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Symptom-specific non-pharmacological interventions for behavioural and psychological symptoms of dementia: protocol of an umbrella review of systematic reviews of randomised controlled trials

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ABSTRACT

Introduction There are various non-pharmacological interventions for dementia care. However, healthcare providers continue to face challenges in determining the most suitable interventions for the behavioural and psychological symptoms of dementia (BPSD), which vary according to individuals. This umbrella review aims to identify and summarise the effective non-pharmacological interventions for each sub-symptom to provide individualised, evidence-based recommendations for clinical practice.

Methods and analysis This review follows the guideline of the Cochrane methodology for umbrella reviews. It focuses only on systematic reviews (SRs) with or without a meta-analysis of randomised controlled trials. Five electronic databases: PubMed, Cumulative Index to Nursing and Allied Health Literature, Embase, PsycINFO and Cochrane Database, will be searched. The screened SRs will be determined for eligibility by the PICO formulation: (Population) older adults with dementia of any type; (Intervention) all types of non-pharmacological intervention; (Comparison) usual care or other non-pharmacological intervention; and (Outcome) BPSD and its sub-symptoms. The quality of the individual SRs will be appraised using A Measurement Tool to Assess Systematic Reviews 2. The overlap of primary studies will also be considered by eliminating an old-date SR conducted by the same authors with the same interest and calculating the Corrected Covered Area. Data will be extracted according to the pre-determined formula, which will organise non-pharmacological interventions according to the sub-symptoms of BPSD and not according to the type of intervention.

Ethics and dissemination Since this is a review paper, ethical approval is not required. The findings of this review will be disseminated through publication in a peer-reviewed journal.

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STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The umbrella review approach allows us to conduct a tertiary-level review to summarise and synthesise the results from systematic reviews (SRs) according to the researcher's interest in the phenomenon.
⇒ Eligibility screening, quality appraisal and data extraction will be duplicated by at least two authors.
⇒ The findings from the umbrella review will provide recommendations for readily applicable guidelines in clinical practice.
⇒ A limitation of this umbrella review will be an exclusion of non-English SRs or individual randomised controlled trials that are not included in any SR, although with a rigorous literature search.

INTRODUCTION

A growing number of people are living with dementia; currently, the prevalence of people living with dementia is reported to be 55 million worldwide.[1] Caring for people living with dementia is burdensome owing to the progressive decline in their cognitive function and gradual loss of daily and social functioning. In particular, it is challenging to provide care for persons who manifest the behavioural and psychological symptoms of dementia (BPSD), which can lead to caregiver fatigue, depression, and burnout.[2]

BPSD, often called neuropsychiatric symptoms of dementia,[3] are a set of heterogeneous non-cognitive symptoms. The Neuropsychiatric Inventory (NPI) is a commonly used tool in categorising BPSD and includes aberrant motor behaviours, agitation or aggression, anxiety, apathy, appetite disorder, delusions, depression, disinhibition, elation/euphoria, hallucinations, irritability and sleep disorder.[4] Although BPSD is the most common during the mid-stage of dementia, symptoms can appear at any stage, with fluctuating severity. Over 90% of persons living with dementia will suffer from BPSD at some point, whether

their symptoms present singularly or in clusters.[3] Previous studies have consistently reported the negative consequences of BPSD, such as poor quality of life in persons living with dementia and their caregivers, impaired daily functioning, a threat to safety,[5] nursing home admission,[6] caregiver burden[7] and increased mortality.[8]

In recent years, there have been arguments about BPSD as this terminology may evoke a negative perspective toward the symptoms of dementia, framing them as problems to be solved or treated using pharmacological intervention or physical restraint.[9] Among the various terminologies suggested, unmet needs seem to be neutral terminology, which is broadly accepted by persons living with dementia and their caregivers.[10 11]

Although this umbrella review will use the term BPSD for the categorisation of the symptoms, the unmet needs model must also be considered. The perspective to view BPSD as an unmet need particularly emphasises the necessity of non-pharmacological interventions as a frame for understanding personhood, taking action to fulfil unmet needs and eventually improving symptoms.[12–14] Non-pharmacological interventions, such as behavioural therapy, validation therapy, psychotherapy, reminiscence, person-centred care, music therapy, bright-light therapy and multisensory approaches are widely considered first-line interventions for BPSD today.[15–17] These interventions are considered non-invasive, safe and have fewer adverse effects than pharmacological interventions.[5] In particular, among older adults who take multiple medications for medical conditions other than dementia, non-pharmacological interventions present a safer option to prevent drug-to-drug interactions and adverse effects of neuropsychiatric medications.[18 19] The non-pharmacological interventions also allow the involvement of various professionals, making them easier to be implemented in diverse clinical settings.

