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Effects of dyadic psychosocial education on people with mild cognitive impairment or dementia and their informal caregivers: protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction Mild cognitive impairment (MCI) and dementia impose a significant burden on individuals and their caregivers. Dyadic psychosocial education, which treats care recipients and their caregivers as a pair of active participants, has the potential to improve health outcomes for people with cognitive impairment and their caregivers. However, the results of recent studies on this subject are contradictory. We aim to evaluate the effectiveness of dyadic psychosocial education for people with MCI or dementia and their informal caregivers.

Methods and analysis Six databases will be searched. We will include all randomised controlled trials that compare dyadic psychosocial education to usual care. The risk of bias will be assessed using the Cochrane Risk-of-Bias Assessment Tool (V.2). Meta-analyses, subgroup analyses and sensitivity analyses will be performed using Stata V.15.1. A narrative synthesis will be conducted if quantitative analysis is not feasible.

Ethics and dissemination This study and subsequent systematic review will not collect individual-level data and, therefore, do not require ethics committee approval. Peer-reviewed publications will disseminate the study results.

PROSPERO registration number CRD42024497554.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Including both mild cognitive impairment and dementia allows for a more comprehensive evaluation of the intervention's applicability.
- ⇒ The certainty of the body of evidence will be assessed to better guide users of the evidence.
- ⇒ The protocol has been registered with PROSPERO, demonstrating the transparency of the process.
- ⇒ Different types of interventions may lead to higher heterogeneity.
- ⇒ Although a comprehensive search of six databases will be conducted, only studies published in Chinese or English will be included, which may introduce some bias.

INTRODUCTION

As the global population ages, the prevalence of mild cognitive impairment (MCI) and dementia is steadily rising.[1] MCI is defined as objective cognitive impairment on neurocognitive testing, without significant impairment in instrumental activities of daily living.[2] MCI progresses to dementia at a rate of between 8% and 15% per year,[3] with a mean progression rate of 12.2%,[1] which is significantly higher than in the general population. Dementia is a syndrome that can be caused by many diseases, and over time, people with dementia experience brain damage, along with cognitive dysfunction and changes in mood and behaviour.[4] More than 55 million people around the world live with dementia, and informal caregivers provide an average of 5 hours of care and supervision per day.[4] In addition to their caregiving duties, these caregivers also face other family, professional and social obligations.[5] Informal caregivers of people with dementia bear significant stress and strain.[6,7] Therefore, support should be provided to both people with cognitive impairment and their informal caregivers.

Currently, there are no medications that can effectively reverse cognitive impairment. Among various psychosocial interventions, psychosocial education stands out as a promising approach. Psychosocial education provides information and psychotherapeutic strategies in an educational format, positively impacting participants' psychosocial health and well-being.[8] Psychosocial education has been used in post-traumatic stress disorder,[9] breast cancer[10] and low back pain populations[11] and has shown favourable results. Dyadic interventions involve both care recipients and their caregivers as a pair of active participants and intervene with them simultaneously, which may be more beneficial to the dyad's health outcomes and relationships than intervening with either participant alone.[12 13]

In recent years, dyadic psychosocial education has been increasingly applied to cognitively impaired populations. One study showed that 2 months of dyadic psychosocial education improved the quality of life of people with Alzheimer's disease.[14] While another study found no effect of the intervention on quality of life.[15] One study[16] reported that dyadic psychosocial education improved cognitive function, subjective memory and mood in people with MCI, as well as reduced depression in caregivers. Another study, however, did not find any benefits of the intervention for people with dementia and their caregivers.[17] Due to the ambiguity of results on this topic, a comprehensive study is needed. However, existing systematic reviews and meta-analyses have primarily focused on people with dementia, often combining multiple psychosocial interventions[18–20] or lacking quantitative analysis,[21 22] which limits our understanding of the role of psychosocial education. Therefore, this study aims to assess the impact of dyadic psychosocial education on people with MCI or dementia and their informal caregivers. These findings may inform the development of psychosocial education for cognitive impairment.

METHODS

This protocol was reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol.[23] In accordance with these guidelines, the protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) (registration number: CRD42024497554). The systematic review and meta-analysis commenced on 13 October 2024, with an expected completion date of 28 February 2025.

