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Art therapies improve cognitive function in elderly with subjective cognitive decline: a protocol for a network meta-analysis

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Title page

Title

Art therapies improve cognitive function in elderly with subjective cognitive decline: a protocol for a network meta-analysis

List of all authors

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Authors' contributions

Qian Liu designed this study with oversight by Xiuying Hu. Qian Liu drafted the protocol, and the draft was modified by Fang Wang and Li Liu. Qian Liu and Lixia Tan will search, select, and identify studies included, and extract data independently, while Li Liu will be the third reviewer for study selection and data extraction. Qian Liu will be responsible for methodology. All authors have approved the publication of this protocol.

Funding Statement

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Conflict of Interest

The authors have no conflicts of interest to disclose.

Art therapies improve cognitive function in elderly with subjective cognitive decline: a protocol for a network meta-analysis

Abstract

Introduction: The number of elderly with subjective cognitive decline has increased in recent years. Subjective cognitive decline is likely to evolve into Alzheimer's disease, which may bring huge burdens and challenges to caregivers and society. With the increase in research, some art therapies have gradually been proven to be effective for cognitive function. Therefore, this study aims to summarize the evidence and identify the most effective art therapy for elderly with subjective cognitive decline.

Methods and analysis: We will include published randomized controlled trials if the intervention is one of the art therapies and applied in elderly with subjective cognitive decline. Eight electronic databases, including the Cochrane Central Register of Controlled Trials, PubMed, Web of Science, Elsevier, China BioMedical Literature Database, China National Knowledge Infrastructure, VIP Database, and Wanfang Database, will be searched from January 2013 to present. Art therapies will mainly include music therapy, painting therapy, dance therapy, horticultural therapy, calligraphy therapy, and reminiscence therapy. The outcome will be cognitive function. Study selection, data extraction and quality assessment will be performed independently by two reviewers. The risk of bias of the included studies will be evaluated according to the Cochrane Collaboration's risk of bias tool, and the evidence quality will be assessed with the Grading of Recommendations Assessment,

Development and Evaluation. To compare the efficacy of different art therapies, standard pairwise meta-analysis and Bayesian network meta-analysis will be conducted for all outcomes. The probabilities of each art therapy for outcomes will be ranked in accordance with the surface under the cumulative ranking curve.

Ethics and dissemination: Ethical approval is not required for reviewing published studies. To provide important evidence for clinicians and guideline developers to determine interventions for patients with subjective cognitive decline, the findings of this study will be submitted to a peer-reviewed journal.

PROSPERO registration number: CRD42023443773.

Key words: subjective cognitive decline; elderly; art therapy; protocol; network meta-analysis

Strengths and limitations of this study

1. This network meta-analysis will integrate direct evidence with indirect evidence and allow the comparison of multiple art therapies in one model.

2. For the first time the cognitive function outcome of art therapies in combination with usual care for elderly with subjective cognitive decline will be comprehensively assessed in a network meta-analysis.

3. Network meta-analysis will promote precision of intervention and provide evidence for the decisions of intervention and the development of guidelines.

4. On account of the retrospective nature of this study, the findings may be influenced by the quantity and quality of the included studies.

Introduction

As a global public health problem that urgently needs to be addressed, Alzheimer's disease leads to the loss of reasoning, memory, language, and ultimately basic self-care skills, which places an enormous burden on families and the health-care system. The development of Alzheimer's disease is insidious, with onset of clinical symptoms preceded years earlier by perceived and/or objective cognitive decline,[1] which is also the early stage of mild cognitive impairment.[2] Subjective cognitive decline refers to the decline in the subjective perception of self-cognitive function compared with the previous normal state, mainly memory decline, but objective neuropsychological tests are not abnormal, and this decline is not related to other acute events.[3] Previous studies have suggested that subjective cognitive decline is a preclinical symptom of Alzheimer's disease.[4-6] A systematic review that included 46 longitudinal studies showed that the risk of developing dementia in the elderly with subjective cognitive decline was 2.48 times higher than that in the elderly without cognitive abnormalities, and the risk of developing mild cognitive impairment was 1.83 times higher than that in the elderly without cognitive abnormalities.[7] Moreover, the findings of a long-term observational study over 10 years indicate that subjective cognitive decline can occur 10 years before the diagnosis of Alzheimer's disease.[8] Therefore, the therapeutic window for addressing Alzheimer's disease can be moved forward, and subjective cognitive decline can be regarded as an important gateway for early prevention and treatment of Alzheimer's disease, which may help alleviate the major public health problem, although there are no approved treatments for Alzheimer's disease and even

mild cognitive impairment.[9]

