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Effects of falls prevention interventions on falls outcomes for hospitalized adults: Protocol for a systematic review with meta-analysis

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Title Page

Effects of falls prevention interventions on falls outcomes for hospitalized adults: Protocol for a systematic review with meta-analysis

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Key Words: accidental falls**,** falls prevention, adults, hospital, systematic review

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Abstract

Introduction: Falls are a major global public health problem and leading cause of accidental or unintentional injury and hospitalisation. Falls in hospital are associated with longer length of stay, readmissions and poor outcomes. Falls prevention is informed by knowledge of reversible falls risk factors and accurate risk identification. The extent to which hospital falls are prevented by evidence-based practice, environmental modifications and optimisation of falls prevention systems awaits confirmation. Published reviews have mainly evaluated community settings and residential care facilities. A better understanding of hospital falls and the most effective strategies to prevent them is vital to keeping people safe. .

Objectives: To evaluate the effectiveness of falls prevention interventions on reducing falls in hospitalised adults (acute and sub-acute wards, rehabilitation, mental health, operating theatre and emergency departments). We also summarise components of effective falls prevention interventions.

Methods and analysis: This protocol has been registered. The systematic review will be informed by Cochrane guidelines and reported according to the PRISMA statement. Inclusion criteria: randomised controlled trials, quasi-randomised trials or controlled clinical trials that evaluate falls prevention interventions for use by hospitalised adults or employees. Electronic databases will be searched using key terms including falls, accidental falls, prevention, hospital, rehabilitation, emergency, mental health, acute and subacute. Pairs of independent reviewers will conduct all review steps. Included studies will be evaluated for risk of bias. Data for variables such as age, participant characteristics, settings and interventions will be extracted and analysed with descriptive statistics and meta-analysis where possible. The results will be presented textually, with flow charts, summary tables, statistical analysis (and meta-analysis where possible) and narrative summaries.

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Ethics and dissemination: Ethical approval is not required. The systematic review will be published in a peer-reviewed journal and disseminated electronically, in print and at conferences. Updates will guide healthcare translation into practice.

PROSPERO registration: PROSPERO 2017: CRD 42017058887. Available from https://www.crd.york.ac.uk/prospero

Key Words: accidental falls, falls prevention, adults, hospital, systematic review

Strengths and limitations of this study

- We will systematically identify and critically appraise the available evidence for effectiveness of hospital falls prevention methods.
- We have endeavoured to reduce bias by using *a priori* inclusion/exclusion criteria, data extraction procedures and risk of bias assessments.
- The study screening, data extraction and assessment of risk of bias will be conducted independently by two authors and a third will arbitrate on disagreements.
- Falls prevention methods targeted towards patients as well as employee- focused education and training systems and processes will be evaluated.
- The inclusion of only English language publications, due to a lack of translation resources, means that potential exists for cultural and publication bias.

BACKGROUND

Description of the condition

The World Health Organisation (WHO) has reported that falls are a major global public health problem and a leading worldwide cause of accidental or unintentional injury deaths after road traffic accidents (1). The estimated number of falls deaths is approximately 424,000 globally with

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falls responsible for 17 million disability-adjusted life years (DALYS). Adults over 65 years are at greatest risk (2, 3). Over one in three adults fall annually and falls are the main cause of hip fractures (4) and hospitalisation (5). The financial costs from fall-related injuries are considerable and the average cost per fall in the group older than 65 years has been estimated as $3611 in Finland and $US1049 in Australia (7-9). Falls related injuries in the US (2014) resulted in an estimated $31 billion in annual Medicare costs (10) and in the UK falls are estimated to cost the UK health system over GBP 2Billion per year (11). Rates of falling events and injuries from falls increase with advancing age, and are particularly high for people with chronic conditions, such as Parkinson's disease and dementia (12, 13).

Falls are the most common adverse events that are reported in hospitalised older adults, with geriatric and rehabilitation wards having the greatest incidence (5, 6). Falls in hospital are associated with longer length of stay and poorer outcomes for patients (4, 5). Between 30% and 40% of falls in hospital result in physical injury such as bruises, hip fractures and head injuries (14-16).

