Effectiveness of exercise interventions on physical function in community-dwelling frail older people: an umbrella review protocol

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Review question/objective: The objectives of this umbrella review are to determine the effectiveness of exercise interventions, alone or in combination with other interventions, for improving physical function in community-dwelling older people who are identified as frail or at risk of frailty, and to identify if any particular intervention type or characteristic is the most effective.

Specifically, the review question is: What is the effectiveness of exercise interventions, alone or in combination with other interventions, for improving physical function in community-dwelling older people identified as frail or at risk of frailty?

Keywords Umbrella review; exercise; frailty; physical function; older people

Background

The World Health Organization expects the number of people aged 65 years and older to triple in the next 30 years.1,2 By 2050, in Australia alone, nearly one quarter of the population will be aged over 65 years.3 Aging is associated with an increased risk of illness and disability, pressure on healthcare services and a decreased quality of life. Maintaining good physical function would help to counter the aforementioned poor outcomes.4

One major health condition that has an insidious impact on health and physical function is the frailty syndrome,5 a prevalent geriatric condition observed in clinical practice and associated with aging.6 It is defined as a “clinically recognizable state of increased vulnerability resulting from age-associated decline in reserve and function”2(p.1) Clinical indicators for frailty include deficit accumulation, fatigue, sedentary behavior, weight loss, cognitive impairment, social isolation, sarcopenia and the impairment of physical function.5

A recent systematic review of 21 community-based cohorts reported that prevalence of frailty in the community increases steadily with age.7 Based on these international figures, it can be extrapolated that by 2050, four million Australians aged 70 years and older will either be frail or at risk of frailty.7 Of note, two studies within this review indicated that the prevalence of frailty and pre-frailty in older Australians was between 10%-15% and 40%-46%, respectively.8,9 Data from another longitudinal cohort of Australian women indicate similar prevalence of frailty and pre-frailty.10

The impairment of physical function interferes with a person’s ability to perform the activities of daily living (ADL).5 Strength, mobility, balance and physical performance are all impaired, resulting in disability, loss of independence, a reduced quality of life and premature mortality.11-14 However, frailty is...
a dynamic syndrome that is both treatable and reversible,\textsuperscript{15,16} and studies have shown that physical, nutritional, cognitive and combined interventions are effective in reversing frailty and improving physical function in community-dwelling frail older people.\textsuperscript{6,17-19} Exercise interventions, in particular, have the potential to prevent, delay and reverse frailty.\textsuperscript{20} They can be used to maintain or restore muscle strength, balance, physical performance and prevent the loss of independence.\textsuperscript{6,15}

Several systematic reviews, including meta-analyses, discuss the effects of exercise interventions on important physical parameters, such as mobility, gait speed, balance and strength.\textsuperscript{21-23} The investigations described in the reviews indicate that multi-component exercise, including strength, endurance and balance training, appears to be the best way to improve physical function in frail older people.\textsuperscript{22} However, there is still uncertainty as to which exercise characteristics (type, frequency, intensity, duration, setting and combinations) are most effective.

In addition, further evidence suggests that multi-component exercise interventions that are combined with protein supplementation may be more effective than exercise alone for improving physical function in older people.\textsuperscript{24-26} However, a systematic review including older adults found that protein supplements in combination with resistance training were associated with gains in fat-free mass, which decreases as we age, contributing to the development of frailty, disability and functional impairment in vulnerable individuals.\textsuperscript{27}

The frailty syndrome already affects or is likely to affect a significant portion of aging individuals, who will consequently lose much of their quality of life because of impaired physical function. Current research suggests that this is preventable through utilizing effective interventions and management of the at-risk population.

The number of identified systematic reviews on this topic\textsuperscript{19,21-23,28-31} indicates the need for an umbrella review to identify important repeated or interrelated findings that could inform future research and clinical trial development.

