are recorded retrospectively, or not monitored continuously throughout the trial. We will include the following outcomes in this review.

Primary outcomes

- Rate of falls (falls per person years).
- Number of people who have sustained one or more falls (risk of falling).
- Number of people who have sustained recurrent falls (defined as two or more falls in a specified time period) (risk of recurrent falls).

Secondary outcomes

- Number of people who have sustained one or more fall-related fractures.
- Number of people who experienced a fall that required hospital admission.
- Number of people who experienced a fall that required medical attention (e.g. attended hospital emergency department, required general practitioner (GP) consultation).
- Health related quality of life (measured using validated scale e.g. EQ-5D or similar).
- Adverse effects of the intervention.

Note: we will record and report intervention adherence data, where available, for use in the interpretation of trial and review findings.

Timing of outcome measurement

We will make assessments at short-term (less than 12 months) and long-term (12 months or longer) follow-up. For studies with less than 12 months of follow-up, we will use the longest duration reported.

Search methods for identification of studies

Electronic searches

Our search will extend the search 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) (2012 Issue 3 to current issue), MEDLINE (March 2012 to present), EMBASE (March 2012 to present) and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) (February 2012 to present) using tailored search strategies.

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 all databases are in Appendix 1.

We will also search the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) and ClinicalTrials.gov for ongoing and recently completed trials. There will be no language or publication status restrictions.

Searching other resources

We will check reference lists of relevant articles. We will also identify ongoing and unpublished trials by contacting researchers in the field.

Data collection and analysis

Selection of studies

Two review authors (SH and OA) will independently screen all titles and abstracts for potentially eligible studies, for which we will obtain full-text reports. The same two review authors will independently perform study selection. They will resolve any disagreements regarding the inclusion or exclusion of individual studies by discussion or, if necessary, will consult a third review author (SL).

Data extraction and management

Pairs of review authors (SH, OA, BC, CS, LC and JC) will independently perform data extraction. We will pilot the data extraction form using a representative sample of studies in order to identify any missing items or unclear coding instructions. The pairs of review authors will resolve any disagreements by discussion or, if they cannot achieve consensus, a third review author will act as an arbitrator (SL). The review authors will not be blinded to names of authors, institutions, journals or outcomes. We will use a 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, lost to follow-up and drop outs in each arms (with reasons).
- Interventions: experimental and control interventions, timing of intervention, whether studies assessed adherence (compliance) with interventions and associated data, and additional co-interventions.
- Outcomes measured: rate of falls, number of people sustaining one or more falls, number of people of sustaining recurrent falls, number of people sustaining one or more fall-related fractures, number of people who experience a fall requiring hospital admission, number of people who experience a fall requiring medical attention, health-related quality of life and adverse effects of the interventions.
- Other details: economic and health resource 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

Two review authors (OA and BC) will independently assess the risk of bias of each included study based on recommendations in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). They will resolve any disagreements by consensus or, if they cannot achieve consensus, a third review author will act as arbitrator (SH). We will assess the risk of bias for the following domains: sequence generation (selection bias); allocation concealment (selection bias); blinding of participants and personnel (performance bias); blinding of outcome assessment (detection bias); incomplete outcome data (attrition bias); and selective outcome

reporting. In our assessment of detection bias, we will assess separately a) rate of falls and risk of falling), b) risk of fractures and c) requiring hospital admission/medical attention. We will consider rate of falls and risk of falling separately in our assessment of completeness of outcome data. 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 at low, high or unclear for each domain. We will use the criteria for judging risk of bias in fall prevention trials based on that described by Gillespie 2012 (*see* Appendix 2).

Measures of treatment effect

We will present the treatment effect for rate of falls, rate of fall-related fractures and rate of hospital admission as rate ratios (RaRs) with 95% confidence intervals (CIs). For the number of fallers, number of recurrent fallers, number of sustaining fall-related fractures and number sustaining one or more hospital admission, we will report risk ratios (RRs) and 95% CIs. For continuous outcomes (health-related quality of life) we will present the mean difference (MD) with 95% CIs where the same outcome measure is used, or standardised mean difference (SMD) with 95% CIs for outcomes measured using different scales. We will only use results based on change scores if final values are unavailable.

Primary outcomes

Rate of falls

The rate of falls is defined as 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 the reported RaR and 95% CIs if available. If included studies report both adjusted and unadjusted RaRs, we will use the unadjusted estimate unless the adjustment was for clustering. If a study does not report a RaR but appropriate raw data are available, we will calculate a RaR (using the total number of falls over the per person years) and 95% CI using Stata®.

