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# BMJ Open

## Risk factors for recurrent falls in older adults: A study protocol for a systematic review with meta-analysis

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-033602
Article Type:	Protocol
Date Submitted by the Author:	12-Aug-2019
Complete List of Authors:	Jehu, Deborah; The University of British Columbia, Physical Therapy; Davis, Jennifer; University of British Columbia, Department of Population & Public Health, Liu-Ambrose, Teresa; University of British Columbia, Department of Physical Therapy,
Keywords:	Systematic review, meta-analysis, recurrent falls, risk factors, older adults

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## ABSTRACT

**Introduction** Older adults who fall recurrently (i.e., > 1 fall per year) are at risk for functional decline and mortality. Key risk factors for recurrent falls in community-dwelling older adults are not well established due to methodological limitations, such as recall bias. A better understanding of the risk factors for recurrent falls will aid in refining clinical practice guidelines for secondary fall prevention strategies. The primary objective of this systematic review and meta-analysis is to examine the risk factors for recurrent falls in prospective studies among community-dwelling older adults.

**Methods and analysis** A comprehensive search for articles indexed in MEDLINE, EMBASE, PsycINFO, and CINAHL databases as well as grey literature will be conducted. We will use MeSH and keyword search terms around the following topics: falls, recurrence, fall-risk, aging, and prospective studies. Prospective studies investigating risk factors for recurrent falls in older adults will be included. One author will complete the search. Two authors will remove duplicates, and screen the titles and abstracts for their potential inclusion against the eligibility criteria. Two authors will screen the full-texts and extract the data using a piloted extraction sheet. Included studies will be evaluated for study quality with the Strengthening the Reporting of OBservational studies in Epidemiology (STROBE) and risk of bias with the Joanna Briggs Institute Prevalence Critical Appraisal tools. The data extraction will include study characteristics as well as sociodemographic, balance and mobility, sensory and neuromuscular, psychological, medical, medication, and environmental factors. The results will be presented via figures, summary tables, meta-analysis (when possible), and narrative summaries.

**Ethics and dissemination** No ethics approval will be required. Findings will be disseminated through publication and media.

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3 **PROSPERO registration number** CRD42019118888  
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5 **Keywords:** Systematic review; meta-analysis; recurrent falls; risk factors; older adults  
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8 **Word count:** 1977  
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## INTRODUCTION

Falls are a major health concern, and the second leading cause of unintentional injury deaths.<sup>1</sup> Older adults who fall more than once per year are defined as recurrent fallers.<sup>2-7</sup> Recurrent fallers are at higher risk for both morbidity and mortality than non-fallers and single fallers.<sup>7-17</sup> Thus, secondary prevention is critical for minimizing functional decline and maintaining quality of life.<sup>14</sup> A better understanding of risk factors for recurrent falls is needed to develop effective secondary fall prevention strategies.

Three systematic reviews have examined risk factors for recurrent falls among community-dwelling older adults but included retrospective fall data.<sup>18-20</sup> Retrospective studies are prone to more recall bias compared with prospective studies, as 5.8 % of non-fallers, 32.8 % of single fallers, and up to 50 % of recurrent fallers deny falling in the previous year when comparing retrospective to prospective falls monitoring.<sup>21</sup> One of these reviews only searched the literature between 2010-2014,<sup>20</sup> greatly limiting the scope of published evidence. The strength of the evidence in two of the three reviews is difficult to determine because assessment of study quality and risk of bias were not performed.<sup>19 20</sup> Thus, there is a need for a systematic review of data solely from prospective studies (of falls) with an evaluation of study quality and risk of bias.

The risk factors unique to recurrent falls remain unclear. Therefore, the purpose of this study is to conduct a systematic review with meta-analysis of the risk factors for recurrent falls in prospective studies only. A secondary aim is to conduct sensitivity analyses to compare studies with low versus high risk of bias to draw accurate conclusions on risk factors for recurrent falls.

## METHODS

### Design

The details of the protocol have been registered on the PROSPERO database under registration number Prospero ID: CRD42019118888. The current review methods followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P; Additional file 1),<sup>22</sup> and Meta-Analysis of Observational Studies in Epidemiology guidelines.<sup>23</sup>

### Inclusion criteria

#### *Types of studies*

All prospective quantitative studies examining risk factors contributing to recurrent falls in older adults published in English or French will be included. Prospective falls data must be collected at least twice per year (e.g., phone calls, fall calendars) to be included in this study. In case of multiple publications for one study, all articles will be used to obtain maximum information.

#### *Types of participants*

Studies will be included if participants: 1) are 60 years of age and older or are a mean age of 65 years and older; 2) are residing in the community, residential care, or clinical environments; and 3a) are recurrent fallers having sustained two or more falls in the prospective follow-up period (i.e., 3 months or longer); or 3b) have had a documented fall(s) in the previous year and are being followed prospectively for subsequent fall(s). Note that a fall will be defined as “an unexpected event in which the participant comes to rest on the ground, floor or lower level”.<sup>24</sup> A recurrent faller will be defined as a person falling more than once in a 12-month prospective period.<sup>2-7</sup> Risk will be defined as “the probability that an unwanted health event (e.g., a future fall) will occur”.<sup>25</sup>



### ***Exclusion criteria***

Studies will be excluded if they: 1) focus on patient groups (e.g. neurodegenerative diseases) to promote a more homogenous sample; 2) only include retrospective falls data; 3) do not separate single fallers from recurrent fallers; and 4) are not prospective (e.g., cross-sectional studies, reviews and meta-analyses). Lastly, we will contact authors to inquire about fall outcome data that are not reported and give them 2 weeks to respond.

### **Search strategy**

The following electronic databases will be searched: MEDLINE (Ovid interface; 1946-2019), EMBASE (Ovid interface: 1974-2019), PsycINFO (Ebsco interface: 1597-2019), and CINAHL (Ebsco interface: 1982-2019) up to 18/03/2019. The search strategy for MEDLINE is provided in Supplementary file 1. We will manually search bibliographies of articles included in the review, the references of other study reviews that match our inclusion criteria, trial registries, and articles citing our eligible articles in Google Scholar and Web of Science. Conference proceedings will also be searched from the International Society for Posture and Gait Research between 1971-2019. We will also consult with content experts in the field to determine whether we have included all relevant articles (Figure 1).<sup>22</sup> The search algorithm for each database will be included in appendices.

### **Study selection**

One author will complete the search and remove the duplicates. Two authors will screen the titles and abstracts for their potential inclusion against the eligibility criteria, screen the full-texts, and extract the data using a pre-tested extraction sheet. After screening and data extraction is complete, the reviewers will compare their extracted data. In case of discrepancies, discussion will be held until consensus is reached. A third review team member will be consulted if

agreement cannot be reached. The PRISMA flow diagram will be constructed after the screening process. Excluded articles will be listed in a supplementary file.

### **Outcome measures and data extraction**

The primary outcome measure will be the rate of prospective falls because frequent fallers generally exhibit more fall risk factors and prospective falls study timelines are heterogeneous.<sup>18</sup> Based on a fall risk classification system;<sup>26</sup> the data extraction sheet will be comprised of the following secondary outcomes.

