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Effectiveness of telerehabilitation and home-based falls prevention programs for community-dwelling older adults: a systematic review and meta-analysis protocol

Karen K Leung,1 Frances M Carr,2 Megan Kennedy,3 Matthew J Russell,4 Zainab Sari,1 Jean AC Triscott,1 Christina Korownyk1

**ABSTRACT**

**Introduction** Falls among older adults are associated with adverse sequelae including fractures, chronic pain and disability, which can lead to loss of independence and increased risks of nursing home admissions. The COVID-19 pandemic has significantly increased the uptake of telehealth, but the effectiveness of virtual, home-based fall prevention programmes is not clearly known. We aim to synthesise the trials on telerehabilitation and home-based falls prevention programmes to determine their effectiveness in reducing falls and adverse outcomes, as well as to describe the safety risks associated with telerehabilitation.

**Methods and analysis** This protocol was developed using the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P). Database searches from inception to August 2022 will be conducted without language restrictions of MEDLINE, EMBASE, Ovid HealthSTAR, CINAHL, SPORTDiscus, Physiotherapy EvidenceDatabase (PEDro) and the Cochrane Library. Grey literature including major geriatrics conference proceedings will be reviewed. Using Covidence software, two independent reviewers will in duplicate determine the eligibility of randomised controlled trials (RCTs). Eligible RCTs will compare telerehabilitation and home-based fall prevention programmes to usual care among community-dwelling older adults and will report at least one efficacy outcome: falls, fractures, hospitalisations, mortality or quality of life; or at least one safety outcome: pain, myalgias, dyspnoea, syncope or fatigue. Secondary outcomes include functional performance in activities of daily living, balance and endurance. Risk of bias will be assessed using the Cochrane Collaboration tool. DerSimonian-Laird random effects models will be used for the meta-analysis. Heterogeneity will be assessed using the $I^2$ statistic and Cochran’s Q statistic. We will assess publication bias using the Egger’s test. Prespecified subgroup analyses and univariate meta-regression will be used.

**Ethics and dissemination** Ethics approval is not required. The results will be disseminated through peer-reviewed publications and conference presentations. PROSPERO registration number CRD42022356759.

**STRENGTHS AND LIMITATIONS OF THIS STUDY**

⇒ This protocol was developed in accordance with Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) Protocols, and the review will follow the PRISMA guidelines.

⇒ Comprehensive database searches without language restrictions will be completed in collaboration with a medical librarian. To reduce the risk of publication bias, grey literature sources will be searched.

⇒ This review is timely given the rapid uptake of telerehabilitation and virtual services during the COVID-19 pandemic. Furthermore, there is a continued need for telehealth to ameliorate the extensive waitlists for in-person healthcare.

⇒ Due to the diversity of fall prevention strategies and the technological support required by various telerehabilitation programmes, we anticipate the presence of significant heterogeneity, which may limit our meta-analytic synthesis.

⇒ Heterogeneity will be quantified and explored through prespecified subgroup analyses and univariate meta-regression.

**INTRODUCTION**

For older adults, remaining independent in the community is an important healthcare goal.1 One in three adults over the age of 65 years has experienced at least one fall,2 which can be associated with significant adverse outcomes that may jeopardise independent living.3 Epidemiological studies have demonstrated that a history of falls triples the risk of nursing home placement.3 Falls also account for 85% of injury-associated hospitalisations among older adults and are the leading cause of mortality due to unintentional injuries.4 Since 2007, deaths due to accidental falls have increased by over 30% especially among those aged 85 years and greater,4 reflecting a rapidly ageing population with an increasing...
burden of frailty. Among survivors, falls can lead to disability and dependence in activities of daily living because of fractures, traumatic head injuries and pain syndromes.