Eligibility criteria

Participants

We will include people diagnosed with MCI or dementia, as well as their informal caregivers. All participants must live in the community and be at least 18 years old.

Interventions

Studies focusing on dyadic psychosocial education will be included. Psychosocial education refers to an educational approach that provides individuals with information and emotional support. Thus, this study will focus on research that mainly provides information and psychological support to individuals through education, with the intervention provided simultaneously to both care recipients and their informal caregivers.

Comparators

Usual care or waitlist.

Outcomes

The primary outcome for people with MCI or dementia is neuropsychiatric symptoms (overall neuropsychiatric symptoms, depression, anxiety, apathy and agitation). For informal caregivers, the primary outcome is health-related quality of life. Secondary outcomes will include the overall cognitive function in people with MCI or dementia, caregiver burden, caregiver mood (depression, anxiety) and the dyadic relationship.

Study design

Randomised controlled trials (RCTs).

Exclusion criteria

Studies not published in Chinese or English, conference abstracts and duplicates will be excluded.

Search strategy

In this study, the following online databases will be searched: PubMed, Embase (Ovid), Web of Science, Cochrane Central Register of Controlled Trials, CINAHL Plus with Full Text (EBSCO) and PsycINFO (EBSCO). Relevant literature published in the past 20 years will be searched using both Medical Subject Headings and free text terms. The reference lists of the included studies will also be reviewed. The search period will cover from 1 January 2004 to 31 December 2024. Table 1 displays the complete search strategy for the PubMed database.

Study selection and data extraction

Study selection

We will import the acquired literature into Endnote to remove duplicates. Two reviewers (PN and M-LG) will then assess the titles and abstracts to exclude studies that do not meet the eligibility criteria. To determine the final studies, we will conduct a final reading of the full text of the potentially included literature. Figure 1 illustrates the selection process.

Data extraction

Two researchers (PN and M-LG) will independently extract data from the included studies. The data to be extracted includes: (1) study information: first author, publication year and the country where the study was conducted; (2) participant characteristics: sample size, age and diagnosis; (3) intervention characteristics: duration, frequency, providers and content and (4) outcome measures: outcomes and time of measurement. The mean and SD of the outcomes will be extracted for subsequent synthesis. If a study includes more than two groups, only the intervention and control groups relevant to our topic will be extracted. Any disagreements will be resolved through discussion and consensus with a third researcher (XH).

Risk of bias assessment (RoB 2)

Two reviewers (PN and M-LG) will assess the RoB in the studies using V. 2 of the Cochrane Risk-of-Bias Assessment Tool (RoB 2).[24] RoB 2 assesses the RoB based on five domains: randomisation process, deviations from intended interventions, missing outcome data, measurement of the outcome and selection of the reported results. A third reviewer (XH) will be consulted in case

