STUDY PROTOCOL

Effectiveness of non-pharmacological falls prevention interventions for people with Multiple Sclerosis, Parkinson’s Disease and stroke: protocol for an umbrella review [version 1; peer review: 1 approved with reservations]

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Abstract

Background: Falls are common among people with neurological diseases and are associated with many negative physical, psychosocial and economic consequences. Implementation of single diagnosis falls prevention interventions is currently problematic due to lack of participants and resources. Given the similarities in falls risk factors across stroke, Parkinson’s Disease (PD) and Multiple Sclerosis (MS), the development of an intervention designed for mixed neurological populations seems plausible and may provide a solution to current implementation challenges. This umbrella review aims to summarise the totality of evidence regarding the effectiveness of non-pharmacological falls prevention interventions for people with MS, PD and stroke and to identify the commonalities and differences between interventions that are effective for each disease to inform the development of an intervention for mixed diagnoses.

Methods: This umbrella review will be conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. Electronic databases and grey literature will be searched. Systematic reviews of randomised controlled trials (RCTS) and studies investigating the effects of non-pharmacological falls prevention interventions on falls outcomes among people with MS, PD and stroke will be included. Methodological quality of included reviews will be assessed using the Assessment of Multiple Systematic Reviews 2 tool. The Grading of Recommendations Assessments, Development and Evaluation framework will be used to rate the quality of evidence. A summary of evidence table and narrative synthesis will be utilised to clearly indicate the findings.

Discussion: This umbrella review presents a novel and timely approach to synthesise existing falls literature to identify effective non-pharmacological interventions for people with MS, PD and stroke. Of importance, this umbrella review will use a robust methodology to explore the key differences and similarities in effective interventions for individuals with
these neurological diseases to facilitate the development of an intervention for mixed neurological groups.

**Keywords**
Multiple Sclerosis, Parkinson’s Disease, Stroke, Falls, Intervention, Umbrella Review

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**Author roles:** O’Malley N: Conceptualization, Funding Acquisition, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing; Clifford AM: Conceptualization, Methodology, Supervision, Writing – Review & Editing; Comber L: Conceptualization, Methodology, Writing – Review & Editing; Coote S: Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Review & Editing

**Competing interests:** Susan Coote is contracted by Novartis to design and develop exercise interventions for people with Multiple Sclerosis.

**Grant information:** Nicola O’Malley is a postgraduate scholar funded by the Irish Research Council through the Government of Ireland Postgraduate Scholarship Programme. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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**How to cite this article:** O’Malley N, Clifford AM, Comber L and Coote S. Effectiveness of non-pharmacological falls prevention interventions for people with Multiple Sclerosis, Parkinson’s Disease and stroke: protocol for an umbrella review [version 1; peer review: 1 approved with reservations] HRB Open Research 2020, 3:17 https://doi.org/10.12688/hrbopenres.13023.1

**First published:** 24 Apr 2020, 3:17 https://doi.org/10.12688/hrbopenres.13023.1
Introduction

Fall rates are high among people with neurological diseases and are often associated with many negative consequences. Therefore, the development of effective falls prevention interventions for this cohort of individuals is a research priority. Up to 73% of stroke survivors experience a fall in the first year post-stroke and as many as 56% of people with Multiple Sclerosis (MS) fall in any given three-month period. Similarly, 59% of people with Parkinson’s Disease (PD) report having at least one fall over a six-month period. Physical injuries are a common consequence of a fall among people with neurological diseases with between 11–17% of falls resulting in injury but notably, this figure has been as high as 72% among stroke survivors. Falls also have a number of psychosocial impacts including fear of falling and reduced self-efficacy, leading to decreased independence, reduced social participation and diminished health-related quality of life. Additionally, falls result in increased acute healthcare utilisation, higher home-care needs and/or greater institutional care needs. This high rate of falls and range of associated physical, social and economic consequences highlights the need for an effective falls prevention intervention.