- Study characteristics: i.e., article citation, country where the study was conducted, setting (community, hospital, long-term care), source of funding, declarations of interest of the primary researchers
- Sociodemographic factors: e.g., age, sex, fall characteristics (e.g., number of recurrent fallers, frequency retrospective and prospective falls, timeline of retrospective and prospective falls, method of collecting fall data, rate of falls, severity of injury(ies), time to first injury, fall risk)
- Balance and mobility factors: e.g., Tinetti Balance & Gait Assessment, Timed Up and Go (s), gait speed (m/s), sit-to-stand (s), sway area (mm<sup>2</sup>)
- Sensory and neuromuscular factors: e.g., visual impairment (e.g., cataracts, glaucoma; %), hearing impairment (%), pain (%), proprioceptive function (° error), dizziness (%), reaction time (ms), muscle strength (N/m<sup>2</sup>)
- Psychological factors: e.g., Mini-Mental State Examination, Trail Making test, fear of falling, Activities-specific Balance Confidence scale, Geriatric Depression Scale, dual-tasking
- Medical factors: comorbidities (% of those with none, 1, 2, or >2)

- Medication use: Medications known to influence balance and/or cognition (e.g., anti-depressants, sedatives, diuretics; % of sample)
- Environmental factors: e.g., footwear (% of those with appropriate vs inappropriate shoes), weather conditions (% of falls in slippery, wet, loose gravel, and dry conditions), time of day (% of falls in the morning vs evening), location (% of falls indoors vs outdoors)

When possible, the means of these outcomes will be collected at baseline before prospective falls. We will examine any retraction statements and errata, which are associated with included studies and, where applicable, update the recorded data accordingly.

### **Missing data management**

Missing fall risk classification outcome data will be requested from authors. If missing data still exists, the analysis will be conducted on the final available data. The potential impact of missing data on the review findings will be addressed in the final report.

### **Study quality and risk of bias assessment**

Two authors will assess the reporting quality of the included articles using the Strengthening the Reporting of OBservational studies in Epidemiology (STROBE) checklist, which has shown good reliability.<sup>27</sup> A study will be deemed as high quality if “yes” is selected for each of the 22 items of the STROBE checklist for cohort studies, while low quality will be assigned if one or more “no” responses are selected. Two independent reviewers will assess the risk of bias of each study using the Joanna Briggs Institute Prevalence Critical Appraisal tool and compare their results for any discrepancies. This tool was developed to assess the methodological quality of studies reporting prevalence data to be included in systematic reviews.<sup>28</sup> Using the Joanna Briggs Institute Prevalence Critical

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3 Appraisal Tool, a low risk of bias will be assigned to each eligible study if “yes” is selected  
4 for each of the 9 questions. Disagreements between reviewers will be resolved through  
5 discussion with a third neutral reviewer. In the discussion, a greater emphasis will be placed  
6 on studies with high quality and low risk of bias. Reporting quality and risk of bias and data  
7 will be presented in tables and figures by STROBE and Joanna Briggs Institute Prevalence  
8 Critical Appraisal tool items for each individual study.  
9

### 17 **Data synthesis and summary of results**

19 The findings from the study will be presented in a narrative synthesis, structured  
20 around the primary fall risk outcome measures, and presented in tables and figures. A table of  
21 study characteristics will be displayed including the following variables: citation, sample  
22 size, % female, mean age, and duration of prospective falls follow-up.  
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28 Where population and outcome of the studies are clinically, methodologically and  
29 statistically similar, a meta-analysis will be done by pooling appropriate data and using  
30 RefWorks 2.0. If enough data support a quantitative synthesis of fall risk outcomes, a  
31 random-effects meta-analysis will be performed on the pooled data given the potential  
32 heterogeneity in participant characteristics.  
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39 The  $I^2$  test will be used to test the statistical heterogeneity among all studies, as well as visual  
40 inspections of forest plots. We will consider a significance level less than 0.10 as evidence of  
41 heterogeneity. Substantial statistical (i.e.,  $I^2 \geq 50\%$ ) or methodological heterogeneity (e.g.,  
42 differences in fall risk factors explored, variation in the tools used to measure fall risk factors)  
43 may impact fall risk factors.<sup>29</sup> A priori subgroup analyses will be explored by comparing  
44 important participant factors between studies (e.g., age, sex, clinical condition, place of  
45 residence, number of recurrent falls) and study risk of bias factors (e.g., adequate adjustment of  
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3 confounding variables, losses of prospective falls calendars) to reveal potential sources of  
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5 heterogeneity. Sensitivity analyses will be conducted to compare results with low vs high risk of  
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7 bias. Studies will not be included for meta-analysis if insufficient data is provided. Funnel plot  
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9 asymmetry will be conducted using a rank correlation between falls risk factors effects and their  
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11 standard error.<sup>30</sup> A minimum of 10 studies will be included in funnel plot analyses to ensure that  
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13 the test power is high enough to distinguish chance from real asymmetry.<sup>29</sup> If asymmetry occurs,  
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15 we will consider reporting bias, poor methodological quality, true heterogeneity, artefactual, and  
16  
17 chance factors during interpretation.<sup>29</sup>  
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### 21 **Data statement**

22 The dataset generated from this study will be available in the published article.  
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### 24 **Patient and public involvement**

25 Patients will not be involved in the design of this study protocol, as no participant  
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27 recruitment will be necessary.  
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### 32 **Amendments**

33 Should amendments to this protocol be necessary, they will be documented on  
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## 42 **DISCUSSION, ETHICS AND DISSEMINATION**

43 Many falls are preventable;<sup>31</sup> however, less is known about how to prevent falls among  
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45 those at a high fall risk. Thus, a better identification of risk factors for recurrent falls would  
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47 inform best practices for fall risk assessment and secondary fall prevention interventions. These  
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49 results may benefit clinicians in better assessing and treating their clients, older adults and their  
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51 caregivers by receiving best practice care, and policy makers with promoting and implementing  
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best practice care. Should the eligible articles present with substantial heterogeneity in risk factors for recurrent falling, we will report the sources of heterogeneity in the results and discuss their impact on the review.

No ethics approval will be required. The results of this systematic review and meta-analysis will be disseminated via peer-reviewed publication and conference presentation.

## ARTICLE SUMMARY

### Strengths and limitations of this study

- This systematic review with meta-analysis will identify risk factors specific to recurrent falls
- Some limitations will include:
  1. The heterogeneity of fall risk factors between studies
  2. The possible poor quality of included reports, which may limit the ability to generate conclusions based on high confidence
  3. Inadvertently omitting studies in the study search process
  4. The imprecision in the pooled effect estimate due to possible small sample sizes in some studies
  5. A healthier representation of recurrent fallers as a result of studies with significant loss to follow-up

### Acknowledgements

A special thank you to Charlotte Beck, who is a librarian and was instrumental in providing advice on structuring the keyword search, as well as to Dr. Carole Lunny, who provided important methodological considerations when conducting systematic reviews with meta-analyses.

**Author contributions**

TLA, JCD, and DAJ developed the research question. DAJ registered the protocol and wrote the first draft of the manuscript. DAJ and JCD developed the search strategy and created the data extraction form. JCD and TLA provided critical review and feedback at each stage of the process. All authors critically reviewed and edited the final manuscript.

**Funding**

This research did not receive any funding.

**Competing interests**

The authors declare that they have no competing interests.

**Patient consent for publication**

Not required.

**Provenance and peer review**

Not commissioned; externally peer reviewed.