Table 1 Search strategy for the PubMed

No	Search terms
#1	("Dementia"[MeSH]) OR ("Alzheimer Disease"[MeSH]) OR ("Cognitive Dysfunction"[MeSH])
#2	("dementia" [Title/Abstract]) OR ("Alzheimer*"[Title/Abstract]) OR ("cognitive dysfunction "[Title/Abstract]) OR ("mild cognitive impairment*"[Title/Abstract]) OR ("cognitive impairment*"[Title/Abstract]) OR ("MCI"[Title/Abstract]) OR ("cognitive decline"[Title/Abstract]) OR ("cognitive defect*"[Title/Abstract]) OR ("cognitive function disorder*"[Title/Abstract])
#3	#1 OR #2
#4	("Caregivers"[MeSH]) OR ("Family"[MeSH]) OR ("Spouses"[MeSH]) OR ("Friends"[MeSH])
#5	(caregiv*[Title/Abstract]) OR (care giv*[Title/Abstract]) OR (carer*[Title/Abstract]) OR (caretaker*[Title/Abstract]) OR (famil*[Title/Abstract]) OR (coupl*[Title/Abstract]) OR (spous*[Title/Abstract]) OR (relativ*[Title/Abstract]) OR (partner*[Title/Abstract]) OR (dyad*[Title/Abstract]) OR (friend*[Title/Abstract])
#6	#4 OR #5
#7	#3 AND #6
#8	(Psychotherapy[MeSH]) OR (psychiatric rehabilitation[MeSH]) OR (education[MeSH]) OR (rehabilitation[MeSH]) OR (problem solving[MeSH]) OR (coping skill[MeSH]) OR (counselling[MeSH]) OR (relaxation[MeSH]) OR (Mindfulness[MeSH])
#9	(psychotherapy[Title/Abstract]) OR (psychiatric rehabilitation[Title/Abstract]) OR (education[Title/Abstract]) OR (rehabilitation[Title/Abstract]) OR (problem solving[Title/Abstract]) OR (coping skill[Title/Abstract]) OR (counselling[Title/Abstract]) OR (relaxation[Title/Abstract]) OR (mindfulness[Title/Abstract])
#10	((psychoeducation*[Title/Abstract]) OR (psycho-education*[Title/Abstract]) OR (psychological[Title/Abstract]) OR (psychosocial[Title/Abstract]) OR (cogniti*[Title/Abstract]) OR (behavio*[Title/Abstract]) OR (emotional[Title/Abstract]) OR (mindful*[Title/Abstract])) AND ((education[Title/Abstract]) OR (support[Title/Abstract]) OR (intervention*[Title/Abstract]) OR (training[Title/Abstract]) OR (care[Title/Abstract]) OR (teaching[Title/Abstract]) OR (therap*[Title/Abstract]))
#11	#8 OR #9 OR #10
#12	#7 AND #11

MeSH, medical subject headings.

of disagreement, and consensus will be reached through discussion.

Data analysis

Missing data

Any missing or incomplete data will be requested from the original authors via email. If the original authors do not respond, we will estimate the missing SDs from the available SEs, 95% CIs, t-value and p values.[25] If this is not possible, a narrative synthesis will be conducted.

Assessment of heterogeneity

Heterogeneity between studies will be assessed using the Cochrane Q statistic and I^2 statistic, with Q statistic >0.10 and $I^2 \leq 50\%$ indicating low heterogeneity, and Q statistic <0.10 and $I^2 > 50\%$ indicating high heterogeneity, respectively.[25]

Data synthesis

Data synthesis will use Stata V.15.1 (Stata Corp., College Station, TX). A meta-analysis will be conducted if data from at least two studies are available for a given outcome.[25] Analyses will use random effects models when heterogeneity is low and fixed effects models when heterogeneity is high. All effect sizes will be expressed as standardised mean differences (SMDs) with 95% CIs. An SMD of 0.2, 0.5 and 0.8 indicates small, medium and large effect sizes, respectively.[26] If clinical heterogeneity between studies is high or missing data prevent estimation, a narrative synthesis will be used. A two-sided p value <0.05 is considered statistically significant.

Subgroup analysis and sensitivity analysis

Subgroup analyses will be conducted to explore sources of heterogeneity based on intervention duration, intervention frequency and RoB levels if heterogeneity between studies is high. Sensitivity analyses will be conducted using the leave-one-out approach to test the robustness of the results. If an outcome is reported in at least 10 studies and heterogeneity is high, meta-regression will be added to investigate the sources of the heterogeneity.

Assessment of publication bias

If at least 10 studies report the same outcome, Egger's test will be used to detect publication bias.[27] A p value of <0.05 indicates possible publication bias.

Assessment of the certainty of evidence

Two reviewers (PN and M-LG) will use the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to assess the certainty of the body of evidence.[28] The GRADE evaluates the body of evidence