In hospital settings, an incidence of 3.4-3.9 falls per person year has been reported in geriatric rehabilitation wards (17, 18), and 6.2 falls per person year in psychogeriatric wards (7). Evidence syntheses show that risk factors for falls in hospital inpatients include gait instability, delirium, cognitive impairment, urinary incontinence, a history of previous falls, visual impairment, multi-morbidity and psychotropic medications (5). For older adults in rehabilitation settings, falls risk factors further include carpet flooring; vestibular dysfunction; delirium; dementia; sleep disturbance; medications such as anticonvulsants, tranquillisers and anti-hypertensives; and dependence on assistance with transfers (4, 8, 17, 18).

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The most current Cochrane systematic review was published in 2012 and evaluated the efficacy interventions for preventing falls in older people in both residential care facilities and hospitals. In residential and nursing care facilities, vitamin D supplementation was effective in reducing the rate of falls yet the efficacy of exercise was unclear (4). In contrast, exercise in subacute hospitals and geriatric rehabilitation centres appears effective (4). Multifactorial interventions that include aerobic exercises, strength training, mobility strategies, medication management, consumer and staff education, provision of effective assistive devices and environmental modifications, reduce falls in hospitals reduction in rate of falls (RaR: 0.69, 95% CI: 0.49 to 0.96: $I^2 = 59\%$) and risk of falling (RR 0.71, 95% CI 0.46 to 1.09: $I^2 = 43\%$) (4, 13, 17-20). However, optimal type and dosage of these multifactorial falls prevention interventions remain unclear. A recent trial that evaluated a combination of four interventions on acute medical and surgical wards showed no effect in reducing falls (23). Further evaluation of individual interventions such as alarms or provision of low-low beds and hourly nursing rounds is required (24-27). A trial that provided individualised patient education with staff feedback significantly reduced falls by 40% and injurious falls in rehabilitation wards (19).

Description of the intervention

The majority of falls are the result of a combination of factors and a wide range of falls prevention methods have been reported. Accurate fall risk assessment is essential. In addition, hospital falls prevention interventions may include patient education, clinician training and environmental modifications. Hospital systems, policies and procedures for preventing falls can also influence outcome by optimising organisational practices.

Why is it important to do this review?

Falls prevention assessments and interventions are informed by knowledge of the reversible risk factors for falls. They are also informed by an ability to identify and manage adult falls risk, as

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well as by managing the environment and staff practices and behaviours. Published reviews have mainly evaluated community settings and residential care facilities (7, 8). There is limited evidence showing which approaches prevent falls in hospitals.

A better understanding of the nature of falls and the most effective strategies to prevent falls in hospital programs is vital to keep adults safe when they are admitted to hospital. Studies to date have not been able to identify which components of falls prevention (including risk assessment and management tools) should be combined to deliver best practice management in hospitals.

REVIEW QUESTION

What are the effects of falls prevention interventions on falls outcomes for adults in hospital settings?

AIMS

(1) Evaluate the effectiveness of falls prevention interventions on reducing falls in hospitalized adults (acute and sub-acute wards, rehabilitation, mental health, operating theatre and emergency departments)

(2) Describe and summarise the components of effective hospital falls prevention interventions.

METHODS AND DESIGN

This protocol has been registered on PROSPERO the international prospective register of systematic reviews (registration number: CRD 42017058887) and available at http://www.crd.york.ac.uk/prospero) and is reported Preferred Reporting Items for Systematic review and Meta-Analysis-Protocol (PRISMA-P) (28, 29). We will conduct a systematic review informed by Cochrane guidelines (30) and reported according to the PRISMA statement (31, 32).

In the event of protocol amendments, the date of each amendment will be accompanied by a

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description of the change and the rationale and SS and MM will be responsible for approving, documenting, and implementing them. An updated protocol will be identified with a new version number and a list of specific amendments that were made to the previous version.