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3 **Figure caption**  
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5 **Figure 1.** PRISMA flow diagram of the identification, screening, and eligibility of included  
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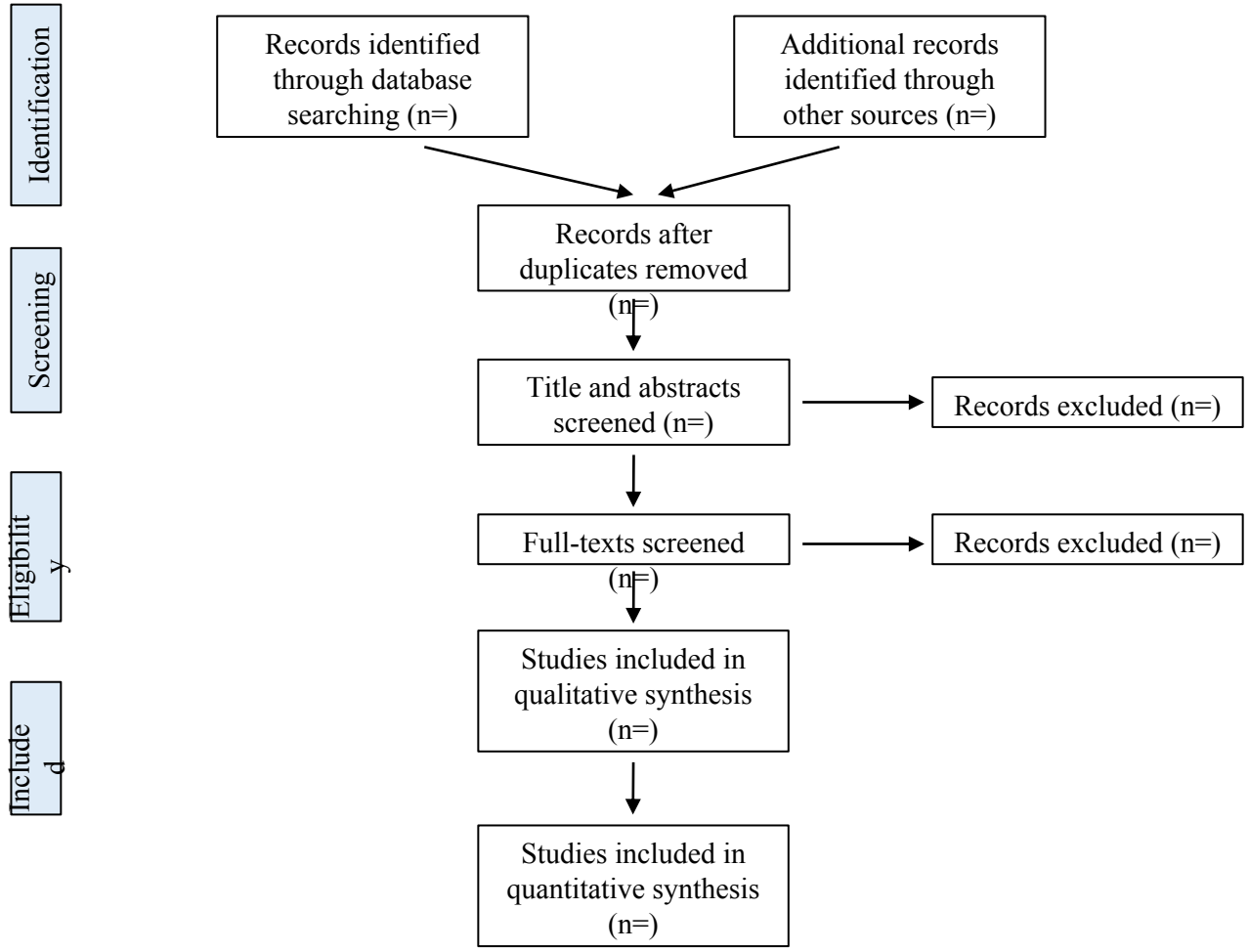
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## MEDLINE Search Strategy

1. Accidental falls/
2. Recurrence/
3. Secondary prevention/
4. 2 or 3
5. 1 and 4
6. ((recurren\* or secondary or subsequent or multiple or future or predict\* or prior or previous\* or history or inciden\* or prospective) adj3 fall\*
7. 5 or 6
8. Risk factors/ or accident prevention/ or uncertainty/
9. (prevention or ((risk or protective) adj3 (assess\* or factor\*)))
10. (screen\* or ((mediat\* or moderat\*) adj3 factor\*))
11. 8 or 9 or 10
12. Fall\*
13. 1 or 12
14. 11 and 13
15. Risk assessment/ or geriatric assessment/
16. 1 and 15
17. Risk adj3 fall\*
18. 16 or 17
19. 14 or 18
20. 7 or 19
21. Aged/ or "Aged , 80 and over"/ or "aging, premature"/ or healthy aging/ or aging/ or "cognitive aging"/ or geriatrics/ or "frail elderly"/ or "geriatric care"/ or "long-term care"/ or "homes for the aged"/
22. (elder\* or geriatric\* or ((old\* or aged) adj (person\* or adult\* or people or patient\*)) or frail)
23. 21 or 22
24. 20 and 23
25. Prospective studies/
26. Follow-up studies/
27. (prospective or follow up)
28. 25 or 26 or 27
29. 24 and 28

## EMBASE Search Strategy

1. falling/
2. Recurrence risk/
3. Secondary prevention/
4. 2 or 3
5. 1 and 4
6. ((recurren\* or secondary or subsequent or multiple or future or predict\* or prior or previous\* or history or inciden\* or prospective) adj3 fall\*
7. 5 or 6
8. Risk factor/ or prevention/ or uncertainty/
9. (uncertainty or prevention or (((risk or protective) adj3 (assess\* or factor\*)))
10. (screen\* or ((mediat\* or moderat\*) adj3 factor\*))
11. 8 or 9 or 10
12. Fall\*
13. 1 or 12
14. 11 and 13
15. Fall risk/ or fall risk assessment/
16. Risk adj3 fall\*
17. 15 or 16
18. 14 or 17
19. 7 or 18
20. Aging/ or elderly care/ or geriatrics/ or frail elderly/ or home care/ or geriatric care/
21. elder\* or geriatric\* or ((old\* or aged) adj (person\* or adult\* or people or patient\*)) or frail
22. 20 or 21
23. 19 and 22
24. Prospective study/
25. Follow up/
26. (prospective or follow up)
27. 24 or 25 or 26
28. 23 and 27

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3 PsycINFO Search Strategy  
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5 S1. DE “Falls”

6 S2. DE “Recurrence”

7 S3. DE “Preventative Medicine”

8 S4. S2 or S3

9 S5. S1 and S4

10 S6. ((recurren\* or secondary or subsequent or multiple or future or predict\* or prior or previous\*  
11 or history or inciden\* or prospective) N3 fall\*

12 S7. S5 or S6

13 S8. DE “Risk Factors” or DE “Prevention” or DE “Uncertainty”

14 S9. (uncertainty or prevention or ((risk or protective) N3 (assess\* or factor\*)))

15 S10. (screen\* or ((mediat\* or moderat\*) N3 factor\*))

16 S11. S8 or S9 or S10

17 S12. Fall\*

18 S13. S1 or S12

19 S14. S11 and S13

20 S15. DE “Screening” or DE “Risk assessment”

21 S16. S1 and S15

22 S17. Risk N3 fall\*

23 S18. S16 or S17

24 S19. S14 or S18

25 S20. S7 or S19

26 S21. DE “Aging” or DE “Geriatrics” or DE “Elder care”

27 S22. elder\* or geriatric\* or ((old\* or aged) N1 (person\* or adult\* or people or patient\*)) or frail

28 S23. S21 or S22

29 S24. S20 and S23

30 S25. DE “Prospective studies”

31 S26. DE “Followup Studies”

32 S27. (prospective or follow up)

33 S28. S25 or S26 or S27

34 S29. S24 and S28  
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### CINAHL Search Strategy

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6 S1. MH “Accidental falls”