The social distancing measures introduced to curb the transmission of COVID-19 have resulted in widespread changes in daily life including for older adults, who were at a 13-fold risk for increased mortality had they acquired the infection during the early phases of the pandemic. Studies across several countries have found that older adults experienced increased social isolation as well as significant declines in physical activity, functional mobility and muscle strength and power. In turn, there were increased fears associated with falling and loss of mobility. Longitudinal studies have reported that while the rates of falls were initially lower compared with the prepandemic era, falls and orthopaedic injuries subsequently increased when restrictions were lifted, potentially reflecting the deconditioning and impaired balance that accrued with sedentarism.

The COVID-19 pandemic has also resulted in fundamental shifts in health services delivery from in-person interactions to telehealth and virtual care. Systematic reviews of previous randomised controlled trials (RCTs) that examined singular and multifactorial combinations of group-based exercise (eg, balance and resistance training), micronutrient supplementation (eg, vitamin D) and the deprescribing of medications associated with falls (eg, sedative–hypnotics) have reported efficacy and cost-effectiveness. A Cochrane review found that supervised group-based exercises reduced the risk of falls by 23%, while other systematic reviews found that community fall prevention programmes with longer durations reduced the risk of injurious falls and fractures but not hospitalisations and mortality. However, community programmes including group exercise interventions were largely halted or reduced because of social distancing measures, which has necessitated the urgent synthesis of best practices and evidence to inform the development of individualised, home-based falls prevention programmes.

Tele-rehabilitation may be defined as interventions to improve the psychological and physical functioning of individuals using various technologies and telecommunication strategies to both provide activities and monitor their progress and safety from a distance. Various home-based fall prevention RCTs have been published in the last 2 years, although findings were heterogenous ranging from fewer falls and fractures to no significant differences in falls, hospitalisations or mortality, compared with usual care, which typically consisted of routine medical care and advice on falls prevention and physical activity. Exploring the factors that may have contributed to the heterogeneity in efficacy, such as participant comorbidities (eg, dementia, frailty and chronic pain) and study design (eg, amount of technological and caregiver support required for successful implementation), is needed.

In addition, systematic analyses examining adverse outcomes associated with home-based fall prevention trials are also essential. While systematic reviews of other home-based programmes, such as cardiac rehabilitation, have reported no significant differences in the rates of adverse cardiac events and hospitalisations, concerns remain of whether home-based exercises for falls prevention can be delivered safely with minimal in-person supervision to subsets of frail older adults who are already at high risks for falls at baseline. Understanding the risks of severe adverse events such as falls during exercise in addition to milder adverse outcomes such as pain, myalgias, fatigue and shortness of breath are important, as these are all barriers to long-term adherence to exercise.

To our knowledge, few systematic reviews have examined the risks and benefits of home-based fall prevention programmes using telehealth for community-dwelling older adults. Two recent systematic reviews examined eHealth interventions and exergaming for older adults, but their primary outcomes were focused on static and dynamic balance. While important, surrogate markers including tests of hand-grip strength and balance are indirect measures of patient-important endpoints such as falls and fractures. Furthermore, a number of falls prevention trials have recently been completed among older adults with conditions such as Parkinson’s disease, cardiopulmonary disease and chronic kidney disease, which have not been included in previous reviews. Given the continued need for home-based rehabilitation to help ameliorate the long waitlists for in-person care in the community, this systematic review will provide a timely assessment and evaluation of these programmes for preventing falls and their adverse sequelae.

Objectives
We will conduct a systematic review and meta-analysis examining the effectiveness and safety of home-based exercise and fall prevention programmes that are delivered remotely through telehealth for community-dwelling older adults. The primary objective of this review is to determine whether trials of home-based falls prevention programmes compared with usual care demonstrate a decrease in the rate of falls (including injurious falls and recurrent falls), fractures, hospitalisations, mortality and quality of life. This review also seeks to examine patient-important adverse events including falls during the exercise intervention, worsening osteoarthritic pain and myalgias, syncope, shortness of breath and fatigue, which may limit the uptake of these programmes. The secondary objectives are to examine surrogate measures of functional performance in activities of daily living, balance and endurance.