1. Eligibility criteria

Types of studies

Studies will be included if they are randomised controlled trials, quasi-randomised trials or controlled clinical trials. In the absence of these methods we will consider comparative studies without randomization, cohort studies and case-controlled studies. Studies will be excluded if not published in English (due to a lack of translation resources). Publications that are reports, reviews, dissertations, letters, comments, books, expert opinion or practice papers will be excluded.

Types of interventions

The review will consider studies that evaluate falls prevention interventions, including but not limited to education (including one-one/group/written/telephone/e-health, online programs and apps), exercises, functional assistance as a falls prevention strategy, health professional education, medications either withdrawing or delivered for falls prevention or multifactorial combinations of the preceding strategies. The interventions must have been delivered in hospital settings.

Comparators

The interventions will be compared, but not limited, to control conditions where there are no falls prevention interventions, where usual care is provided or where the intervention group receives falls prevention in addition to usual care or another falls prevention approach.

Outcome measures

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We will include trials with data at baseline and data during and/or after the investigated intervention. Trials must report raw data that allow calculations to be made or statistics relating to rate or number of any type of fall, or the number of participants sustaining a fall during follow-up. The primary outcomes will be rate of falls (e.g. expressed as the number of falls per 1000 person days), number of falls, number of fallers (proportion of participants whom became fallers expressed as a percentage of the participants who fell) and time to first fall (days).

The secondary outcomes include the number of participants sustaining fall-related injuries (e.g. rates of injurious falls expressed as, e.g. the number of falls with injury per 1000 patient days) and the number of participants who sustain fractures as result of a falls expressed as fractures per 1000 patient days. Where data are available an additional outcome of the number of patients sustaining a hip fracture will be expressed as hip fracture per 1000 patient days. Secondary outcomes will also include the proportion of participants with injurious falls expressed as percentage of participants who sustained an injury as the result of a fall). Complications or adverse events reported as resulting from delivering the interventions will also be evaluated. A cost-benefit analysis of health care provider costs and costs of environmental modifications are additional secondary measures.

Study setting

We define hospitals as "establishments that are primarily engaged in providing emergency care, inpatient care rehabilitative services, outpatient services and hospital-in-the-home for patients" (4) as well as mental health and operating theatre. The World Health Organisation (WHO) defines hospitals as "health care institutions that have an organised medical and other professional staff, and inpatient facilities, and deliver services 24 hours a day, 7 days a week. They offer a range of acute, convalescent and terminal care using diagnostic and curative services" (33).

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Types of participants

Studies will be included if they include hospitalised adults aged over 21 years or hospital staff. They will be excluded if they are conducted in a hospice, palliative care, paediatric ward, home or residential care facility.

2. Identification and selection of studies

We will search electronic databases including MEDLINE, EMBASE, CINAHL, The Cochrane Central Register of Controlled Trials, AMED, PEDro, PsychInfo and Sport Discus. A manual search of reference lists and Citation Tracking of relevant studies will also be conducted to identify additional papers and content experts will be consulted. The search will be conducted without date limits up until March 2017, using explosions and combinations of key search terms including, for example, falls, accidental falls, prevention, hospitals, hospital units, rehabilitation centres, acute care and subacute care. Study selection will be documented and summarised in a PRISMA compliant flow chart (Figure 1). A draft MEDLINE search strategy is included in Appendix 1. The MEDLINE strategy will be adapted to the syntax and subject headings of the other databases.

The search results will be downloaded to a reference database. After deletion of duplicates, one reviewer will perform initial screening of titles by applying the *a priori* eligibility criteria (Appendix 2). Two independent researchers will then screen titles and abstracts of remaining references and perform full text review as necessary to identify those studies that fulfill selection criteria. Disagreements will be resolved through discussion and a third reviewer if consensus cannot initially be reached.