**Inclusion criteria**

**Types of participants**

The current umbrella review will examine systematic reviews involving sample populations of individuals:

- Aged 60 years and above (at least 50% of the people included in the review should be 60 years or older, OR the mean age of the people in the study should be at least 60 years).
- Living in the community (at least 50% of people included in the review should be living in the community in their own homes).
- Identified as frail or at risk of frailty using an operationalized definition of frailty or standardized criteria to measure frailty (at least 50% of the people included in the review should be identified as frail or at risk of frailty).

The following definitions of frailty identified by Bouillon \textit{et al.}\textsuperscript{32} will be accepted in this umbrella review: Groningen Frailty Indicator,\textsuperscript{33} frailty index,\textsuperscript{34} Canadian Study of Health and Aging Clinical Frailty Scale,\textsuperscript{35} Vulnerable Elder Survey-13,\textsuperscript{36} Tilburg Frailty Indicator,\textsuperscript{37} Physical Frailty Score,\textsuperscript{38} Phenotype of Frailty,\textsuperscript{16} Edmonton Frail Scale\textsuperscript{39} and the Study of Osteoporotic Fractures Index.\textsuperscript{40}

Reviews that do not provide sufficient detail about the sample populations of included studies will be excluded. Reviews that do not use an operationalized definition of frailty or standardized criteria to measure frailty according to Bouillon \textit{et al.}\textsuperscript{32} will be excluded. Reviews that focus on healthy older people or older people who are in hospital, subacute settings or nursing homes will be excluded. Nursing homes are defined as “a facility with a domestic-styled environment that provides 24-hour functional support and care for persons who require assistance with ADL and who often have complex health needs and increased vulnerability”.\textsuperscript{41(p.183)}

**Types of intervention(s)/phenomena of interest**

This umbrella review will include systematic reviews that evaluate exercise interventions of any form, duration, frequency and intensity, alone or in combination with other interventions designed to alter physical function of frail older people. The types of exercise interventions will include, but are not limited to:

- Resistance and strength training
- Aerobic and endurance training
- Balance training
If other exercise interventions are identified during the review, they will be assessed for inclusion. Systematic reviews that involve interventions that are not combined with exercise will be excluded. To determine the effectiveness of exercise interventions, they will be compared to either a control group (i.e. no intervention, placebo intervention and usual care) or a comparator group (i.e. another type of exercise and exercise in combination with other interventions).

Outcomes
The current umbrella review will include systematic reviews of quantitative measures of physical function in frail older people. The types of outcomes will include, but are not limited to:
- Muscular strength measured by, for example, grip strength or lower limb strength
- Gait ability and performance measured by, for example, gait speed
- Balance measured by, for example, berg balance scale or tandem stand
- Mobility measured by, for example, timed up and go test. This umbrella review will exclude systematic reviews of physical function parameters that are not measured quantitatively by standard or appropriate measurements.

Types of studies
The current umbrella review will include any quantitative systematic reviews with or without meta-analysis that examine the effectiveness of exercise interventions, alone or in combination with other interventions, in relation to improving physical function in frail older people. Systematic reviews that meet the following criteria will be considered for inclusion:
- Clearly articulated and comprehensive search strategy including multiple bibliographic databases (of no less than three bibliometric databases)
- Evidence of critical appraisal/assessment of risk of bias.

If it is not clear whether the inclusion criteria are met, authors will be contacted for confirmation before excluding the review. Furthermore, literature reviews, withdrawn or retracted publications and systematic reviews not published in English will be also excluded.

Search strategy
A three-step search strategy will be utilized in this review with the aim of locating published systematic reviews with or without meta-analyses. An initial limited search of PubMed and EMBASE will be undertaken followed by an analysis of the text of the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Third, the reference list of all identified reports and articles will be searched for additional studies. Studies written in English and published from 1990 until the present date will be considered for inclusion in this umbrella review. The selection of 1990 was a conservative estimate of the earliest likely publication of a systematic review on this topic as this pre-dates some of the earliest operationalized definitions of frailty and standardized criteria to measure frailty according to Bouillon et al. In addition, extending the search as far back as 1990 will help to allow us to identify whether a review is an update of a previous review.