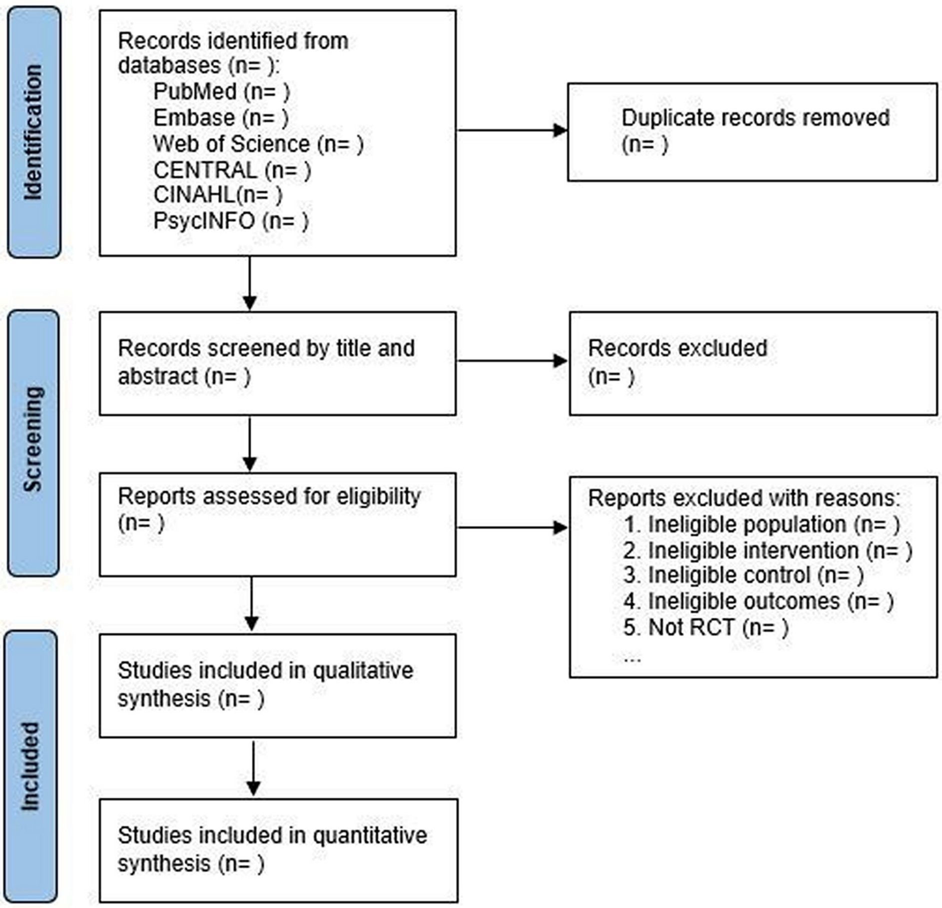

Figure 1 Flow chart of the selection process. CENTRAL, Cochrane Central Register of Controlled Trials; RCTs, randomised controlled trials.

in five domains: RoB, inconsistency, indirectness, imprecision and publication bias. The body of evidence will ultimately be rated as high, moderate, low or very low.

Patient and public involvement

None.

ETHICS AND DISSEMINATION

Ethical approval is not required as this study will not collect individual-level data and is based on published literature. We plan to disseminate the results of this study through peer-reviewed journals.

DISCUSSION

Guidelines recommend non-pharmacological interventions as a key approach to dementia prevention and care.[29 30] As a non-pharmacological intervention, dyadic psychosocial education has been explored in the field of cognitive impairment; however, evidence supporting its effectiveness for both care recipients and their caregivers remains limited. To our knowledge, this is the first systematic review and meta-analysis of RCTs assessing dyadic psychosocial education for people with MCI or dementia and their informal caregivers. These findings will guide healthcare providers in choosing appropriate interventions for cognitive impairment.

This study has three main advantages. First, we will not restrict the type of cognitive impairment; both people with MCI and dementia will be included, allowing us to assess the applicability of dyadic psychosocial education to a broader population. Second, we will evaluate the certainty of the body of evidence, which will strengthen the recommendations and further guide future research and practice. Finally, the protocol is registered with PROSPERO, ensuring the transparency of the process.

However, we anticipate that the study will face several challenges and limitations. First, due to the nature of the intervention, the psychosocial education approaches in the included studies may vary widely, leading to high heterogeneity. We will use subgroup analyses, sensitivity analyses or meta-regression to explore the sources of heterogeneity. Second, although we will conduct a comprehensive search across six databases, we only include studies published in Chinese or English, which may miss some relevant studies and increase the potential for bias.

Amendments

Any protocol changes will be accounted for in the systematic review.

Contributors PN: designed the study, designed the search strategy and drafted the manuscript. M-LG: designed the study and revised the manuscript. LL: designed the study and revised the manuscript. XH: designed the study, revised the manuscript and supervised the study. All authors approved the submitted version. Guarantor: XH.

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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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