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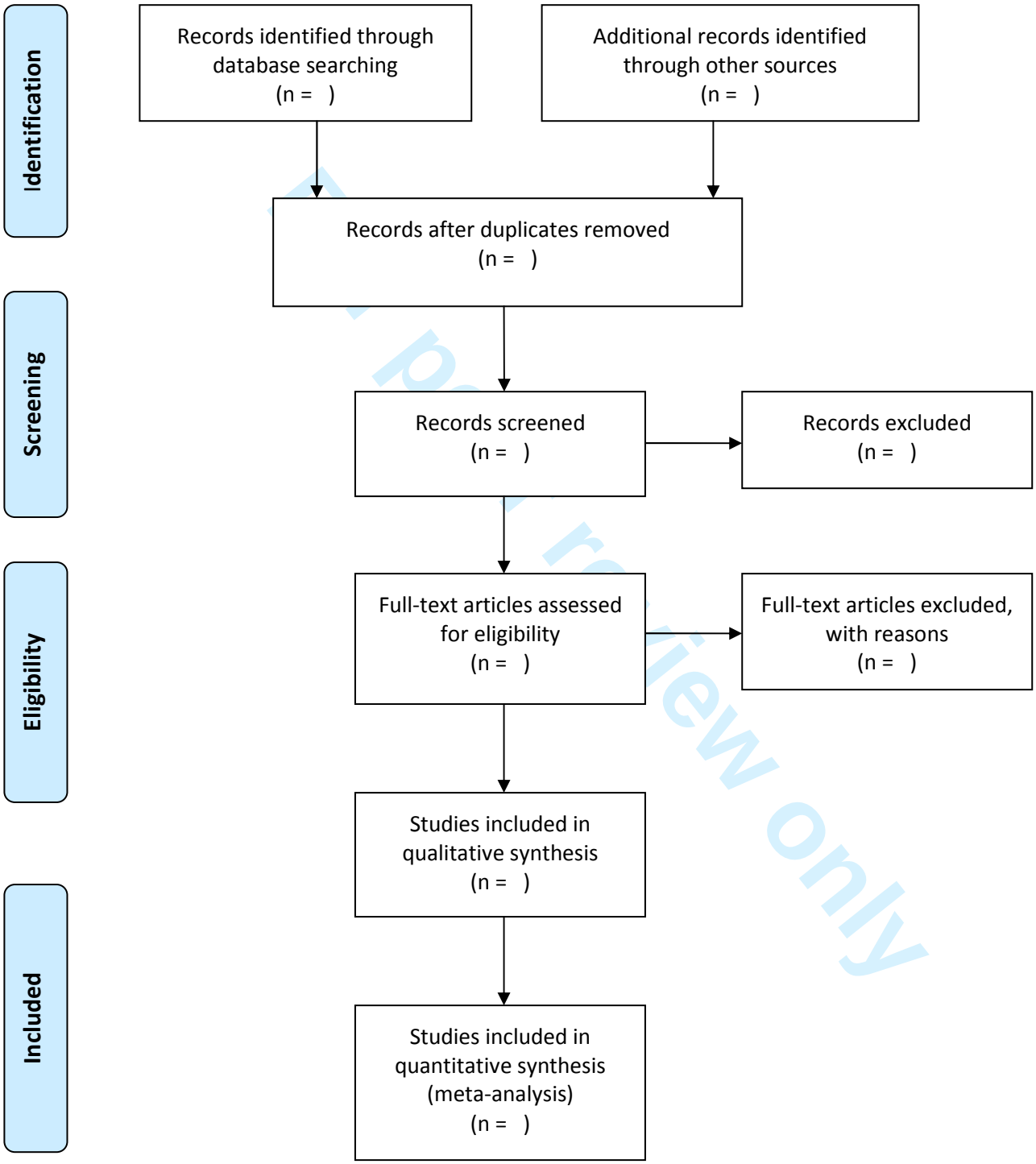

Figure 1: PRISMA compliant flowchart

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3. Method quality/Risk of Bias assessment

Studies considered eligible for inclusion will be evaluated for method quality/risk of bias but not excluded on the basis of method quality. We will use either the PEDro scale (34, 35) or the Cochrane Risk of Bias Instrument that assesses against 12 criteria: randomisation, concealed allocation, blinding, incomplete data, baseline comparability intention to treat analysis, co-interventions and outcome assessment timing and score each of the individual criteria as 'high risk', 'low risk', or 'unclear risk' (30). Reviewers will not be involved in risk of bias assessment for studies on which they were co-authors.