7 S2. MH “Recurrence”

8 S3. S1 and S2

9 S4. ((recurren\* or secondary or subsequent or multiple or future or predict\* or prior or previous\*  
10 or history or inciden\* or prospective) N3 fall\*

11 S5. S3 or S4

12 S6. MH “Risk Factors” or MH “Fall Prevention” or MH “Uncertainty”

13 S7. (uncertainty or prevention or ((risk or protective) N3 (assess\* or factor\*)))

14 S8. (screen\* or ((mediat\* or moderat\*) N3 factor\*))

15 S9. S6 or S7 or S8

16 S10. Fall\*.mp

17 S11. S1 or S10

18 S12. S9 and S11

19 S13. MH “Fall Risk” or MH “Fall Risk Assessment Tool”

20 S14. MH “Health Screening”

21 S15. S1 and S14

22 S16. Risk N3 fall\*

23 S17. S13 or S15 or S16

24 S18. S12 or S17

25 S19. S5 or S18

26 S20. MH “Aging” or MH “Aged” or MH “Aged, 80 and Over” or MH “Geriatrics” or MH “Frail  
27 Elderly”

28 S21. elder\* or geriatric\* or ((old\* or aged) N1 (person\* or adult\* or people or patient\*)) or frail

29 S22. S20 or S21

30 S23. S19 and S22

31 S24. MH “Prospective studies”

32 S25. (prospective or follow up)

33 S26. S24 or S25

34 S27. S23 and S26  
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# Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Reporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

			Page Number
<b>Title</b>			
Identification	<a href="#">#1a</a>	Identify the report as a protocol of a systematic review	1
Update	<a href="#">#1b</a>	If the protocol is for an update of a previous systematic review, identify as such	NA

**Registration**

[#2](#) If registered, provide the name of the registry (such as PROSPERO) and registration number 3 and 5

**Authors**

[#3a](#) Contact Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author 1

[#3b](#) Contribution Describe contributions of protocol authors and identify the guarantor of the review 11-12

**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 NA

**Support**

[#5a](#) Sources Indicate sources of financial or other support for the review 12

[#5b](#) Sponsor Provide name for the review funder and / or sponsor 12

[#5c](#) Role of sponsor or funder Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol 12

**Introduction**

1	Rationale	<a href="#">#6</a>	Describe the rationale for the review in the context of what is	4
2			already known	
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6	Objectives	<a href="#">#7</a>	Provide an explicit statement of the question(s) the review	4
7			will address with reference to participants, interventions,	
8			comparators, and outcomes (PICO)	
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14	<b>Methods</b>			
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17	Eligibility criteria	<a href="#">#8</a>	Specify the study characteristics (such as PICO, study	5-6
18			design, setting, time frame) and report characteristics (such	
19			as years considered, language, publication status) to be	
20			used as criteria for eligibility for the review	
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27	Information	<a href="#">#9</a>	Describe all intended information sources (such as	6
28			electronic databases, contact with study authors, trial	
29	sources		registers or other grey literature sources) with planned dates	
30			of coverage	
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37	Search strategy	<a href="#">#10</a>	Present draft of search strategy to be used for at least one	Suppl
38			electronic database, including planned limits, such that it	file 1
39			could be repeated	
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45	Study records -	<a href="#">#11a</a>	Describe the mechanism(s) that will be used to manage	8
46			records and data throughout the review	
47	data management			
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50	Study records -	<a href="#">#11b</a>	State the process that will be used for selecting studies	6-7
51			(such as two independent reviewers) through each phase of	
52	selection process		the review (that is, screening, eligibility and inclusion in	
53			meta-analysis)	
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1	Study records -	<a href="#">#11c</a>	Describe planned method of extracting data from reports	6-8
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3	data collection		(such as piloting forms, done independently, in duplicate),	
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5	process		any processes for obtaining and confirming data from	
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7			investigators	
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11	Data items	<a href="#">#12</a>	List and define all variables for which data will be sought	7-8
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13			(such as PICO items, funding sources), any pre-planned	
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15			data assumptions and simplifications	
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19	Outcomes and	<a href="#">#13</a>	List and define all outcomes for which data will be sought,	7-8
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21	prioritization		including prioritization of main and additional outcomes, with	
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23			rationale	
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26	Risk of bias in	<a href="#">#14</a>	Describe anticipated methods for assessing risk of bias of	8-9
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28	individual studies		individual studies, including whether this will be done at the	
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30			outcome or study level, or both; state how this information	
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32			will be used in data synthesis	
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36	Data synthesis	<a href="#">#15a</a>	Describe criteria under which study data will be	9-10
37				
38			quantitatively synthesised	
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42	Data synthesis	<a href="#">#15b</a>	If data are appropriate for quantitative synthesis, describe	9-10
43				
44			planned summary measures, methods of handling data and	
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46			methods of combining data from studies, including any	
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48			planned exploration of consistency (such as I <sup>2</sup> , Kendall's $\tau$ )	
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51	Data synthesis	<a href="#">#15c</a>	Describe any proposed additional analyses (such as	9-10
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53			sensitivity or subgroup analyses, meta-regression)	
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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Data synthesis	<a href="#">#15d</a>	If quantitative synthesis is not appropriate, describe the type of summary planned	9-10
22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	Meta-bias(es)	<a href="#">#16</a>	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	5, 9-10
None	Confidence in cumulative evidence	<a href="#">#17</a>	Describe how the strength of the body of evidence will be assessed (such as GRADE)	8-9

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# BMJ Open

## Risk factors for recurrent falls in older adults: A study protocol for a systematic review with meta-analysis

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-033602.R1
Article Type:	Protocol
Date Submitted by the Author:	17-Dec-2019
Complete List of Authors:	Jehu, Deborah; The University of British Columbia, Physical Therapy; Davis, Jennifer; University of British Columbia, Department of Population & Public Health, Liu-Ambrose, Teresa; University of British Columbia, Department of Physical Therapy,
<b>Primary Subject Heading</b>:	Rehabilitation medicine
Secondary Subject Heading:	Diagnostics
Keywords:	Systematic review, meta-analysis, recurrent falls, risk factors, older adults

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10 Jehu DA<sup>1,2</sup>, Davis JC<sup>3</sup>, Liu-Ambrose T<sup>1,2\*</sup>.

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## ABSTRACT

**Introduction** Older adults who fall recurrently (i.e., > 1 fall per year) are at risk for functional decline and mortality. Key risk factors for recurrent falls in community-dwelling older adults are not well established due to methodological limitations, such as recall bias. A better understanding of the risk factors for recurrent falls will aid in refining clinical practice guidelines for secondary fall prevention strategies. The primary objective of this systematic review and meta-analysis is to examine the risk factors for recurrent falls in prospective studies among community-dwelling older adults.