METHODS
The Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) and PRISMA Protocol (PRISMA-P) will guide this protocol and subsequent review
ences.22 Although we acknowledge the challenges of sufficiently long to detect clinically significant differences.22 Although we acknowledge the challenges of recruiting older adults for RCTs during the pandemic,38 we will exclude trials with fewer than 20 participants in each treatment arm, which may be underpowered to detect small to medium effect sizes.40 Moreover, in a comparable RCT examining exercise for falls prevention in long-term care, an a priori power calculation showed that a minimum total sample size of 35 participants was needed to detect a small effect size with an α of 0.05 and β of 0.8, after accounting for potential dropout rates.41 We will exclude observational research such as cohort, case–control and qualitative studies due to their inherent increased risk of bias and confounding, which may preclude causal associations.12

The population will consist of community-dwelling older adults, and we will exclude studies conducted in nursing homes or long-term care facilities where access to 24-hour skilled nursing care is necessary for maintaining health and well-being.43 Therefore, we operationally define community dwelling as residing in one’s home or in a congregate apartment environment including independent living, lodges or assisted living,44 where continuous skilled nursing care is not provided. RCTs will be included if the mean age of participants is greater than 60. We will exclude trials conducted in hospitals, rehabilitation settings and hospices.

Eligible interventions will be single or multifactorial falls prevention programmes designed for home environments that are delivered remotely or through telehealth. Trials that have the initial baseline assessment and periodic outcome reviews completed in a community or clinic setting will be eligible if at least 50% of the exercise programme occurs in the home. Trials must have relevant comparator groups that were unexposed to the home-based falls prevention programme or received usual care.

Finally, trials are eligible if they reported at least one efficacy outcome regarding rates of falls (including injurious or recurrent falls), fractures, hospitalisations, mortality or quality of life. Trials will also be eligible if they reported at least one safety outcome regarding severe adverse events, such as falls during exercise and injuries or hospitalisations attributed to the intervention by each trial’s safety committee,46 as well as mild to moderate adverse events, such as pain, myalgias, shortness of breath, fatigue, dizziness or syncope. Trials reporting secondary surrogate markers of functional performance in activities of daily living, balance and endurance measured using validated scales (eg, the Barthel Index or Short Physical Performance Battery) will only be included if they also report on one of the efficacy or safety outcomes.

**Preliminary search strategy**

Database searches from inception to August 2022 will be conducted of MEDLINE, EMBASE, and Healthstar via OVID, CINAHL and SPORTDiscus via EBSCOhost, Physical Therapy Evidence Database (PEDro), and the Cochrane Library via Wiley. To increase the search sensitivity, language, date of publication and other limits will not be applied. The search will be reported in adherence to the PRISMA for Searching extension.47 To reduce publication bias, the reviewers will search electronic grey literature sources from 2015 to August 2022 including ProQuest Dissertations & Theses Global and Scopus as well as the conference proceedings from the Canadian Geriatrics Society, American Geriatrics Society, British Geriatrics Society and the International Association of Geriatrics and Gerontology. The reviewers will complete citation chaining using Scopus in order to examine the citations of retained articles and to locate additional publications.

Experts and research teams will be contacted regarding their knowledge of any missed or ongoing systematic reviews.

In consultation with a research librarian (MK), a search strategy will be developed to broadly identify publications relevant to older adults and nursing home admissions. Box 1 presents the proposed search strategy in MEDLINE. A validated systematic review and meta-analysis methodological filter will be applied.48 Terms will be truncated to capture alternative spelling, and search queries will be linked with AND to expand the search. The search terms proposed will prioritise sensitivity over precision with the goal of maximising the search returns.49

**Study selection**

All the retrieved documents will be managed using Covidence software.50 Two of the authors will independently determine the eligibility in duplicate by first performing a screen of the titles and abstracts. Abstracts published in Chinese, Japanese or Arabic will be translated by fluent reviewers. Abstracts published in other languages will be translated using Google Translate software, which, in a previous methodological study, an acceptable level of agreement with native speakers in nine different languages was observed during the data extraction process for a systematic review.51 Any abstracts retained for full-text review will then be translated via professional resources available through the Cochrane Engage platform.52