The sources to be searched include:
- PubMed
- EMBASE
- CINAHL
- Scopus
- The Cochrane Database of Systematic Reviews
- Database of Abstracts of Reviews of Effects
- Joanna Briggs Institute (JBI) Database of Systematic Reviews and Implementation Reports
- Web of Sciences
- The Campbell Collaboration Library of Systematic Reviews
- Google Scholar.

Gray literature will be searched using Google, the Gray Literature Report (http://www.greylit.org/) and ProQuest Dissertations and Theses that will also include a search for unpublished studies.

The initial search terms/keywords in PubMed will be:
- exercise or "physical activity" or intervention or therapy or training AND
- frailty or frail or pre-frail or prefrail or “at-risk of frailty” AND
elderly or “older person” or “older adult” [filter: Aged: 60+ years] AND
[filter: “systematic review”].

The keywords, index terms, titles and abstracts of retrieved studies relevant to the topic will then be carefully assessed to identify all of the search terms for a comprehensive secondary search of the literature. This second phase will incorporate all of the identified search terms. This search will be followed by the third phase of searching the reference lists of all included studies.

Papers will be assessed for relevance utilizing the title, abstract and index terms, including papers found from searching a reference list of relevant papers. Screening will be conducted independently by two reviewers.

Assessment of methodological quality
Papers selected for retrieval will be appraised using eligibility criteria listed in Appendix I. Studies that meet all the eligibility criteria will be appraised using standardized critical appraisal instruments from the JBI System for the Unified Management, Assessment and Review Instrument and The JBI Reviewers’ Manual 2014 (Appendix II). Any disagreements that arise between the reviewers will be resolved through discussion or with a third reviewer. We will not exclude studies on the basis of critical appraisal score, and all studies that are appraised and meet the eligibility criteria will be included in data extraction. We will use sensitivity analysis based on study quality to determine whether study quality impacts on the findings of the umbrella review. We will rank the quality of each study based on the critical appraisal results using the following scale: 0-33% of criteria met (low quality), 34-66% of criteria met (medium quality) and 67% or more of criteria met (high quality). Any “not applicable” criteria will be excluded from these estimates of study quality. Reasons why any criteria were not applicable will be provided.

Data extraction
The data of interest will be extracted using a standardized JBI instrument designed for umbrella reviews (Appendix III). The following information will be extracted:

- Type of review
- Countries where the studies were conducted
- Number of studies in the review
- Participants (number, age group and comorbidities)
- Type(s) of intervention(s) including duration, intensity and frequency
- Outcomes identified (type/characteristics)
- Length and completeness of follow-up
- Primary outcome measures
- Method of analyses
- Heterogeneity
- Effect size
- Confidence intervals.

Data synthesis
The data extracted from selected reviews related to interventions will be tabulated and accompanied by narrative synthesis to address the review question. Tables of quantitative results recording the overall size of the effects of intervention and a clear description of the intervention will be presented with supporting interpretation. Tables will include extensive records of the outcomes for each systematic review, including the number of studies, total number of participants, heterogeneity of results, setting, age, comorbidity and information about the intervention. Where possible, the sensitivity of the study findings will be considered based on the determinants of study quality, as assessed by critical appraisal.

The results of the umbrella review will be provided in tabular form in a “Summary of Evidence” table that includes the intervention name, the included systematic review(s) and a simple visual indicator of the effectiveness of the intervention using the three colors of the traffic light: a beneficial or effective intervention (green), no effect or difference compared to a control treatment (amber) and a detrimental intervention or one that is less effective than a control treatment (red). The quality of the evidence will be determined using Grading of Recommendations Assessment, Development and Evaluation criteria, where possible. A four-point rating scale will be used to rate the quality of the evidence: high, moderate, low and very low. The quality of evidence will be classified by evaluating it using the following criteria: methodological limitations, consistency, risk of bias and relevance to the study population. In the event that there are missing data, the authors of this umbrella review will endeavor to contact the author(s) of the paper in question to seek clarification.
References
Appendix I: Verification of review eligibility