**Methods and analysis** A comprehensive search for articles indexed in MEDLINE, EMBASE, PsycINFO, and CINAHL databases as well as grey literature was conducted on April 25, 2019. We will use MeSH and keyword search terms around the following topics: falls, recurrence, fall-risk, aging, and prospective studies. Prospective studies with monthly falls monitoring for 12 months, investigating risk factors for recurrent falls in older adults will be included. One author will complete the search. Two authors will remove duplicates and screen the titles and abstracts for their potential inclusion against the eligibility criteria. Two authors will screen the full-texts and extract the data using a piloted extraction sheet. Included studies will be evaluated for the risk of bias with the Joanna Briggs Institute Prevalence Critical Appraisal tools. The quality of reporting will be determined with the Strengthening the Reporting of OBservational studies in Epidemiology (STROBE). The data extraction will include study characteristics as well as sociodemographic, balance and mobility, sensory and neuromuscular, psychological, medical, medication, and environmental factors. The results will be presented via figures, summary tables, meta-analysis (when possible), and narrative summaries.

**Ethics and dissemination** No ethics approval will be required. Findings will be disseminated through publication and media.

**PROSPERO registration number** CRD42019118888

**Keywords:** Systematic review; meta-analysis; recurrent falls; risk factors; older adults

**Word count:** 2216

### **Strengths and limitations of this study**

- This systematic review with meta-analysis will identify risk factors specific to recurrent falls
- Some limitations will include:
  1. The heterogeneity of fall risk factors as well as the possible poor quality of included reports, which may limit the ability to generate conclusions based on high confidence
  2. The imprecision in the pooled effect estimate due to possible small sample sizes in some studies
  3. A healthier representation of recurrent fallers as a result of studies with significant loss to follow-up

## INTRODUCTION

Falls are a major health concern, and the second leading cause of unintentional injury deaths.<sup>1</sup> Older adults who fall more than once per year are defined as recurrent fallers.<sup>2-7</sup> Recurrent fallers are at higher risk for both morbidity and mortality than non-fallers and single fallers.<sup>7-17</sup> Thus, secondary prevention is critical for minimizing functional decline and maintaining quality of life.<sup>14</sup> A better understanding of risk factors for recurrent falls is needed to develop effective secondary fall prevention strategies.

Three systematic reviews have examined risk factors for recurrent falls among community-dwelling older adults but included retrospective fall data.<sup>18-20</sup> Retrospective studies are prone to more recall bias compared with prospective studies, as 5.8 % of non-fallers, 32.8 % of single fallers, and up to 50 % of recurrent fallers deny falling in the previous year when comparing retrospective to prospective falls monitoring.<sup>21</sup> One of these reviews only searched the literature between 2010-2014,<sup>20</sup> greatly limiting the scope of published evidence. The strength of the evidence in two of the three reviews is difficult to determine because assessment of study quality and risk of bias were not performed.<sup>19 20</sup> Thus, there is a need for a systematic review of data solely from prospective studies (of falls) with an evaluation of study quality and risk of bias.

The risk factors unique to recurrent falls remain unclear. Therefore, the purpose of this study is to conduct a systematic review with meta-analysis of the risk factors for recurrent falls in prospective studies only. Secondary questions include 1) do these risk factors vary as a function of biological sex; and 2) do these risk factors vary as a function of living situation. Another secondary aim is to conduct sensitivity analyses to compare studies with low versus high risk of bias to draw accurate conclusions on risk factors for recurrent falls.

## METHODS

### Design

The details of the protocol have been registered on the PROSPERO database under registration number Prospero ID: CRD42019118888. The current review methods followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P; Additional file 1),<sup>22</sup> and Meta-Analysis of Observational Studies in Epidemiology guidelines.<sup>23</sup>

### Inclusion criteria

#### *Types of studies*

All prospective quantitative studies examining risk factors contributing to recurrent falls in older adults published in English or French will be included. Prospective falls data must be collected at least monthly (e.g., phone calls, fall calendars) for 12 months to be included in this study. In case of multiple publications for one study, all articles will be used to obtain maximum information.

#### *Types of participants*

Studies will be included if participants: 1) are 60 years of age and older or are a mean age of 65 years and older; 2) are residing in the community, residential care, or clinical environments; and 3a) are recurrent fallers having sustained two or more falls in the first prospective year following the initial assessment; or 3b) have had a documented fall(s) in the previous 6 months and are being followed prospectively for 6 months for subsequent fall(s).

Note that a fall will be defined as “an unexpected event in which the participant comes to rest on the ground, floor or lower level”.<sup>24</sup> A recurrent faller will be defined as a person falling more than once in a 12-month prospective period.<sup>2-7</sup> Risk will be defined as “the probability that an unwanted health event (e.g., a future fall) will occur”.<sup>25</sup>

### ***Exclusion criteria***

Studies will be excluded if they: 1) focus on patient groups (e.g. neurodegenerative diseases) to promote a more homogenous sample; 2) only include retrospective falls data; 3) do not separate single fallers from recurrent fallers; and 4) are not prospective (e.g., cross-sectional studies, reviews and meta-analyses). Lastly, we will contact authors to inquire about fall outcome data that are not reported and give 4 weeks to respond.

### **Search strategy**

The following electronic databases will be searched: MEDLINE (Ovid interface; 1946-2019), EMBASE (Ovid interface: 1974-2019), PsycINFO (Ebsco interface: 1597-2019), and CINAHL (Ebsco interface: 1982-2019) on April 25, 2019. The search strategy for each database is provided in Supplementary file 1. We will manually search bibliographies of articles included in the review, the references of other study reviews that match our inclusion criteria, trial registries, and articles citing our eligible articles in Google Scholar and Web of Science. Conference proceedings will also be searched from the International Society for Posture and Gait Research between 1971-2019. We will also consult with content experts in the field to determine whether we have included all relevant articles (Figure 1).<sup>22</sup> The search algorithm for each database will be included in appendices.

### **Study selection**

One author will complete the search and remove the duplicates. Two authors will screen the titles and abstracts for their potential inclusion against the eligibility criteria, screen the full-texts, and extract the data using a pre-tested extraction sheet. After screening and data extraction is complete, the reviewers will compare their extracted data. In case of discrepancies, discussion will be held until consensus is reached. A third review team member will be consulted if

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2  
3 agreement cannot be reached. The PRISMA flow diagram will be constructed after the screening  
4  
5 process. Excluded articles will be listed in a supplementary file.  
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### 8 **Outcome measures and data extraction**

9

10 The primary outcome measure will be the rate of prospective falls because frequent  
11 fallers generally exhibit more fall risk factors and prospective falls study timelines are  
12 heterogeneous.<sup>18</sup> The fall rate per year will be calculated for each study using the following  
13  
14 formula:  
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$$18 \text{ Fall rate} = \frac{\text{average number of falls per participant}}{\text{days in the follow-up time period}} \times 365 \text{ days}$$