All titles and abstracts that are rated discordantly will be retained for full-text review. The observed agreement between reviewers at the screening stage will be quantified using the kappa statistic. Two reviewers will then independently review the full texts in duplicate. Disagreements about retention will be discussed with input from a third reviewer until consensus is achieved. In instances where multiple publications are available on the same trial (eg, conference abstract and article), we will retain...
Box 1  Sample MEDLINE search strategy

1. Accidental Falls/
2. (fall* adj3 (risk* or prevent* or reduc*)).mp.
3. (“accidental* fall*” or “uninten* fall*”).mp.
4. 1 or 2 or 3
5. telemedicine/ or telerehabilitation/
6. (Telehealth or tele-health or telemedicine or tele-medicine or tele-rehab* or tele-rehab* or teleconsult* or tele-consult* or “electronic health” or “mobile health” or “digital health”).mp. not “electronic health record*”.ab.
7. (eHealth or mHealth).mp.
8. (“remote* deliver*” or teleconference* or tele-conferenc* or video-conferenc* or video-conferenc* or “remote intervention*” or “video consult*”).mp.
9. (online* or internet* or website* or web-site* or “web-based” or “web-intervention*” or video* or virtual* or technology* or “digital technology*”).ti,ab.
10. (iPad* or tablet* or smartphone* or “smart phone*” or “mobile phone*” or “cell phone*” or iPhone* or Samsung or Android or “mobile app*” or computer* or laptop* or “smart home*” or Kinect or Google).mp.
11. (playstation or “play station” or videogam* or “video gam*” or “gam* console*” or Wii or Nintendo or Xbox or x-box or “virtual reality” or “augmented reality” or “google glass*” or “gam* or exergam*”).mp.
12. exp Video Games/
13. Internet-Based Intervention/
14. computers/ or microcomputers/ or exp computers, handheld/ or gamification/ or mobile applications/ or web browser/
15. wearable electronic devices/ or fitness trackers/ or smart glasses/
16. (“wearable device*” or “wearable technolog*” or Fitbit or “fit bit” or “fitness tracker*” or “physical activity tracker*” or “Apple Watch”).mp.
17. or 5-16
18. exercise/ or exergaming/ or muscle stretching exercises/ or physical conditioning, human/ or circuit-based exercise/ or endurance training/ or plyometric exercise/ or resistance training/
19. exp Exercise Therapy/
20. exp Postural Balance/
21. Physical Fitness/
22. physical therapy modalities/ or exp exercise movement techniques/ or exp musculoskeletal manipulations/
23. (exercis* or (balance adj2 (exercis* or therap* or intervention* or train*)) or “work out*” or “workout” or “physical activit*” or “resistance training” or “strength training” or “physical fitness” or physio* or “physical therap*” or rehab*).mp.
24. or 18-23
25. randomized controlled trial.pt.
26. clinical trial.pt.
27. randomi?ed.ti,ab.
28. placebo.ti,ab.
29. dt.fs.
30. randomly.ti,ab.
31. trial.ti,ab.
32. groups.ti,ab.
33. or/25-32
34. animals/
35. humans/
36. 34 not (34 and 35)
37. 33 not 36
38. 4 and 17 and 24 and 37

the more comprehensive journal article. The observed agreement between reviewers will again be quantified using the kappa statistic.

Data extraction and quality assessment

Two reviewers will independently extract the data using a standardised template developed with Covidence software. We will collect study characteristics including the year of publication, regions of study, sample size, mean age and sex ratios. For each RCT, we will extract the median frailty severity scores where available, proportion of individuals with dementia, whether participants at baseline are at high or low risk for falls, and overall comorbidity burden.