The growing attention toward the benefits of non-pharmacological interventions, have led to many primary trials and reviews being published. In dementia research, umbrella reviews have been conducted to investigate the effectiveness of non-pharmacological therapy for BPSD by synthesising the results from secondary-level synthesis reviews (eg, systematic reviews (SR)). The findings from these tertiary-level reviews have generally shown that non-pharmacological interventions were effective in improving BPSD.[20–23] Regarding individual non-pharmacological therapy, music therapy and cognitive–behavioral therapy were effective in treating symptoms of depression or anxiety,[22 24 25] whereas home-based behavioural management, person-centred care and dementia care mapping were effective for addressing severe agitation.[24]

Although previously published umbrella reviews have focused on the types of non-pharmacological interventions, such approaches have failed to provide practical guidance in clinical settings because BPSD presents as a symptom or cluster of symptoms. In current evidence, the effectiveness of non-pharmacological interventions for each sub-symptom of BPSD is also limited to certain symptoms (ie, depression, anxiety and agitation).[22 24 25] Healthcare providers still face the challenge of which non-pharmacological interventions should be chosen depending on the clinical manifestations, despite the evidence to apply and choose interventions because there is no guidance.[26] BPSD has a complex aetiology with a wide range of 12 symptoms. Furthermore, each symptom has several determinants; therefore, it is difficult to identify which interventions would be effective for each symptom.[27] Considering the complexity of BPSD aetiology, there is no non-pharmacological treatment that covers all the symptoms. However, to be helpful in clinical settings, a review of non-pharmacological interventions of BPSD according to its sub-symptoms is required. Thus, this umbrella review aims to identify and evaluate evidence regarding symptom-specific non-pharmacological interventions to reduce BPSD in older adults living with dementia. In particular, we will focus on investigating the effectiveness of non-pharmacological interventions on the sub-symptoms of BPSD. The primary review question underlying this umbrella review is 'What are the most effective non-pharmacological interventions to reduce each BPSD and the sub-symptoms of BPSD?'. The secondary review questions are 'Which sub-symptoms of BPSD were targeted for non-pharmacological interventions?' and 'What are the types and characteristics of non-pharmacological interventions used to reduce each sub-symptom of BPSD?'.

METHODS

Study design

This umbrella review will follow the guideline of Cochrane methodology for umbrella reviews.[28] Before starting the review, we registered the protocol of this review at the International Prospective Register of Systematic Reviews. The anticipated start and end dates of the review are from February 2023 to September 2023.

Search methods

We have developed search strategies through several research meetings and consultations with a university librarian. The search databases will include PubMed, Cumulative Index to Nursing and Allied Health Literature, PsycINFO, Embase and the Cochrane Database of Systematic Reviews. The search date range will comprise the last 10 years (January 2012–January 2023) to capture the most recent comprehensive findings based on the methodological recommendations on conducting umbrella reviews.[29] Peer-reviewed SRs published in English will be included.

The PICO framework of our umbrella review is as follows:

1. Population: older adults with dementia of any type.
2. Intervention: all types of non-pharmacological interventions.
3. Comparison: usual care, waitlist control or other types of non-pharmacological interventions.

4. Outcome: one or more BPSD-related symptoms measured using a valid measurement tool.

The search terms were developed based on this PICO framework. The key search terms include "older adult" AND "dementia" AND "non-pharmacological intervention" AND "BPSD" AND "systematic review". We consulted a university librarian, an expert in literature searches, about the search terms before commencing the search. Online supplemental tables A1–A5 show examples of an organised search term for each search engine.

After searching for potential sources of evidence, data will be extracted, and duplicates will be removed using EndNote and Excel. Two independent authors will perform the initial screening of the titles and abstracts, and the discordance in crosschecks at this phase will be resolved through research team meetings. After excluding irrelevant SRs, we will investigate the full texts. Four independent authors will be involved in the full-text screening. Specifically, the four authors will be divided into two teams, and each team of two authors will review the assigned number of SRs. Where agreement cannot be reached between the two authors within the team, a third author from another team will be consulted to decide eligibility. To increase the consistency of study selection between the two teams, the full text will be cross-checked and reviewed by one author from another team. Thus, at least three authors will review each SR to determine its suitability for eligibility.

Inclusion and exclusion criteria

A specific description of each category for study selection is presented in table 1. In addition to the PICO framework, the scope of our umbrella review will be limited to SRs with randomised controlled trials (RCTs) only and will mainly target interventions in community and long-term care settings where persons living with dementia maintain their daily routines.

Quality appraisal

A Measurement Tool to Assess Reviews 2 (AMSTAR 2) will be used to evaluate the methodological quality of the SRs.[30] Two independent authors will assess the quality of the included SRs and provide their decision on 16 items of AMSTAR 2. Before beginning the process, the two authors will pilot the use of AMSTAR 2 on two or three SRs or meta-analyses to ensure consistent ratings between the authors. For each item, the answer will be 'yes', 'partial yes' or 'no'. Any disagreement between the two authors and uncertainties will be resolved by consensus and team meetings. Each SR will be categorised into 'high' (none or one 'non-critical weakness'), 'moderate' (more than one 'non-critical weakness'), 'low' (one 'critical flaw' with/without 'non-critical weakness') or 'critically low' (more than one 'critical flaw' with/without 'non-critical weakness') using the online AMSTAR 2 (https://amstar.ca/Amstar_Checklist.php).[30]

Data extraction

We will extract data from the SRs in two stages. First, descriptive characteristics of SRs will be extracted, including author, publication year, number of RCTs included, number of primary studies included, number of participants included, purpose, date of search, population (ie, age range, dementia type), type of intervention and control, key findings (ie, outcomes, effect sizes) and the certainty of the evidence described. Key findings related to our review questions will then be extracted, especially focusing on the sub-symptoms of BPSD according to the NPI.[4] Data extraction will be further refined as a review process and will be explained in the final review.

