The effect of complex falls prevention interventions on falls in residential aged care settings: a systematic review protocol

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Review question/objective: The objective of this review is to synthesize the best available evidence on the effectiveness of complex falls prevention interventions on fall reductions in the residential aged care population, implemented at two or more of the following levels: organization, facility or resident. Specifically the review question is: What is the effect of complex falls prevention interventions on falls in residential aged care settings?

Keywords Falls prevention; implementation; intervention; organization approach; residential aged care


Background

Falls in the residential aged care (RAC) sector are a major concern worldwide with rates reported to range between three and 13 falls per 1000 occupied bed days.¹–⁴ The estimated incidence of injurious falls in Australian aged care facilities in 2009–2010 was 8352 per 100,000 persons; this is six times higher than the age-standardized rate of falls for older people living in their own home.⁵ For the older person, falling can result in loss of independence and confidence, physical injury such as fractures, reduced quality of life and in some cases mortality.²,³,⁶ Consequently, there are additional resident care and rehabilitation requirements for RAC staff and RAC organizations⁷,⁸ as well as an increased economic burden on the healthcare system.⁹,¹⁰

The cause of most falls is complex, involving combinations of risk factors present at the time of the fall event.¹,¹¹ Older people residing in aged care facilities are recognized as a high falls risk population due to the frequent presence of many of these risk factors, including activities of daily living (ADL) disability, cognitive and visual impairments, multiple medications and reduced strength and balance.¹,¹¹,¹² A European study of 57 long-term care homes with over 4000 residents observed cognitive impairment in 68% of residents and ADL disability in 81.3%,¹³ suggesting that older people in residential care are particularly vulnerable when it comes to falls and often lack the capability of preventing falling without prompting or assistance. Falls prevention is challenging as it involves a number of interacting components making both intervention and evaluation complex.¹⁴,¹⁵

Researchers have trialed a range of different intervention approaches in addressing falls among this older population, from single strategies implemented by individuals to multifactorial approaches delivered by multidisciplinary staff.¹¹,¹⁶,¹⁷ Two recent meta-analyses examining falls prevention programs in RAC populations showed different findings; the Cochrane review¹¹ concluded that supplementing residents with low vitamin D levels reduced the rate of falls by 37% (95% confidence interval [CI] 0.46–0.86) but not an individual’s risk of falling, while Vlaeyen et al.¹⁸ reported that multifactorial fall prevention interventions decreased falls by 33% (95% CI 0.55-0.82) and the number of people with recurrent falls by 21% (95% CI 0.65–0.97). However, these reviews focused on individual or multifactorial approaches at the clinical level and
while the latter included some mixed population studies while the latter included some mixed population studies\textsuperscript{11} while the latter included only nursing home populations and randomized or cluster randomized controlled designs.\textsuperscript{18} Randomized designs are a challenge in this RAC population for several reasons. High levels of cognitive impairment make consent an issue, thus in RAC settings approximately 49% of residents are recruited and by 12 months 16% are lost, largely due to mortality. Adherence to interventions can also vary considerably, for example, 11–93% for multifactorial interventions and by 12 months only a third of those in residential care are likely to be still adhering to interventions.\textsuperscript{19} This suggests that results from RCTs in RAC populations must also be interpreted with caution; therefore, other designs that are flexible and inclusive may also provide useful evidence.\textsuperscript{2,19}

Implementing falls prevention evidence based practice in a RAC setting predominantly requires staff to master the content of such a program and apply it to the care of the residents.\textsuperscript{14} An organization’s capacity to deliver system wide approaches to address complex issues, such as effective falls prevention, is strongly influenced by its managerial direction and culture, which in turn must support change.\textsuperscript{20,21} This requires collaboration between managers, staff and researchers to establish effective policy through interdisciplinary problem solving, discussion and staff behavioral change.\textsuperscript{22–24} Consequently, some researchers have suggested that organizations need to make changes at multiple levels using a systematic approach to enable evidence to be translated into practice.\textsuperscript{14,20,25–27} Interventions that are delivered across multiple levels have been characterized as complex because a number of groups and organizational levels are being targeted.\textsuperscript{14} For falls prevention interventions delivered in RAC settings, these levels can be categorized as resident, RAC facility and RAC organization, and if at least two or all of these levels are targeted then the intervention can be considered complex. Resident level describes intervention delivery involving resident participation, such as the resident undertaking an exercise program or having a medication review. Facility level describes interventions that target RAC staff, such as falls prevention education or safety maintenance on resident equipment training for staff. Organization level describes interventions involving RAC management participation in bringing about practical change such as revising professional staff roles and reviewing policy around falls prevention. A limited number of studies have evaluated complex multi-level interventions that included elements that address aspects of organizational change including staff training, reassignment of staff roles and adoption of best practice at a facility level.\textsuperscript{8,28,29} Such studies included a participatory action research design that trained a falls resource nurse to lead the implementation of evidence-based strategies resulting in a reduction in the proportion of fallers in RAC facilities\textsuperscript{28} while a falls management program targeting cultural change and quality improvement had no effect on falls.\textsuperscript{29} Another study, led by a falls coordinator using tailored falls risk management delivering best practice interventions, found that fall rates increased in similar RAC settings.\textsuperscript{8} These variations in results have hence led to uncertainties about the effectiveness of such approaches.

