JBI Systematic Review Protocol

Review Title

The efficacy of complementary therapies for agitation among older persons in residential aged care: a systematic review

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Collaborating Centre
NSW Centre for Evidence based Health Care; A Collaborating Centre of the Joanna Briggs Institute
Background
This systematic review aims to examine the efficacy of complementary therapies for managing agitation in older people living in residential aged care facilities (RACFs). RACFs provide accommodation for people who can no longer live in their own home due to illness or disability. They provide personal and nursing care, equipment, meals and essential cleaning services to those who reside in them.\(^1\) The review aims to provide a comprehensive and unbiased summary of the available research, bringing together critically appraised studies in a single document in summary form, making this information accessible to the nursing profession. This systematic review will provide the evidence RACF nursing management to ascertain and identify complementary therapies that prove effective in agitation management.

Agitation in RACFs is a challenging issue for nurses.\(^2, 3, 4, 5\) Agitation affects residents regardless of cognitive ability\(^6, 7\) and stems from incongruence between the needs of the people experiencing agitation and the degree to which the environment suits them. Agitation is thought to be coping mechanisms to protect the person from real or imaginary threats in their environment.\(^6, 7\) Up to 93% of residents in RACFs experience at least one agitated episode a week.\(^2, 3, 8\) Agitation includes but is not limited to physically aggressive behaviours of hitting, kicking or spitting; non physically aggressive behaviours of wandering, hoarding or undressing; and verbally aggressive behaviours of cursing or non aggressive repetitive speech.\(^9\) Nurses therefore are frequently challenged to manage residents with agitation.\(^2, 3\) This often results in overmedication, physical restraint or unmet needs with resident outcomes being increased cognitive decline, falls and social isolation necessitating increased nursing time.\(^10, 11\) Complementary therapies attempt to address causative issues of agitation by fulfilling unmet care needs by reducing sensory deprivation, boredom and loneliness.

Complementary therapies may provide an alternative first line treatment for agitation.\(^10-12\) Complementary therapies are health techniques which are not commonly taught in Western medical schools.\(^13\) Therapies are based on traditional philosophies and aim to restore patient health while not interfering or interacting with concurrent orthodox healthcare regimes. Complementary therapies include four domains of practice they are
biological practices, energy-based therapies, manipulation and body based practices and mind-body therapies. Complementary therapies investigated for the management of agitation management include aromatherapy, exercise, massage, music and therapeutic touch.

The Australian Nursing and Midwifery Board endorse the use of complementary therapies in nursing and midwifery. Therapies are known for their relaxing and often enjoyable application popular in the care management of frail persons owing to their gentle nature. Complementary therapies require minimal training, supplies, time and are easily implemented by nurses. A national, population-based survey of complementary medicine use suggests many older Australians’ are comfortable using complementary therapies. Complementary therapies are currently used in palliation and oncology for anxiety and pain, complementary therapies are becoming more available in RACFs throughout Australia.

Several studies report complementary therapies significantly reduce agitation in older people in RACFs. However examination of the research methodologies in these studies often shows a lack of rigor, compromising results and limiting the amount of evidence supporting interventions. The outcomes of these studies show significant decreases in agitated behavior warranting further investigation. The implementation of complimentary therapies in RACFs to manage agitation in residents is highly beneficial to their quality of life.

This systematic review endeavors to inform current practice of the benefits, limitations and future research needs for the management of agitation symptoms for older people in RACFs. Through evidence based outcomes it seeks, to reduce the challenges of care currently faced by RACF nurses and increases the quality of life experienced by the older person suffering agitation symptoms.
**Definitions of Terms**

**Agitation** is defined as having a physical, emotional and vocal dimension that manifests in many behaviours which include but are not limited to restlessness, inability to keep still, shouting, physical aggression and feelings of extreme anxiousness. These behaviours lead to a person being unable to carry out normal activities of daily living.  

**Complementary therapies** will be defined as non medication therapies of four types mind/body therapies; manipulation and body based practices; energy therapies and biological based practices.  

**Older person** will be defined as those individuals over the age of sixty five.  

**Music therapy** will be defined as exposure to music capable of enhancing the minds capacity to affect body function. It enables people to cope with emotional conflict, increase their self awareness and express unspoken and often unconscious concerns.  