Before starting the data extraction, a template will be created using Excel through a team discussion. The data will be extracted by one author using this template. Two other authors will review the extracted data and cross-check them. Accordingly, three authors will conduct

Table 1 Inclusion and exclusion criteria

	Inclusion	Exclusion
Population	► Systematic reviews or meta-analyses that include persons living with dementia	► Systematic reviews or meta-analyses that do not include persons living with dementia ► Systematic reviews or meta-analyses in which target groups other than dementia are mixed (eg, cognitively normal and mild cognitive impairment groups)
Intervention	► Systematic reviews or meta-analyses that include at least one non-pharmacological intervention	► Systematic reviews or meta-analyses that include pharmacological interventions (eg, drugs), a therapeutic intervention that needs a prescription (eg, brain stimulation), or supplements (eg, herbal medicine, cannabinoids) ► Systematic reviews or meta-analyses that include interventions for informal/formal caregivers or staff (eg, dyadic, educational intervention)
Control	► Systematic reviews or meta-analyses that include usual care, waitlist control or other types of non-pharmacological interventions	► Systematic reviews or meta-analyses that include a control group receiving pharmacological interventions
Outcome	► Systematic reviews or meta-analyses that include one or more BPSD symptoms (eg, agitation) measured using valid measurement tools (eg, Cohen-Mansfield Agitation Inventory)	► Systematic reviews or meta-analyses that do not include BPSD outcomes
Setting	► Systematic reviews or meta-analyses that mostly include long-term care settings or community settings	► Systematic reviews or meta-analyses that only include acute or sub-acute settings

BPSD, behavioural and psychological symptoms of dementia.

the data extraction. Any uncertainties or discordance between authors will be resolved through a review team meeting.

Regarding the overlap of primary RCTs, we will use the Corrected Covered Area (CCA) to address the degree of overlapping. A CCA matrix will be formulated with columns (included SRs) and rows (included RCTs in each SR), and the CCA will be calculated and demonstrated in a table.[31] The CCA is calculated by multiplying the number of the first occurrence of primary RCTs by the total number of reviews and then subtracting the number of the first occurrence of primary RCTs. This value will then be used to divide the value obtained by subtracting the number of first occurrences of primary RCTs from the total number of RCTs, including double counting. The degree of overlap is determined by the following criteria: 0%–5% indicates low overlap; 6%–10% moderate overlap; 11%–15% high overlap, and greater than 15% indicates a very high overlap.[31] If there are SRs conducted by the same authors to update the previous SR with the same interest, only the most recent SR will be included.[32]

Data synthesis

First, a narrative synthesis will be presented. The BPSD-related outcomes will be organised in the tables, and statistical data obtained from the meta-analysis will be presented as ORs or risk ratios if described in the included SRs. Then, we will resynthesise all the BPSD outcomes based on the sub-symptoms of BPSD. If possible, we will summarise the intervention effects for each intervention according to the sub-symptoms of BPSD. The results will be synthesised considering each review's quality and CCA scores, and continuous team meetings will be conducted to determine the review selection and data synthesis according to the review quality and CCA scores.

Confidence in the synthesised findings of the review

This umbrella review will examine and summarise the certainty of the evidence described in each SR if it evaluated its confidence using a tool such as the Grading of Recommendations Assessment, Development and Evaluation approach.

Patient and public involvement

This umbrella review analyses existing systematic research, which includes no patients or members of the public.

DISCUSSION

BPSD can pose a great challenge in dementia care. Although tertiary reviews exist, no reviews based on the sub-symptoms of BPSD have been conducted thus far. Given the limitations in the choice of resources in real-world settings, reviews on BPSD based on sub-symptoms are urgently needed. This umbrella review will provide a substantial update on previous overviews of BSPD.[20–25] Unlike previous reviews, this umbrella review will synthesise the results according to the sub-symptoms of BPSD. Therefore, we believe that our umbrella review will provide recommendations for readily applicable guidelines in dementia care.

Ethics and dissemination

Ethical approval was not required for the umbrella review or protocol. The findings of the umbrella review will be shared through publication in a peer-reviewed journal.

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Contributors EC, JYL and MJK led the conceptualisation and design of this work. JYL registered the protocol in PROSPERO. MJK organised a search strategy. EC, MJK, MY, JJ, JC and JYL provided input into the study design and search strategy and edited the draft protocol. EC, MJK, MY, JJ, JC and JYL read and approved the final manuscript.

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Competing interests None declared.

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.

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