Meta-bias (such as publication bias across studies, selective reporting within studies)

To examine for the presence of reporting bias, we will determine whether the study protocol was published before recruitment of patients of the study was started. For studies published after July 1st 2005, the Clinical Trial Register at the International Clinical Trials Registry Platform of the World Health Organisation (http://apps.who.int/trialssearch) shall be screened for study registration. We will evaluate whether selective reporting of outcomes is present (outcome reporting bias) and compare the fixed effect estimate against the random effects model to assess the possible presence of small sample bias in the published literature (whereby the intervention effect is arguably more beneficial in smaller studies). In the presence of small sample bias, the random effects estimate of the intervention is more beneficial than the fixed effect estimate (30).

4. Data extraction and management

Pairs of independent reviewers will independently extract data using a pre-tested standardized data extraction form. The main headings will include: methods, population characteristics, intervention characteristics, and both baseline and post-intervention outcome scores. We will collect the following information:

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- Study characteristics (e.g. country where the study was conducted, population source (consumer, staff, clinician) or setting, recruitment modality, source of funding, inclusion criteria)
- Population characteristics (e.g. number of participants, age, sex, type of cohort, whether acute, sub-acute, mental health, operating theatre, emergency department or rehabilitation setting, average length of stay in hospital. Diagnostic criteria will be specified where studies are conducted in a specific population e.g. stroke, amputee, post surgical cohort)
- Intervention characteristics (e.g. description of components, falls risk assessment tool, duration and number of sessions, description of how the intervention is delivered, profession delivering the intervention, co-interventions)
- For studies that include exercises the Consensus on Exercise Reporting Template will be applied to extract elements of the exercise program (36, 37)
- Outcome data (e.g. rate of falls, number of fallers, and time to first fall, injuries reported from falls. To calculate rates of falls and injurious falls the observation period, both control and intervention phases will be collected (days).

Outcome data will be extracted for short-term, medium-term and long-term follow up assessments and the corresponding authors of included studies will be contacted to obtain any missing data when needed. The completed data extraction forms will be examined for consistency and any disagreements will be resolved by discussion and consensus or third party adjudication where necessary.

5. Data synthesis

We will express dichotomous outcomes as risk ratios (RRs) with 95% CIs and continuous outcomes as mean differences (MDs) with 95% CIs if different trials used the same measurement instrument to measure the same outcome. Alternatively, we will analyse continuous outcomes using the standardised mean difference (SMD) when trials measure the same outcome but employ

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different measurement instruments to measure the same conceptual outcome. We will summarise the overall quality of evidence with the GRADE approach (30). Meta-analyses will be conducted for each outcome where relevant data from two or more studies are available.

Missing data

When there are missing data, we will attempt to contact the original authors of the study to obtain the relevant missing data. Important numerical data will be carefully evaluated. If missing data cannot be obtained, an imputation method will be used (30). For studies having insufficient data to enter in the meta-analysis, even after contacting the authors, we will report the results qualitatively (30). Sensitivity analysis will be used to assess the impact on the overall treatment effects of inclusion of trials which do not report an intention to treat analysis, have high rates of participant attrition, or with other missing data. Where data are imputed or calculated (e.g. SDs calculated from SEs, 95% CIs or P-values, or imputed from graphs or from SDs in other trials) we will report this in the tables of Characteristics of included studies.

Assessment of heterogeneity

Clinical heterogeneity will be evaluated by considering the variability in participant factors among trials (for example age) and trial factors (randomization concealment, blinding of outcome assessment, losses to follow-up, treatment type, co-interventions). Heterogeneity will be evaluated using the standard chi-squared (χ^2) test to determine whether a fixed or random effects model is chosen. Quantitative data will, where possible, be pooled for meta-analysis. Where pooling is not possible the findings will be presented in a narrative form. Subgroup analysis will be explored based on grouping trials that have comparable interventions. We will try to explain the source of heterogeneity by subgroup analysis or sensitivity analysis (30).