**Massage** will be defined as physical touch using systematic movement on body parts.  

**Therapeutic touch** will be defined as the use of hands to realign and balance the energetic field surrounding a person’s body.  

**Aromatherapy** will be defined as the use of essential oils inhaled, applied to the skin or added to baths.  

**Exercise** will be defined as instructed movement verbalised, demonstrated or implied that is mimicked by the participant to an appropriate tempo. This may include but is not limited to gentle movement, dancing, walking or gardening.  

The databases of the Cochrane Collaboration, the Joanna Briggs Institute (JBI), National Health Service (NHS) Centre for review and the agency for Healthcare
Research and Quantity (AHRQ) were searched prior to commencement of this review. No systematic review on this topic has been identified.

**Review Questions/Objectives**

The following question guides the systematic review: *What is the efficacy of complementary therapies in the symptom management of agitation in older people living in a RACF?*

This systematic review aims to identify the efficacy of complementary therapy interventions in reducing the frequency and severity of agitated behaviour among older people in RACF. Specific questions to be addressed include:

1. What type of complementary therapies are been implemented for the symptom management of agitation in older people residing in a RACF?

2. Which complementary therapies are identified as being effective in reducing the frequency and severity of agitation in older people in a RACF?

**Inclusion Criteria**

**Types of Studies**

All randomised controlled trials (RCTs) evaluating the efficacy of complementary therapies in the symptom management of agitation will be considered as they are ranked highest according to reliability for intervention effectiveness. Other types of study design including quasi-experimental and observational studies will be considered if RCTs are not located in the literature search. RCTs conducted in any country will be considered for inclusion in the review, however due to lack of interpreter facilities only papers published in English will be included. Unpublished RCTs are also considered in an attempt to eliminate publication bias from the final results.
Types of Participants

Older people living in RACFs will be included regardless of cognitive ability, gender or ethnicity and existing co-morbidities. Trials of RCTs investigating symptom management of agitation in older people over the age of sixty five will be examined. Trials undertaken in settings other than RACFs will be excluded.

Types of Interventions

The types of interventions to be explored in this review are complementary therapies include:

- aromatherapy
- exercise
- massage
- music therapy
- therapeutic touch

These interventions are of interest as they are non invasive, have minimal interactions with current medications and require minimal time, resources and training by nurses. 10

Types of Outcome Measures

The outcome measures to be explored include severity and frequency of agitated behaviours. Outcomes will be measured with a variety of standardised and non standardised measurement tools using observation, with long term and short term measures. Measures will review the findings of frequency and severity of agitation.

Reasons for exclusion

Studies will be excluded if they were not undertaken in settings other than RACFs, or participants were under the age of 65 years. Nonpharmacological studies which did not comply with complementary therapies domains as stated by the World Health Organizations traditional medicine strategy were excluded. 11
Search Strategy

The search strategy aims to identify all relevant studies. Keywords were identified through preliminary searches, taking into account spelling and terminology variation. Search strategies for individual databases were developed in conjunction with a research librarian:

- CINAHL (1937 – current)
- Cochrane library (1800 – current)
- Medline (1826 - current)
- Scopus (1966 – current)
- PsycINFO (1987 – current)
- ScienceDirect (1823 - current)
- ProQuest Social Science Journals (1971- current)
- EMBASE (1947 – current)
- Ageline (1978- current)
- Mednar
- Proquest

Alerts in each database have been set up to inform the researcher of newly published relevant literature. The search also seeks to include unpublished studies where possible using Mednar and Proquest databases, to eliminate publication bias. The reference lists from identified papers will be searched for additional studies.

Studies located in the search strategies will be recorded into the bibliographic software Endnote X2.0. Any duplicates of studies will be deleted. Studies will then be independently reviewed by two separate reviewers in accordance with the inclusion and exclusion criteria. Studies reported in more than one publication will only be reviewed once. Disagreements between reviewers will be settled by a third reviewer.