Recently there has been an increase in the number of interventions developed and evaluated for falls prevention among individuals with one specific neurological disease. This condition-specific approach to intervention is reflected in clinical practice where provision of services is typically disease-specific. However, implementation of these interventions in the community is a challenge as finding sufficient numbers and resources to run single diagnosis groups is problematic for clinicians. The National Strategy & Policy for the Provision of Neuro-Rehabilitation Services in Ireland has demonstrated the current deficits in services available to people with neurological diseases and the associated negative consequences at both the individual and system level. This implementation strategy highlights the need for high-quality, person-centred care and timely access to services for people with neurological diseases to optimise outcomes. One potential solution to this is the development of interventions that can be applied to mixed neurological populations rather than a group with one specific disease. Little is currently known about the feasibility or effectiveness of adopting this mixed population approach to falls rehabilitation with a scoping literature search revealing only one study examining the effect of a falls prevention intervention for people with MS, PD and stroke. However, people with these neurological diseases share many common symptoms and risk factors for falls, such as mobility impairments, reduced balance and cognitive deficits, and therefore, given these similarities, it is likely that programmes for mixed neurological groups are feasible. A mixed population approach to the development and provision of interventions has the potential to increase the number of eligible participants, reduce strain on healthcare resources and increase the number of services available to community-dwelling individuals living with neurological conditions, thereby meeting the rehabilitation needs of these individuals while simultaneously negating the negative effects associated with insufficient service provision. Therefore, the development of an intervention for individuals with mixed neurological diseases is timely to address the current implementation and service provision challenges in the community.

Methods

Protocol and registration

An umbrella review will be conducted to identify systematic reviews (with or without meta-analysis) of studies investigating the effectiveness of non-pharmacological interventions to prevent falls among people with neurological diseases. In line with recommendations to improve transparency and reduce bias, this protocol was developed to outline the key objectives of this umbrella review and what methodology will be employed. This protocol was designed using the guidance of the relevant items of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement, with reference to the Joanna Briggs Institute (JBI) Reviewer’s Manual and the PRISMA guidelines. The PRISMA-P was developed to facilitate the design of protocols for systematic reviews, however, the relevant sections of the checklist will be used for this protocol in the
absence of specific guidelines for the conduction and reporting of umbrella reviews. The protocol was registered with the International Prospective Register of Systematic Reviews, PROSPERO, on 19th March 2020.

Search strategy
The following electronic databases will be searched to identify potentially relevant reviews: The Cochrane Database of Systematic Reviews, Joanna Briggs Institute Database of Systematic Reviews and Implementation Reports, Database of Abstracts of Reviews of Effects, PubMed, Embase, Ebsco (Academic Search Complete, AMED, Biomedical Reference Collection, CINAHL, Medline, PsycInfo, SPORTDiscus), Epistemikos, PEDro and the PROSPERO register. The authors developed a comprehensive search strategy to identify papers relevant to the primary aims of the overview. To illustrate, the full electronic database search string for the CINAHL database is detailed in Box 1. In addition, reference lists of included reviews will be hand-searched to identify other potentially relevant reviews. In line with best practice guidelines for the conduction of umbrella reviews, our comprehensive search will also encompass a search for grey literature, as well as government and non-government organisations’ reports.