Risk of falling

We will define the risk of falling separately for the number of people who fell once or more (fallers) and the number of people who sustained recurrent falls (defined as two or more falls). The RR compares the risk of falling in any two groups during each trial. We will use the reported estimate of risk (RR) and 95% CIs if available. If an included study reports both adjusted and unadjusted estimates we will use the unadjusted estimate, unless the adjustment was for clustering. If a study reports an odds ratio (or an effect estimate and 95% CI is not reported) and appropriate data are available, we will calculate a RR and 95% CI using Stata 2015.

Secondary outcomes

For the number of participants that sustain one or more fall-related fractures, one or more hospital admission and the number with an adverse event, we will use an RR as described in 'Risk of falling' above.

Unit of analysis issues

For studies that are cluster-randomised (e.g. by medical practice), we will perform adjustments for clustering according to guidance provided in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b) if this has not been performed correctly in the original study. We will use an intra-class correlation coefficient (ICC) of 0.01, as reported by Smeeth 2002. We will not adjust for the possibility of a clustering effect in studies that randomise by household.

For studies with multiple intervention groups, we will include each pair-wise comparison separately, but with the shared intervention group (typically the control group) divided evenly among the different comparisons. This will avoid the loss of valuable information from multiple group studies and avoid problems associated with the same group of participants being included in the analysis twice. We will follow guidance provided in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011d) on dealing with multiple groups from one study.

Dealing with missing data

We will attempt to contact study investigators for any key missing or unclear data or information on their trial. To avoid the risk of overly positive answers, we will ask open-ended questions (e.g. "Please describe all measures used") followed up by more focused questions if further clarification is required. For all outcomes, 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 in each group as long as there is no significant loss to follow-up. We will record the reasons for missing data across treatment groups. We will conduct sensitivity analyses to explore the effects of missing data (incomplete outcome data) on the treatment effect. If a study does not report SDs for continuous outcomes, we will calculate these from standard errors, CIs or exact probability (P) values where possible. We will not impute missing SDs.

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 we consider studies sufficiently homogeneous in their study design, we will perform a meta-analysis and assess the statistical heterogeneity. We will assess statistical heterogeneity of treatment effects between trials using the Chi² test with a significance level at $P < 0.1$ and the I^2 statistic. We will base

our interpretation of the I^2 statistic results on that suggested by Higgins 2011c: 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

If there are more than 10 studies included in the meta-analysis, we will explore potential publication bias by generating a funnel plot and test this statistically using a linear regression test. A P value of less than 0.1 could be an indication of a publication bias or small study effects.

Data synthesis

We will analyse multifactorial interventions and multiple component interventions separately.

- We will analyse multifactorial interventions, whereby participants receive different combinations of intervention based on an individual assessment of risk, as one group. We will stratify each analysis by the type of comparator intervention. We will analyse studies where the intervention is compared with 'usual care' (i.e. no change in usual activities) or an attention control intervention (i.e. an intervention that is not thought to reduce falls, e.g. general health education or social visits) separately to those that are compared with exercise as a single active falls prevention intervention.
- We will group multiple component interventions by the combination of interventions (i.e. where the same combination of single categories of intervention are delivered to all participants). We will analyse each combination separately.

We will use the fall prevention intervention classification system (taxonomy) developed by the Prevention of Falls Network Europe (ProFaNE) (Lamb 2011). These categories include: exercises (supervised/unsupervised), medication (drug target), surgery, management of urinary incontinence, fluid or nutrition therapy, vision assessment, psychological interventions, environment/assistive technology, social environment and interventions to increase knowledge. Full details are available in the ProFaNE Taxonomy Manual.

Where appropriate, we will pool results of comparable studies using both fixed-effect and random-effects models. We will decide the choice of the model to report 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. We will use 95% CIs throughout. We will consider not pooling data where there is considerable heterogeneity (I^2 statistic value of greater than 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 report these in the text.

When considered appropriate, we will pool data using the generic inverse variance method in Review Manager (RevMan) (RevMan 2014). This method enables pooling of the adjusted and unadjusted treatment effect estimates (RaRs or RRs) 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 RevMan requires entering the natural logarithm of the RaR or RR and its standard error for each trial; we will calculate these using the RevMan calculator (RevMan 2014).

Subgroup analysis and investigation of heterogeneity

We will explore potential sources of heterogeneity by carrying out the following prespecified subgroup analyses.