Assessment of Methodological Quality
The Joanna Briggs Institute (JBI) quality appraisal checklist will be used to assess the methodological quality of studies which meet the inclusion criteria (Appendix I). The appraisal will be performed separately by two independent reviewers, with disagreements settled in consultation with a third reviewer. The JBI quality appraisal checklist identifies bias that may exist in the selected studies to determine whether the outcome results are valid. To ensure methodological quality the checklist criteria includes: evidence of allocation concealment at randomisation, details of study sample withdrawals, inclusion and exclusion criteria for study sample, information on validity of outcome measurements and potential bias of the study. Studies of low methodological quality as determined by the critical appraisal will be excluded from the synthesis, however will be mentioned in the review discussion.

Data Extraction

Data will be extracted by the reviewers and summarised using the JBI data extraction tool (Appendix II). Collected data includes participant demographics, sample inclusion and exclusion criteria, study setting, number and reasons for withdrawals from study, type and description of complementary therapy intervention, application and follow up of intervention, measure of outcomes, statistical methods and study outcome descriptions. The data extraction tool will be trialed before use with discrepancies resolved through discussion. Attempts to obtain missing data will be made by contacting the studies authors.

This systematic review attempts to bring the same level of rigor to reviewing research studies as should be used in conducting the individual studies initially. The outcome of a systematic review is only as good as the quality of the papers they include therefore strict adherence to rigor is necessary. The methodology and the rigor placed on each study in this systematic review is based on critical appraisal so that it may be replicated if necessary. Data is extracted by independent researchers using the validated JBI data extraction tool for data to be synthesised with ease.20

Data Synthesis
Quantitative papers will, where possible be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double entry. Odds ratio (for categorical) and weighted mean differences (for continuous data) and their 95% confidence interval will be calculated for analysis. Heterogeneity will be assessed using the standard Chi-square. Where statistical pooling is not appropriate, findings will be presented in narrative summary.

Acknowledgement

I would like to thank Professor Esther Chang for her extensive knowledge, valuable advice, and boundless enthusiasm to produce quality research. I would also like to thank Dr Amanda Johnson for her extensive knowledge, practical guidance and encouragement that have kept me motivated. I would also like to thank Geoff Lattimore, UWS medical librarian, for his extensive knowledge of database systems and assistance in the development of search strategies.

Potential conflicts of Interest

Nil
REFERENCES


Appendix I
JBI Critical Appraisal Instrument for Experimental Studies

Reviewer ___________________________________________ Date _______________________

Author _______ ______ Year ______ Record Number __________

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<thead>
<tr>
<th>No.</th>
<th>Question</th>
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<th>No</th>
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<tbody>
<tr>
<td>1)</td>
<td>Was the assignment to treatment groups truly random?</td>
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<td>2)</td>
<td>Were participants blinded to treatment allocation?</td>
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<td>3)</td>
<td>Was allocation to treatment groups concealed from the allocator?</td>
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<td>4)</td>
<td>Were the outcomes of people who withdrew described and included in the analysis?</td>
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<td>5)</td>
<td>Were those assessing the outcomes blind to the treatment allocation?</td>
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<td>6)</td>
<td>Were control and treatment groups comparable at entry?</td>
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<td>7)</td>
<td>Were groups treated identically other than for the named interventions?</td>
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<td>8)</td>
<td>Were outcomes measured in the same way for all groups?</td>
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<td>9)</td>
<td>Were outcomes measured in a reliable way?</td>
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<td>10)</td>
<td>Was appropriate statistical analysis used?</td>
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Overall appraisal: Include Exclude Seek further info

Comments (including reasons for exclusion):
## Appendix II

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

Reviewer: _______________________________ Date: ________________

Author: _______________________________ Year: ________________

Record Number: ____________________

#### Study Method:

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

#### Participants:

- Setting: ____________________________________________
- Population: ____________________________________________
- Sample size: ____________________________________________

#### Intervention:

- Intervention 1: ____________________________________________
- Intervention 2: ____________________________________________
- Intervention 3: ____________________________________________

#### Clinical Outcome Measures:

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<th>Outcome Description</th>
<th>Scale/Measure</th>
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#### Study Results:

##### Dichotomous Data

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<th>Intervention ( ) Number/Total Number</th>
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##### Continuous Data

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#### Author’s Conclusions:

__________________________________________________________________________
__________________________________________________________________________

#### Reviewer’s Comments:

__________________________________________________________________________