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23 Based on a fall risk classification system;<sup>26</sup> the data extraction sheet will be comprised of  
24 the following secondary outcomes.  
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- 27 • Study characteristics: i.e., article citation, country where the study was  
28 conducted, setting (community, hospital, long-term care), source of funding,  
29 declarations of interest of the primary researchers
- 30 • Sociodemographic factors: e.g., age, sex, fall characteristics (e.g., number of  
31 recurrent fallers, frequency retrospective and prospective falls, timeline of  
32 retrospective and prospective falls, method of collecting fall data, rate of falls,  
33 severity of injury(ies), time to first injury, fall risk)
- 34 • Balance and mobility factors: e.g., Tinetti Balance & Gait Assessment, Timed  
35 Up and Go Test (s), gait speed (m/s), sit-to-stand (s), sway area (mm<sup>2</sup>)
- 36 • Sensory and neuromuscular factors: e.g., visual impairment (e.g., cataracts,  
37 glaucoma; %), contrast sensitivity (dB), vision score, hearing impairment (%),  
38 pain (%), proprioceptive function (° error), dizziness (%), reaction time (ms),  
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3 muscle strength (N/m<sup>2</sup>)  
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6 • Psychological factors: e.g., Mini-Mental State Examination, Trail Making test,  
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8 fear of falling, Activities-specific Balance Confidence scale, Geriatric  
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10 Depression Scale, dual-tasking, Central Nervous System measures (e.g.,  
11  
12 magnetic resonance imaging)  
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14  
15 • Medical factors: comorbidities (% of those with none, 1, 2, or >2)  
16  
17 • Medication use: Medications known to influence falls or fall-risk factors (e.g.,  
18  
19 anti-depressants, sedatives, diuretics, vitamin D; % of sample)  
20  
21  
22 • Environmental factors: e.g., footwear (% of those with appropriate vs  
23  
24 inappropriate shoes), weather conditions (% of falls in slippery, wet, loose  
25  
26 gravel, and dry conditions), time of day (% of falls in the morning vs  
27  
28 evening), location (% of falls indoors vs outdoors)  
29  
30

31 When possible, the means of these outcomes will be collected at baseline before  
32  
33 prospective falls. Regression coefficients, standard errors, odds ratios, and relative risk will  
34  
35 also be extracted. We will examine any retraction statements and errata, which are associated  
36  
37 with included studies and, where applicable, update the recorded data accordingly.  
38  
39

#### 40 **Missing data management**

41  
42 Missing fall risk classification outcome data will be requested from authors. If missing  
43  
44 data still exists, the analysis will be conducted on the final available data. The potential  
45  
46 impact of missing data on the review findings will be addressed in the final report.  
47  
48

#### 49 **Quality of reporting**

50  
51 Researchers and clinicians are often constrained with reports of studies including  
52  
53 inadequate detail of information for data synthesis and implementation of findings.<sup>27</sup> Given  
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2  
3 the human and financial resources required to conduct clinical studies, inadequate reporting  
4 has ethical and moral implications.<sup>28</sup> The Strengthening the Reporting of OBServational  
5 studies in Epidemiology (STROBE) checklist was designed to guide researchers in the  
6 quality of reporting<sup>29</sup> and has shown good reliability,<sup>30</sup> however it was not designed to  
7 evaluate the quality of reporting.<sup>31</sup> To our knowledge, there are no dedicated or validated  
8 tools to assess the quality of reporting. Therefore, two authors will determine the reporting  
9 quality of the included articles using the STROBE to guide the interpretation of our findings.  
10 A study will be deemed as high quality if most criteria are met, while low quality will be  
11 assigned if few criteria are met. Reporting quality data from each study will be presented in  
12 tables and/or figures by STROBE tool items.

### 25 26 **Risk of bias assessment**

27  
28 Two independent reviewers will assess the risk of bias of each study using the Joanna  
29 Briggs Institute Prevalence Critical Appraisal tool and compare their results for any  
30 discrepancies. This tool was developed to assess the methodological quality of studies  
31 reporting prevalence data to be included in systematic reviews.<sup>32</sup> Using the Joanna Briggs  
32 Institute Prevalence Critical Appraisal Tool, a low risk of bias will be assigned to each  
33 eligible study if most methodological criteria are met, while a high risk of bias will be  
34 assigned for studies with few criteria are met. Disagreements between reviewers will be  
35 resolved through discussion with a third neutral reviewer on the team. In the discussion, a  
36 greater emphasis will be placed on studies with a low risk of bias. The risk of bias data from  
37 each study will be presented in tables and/or figures by Joanna Briggs Institute Prevalence  
38 Critical Appraisal tool items.

### 53 54 **Data synthesis and summary of results**

1  
2  
3 The findings from the study will be presented in a narrative synthesis, structured  
4 around the fall risk outcome measures, and presented in tables and figures. A table of study  
5 characteristics will be displayed including the following variables: citation, sample size, %  
6 female, mean age, and duration of prospective falls follow-up.  
7  
8  
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10  
11  
12 Where population and outcome of the studies are clinically, methodologically and  
13 statistically similar, a meta-analysis will be done by pooling appropriate data and using  
14 RefWorks 2.0. If enough data support a quantitative synthesis of fall risk outcomes, a  
15 random-effects meta-analysis will be performed on the pooled data given the potential  
16 heterogeneity in participant characteristics.  
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24 The  $I^2$  test will be used to test the statistical heterogeneity among all studies, as well as  
25 visual inspections of forest plots. We will consider a significance level less than 0.10 as evidence  
26 of heterogeneity. Substantial statistical (i.e.,  $I^2 \geq 50\%$ ) or methodological heterogeneity (e.g.,  
27 differences in fall risk factors explored, variation in the tools used to measure fall risk factors)  
28 may impact fall risk factors.<sup>33</sup> A priori subgroup analyses will be explored by comparing  
29 important participant factors between studies (e.g., age, sex, clinical condition, place of  
30 residence, number of recurrent falls) and study risk of bias factors (e.g., adequate adjustment of  
31 confounding variables, losses of prospective falls calendars) to reveal potential sources of  
32 heterogeneity. Sensitivity analyses will be conducted to compare results with low vs high risk of  
33 bias. Studies will not be included in the meta-analysis if insufficient data are provided or if they  
34 have a high risk of bias. Funnel plot asymmetry will be conducted using a rank correlation  
35 between falls risk factors effects and their standard error.<sup>34</sup> A minimum of 10 studies will be  
36 included in funnel plot analyses to ensure that the test power is high enough to distinguish  
37 chance from real asymmetry.<sup>33</sup> If asymmetry occurs, we will consider reporting bias, poor  
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3 methodological quality, true heterogeneity, artefactual, and chance factors during  
4  
5 interpretation.<sup>33</sup>  
6

### 7 **Data statement**

8  
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10 The dataset generated from this study will be available in the published article.  
11

### 12 **Patient and public involvement**

13  
14 Patients will not be involved in the design of this study protocol, as no participant  
15 recruitment will be necessary.  
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### 18 **Amendments**

19  
20 Should amendments to this protocol be necessary, they will be documented on  
21  
22 PROSPERO.  
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## 28 **DISCUSSION, ETHICS AND DISSEMINATION**

29  
30 Many falls are preventable;<sup>35</sup> however, less is known about how to prevent falls among  
31 those at a high fall risk. Thus, a better identification of risk factors for recurrent falls would  
32 inform best practices for fall risk assessment and secondary fall prevention interventions. These  
33 results may benefit clinicians in better assessing and treating their clients, older adults and their  
34 caregivers by receiving best practice care, and policy makers with promoting and implementing  
35 best practice care. Should the eligible articles present with substantial heterogeneity in risk  
36 factors for recurrent falling, we will report the sources of heterogeneity in the results and discuss  
37 their impact on the review.  
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49 No ethics approval will be required. The results of this systematic review and meta-  
50 analysis will be disseminated via peer-reviewed publication and conference presentation.  
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## ARTICLE SUMMARY

### Acknowledgements

A special thank you to Charlotte Beck, who is a librarian and was instrumental in providing advice on structuring the keyword search, as well as to Dr. Carole Lunny, who provided important methodological considerations when conducting systematic reviews with meta-analyses.