We will classify whether the interventions are for falls prevention in general or for specific medical subgroups, such as individuals with neurological (eg, stroke or Parkinson’s disease) or cardiopulmonary conditions (eg, congestive heart failure or chronic obstructive pulmonary disease). We will extract descriptions of the interventions and group them using the taxonomy developed by the Prevention of Falls Network Europe including singular versus multifactorial interventions, gait, balance and functional task training.55 We will further categorise interventions based on the amount of technological support required including low (eg, exercise handouts, videos or web-based exercises, or telephone support), moderate (eg, the aforementioned in addition to computer-based teleconference and exergaming technologies such as Wii or remote monitoring devices) and high (eg, the aforementioned in addition to augmented reality devices). We will extract information regarding the median duration of the interventions, lengths of follow-up, attrition rates and any reported dose–response relationships.

Where possible, we will prioritise the outcomes from the intention-to-treat analyses. If multiple treatment arms are present, we will weigh possible combine related arms to reduce the risk of bias caused by multiple comparisons to one control group.54 Specifically, related treatment arms may be combined if they are qualitatively similar with no significant differences in outcomes between groups (eg, volitional step training with vs without an unstable platform)55 to enable a single pairwise comparison (eg, volitional step training in general) with usual care. The primary outcomes of interest are rates of falls (including injurious or recurrent falls), fractures, hospitalisations, mortality or quality of life. We will also extract for safety outcomes of pain, myalgia, shortness of breath, fatigue, dizziness or syncope. Finally, we will extract for secondary surrogate measures of functional performance in activities of daily living, balance and endurance measured using validated scales (eg, the Barthel Index or Short Physical Performance Battery). In instances where there is insufficient data, the corresponding authors of the trials will be contacted at least two times for supplemental data.

The risk of bias in each trial with be assessed using the Cochrane Collaboration’s tool and will be critically
appraised for risk of selection bias, performance bias, detection bias, attrition bias and reporting bias.

**Data synthesis and analysis**

A narrative synthesis of the primary and secondary outcomes will be presented. Meta-analysis will be further conducted using Stata V16 meta-package if at least two point estimates are available per outcome. Separate Dersimonian-Laird random-effect models will be used to pool the effect estimates. Given the diverse social contexts and variety of telehealth strategies used in the studies, we will use random-effect models, which yield more conservative pooled estimates and take into consideration the variation in effect sizes observed between studies.

For discrete outcomes such as falls, fractures and mortality, we will treat event rate ratios, incidence density ratios and hazards ratios as equivalent to relative risks (RR) for meta-analytic purposes. OR will be transformed into RR, using the following procedure: $RR = OR / [(1−P_0)+(P_0×OR)]$, where $P_0$ is the incidence of the outcome in the control group. For continuous outcomes such as change scores in functional abilities and quality of life, we will calculate the standardised mean differences (SMD), which eliminate the unit of analysis errors when pooling together measurements using different scales.

To enable interpretability and comparability of discrete and continuous outcomes together, SMD may be transformed to ORs in accordance to the Cochrane Handbook using the formula, $\text{Ln}(OR)=\text{SMD}×3^{0.5}$. Sensitivity analyses will be completed to assess for the effects of these transformations and imputations.

We will assess the heterogeneity by visually inspecting the forest plots, and we will quantify the magnitude using the $I^2$ and Cochran’s Q statistic (significance of $p<0.05$). We will assess publication bias and small study effects using the Egger’s test (significance of $p<0.05$) and by visual inspection of the funnel plots. A sensitivity analysis will be conducted regarding the effects of including grey literature in the meta-analysis.