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Meta-analysis

Pooling of data will only occur for studies that investigated the same falls prevention intervention. This means that pooling of data will be done separately for each falls prevention intervention (e.g. exercises). Studies having a multimodal approach will be pooled together (e.g. exercises, education, environmental adaptations). Meta-analysis will be performed only from studies regarded as suitably homogeneous (30). Homogeneity of studies will be evaluated by exploring their similarities and differences, taking into consideration the study population, type of intervention, reference treatments, outcomes, measurements instruments and timing of follow up. If a meta-analysis is not possible, the results from clinically comparable trials will be presented descriptively (30).

Regardless of whether there are sufficient data available to use quantitative analyses to summarize the data, the overall quality of the evidence for each outcome will be determined. To accomplish this the GRADE approach and the GRADE guidelines on how to apply the GRADE methodology framework in more detail will be used. Factors that may decrease the quality of the evidence are: study design and risk of bias, inconsistency of results, indirectness (not generalisable), imprecision (sparse data) and other factors (e.g. reporting bias). The quality of the evidence for a specific outcome will be reduced by a level, according to the performance of the studies against these five factors (28).

Subgroup analysis

Subgroup analyses will be used to explore possible sources of heterogeneity, based on the following:

- Patient characteristic (age, diagnosis, type of ward, i.e. whether acute, sub-acute, rehabilitation, operating theatre, mental health, surgical or medical)

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- Types of treatment: whether single or multi-factorial interventions such as those including staff, inpatients and/or carers or environmental modifications.

RESULTS

The results will be presented textually, with flow charts, summary tables, statistical analysis (and meta-analysis where possible) and narrative summaries.

DISCUSSION

We have presented the rationale and design of a systematic review of interventions designed to reduce falls in hospitalized adults. The review will identify effective processes and their elements. The results will inform research into optimal fall risk assessment procedures and effective prevention interventions. It shall also shed light on how best to promote the uptake and implementation of best practice and how to educate patients and clinicians to prevent falls and associated injuries.

DISSEMINATION PLAN

The findings of this study will be disseminated through the media, peer-reviewed publications and conference, seminar and consumer forum presentations.

Competing interests

The authors declare there are no competing or conflicting interests.

Authors' contribution

SS and MM conceived the idea for the study. All authors (SS, MM, AMH and DC) were responsible for the study design, the content of the review protocol and all manuscript revisions. SS drafted the protocol manuscript with input from MM, AMH and DC. All authors (SS, MM,

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AMH and DC) have read and approved the final protocol manuscript. The corresponding author guarantees that the authorship statement is correct.

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Legend

Figure 1: Flow diagram of the selection process

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Appendix 1: Example search strategy: MEDLINE (OvidSP)

1. Accidental Falls/
2. (falls or faller$).tw.
3. or/1-2
4. exp adults/
5. (Adult$).tw.
6. 6 or/4-5
7. and/3,6 (12226)
8. Acute Care/
9. emergency/
10. Hospitalization/
11. Subacute Care/
12. exp Hospitals/
13. Hospital Units/
14. Rehabilitation Centers/
15. ((long stay or acute or sub-acute or subacute or outpatient or hospital) adj3 (care or ward$1)).tw.
16. ((rehabilitation or outpatient) adj (ward$1 or hospital$1 or unit$1)).tw.
17. or/8-16
18. and/7,17
19. randomized controlled trial.pt.
20. controlled clinical trial.pt.
21. randomized.ab.
22. placebo.ab.
23. Clinical Trials as Topic/
24. randomly.ab.
25. trial.ab.
26. or/19-25
27. exp Animals/ not Humans/
28. 26 not 27