### Author contributions

TLA, JCD, and DAJ developed the research question. DAJ registered the protocol and wrote the first draft of the manuscript. DAJ and JCD developed the search strategy and created the data extraction form. JCD and TLA provided critical review and feedback at each stage of the process. All authors critically reviewed and edited the final manuscript.

### Funding

This research did not receive any funding.

### Competing interests

The authors declare that they have no competing interests.

### Patient consent for publication

Not required.

### Provenance and peer review

Not commissioned; externally peer reviewed.

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2  
3 **Figure caption**  
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5 **Figure 1.** PRISMA flow diagram of the identification, screening, and eligibility of included  
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8 articles.  
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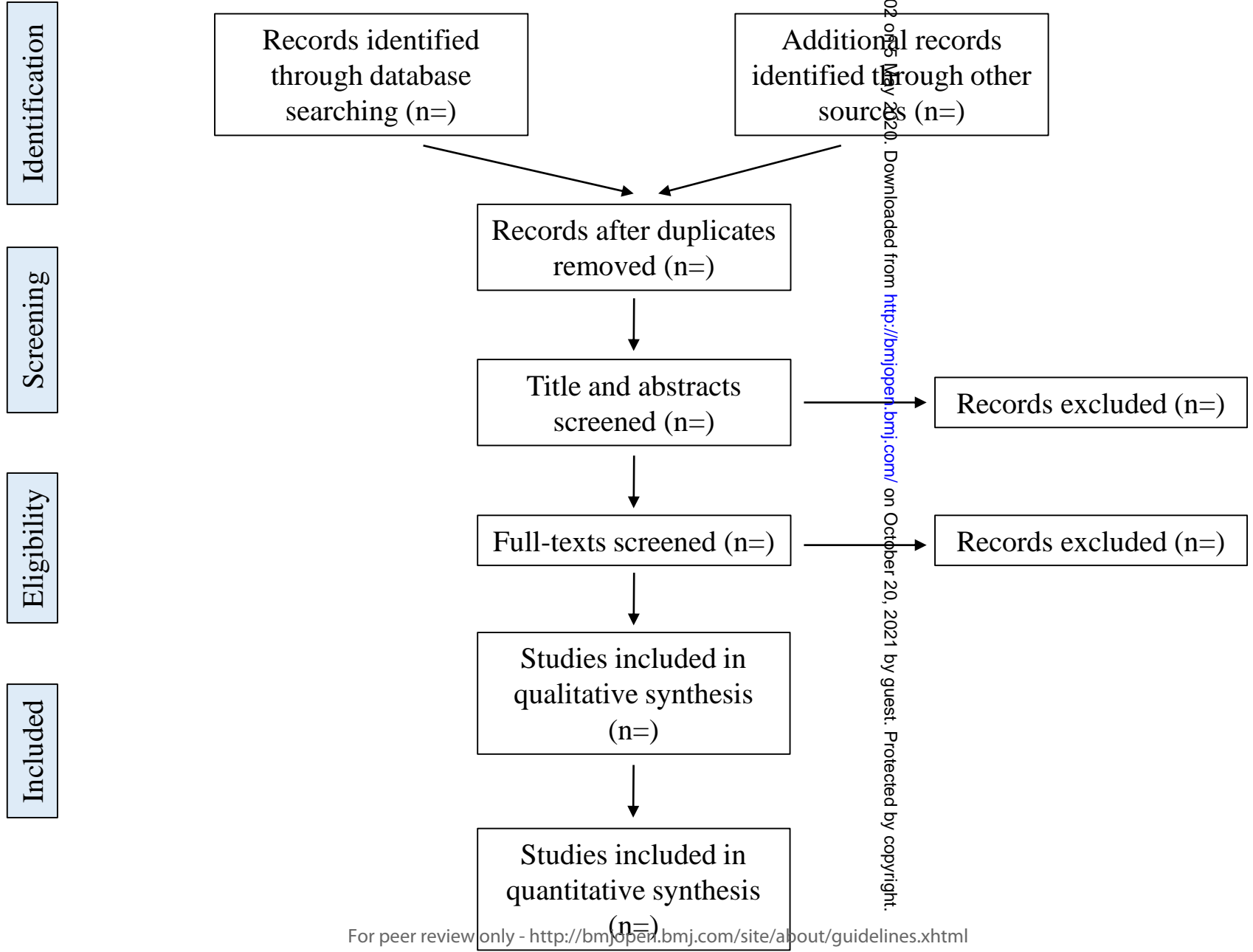


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Identification

Screening

Eligibility

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## MEDLINE Search Strategy

Line	Search term	Hits
1	Accidental falls/	22949
2	Fall*	210524
3	1 or 2	210524
4	Recurrence/	178628
5	Secondary prevention/	19552
6	(recurren* or secondary or subsequent or multiple or future or predict* or prior or previous* or history or inciden* or prospective) adj3 fall*	8047
7	4 or 5	197191
8	1 and 7	381
9	6 or 8	8200
10	Risk factors/ or accident prevention/ or uncertainty/	809583
11	(prevention or ((risk or protective) adj3 (assess* or factor*)))	2495194
12	(screen* or ((mediat* or moderat*) adj3 factor*))	705181
13	10 or 11 or 12	3059424
14	3 and 13	39768
15	Risk assessment/ or geriatric assessment/	274005
16	Risk adj3 fall*	8418
17	1 and 15	3736
18	16 or 17	10283
19	14 or 18	42078
20	9 or 19	45406
21	Aged/ or “Aged 80 and over”/ or “aging premature”/ or healthy aging/ or aging/ or “cognitive aging”/ or geriatrics/ or “frail elderly”/ or “geriatric care”/ or “long-term care”/ or “homes for the aged”/	3146188
22	(elder* or geriatric* or ((old* or aged) adj (person* or adult* or people or patient*)) or frail)	408801
23	21 or 22	3232687
24	20 and 23	20463
25	Prospective studies/	518785
26	Follow-up studies/	625713
27	(prospective or follow up)	1673498
28	25 or 26 or 27	1673498
29	24 and 28	4678

## EMBASE Search Strategy

Line	Search term	Hits
1	Falling/	18703
2	Fall*	198022
3	1 or 2	198022
4	Recurrence risk/	44494
5	Secondary prevention/	16931
6	(recurren* or secondary or subsequent or multiple or future or predict* or prior or previous* or history or inciden* or prospective) adj3 fall*	8902
7	4 or 5	61152
8	1 and 7	93
9	6 or 8	8970
10	Risk factor/ or prevention/ or uncertainty/	801974
11	(uncertainty or prevention or ((risk or protective) adj3 (assess* or factor*)))	1996608
12	(screen* or ((mediat* or moderat*) adj3 factor*))	800256
13	10 or 11 or 12	2659761
14	3 and 13	36587
15	Fall risk/ or fall risk assessment/	2392
16	Risk adj3 fall*	9586
17	15 or 16	9586
18	14 or 17	39923
19	9 or 18	44158
20	Aging/ or elderly care/ or geriatrics/ or frail elderly/ or home care/ or geriatric care/	253413
21	elder* or geriatric* or ((old* or aged) adj (person* or adult* or people or patient*)) or frail	462936
22	20 or 21	608097
23	19 and 22	12536
24	Prospective study/	275099
25	Follow up/	893012
26	(prospective or follow up)	1604690
27	24 or 25 or 26	1604690
28	23 and 27	2523