**Box 1. Search Strategy for CINAHL**

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<td>S2:</td>
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<td>TI (stroke OR CVA OR cerebrovascular OR apoplexy OR vascular OR MS OR “multiple sclerosis” OR demyelin* OR PD OR “parkinson’s disease” OR “parkinson disease” OR “parkinson’s disease” OR Parkinson* OR Parkinson* OR neurol*) OR AB (stroke OR CVA OR cerebrovascular OR apoplexy OR vascular OR MS OR “multiple sclerosis” OR demyelin* OR PD OR “parkinson’s disease” OR Parkinson* OR Parkinson* OR neurol*)</td>
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<td>S3:</td>
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<tr>
<td>TI (stroke OR CVA OR cerebrovascular OR apoplexy OR vascular OR MS OR “multiple sclerosis” OR demyelin* OR PD OR “parkinson’s disease” OR “parkinson disease” OR “parkinson’s disease” OR Parkinson* OR Parkinson* OR neurol*) OR AB stroke OR CVA OR cerebrovascular OR apoplexy OR vascular OR MS OR “multiple sclerosis” OR demyelin* OR PD OR “parkinson’s disease” OR “parkinson disease” OR “parkinson’s disease” OR Parkinson* OR Parkinson* OR neurol*) AND (S1 AND S2)</td>
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<td>TI (intervention OR prevention OR rehabilitation OR treatment OR therap* OR AB intervention OR prevention OR rehabilitation OR treatment OR therap*) AND (S3 AND S4)</td>
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<td>S6:</td>
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<tr>
<td>TI (systematic OR review OR “meta-analysis”) OR AB (systematic OR review OR “meta-analysis”)</td>
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<td>S7:</td>
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<td>TI (systematic OR review OR “meta-analysis”) OR AB systematic OR review OR “meta-analysis”) AND (S5 AND S6)</td>
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Inclusion and exclusion criteria
This umbrella review will include quantitative systematic reviews (with or without meta-analysis), mixed-methods systematic reviews (quantitative elements only will be included) or pooled analyses and research syntheses investigating the effectiveness of falls prevention interventions for people with MS, PD and stroke. This umbrella review will include only research syntheses published in the English language due to resources. No restriction will be placed on date of publication. If a review is an update of a previous review, the most recent update will be included and the older versions will be excluded.

Potentially relevant papers will be assessed for inclusion as a systematic review by two independent reviewers (NO’M and AC/SC) using the JBI Critical Appraisal Checklist for Systematic Reviews and Research Syntheses. Any disagreements between reviewers will be resolved through discussion or by a third reviewer (AC/SC) until consensus is achieved. Upon completion of this appraisal, literature reviews that do not include key features of accepted systematic review methodology, outlined by JBI, will be excluded from this umbrella review. If necessary, the authors of the reviews will be contacted to clarify any unclear or missing details before the review is excluded.

The inclusion criteria based on population, intervention, comparison, outcome and study design (PICOS) are outlined in Table 1.

Study selection
The papers yielded from the search of each individual electronic database will be exported to the master reference management library Rayyan, where duplicate papers will then be removed. The titles and abstracts will be screened by two reviewers (NO’M and AC/SC) against the eligibility criteria for any obviously irrelevant papers. Following this, the full text of potentially relevant reviews will be screened by two independent reviewers (NO’M and AC/SC) to confirm inclusion in the final overview of reviews. Any discrepancies between reviewers will be resolved through a discussion or by a third reviewer (AC/SC) until consensus is achieved. A PRISMA flow diagram of the included studies will be completed.

Data extraction
Data will be extracted by one reviewer using a standardised data extraction form (NO’M). The extracted data will be verified by a second reviewer (AC/SC). Disagreements regarding data extraction will be resolved through discussion or by consulting a third reviewer (AC/SC) until consensus is achieved. The data extraction form will include the following:

1. Citation details of included review
2. Objectives of included review
3. Type of review
4. Participant characteristics
5. Setting and context of the review
6. Number of databases searched
7. Date range over which database searching was conducted
8. Date range over which studies included in the review that inform each outcome of interest were published
9. Number of studies, types of studies and country of origin of studies included in each review
10. Instrument used to critically appraise the primary studies and their quality rating

11. Primary falls outcomes and secondary outcomes of interest reported in reviews

12. Methods employed to synthesise the evidence

13. Any comments or notes that the authors have regarding the included review

Methodological quality assessment
The methodological quality of included reviews will be assessed by two independent reviewers (NO’M) using the Assessment of Multiple Systematic Reviews 2 (AMSTAR 2) tool. The AMSTAR 2 is a 16-item checklist utilised to assess the quality of systematic reviews that include randomised or non-randomised studies of healthcare interventions. Reviewers score each domain with ‘yes’ or ‘no’, or in some domains there is a third option of ‘partial yes’. The overall score of the AMSTAR 2 will be used to rate the quality of each included review investigating the effectiveness of falls prevention interventions as high, moderate, low or critically low.