We will perform a priori subgroup analyses stratifying by intervention type (eg, singular vs multifactorial interventions), programme type (eg, balance vs strength exercises), technological requirements (eg, low, moderate or high), proportion of the intervention delivered remotely at home, baseline frailty (eg, prefrail, frail or severely frail), baseline mobility (eg, independent walkers vs gait-aid users), baseline falls risk (primary prevention for adults at risk for falls vs secondary prevention for adults with recurrent falls), presence of dementia, amount of caregiver support required and disease-specific interventions (eg, neurological vs cardiopulmonary). We will also conduct a stratified analysis based on the indicators of study quality (eg, low vs high risk of bias). Sensitivity analyses will be conducted to examine the effects of methodological decisions such including pilot studies, non-English language RCTs and combining multiple treatment arms. Univariate meta-regression will be used to examine the relationship between these factors, effect sizes and the heterogeneity statistics.

Finally, to contextualise our findings, we will calculate the pooled number needed to treat to prevent one fracture by taking the inverse of the pooled risk differences. We will further use the Grading of Recommendations, Assessment, Development and Evaluations to rate the overall certainty and quality of the evidence, which could be used to make evidence-informed decisions for clinical care.

**Patient and public involvement**

Patients were not directly involved in this systematic review and meta-analysis. However, the objectives of this review align with the Seniors Health Research Priority Setting Partnership developed in Alberta, Canada, which engaged end users including patients, caregivers, agency representatives and clinicians to identify health research priority topics and to support knowledge synthesis grants. This review was funded by a knowledge synthesis grant, which sought to examine strategies for maintaining independence in the community and improving healthcare accessibility for older adults living in rural and remote communities through telehealth.

**ETHICS AND DISSEMINATION**

Ethics approval is not required for this systematic review and meta-analysis. We will use the Canadian Institutes of Health Research Knowledge Translation Planning Guide for disseminating the results, including through peer-reviewed publications and presentations at academic conferences. The results will be shared locally at hospital grand rounds presentations to a multidisciplinary audience including physicians, physiotherapists, occupational therapists and other clinicians who deliver similar falls interventions as those being evaluated in this systematic review. Finally, we will disseminate the results using lay-appropriate language to our local partners and their clients in our informal clinical networks.

**Amendments**

In the event of a protocol amendment, the date of the amendment along with a description of the change and rationale will be provided to PROSPERO. Changes will not be directly incorporated into the original protocol.

**Author affiliations**

1Department of Family Medicine, University of Alberta Faculty of Medicine and Dentistry, Edmonton, Alberta, Canada
2Department of Internal Medicine (Geriatrics), University of Alberta Faculty of Medicine and Dentistry, Edmonton, Alberta, Canada
3John W. Scott Health Sciences Library, University of Alberta, Edmonton, Alberta, Canada
4PolicyWise for Children & Families, Edmonton, Alberta, Canada

**Acknowledgements** We thank Dr Peter Tian in the department of family medicine at the University of Alberta for his assistance in coordinating the logistics of this research project.
Contributors KL drafted the manuscript with input from all coauthors. MK developed the search strategy. KL, FMC, MK, JACT and CK contributed to development of the selection criteria, and KL, MJR, and CK developed the strategy for assessing the risk of bias and data extraction criteria. KL, MJR and ZS provided support with language translation. All authors have read and provided approval of this manuscript prior to submission.

Funding This work was supported by the Alberta Health Services Provincial Seniors Health and Continuing Care Knowledge Synthesis Grant. The funder was not involved in the development of the protocol and analytic plan and will not be involved in the interpretation or dissemination of the results.

Competing interests KL was a clinician member of the Steering Group for the Alberta Health Services Seniors’ Health Priority Setting Partnership, which was a volunteer role that ended in 2019. The other authors do not have any competing interests to declare.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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ORCID iD Karen K Leung http://orcid.org/0000-0002-3365-9245