The efficacy of pharmacological interventions is limited. To avoid the side effects of antipsychotics, more attention is given to the application of nonpharmacological interventions.[10] Art therapy is an emerging nonpharmacological intervention with distinctive features that integrates psychology, art and medicine. Art therapy can take a variety of forms, such as music, singing, dancing, reading and poetry groups, museum/gallery art and collections, creative writing, life story narrative reminiscence, painting, printmaking, collage, pottery, sewing, knitting, woodwork and gardening.[11] As a kind of nonpharmacological intervention, art therapy has been widely proven to be beneficial in the care of patients with cognitive impairment and has been used in clinical practice in Europe and the United States.[12] It is helpful to reduce the mental and behavioral abnormalities of patients and slow down the progress of cognitive impairment, to achieve great effects in treatment and care. It is suggested that music listening can help to improve both subjective memory function and objective cognitive performance in adults with subjective cognitive decline.[13] Several randomized controlled trials have demonstrated that dance therapy can improve cognitive function, especially episodic memory and processing speed.[14-16] Moreover, painting therapy has been proven to improve cognitive function in patients with mild cognitive impairment.[17] A narrow review has summarized the positive effects of therapeutic gardens on the health, spanning physical, social, psychological and cognitive effects.[18] Additionally, spiritual reminiscence programs using expressive arts therapy are conducive to improving cognitive function.[19]

With the increase in relevant research, art therapy has gradually been proven to be of great significance in alleviating cognitive decline. However, the advantages and disadvantages of the effects of different art therapies on elderly with subjective cognitive decline are still inconclusive at present, and studies directly comparing the differences in various art therapies are lacking. Network meta-analysis is capable of summarizing direct and indirect evidence, thus evaluating and comparing the relative efficacy of multiple treatments.[20] More importantly, network meta-analysis can provide the ranking of intervention options in accordance with their effectiveness. Therefore, to provide important evidence for care decision-making for elderly with subjective cognitive decline, this study will evaluate the effects of different art therapies through a network meta-analysis.

Methods and analysis

This network meta-analysis protocol was registered on the PROSPERO platform (CRD42023443773). The results of this network meta-analysis will be reported following the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols.[21]

Eligibility criteria

Type of participants

Elderly diagnosed with subjective cognitive decline will be included, according to the criteria published by the Subjective Cognitive Decline Initiative.[22 23] Inclusion criteria are (1) there is a continuous decline in cognitive function of self perception compared to the previous state of accessibility, and it is not related to acute events; (2)

the standard cognitive test shows no abnormalities after adjustment for age, gender, and years of education, and do not meet the diagnostic criteria for mild cognitive impairment; (3) complaints of continuous memory decline in the past 5 years; (4) 60 years or older; (5) subjective memory decline (not in other cognitive domains), and concerns about the cognitive decline. The exclusion criteria are (1) diagnosed with various types of dementia; (2) a clear history of cerebrovascular disease or recent brain trauma; (3) nervous system diseases that may affect the cognitive function, such as brain tumors, Parkinson's disease, encephalitis, epilepsy, delirium and carbon monoxide poisoning; (4) other major diseases that may affect subjective cognitive function, such as severe metabolic diseases and severe cardiopulmonary diseases; and (6) severe mental illnesses, such as schizophrenia, bipolar disorder, severe depression, and severe anxiety.

Type of studies

Only randomized controlled trials written in English or Chinese will be included. Cluster randomized controlled trials and cross-over randomized controlled trials will be excluded. Trials without a control group will be excluded. If the control group did not receive art therapy or usual care, the trial will also be excluded.