It has been suggested that the use of PRISMA in conjunction with a comprehensive, validated critical appraisal tool facilitates judgement not only of the methodological quality of the included reviews but also the general quality of reporting. Consequently, the full text of all included reviews will be cross-checked against the PRISMA reporting guidelines checklist.

Quality of evidence
The Grading of Recommendations Assessments, Development and Evaluation (GRADE) framework was designed to provide guidance for rating the quality of evidence and grading the strength of recommendations in healthcare. This approach is primarily used to assess the quality of evidence in systematic reviews, but has been also applied to umbrella reviews in the absence of a more specific framework. The GRADE approach will be used to assess the quality of the evidence relating to the following outcomes included in RCTs in systematic reviews:

1. Total number of falls
2. Falls rate
3. Number of fallers

Overlap of primary studies
Overlap of primary studies is a challenge unique to umbrella reviews. Presently, there is an absence of guidance on how best to deal with this phenomenon. In the presence of complete overlap between reviews, the most recent review will be included in data synthesis and analysis. In the presence of partial overlap, all reviews will be included but the authors will note the degree of duplication and discuss its implications on the findings of this umbrella review.

Discordance between reviews
There are a number of reasons for discordant reviews and the conduction of umbrella reviews allows researchers to address the issue of discordance and identify its cause. In the event of discordant reviews in our overview, the algorithm designed by Jadad et al. (1997) will be utilised to resolve issues of discordance.

Data synthesis and analysis
This umbrella review will provide a summary of evidence table that will name the intervention, outline the included research synthesis and provide a clear indication of the results. Given the anticipated heterogeneity in populations, outcomes and analyses, the findings of included reviews will be summarised through a narrative synthesis with the quantitative tabulation of results as appropriate. Where possible, the sensitivity of the review findings will be considered in the context of its methodological quality, as determined by the AMSTAR 2, to examine the effects of synthesising reviews of varying quality. In the first instance, analyses will be completed using systematic reviews of any methodological quality that include all study designs. If sufficient reviews including randomised-controlled trials only are retrieved,
Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).


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This is a study protocol for an umbrella review - registered in PROSPERO - that will include systematic reviews of randomised controlled trials and studies investigating the effects of non-pharmacological falls prevention interventions on falls outcomes. The PRISMA checklist was used to review the study protocol. The following suggestions may help improving the protocol further.

There is a wide range of neurological diseases and I therefore suggest that the authors refrain from using this expression when addressing the population of interest and instead use MS; PD and stroke. I also suggest that the authors problematise lumping together stroke, MS and PD since the underlying mechanisms to the diseases differ and explain how an intervention UNS will be advantageous for a person-centered care. The authors may want to elaborate whether the rationale to find sufficient numbers and resources to run single group interventions could mean that less specified and thus less effective interventions will be recommended in the future, i.e., is the rational strong enough?

Beforehand decision on inclusion/exclusion criteria regarding length/intensity; supervised/unsupervised and content (training; assistive devices or orthosis; environmental changes; behavioural) of the interventions investigated should be expressed. Provide a rational for the decisions.

Please provide a more stringent and yet more detailed PICO. For example age, disease duration, disease symptoms, co-morbidity etc.

Add the systematic review registration number in PROSPERO.

Information on quality rating of primary studies included in the reviews will be extracted. It would strengthen the review if the ratings were checked by the authors, using a predetermined tool.

Cut-offs for categorizing the AMSTAR scores into high, moderate, low or critically low quality should be provided.

Please consider to include the review with the highest quality if there is an complete overlap instead of
including the most recent review.

I strongly suggest that subanalyses for disease; type of intervention and total amount of intervention are considered.

Is the rationale for, and objectives of, the study clearly described?
Partly

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Falls and balance training in people with MS.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.