- Higher versus lower falls risk at enrolment (i.e. comparing trials with participants selected for inclusion based on history of falling or other specific risk factors for falling, versus unselected).
- For the multiple interventions which included a vitamin D component, trials that recruited participants with lower baseline vitamin D levels versus those that did not.
- For the multifactorial interventions, trials that actively provided treatment to address identified risk factors versus those where the intervention consisted mainly of referral to other services or the provision of information to educate older people and their families about falls and potential risk factors.

We will perform the test for subgroup differences available in RevMan (RevMan 2014), where appropriate.

Sensitivity analysis

Where possible, we will assess the robustness of our findings by conducting sensitivity analyses. We will examine the effects of the following.

- Inclusion of trials at high or unclear risk of selection bias from inadequate concealment of allocation.
- Inclusion of trials at high or unclear risk of detection bias from inadequate blinding of outcome assessors.
- Inclusion of trials at high or unclear risk of attrition bias from incomplete outcome data.
- The effect of time on the impact of the intervention (i.e. comparing differences in treatment effect over time - earlier trials versus later trials).
- The choice of statistical model for pooling (fixed-effect versus random-effects).
- Cluster versus individual randomised trials.

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

We will use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to assess the quality of the body of evidence for each outcome listed in the 'Types of outcome measures' section (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. 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' section. Where there is sufficient evidence, we will prepare a 'Summary of findings' table for the three primary outcomes and first four listed secondary outcomes.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search strategies

We will limit all searches to 2012 onwards.

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 (41169)
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 (911601)
19 7 and 17

EMBASE (Ovid Interface)

1 Falling/ (28836)
2 (falls or fallers).tw. (42066)
3 or/1-2 (58148)
4 exp Aged/ (2360305)
5 (senior*1 or elder* or old* or aged or ag?ing or postmenopausal or community dwelling).tw. (2129209)
6 or/4-5 (3924727)
7 3 and 6 (28594)
8 exp Randomized Controlled Trial/ or exp Single Blind Procedure/ or exp Double Blind Procedure/ or Crossover Procedure/ (441636)
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. (1464201)
10 8 or 9 (1542955)
11 (exp Animal/ or animal.hw. or Nonhuman/) not (exp Human/ or Human cell/ or (human or humans).ti.) (5419392)
12 10 not 11 (1361826)
13 7 and 12 (4057)

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

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-

(*Continued*)

	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' 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-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' 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 (e.g. control group received matching placebo medication prepared by a pharmacist) OR no blinding or incomplete blinding, but the review authors judge that the outcomes (falls and fractures) are

(*Continued*)

	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' 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 and fallers: ○ judgement of 'low risk' if falls were recorded/ confirmed in all allocated groups using the same method and the personnel recording/confirming falls were blind to group allocation; ○ judgement of 'high risk' if falls were not recorded/ confirmed in all allocated groups using the same method or the personnel recording/confirming falls 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' if there is insufficient information to make a judgement of 'low risk' or 'high risk'. • Hospital admission and medical attention: ○ judgement of 'low risk' if requiring hospital admission/medical attention as a result of a fall was recorded/ confirmed in all allocated groups using the same method (e.g. from primary care records); ○ judgement of 'high risk' if requiring hospital admission/medical attention as a result of a fall was not recorded/confirmed in all allocated groups using the same method (e.g. from primary care records) or the only evidence for requiring medical attention was from self reports from participants or carers; ○ judgement of 'unclear' 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 missing outcome data are missing and losses are balanced in numbers across intervention groups with similar reasons for missing data across groups or missing data

(*Continued*)

	have been imputed using appropriate methods. • Judgement of 'high risk' if greater than 20% of missing outcome data, 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' 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 repot 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' 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 etc, with monthly, or more frequent, follow-up by the researchers. • Judgement of 'high risk' if ascertainment relied on participant recall at longer intervals than 1 month during the study or at its conclusion. • Judgement of 'unclear' 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 2011a).

CONTRIBUTIONS OF AUTHORS

SH contributed to writing the protocol and will act as guarantor of the review.

OA and SL contributed to writing the protocol.

BC, CS, LC and JC commented on the protocol draft.

DECLARATIONS OF INTEREST

SH has no known conflicts of interest.

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BC has no known conflicts of interest.

CS is an author of the original version of this review (Gillespie 2012) and is lead author of an associated review ('Exercise for preventing falls in older people living in the community').

LC is an author of the original version of this review (Gillespie 2012).

JC has no known conflicts of interest.

SL is an author of the original version of this review (Gillespie 2012) and is lead author of the ProFaNE consensus for falls guidance.

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NOTES

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