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29. and/18,28

Appendix 2: Standardized form used to apply criteria for study inclusion

Inclusion criteria	**Yes**	**No**
Study Design • Randomised controlled trials, quasi-randomised trials or controlled clinical trials, published in peer-reviewed journals		
Population • Hospitalized adults of either sex or hospital staff		
Setting • Hospitals defined as "establishments that are primarily engaged in providing emergency care, inpatient nursing, rehabilitative services, outpatient services and hospital-in-the-home for patients"		
Intervention • Studies that evaluate falls prevention interventions, including *but not limited to* education (including one-one/group /written/telephone/e-health, carer apps), exercises, functional assistance as a falls prevention strategy, health professional education, medications either withdrawing or delivered for falls prevention or multifactorial combinations of the preceding strategies		
Data • Papers are only eligible for inclusion if they report data that enables statistical analysis i.e. point estimates and measures of effect or survival curves e.g. time to first fall		
Exclusion criteria		
• Residential care or home settings • Papers not published in English • Papers that were editorials, expert opinion, letters or commentary		
INCLUDE	**EXCLUDE**	
• **To be included papers must be rated as yes for all inclusion criteria and have no exclusion criteria** • Proceed to data extraction and content assessment		

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PRISMA-P 2015 checklist: recommended items to address in a systematic review protocol

Section & topic	Item no:	Checklist item	Page
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	3
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	1, 9
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	5
Support			
Sources	5a	Indicate sources of financial or other support for the review	9
Sponsor	5b	Provide name for the review funder and/or sponsor	9
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	9
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3, 4
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4
METHODS			
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Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	7
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	20
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	7
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	7
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	8
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	8
Outcomes & prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	8

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Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	8
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	8, 9
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	9
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	9
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Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	8

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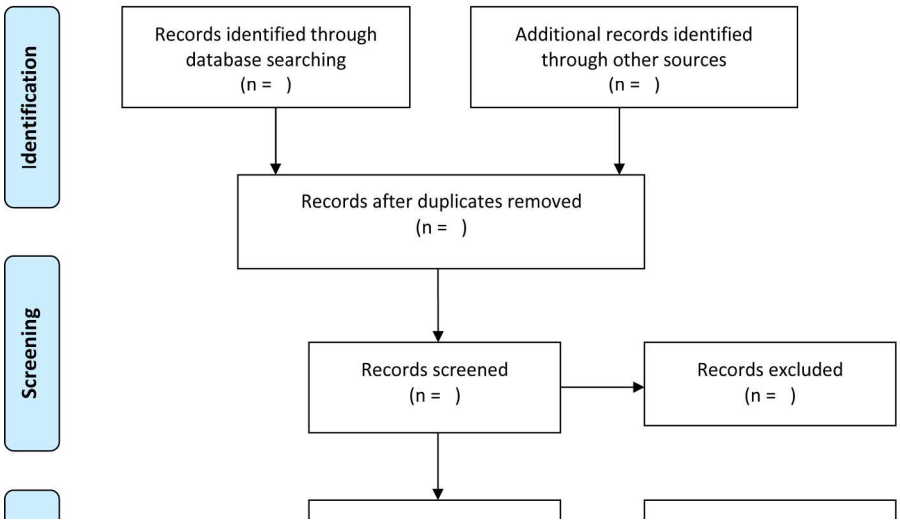

Figure 1: PRISMA compliant flow chart

170x227mm (300 x 300 DPI)

Appendix 1: Example search strategy: MEDLINE (OvidSP)

1. Accidental Falls/
2. (falls or faller$).tw.
3. or/1-2
4. exp adults/
5. (Adult$).tw.
6. 6 or/4-5
7. and/3,6 (12226)
8. Acute Care/
9. emergency/
10. Hospitalization/
11. Subacute Care/
12. exp Hospitals/
13. Hospital Units/
14. Rehabilitation Centers/
15. ((long stay or acute or sub-acute or subacute or outpatient or hospital) adj3 (care or ward$1)).tw.
16. ((rehabilitation or outpatient) adj (ward$1 or hospital$1 or unit$1)).tw.
17. or/8-16
18. and/7,17
19. randomized controlled trial.pt.
20. controlled clinical trial.pt.
21. randomized.ab.
22. placebo.ab.
23. Clinical Trials as Topic/
24. randomly.ab.
25. trial.ab.
26. or/19-25
27. exp Animals/ not Humans/
28. 26 not 27
29. and/18,28

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Appendix 2: Standardized form used to apply criteria for study inclusion

Inclusion criteria	**Yes**	**No**
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