## PsycINFO Search Strategy

Line	Search term	Hits
S1	DE "Falls"	2638
S2	Fall*	54226
S3	S1 or S2	54226
S4	DE "Recurrence"	9915
S5	DE "Preventative Medicine"	5085
S6	((recurren* or secondary or subsequent or multiple or future or predict* or prior or previous* or history or inciden* or prospective) N3 fall*)	2378
S7	S4 or S5	9915
S8	S1 and S7	22
S9	S6 or S8	2380
S10	DE "Risk Factors" or DE "Prevention" or DE "Uncertainty"	159621
S11	(uncertainty or prevention or ((risk or protective) N3 (assess* or factor*)))	551410
S12	(screen* or ((mediat* or moderat*) N3 factor*))	123547
S13	S10 or S11 or S12	642511
S14	S3 and S13	10567
S15	DE "Screening" or DE "Risk Assessment"	33853
S16	Risk N3 fall*	2545
S17	S1 and S15	357
S18	S16 or S17	2602
S19	S14 or S18	11306
S20	S9 or S19	12409
S21	DE "Aging" or DE "Geriatrics" or DE "Elder Care"	86395
S22	elder* or geriatric* or ((old* or aged) N1 (person* or adult* or people or patient*)) or frail	208330
S23	S21 or S22	236857
S24	S20 and S23	3564
S25	DE "Prospective Studies"	30814
S26	DE "Followup Studies"	12371
S27	(prospective or follow up)	193819
S28	S25 or S26 or S27	197714
S29	S24 and S28	726

## CINAHL Search Strategy

Line	Search term	Hits
S1	MH "Accidental falls"	19553
S2	Fall*	53307
S3	S1 or S2	53307
S4	MH "Recurrence"	41148
S5	((recurren* or secondary or subsequent or multiple or future or predict* or prior or previous* or history or inciden* or prospective) N3 fall*)	4540
S6	S1 and S4	165
S7	S5 or S6	4599
S8	MH "Risk Factors" or MH "Fall Prevention" or MH "Uncertainty"	165086
S9	(uncertainty or prevention or ((risk or protective) N3 (assess* or factor*)))	955116
S10	(screen* or ((mediat* or moderat*) N3 factor*))	176692
S11	S8 or S9 or S10	1067833
S12	S3 and S11	21408
S13	MH "Fall Risk" or MH "Fall Risk Assessment Tool"	123
S14	MH "Health Screening"	40065
S15	Risk N3 fall*	8045
S16	S1 and S14	178
S17	S13 or S15 or S16	8126
S18	S12 or S17	22921
S19	S7 or S18	24292
S20	MH "Aging" or MH "Aged" or MH "Aged 80 and Over" or MH "Geriatrics" or MH "Frail Elderly"	760988
S21	elder* or geriatric* or ((old* or aged) N1 (person* or adult* or people or patient*)) or frail	218006
S22	S20 or S21	822798
S23	S19 and S22	13253
S24	MH "Prospective studies"	393051
S25	(prospective or follow up)	568391
S26	S24 or S25	568391
S27	S23 and S26	3030

# Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

## Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Reporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. *Syst Rev.* 2015;4(1):1.

		Reporting Item	Page Number
<b>Title</b>			
Identification	<a href="#">#1a</a>	Identify the report as a protocol of a systematic review	1
Update	<a href="#">#1b</a>	If the protocol is for an update of a previous systematic review, identify as such	NA
<b>Registration</b>			
	<a href="#">#2</a>	If registered, provide the name of the registry (such as PROSPERO) and registration number	3 and 5
<b>Authors</b>			
Contact	<a href="#">#3a</a>	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1



1	Contribution	<a href="#">#3b</a>	Describe contributions of protocol authors and identify the guarantor of the review	12
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4	<b>Amendments</b>			
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7		<a href="#">#4</a>	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	NA
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14	<b>Support</b>			
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16	Sources	<a href="#">#5a</a>	Indicate sources of financial or other support for the review	12
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18	Sponsor	<a href="#">#5b</a>	Provide name for the review funder and / or sponsor	12
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21	Role of sponsor or funder	<a href="#">#5c</a>	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	12
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25	<b>Introduction</b>			
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27	Rationale	<a href="#">#6</a>	Describe the rationale for the review in the context of what is already known	4
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31	Objectives	<a href="#">#7</a>	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4
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36	<b>Methods</b>			
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38	Eligibility criteria	<a href="#">#8</a>	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	5-6
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45	Information sources	<a href="#">#9</a>	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	6
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52	Search strategy	<a href="#">#10</a>	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Suppl file 1
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1	Study records -	<a href="#">#11a</a>	Describe the mechanism(s) that will be used to manage	8
2	data management		records and data throughout the review	
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4	Study records -	<a href="#">#11b</a>	State the process that will be used for selecting studies	6-7
5	selection process		(such as two independent reviewers) through each phase	
6			of the review (that is, screening, eligibility and inclusion in	
7			meta-analysis)	
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11	Study records -	<a href="#">#11c</a>	Describe planned method of extracting data from reports	6-8
12	data collection		(such as piloting forms, done independently, in duplicate),	
13	process		any processes for obtaining and confirming data from	
14			investigators	
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18	Data items	<a href="#">#12</a>	List and define all variables for which data will be sought	7-8
19			(such as PICO items, funding sources), any pre-planned	
20			data assumptions and simplifications	
21				
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24	Outcomes and	<a href="#">#13</a>	List and define all outcomes for which data will be sought,	7-8
25	prioritization		including prioritization of main and additional outcomes,	
26			with rationale	
27				
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29	Risk of bias in	<a href="#">#14</a>	Describe anticipated methods for assessing risk of bias of	9
30	individual studies		individual studies, including whether this will be done at the	
31			outcome or study level, or both; state how this information	
32			will be used in data synthesis	
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36	Data synthesis	<a href="#">#15a</a>	Describe criteria under which study data will be	10-11
37			quantitatively synthesised	
38				
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40	Data synthesis	<a href="#">#15b</a>	If data are appropriate for quantitative synthesis, describe	10-11
41			planned summary measures, methods of handling data and	
42			methods of combining data from studies, including any	
43			planned exploration of consistency (such as I <sup>2</sup> , Kendall's $\tau$ )	
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45				
46	Data synthesis	<a href="#">#15c</a>	Describe any proposed additional analyses (such as	10-11
47			sensitivity or subgroup analyses, meta-regression)	
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50	Data synthesis	<a href="#">#15d</a>	If quantitative synthesis is not appropriate, describe the	10-11
51			type of summary planned	
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54	Meta-bias(es)	<a href="#">#16</a>	Specify any planned assessment of meta-bias(es) (such as	10
55			publication bias across studies, selective reporting within	
56			studies)	
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1 Confidence in [#17](#) Describe how the strength of the body of evidence will be 8-9  
2 cumulative assessed (such as GRADE)  
3 evidence  
4  
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6 None The PRISMA-P checklist is distributed under the terms of the Creative Commons Attribution  
7 License CC-BY 4.0. This checklist can be completed online using <https://www.goodreports.org/>, a tool  
8 made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)  
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For peer review only