A preliminary search of The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, latest issue), the JBI Database of Systematic Reviews and Implementation Reports, MEDLINE and CINAHL found no existing systematic reviews on this topic. PROSPERO lists an ongoing systematic review of studies that identify factors that may complicate or facilitate falls prevention implementation at the program level in RAC facilities\textsuperscript{30} rather than comparing the effect of complex multi-level organization wide interventions. To our knowledge, there are no recent systematic reviews either published or underway that synthesize evidence on the effectiveness of complex falls prevention interventions in the RAC population. The absence of synthesized best available evidence for multi-level organization wide approaches to falls prevention in the RAC setting justifies the need for this current review. Given that clinicians and falls researchers are now undertaking and evaluating these complex multi-level interventions, there is a need to know how effective they are at reducing fall outcomes.

**Inclusion criteria**

**Types of participants**
The current review will consider all studies that include people aged 65 years or older. Studies that describe people who are below 65 years will be included, if the mean age of the group is over 65 years. Studies will be considered for inclusion if they have been conducted in long-term care...
settings where older people are provided with 24-hour supervision and/or care assistance. Studies will be excluded if they have been conducted in any of the following: community based setting, assisted living in retirement communities, retirement home, continuing care retirement center, palliative care facility, transition care or hospital. Other falls researchers have found that the participant characteristics and environment differ between these settings and hence they require different falls prevention interventions.

Types of intervention(s)/phenomena of interest
The current review will consider studies that evaluate complex falls prevention interventions that are delivered across at least two or all of the following levels: residents, RAC facility and RAC organization. Interventions may include multiple or multifactorial falls prevention interventions delivered by single discipline or multidisciplinary staff teams, collaborative teams, clinical networks or communities of practice. For example, residents may receive vitamin D supplementation and hip protectors, the facility may provide falls prevention education for staff and the organization may revise its professional staff roles to lead falls prevention change. Conversely, studies considered ‘non-complex’ will be excluded, for example, single interventions delivering either an exercise program to residents or falls prevention education to care staff.

Comparators
Comparisons of intervention complexity by delivery level, that is, whether the interventions were delivered at resident, facility and/or organization levels will be included. The current review will consider studies that offer no comparison, a passive comparison (such as standard care) or an active comparison (such as variation of the intervention).

Outcomes
Studies will only be included in this review if an outcome measure related to falls incidence is used. The outcome measures must be measured before and after the investigated intervention. Outcome measures related to falls incidence may include the rate of falls (expressed as the number of falls per 1000 occupied bed days), the number of participants who become fallers (expressed as the number of participants who fell) and the rate of injurious falls (expressed as the number of falls with injury per 1000 occupied bed days).

Types of studies
The current review will include any experimental study design that incorporates randomized controlled trials, controlled clinical trials and quasi-experimental studies. In the absence of these methods, comparative studies without randomization, cohort and case control studies and quasi-experimental studies with a pre-and post-design will be considered for inclusion. Studies will only be included if they use repeated measures and compare an intervention against standard treatment, no treatment or another intervention.

Search strategy
The current review aims to find both published and unpublished studies, written in English from January 1, 1990 to May 31, 2016. The incidence of falls in RAC settings began to be addressed in published studies from around 1990. Falls prevention strategies that involve concepts to engage healthcare organizations and employees in improving outcomes were also conceived after 1990, hence the search date parameter. A three-step search strategy will be used when undertaking this review. An initial limited search of MEDLINE (PubMed) and CINAHL Plus with full text (EBSCO) using initial key words will be undertaken with the aim of identifying all possible key words from the text words contained in the title and abstract of the retrieved literature. A second extensive search using all key words identified and terms will then be carried out across all included databases. Third, the reference list of all identified literature will be searched for additional studies not previously identified during the first or second search strategy.

The databases to be searched include CENTRAL (The Cochrane Library, latest issue), MEDLINE, CINAHL, Embase, AMED and Psych INFO. The search for unpublished studies will include an electronic search of trials registers; Current Controlled Trials (http://www.controlled-trials.com), the National Institute of Health Clinical Database (http://clinicaltrials.gov), Universal Index of Doctoral Dissertations in Progress, Mednar, Grey Literature Report and Google. All studies identified during the database search will be retrieved and examined to ensure relevance and that they meet the inclusion criteria.
criteria using the title, abstract and description/MESH heading by two independent reviewers. If the two independent reviewers disagree on whether a study should be included, a third independent reviewer will be consulted until a consensus has been reached.