**Verification of review eligibility: inclusion criteria**

| Design: The article is/contains a systematic review with or without meta-analysis | Yes |
| Review type: For effectiveness reviews, a comparator group is utilized | Yes |
| Participants: Participants of interested are older people aged 60 years and over, Identified as pre-frail, frail or at-risk of frailty in title, abstract or text And living in the community | Yes |
| Interventions: Interventions of interest are exercise interventions, alone or combined with other interventions | Yes |
| Outcomes: Outcomes of interest are: muscular strength, gait ability including gait speed and gait performance, balance and mobility | Yes |

If you have not answered “yes” to all of the above questions, you should exclude the study. If you answered yes to all, please continue.
# Appendix II: JBI critical appraisal checklist for systematic reviews and research syntheses

Reviewer _______________________________ Date ______________________

Author _______________________________ Year ______________ Record Number _________

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
<th>Not applicable</th>
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<tbody>
<tr>
<td>1.</td>
<td>Is the review question clearly and explicitly stated?</td>
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<td>2.</td>
<td>Were the inclusion criteria appropriate for the review question?</td>
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<td>3.</td>
<td>Was the search strategy appropriate?</td>
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<td>4.</td>
<td>Were the sources and resources used to search for studies adequate?</td>
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<td>5.</td>
<td>Were the criteria for appraising studies appropriate?</td>
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<td>6.</td>
<td>Was critical appraisal conducted by two or more reviewers independently?</td>
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<td>7.</td>
<td>Were there methods to minimize errors in data extraction?</td>
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<td>8.</td>
<td>Were the methods used to combine studies appropriate?</td>
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<td>9.</td>
<td>Was the likelihood of publication bias assessed?</td>
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<td>10.</td>
<td>Were recommendations for policy and/or practice supported by the reported data?</td>
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<td>11.</td>
<td>Were the specific directives for new research appropriate?</td>
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Overall appraisal: Include [ ] Exclude [ ] Seek further info [ ]
## Appendix III: JBI data extraction form for review for systematic reviews and research syntheses

<table>
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<th>Study Details</th>
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<tr>
<td><strong>Author/Year</strong></td>
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<tr>
<td><strong>Objectives</strong></td>
</tr>
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</table>
| **Participants** (characteristics/total number or %) | Male: ___ (n or %)  Female: ___ (n or %)  Total: ___ (n or %)  
Identified as frail: __________ (n or %)  
Standardised method/definition to assess frailty:  □ yes  □ no  
Method/definition used:  _________________________________  
Ethnicity of participants: |  |
<p>| <strong>Setting/Context</strong> |  |
| <strong>Description of Interventions/Phenomena of Interest</strong> | Exercise:  |
| | Resistance/strength training:  |
| | Aerobic/endurance training  |
| | Balance training  |
| | Flexibility/stretching training  |
| | Multi-component training  |
| Other: |  |
| Combinations: |  |
| <strong>Characteristics of Intervention</strong> | Duration  |
| | Frequency  |
| | Intensity  |
| <strong>Search Details</strong> | Sources searched |  |
| | Range (years) of included studies |  |
| | Number of studies included |  |</p>
<table>
<thead>
<tr>
<th>Types of studies included</th>
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<tr>
<td>Country of origin on included studies</td>
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**Appraisal**

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<th>Appraisal instruments used</th>
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<td>Appraisal rating</td>
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**Analysis**

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<th>Method of Analysis</th>
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<td>Strength:</td>
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<td>Gait ability/performance:</td>
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<td>Balance:</td>
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<td>Mobility:</td>
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<td>Other:</td>
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**Outcome assessed**

**Results/Findings**

**Limitations**

**Significance/direction**

**Heterogeneity**

**Comments**