REFERENCES


50 Covidence. Covidence systematic review software, veritas health innovation. Melbourne, Australia.


Appendix A: PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist:

recommended items to address in a systematic review protocol*

<table>
<thead>
<tr>
<th>Section and topic</th>
<th>Item No</th>
<th>Checklist item</th>
<th>Page (Paragraph#)</th>
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<tbody>
<tr>
<td><strong>ADMINISTRATIVE INFORMATION</strong></td>
<td></td>
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<tr>
<td>Title: Identification</td>
<td>1a</td>
<td>Identify the report as a protocol of a systematic review</td>
<td>1</td>
</tr>
<tr>
<td>Update</td>
<td>1b</td>
<td>If the protocol is for an update of a previous systematic review, identify as such</td>
<td>N/A</td>
</tr>
<tr>
<td>Registration</td>
<td>2</td>
<td>If registered, provide the name of the registry (such as PROSPERO) and registration number</td>
<td>3</td>
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<tr>
<td>Authors:</td>
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<tr>
<td>Contact</td>
<td>3a</td>
<td>Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author</td>
<td>1</td>
</tr>
<tr>
<td>Contributions</td>
<td>3b</td>
<td>Describe contributions of protocol authors and identify the guarantor of the review</td>
<td>15(3)</td>
</tr>
<tr>
<td>Amendments</td>
<td>4</td>
<td>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</td>
<td>15(1)</td>
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<tr>
<td>Support:</td>
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<tr>
<td>Sources</td>
<td>5a</td>
<td>Indicate sources of financial or other support for the review</td>
<td>15(4)</td>
</tr>
<tr>
<td>Sponsor</td>
<td>5b</td>
<td>Provide name for the review funder and/or sponsor</td>
<td>15(4)</td>
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<tr>
<td>Role of sponsor or funder</td>
<td>5c</td>
<td>Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol</td>
<td>15(4)</td>
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<tr>
<td><strong>INTRODUCTION</strong></td>
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<tr>
<td>Rationale</td>
<td>6</td>
<td>Describe the rationale for the review in the context of what is already known</td>
<td>4(1)-7</td>
</tr>
<tr>
<td>Objectives</td>
<td>7</td>
<td>Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)</td>
<td>7(1)</td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
<td></td>
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<tr>
<td>Eligibility criteria</td>
<td>8</td>
<td>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</td>
<td>7(1)-9</td>
</tr>
<tr>
<td>Information sources</td>
<td>9</td>
<td>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</td>
<td>9(2)-10</td>
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<tr>
<td>Search strategy</td>
<td>10</td>
<td>Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated</td>
<td>Table 1</td>
</tr>
<tr>
<td>Study records:</td>
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<tr>
<td>Data management</td>
<td>11a</td>
<td>Describe the mechanism(s) that will be used to manage records and data throughout the review</td>
<td>10(2)</td>
</tr>
<tr>
<td>Selection process</td>
<td>11b</td>
<td>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)</td>
<td>10(2)</td>
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<tr>
<td>Data collection process</td>
<td>11c</td>
<td>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</td>
<td>10(2-3)</td>
</tr>
<tr>
<td>Data items</td>
<td>12</td>
<td>List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications</td>
<td>11(1)-12</td>
</tr>
<tr>
<td>Outcomes and prioritization</td>
<td>13</td>
<td>List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale</td>
<td>11(3)</td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>14</td>
<td>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</td>
<td>12(2)</td>
</tr>
<tr>
<td>Data synthesis</td>
<td>15a</td>
<td>Describe criteria under which study data will be quantitatively synthesised</td>
<td>10(3)</td>
</tr>
<tr>
<td></td>
<td>15b</td>
<td>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)</td>
<td>12(2)-13</td>
</tr>
<tr>
<td></td>
<td>15c</td>
<td>Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)</td>
<td>13(3)-14</td>
</tr>
<tr>
<td></td>
<td>15d</td>
<td>If quantitative synthesis is not appropriate, describe the type of summary planned</td>
<td>10(3)</td>
</tr>
<tr>
<td>Meta-bias(es)</td>
<td>16</td>
<td>Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)</td>
<td>12(2)</td>
</tr>
<tr>
<td>Confidence in cumulative evidence</td>
<td>17</td>
<td>Describe how the strength of the body of evidence will be assessed (such as GRADE)</td>
<td>14(1)</td>
</tr>
</tbody>
</table>