Assessment of methodological quality
Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix I). Data will be extracted and quality assessed by one reviewer and checked by a second reviewer with discrepancies resolved by discussion and arbitration with another reviewer if necessary. Studies will not be excluded on the basis of methodological quality.

Data extraction
Quantitative data will be extracted from the retrieved papers by two independent reviewers using the standardized data extraction tools from the JBI-MAStARI (Appendices I and II). The data extracted will include details about the interventions, populations, study methods and outcomes of significance to the review objective.

Data synthesis
Quantitative data will, where possible, be pooled in statistical meta-analysis using Cochrane Review Manager software (RevMan v5.3). All results will be subject to double data entry. Statistical analysis will be carried out for primary outcomes wherever possible using the inverse variance method. All studies will be analyzed in terms of primary outcomes where data are available regardless of their settings or combinations of intervention. Pooled risk ratios (RR) with 95% CIs will be calculated using a random effect model as the authors may be uncertain of the homogeneity of RAC populations and setting of studies. Rate ratios will be pooled comparing (i) rate of falls, (ii) the number of residents who became fallers, and (iii) rate of injurious falls. Heterogeneity will be assessed statistically using the standard chi-squared. Where statistical pooling is not possible, the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

Acknowledgements
JFC and AMH were responsible for conceptualizing and drafting the protocol CEB, DN and CN provided iterative reviews contributing to the protocol development. This study is supported through the Australian Government’s Collaborative Research Network (CRN) program awarded to The University of Notre Dame Australia. Jacqueline Francis-Coad is a doctoral candidate supported by the award.

References


Appendix I: JBI critical appraisal checklist

**JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial**

Reviewer: ___________________________  Date: ___________________________

Author: ___________________________  Year: ______  Record Number: ______

1. Was the assignment to treatment groups truly random?  
   [ ] Yes  [ ] No  [ ] Unclear  [ ] Not Applicable

2. Were participants blinded to treatment allocation?  
   [ ] Yes  [ ] No  [ ] Unclear  [ ] Not Applicable

3. Was allocation to treatment groups concealed from the allocator?  
   [ ] Yes  [ ] No  [ ] Unclear  [ ] Not Applicable

4. Were the outcomes of people who withdrew described and included in the analysis?  
   [ ] Yes  [ ] No  [ ] Unclear  [ ] Not Applicable

5. Were those assessing outcomes blind to the treatment allocation?  
   [ ] Yes  [ ] No  [ ] Unclear  [ ] Not Applicable

6. Were the control and treatment groups comparable at entry?  
   [ ] Yes  [ ] No  [ ] Unclear  [ ] Not Applicable

7. Were groups treated identically other than for the named interventions?  
   [ ] Yes  [ ] No  [ ] Unclear  [ ] Not Applicable

8. Were outcomes measured in the same way for all groups?  
   [ ] Yes  [ ] No  [ ] Unclear  [ ] Not Applicable

9. Were outcomes measured in a reliable way?  
   [ ] Yes  [ ] No  [ ] Unclear  [ ] Not Applicable

10. Was appropriate statistical analysis used?  
    [ ] Yes  [ ] No  [ ] Unclear  [ ] Not Applicable

Overall appraisal:  Include [ ]  Exclude [ ]  Seek further info. [ ]

Comments (including reason for exclusion)

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# JBI Critical Appraisal Checklist for Comparable Cohort/Case Control

**Reviewer**  
**Date**

**Author**  
**Year**  
**Record Number**

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<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
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<td>1. Is sample representative of patients in the population as a whole?</td>
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<td>2. Are the patients at a similar point in the course of their condition/illness?</td>
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<td>3. Has bias been minimised in relation to selection of cases and of controls?</td>
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<td>4. Are confounding factors identified and strategies to deal with them stated?</td>
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<td>5. Are outcomes assessed using objective criteria?</td>
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<td>6. Was follow up carried out over a sufficient time period?</td>
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<td>7. Were the outcomes of people who withdrew described and included in the analysis?</td>
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<td>8. Were outcomes measured in a reliable way?</td>
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**Overall appraisal:**  
Include □  
Exclude □  
Seek further info. □

**Comments (Including reason for exclusion)**

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Appendix II: JBI data extraction tool

**JBI Data Extraction Form for Experimental / Observational Studies**

**Reviewer** .............................................. **Date** ..............................................

**Author** .............................................. **Year** ..............................................

**Journal** ............................................ **Record Number** ..............................

**Study Method**

- RCT  □
- Quasi-RCT  □
- Longitudinal  □
- Retrospective  □
- Observational  □
- Other  □

**Participants**

- Setting

- Population

**Sample size**

- Group A ____________  Group B ____________

**Interventions**

- Intervention A

- Intervention B

**Authors Conclusions:**

- 

- 

**Reviewers Conclusions:**

- 

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### Study results

#### Dichotomous data

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#### Continuous data

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