Type of intervention

Any art therapy that is combined with usual care and implemented in elderly with subjective cognitive decline will be included. However, multi-component interventions will be excluded. These art therapies may be aimed at improving cognitive function. The types of art therapies for elderly with subjective cognitive decline may include (1)

music therapy, (2) dance therapy,[Error! Reference source not found.] (3) reading therapy,[Error! Reference source not found.] (4) painting therapy,[Error! Reference source not found.] (5) horticultural therapy,[Error! Reference source not found.] (6) reminiscence therapy[Error! Reference source not found.] and (7) calligraphy therapy.[Error! Reference source not found.]

Comparison

Comparator will be considered a usual care of subjective cognitive decline (such as guidance of drugs, diet, rehabilitation and complication prevention) or another art therapy combined with usual care.

Type of outcomes

The outcome will focus on cognitive function, which might be measured by a validated cognitive outcome measure, for example, subjective cognitive decline Questionnaire, the Mini-Mental State Examination, Montreal Cognitive Assessment, Addenbrooke's Cognitive Examination-III, Mini-Addenbrooke's Cognitive Examination, Memory Impairment Screen, Quick Screen for Mild Cognitive Impairment, Clock-Drawing Test, or Repeatable Battery for the Assessment of Neuropsychological Status.

Data sources and search strategy

The search used a combination of Medical Subject Headings and free words for professional searches. The search items will include subjective cognitive decline or SCD, art therapy (music* or singing or danc* or painting or drawing or collage or clay or theatre or drama or reading or poetry or woodwork or garden* or horticultural or handwriting or penmanship or calligraphy or ceramics or pottery or writing or sculpture

or carving or narrative or reminiscence or printmaking or sewing or knitting or museum or gallery) and randomized controlled trial. Searches will be undertaken in electronic databases to identify published studies, including the Cochrane Central Register of Controlled Trials, PubMed, Web of Science, Elsevier, China BioMedical Literature Database, China National Knowledge Infrastructure, VIP Database, and Wanfang Database. A draft search strategy is summarized in Supplementary Material 1. The retrieval time will be from January 2013 to the present. In addition to the database search, the references of the included studies will be scanned to identify additional eligible studies.

Study selection

All investigators will receive appropriate training prior to study selection. All retrieved studies will be imported into NoteExpress software to download references. Duplicate studies will be removed. The titles and abstracts of selected studies will be screened independently by two reviewers to exclude studies that obviously do not meet the inclusion criteria. The preliminary results will be cross-checked. Then, the remaining full-text studies will be examined independently by the same two reviewers to determine eligibility. If there are disagreements, the third reviewer will be asked to evaluate the full text. Any discrepancies will be resolved through group discussions. We will record the excluded studies and reasons for exclusion. Figure 1 shows the process of study selection.

Data extraction

All researchers of this study will discuss and design a standard form for data

extraction. Then, two reviewers will independently extract data in accordance with the standard form, including author (s), year of publication, sample size, characteristics of patients (gender and age), intervention (type, frequency and duration), and measurements of outcome. After completing data extraction, the results of two reviewers will be crosschecked to ensure that there is no mistake. Team discussion will be used to resolve the disagreements.

Risk of bias assessment

The revised version of the Cochrane tool (RoB 2) will be used to assess the risk of bias for all included studies.[24] This tool will assess five domains, including (1) bias arising from the randomization process, (2) bias due to deviations from intended interventions, (3) bias due to missing outcome data, (4) bias in the measurement of the outcome and (5) bias in the selection of the reported result. The assessment of each domain will be rated as 'low risk of bias', 'some concerns' and 'high risk of bias'. The response options for an overall risk-of-bias judgment are the same as those for individual domains. If all domains are rated as 'low risk of bias', this trial will be judged to be at low risk of bias. If at least one domain is rated as 'some concerns' and no domain is rated as 'high risk of bias', this trial will be judged to be 'some concerns'. If at least one domain is rated as 'high risk of bias' or multiple domains are rated as 'some concerns' in a way that substantially lowers confidence in the result, this trial will be judged to be at high risk of bias. Two reviewers will independently evaluate the risk of bias for each study and then cross-check the results. Differences will be resolved through team discussion with the third reviewer.

Statistical analysis

Pairwise meta-analysis

We will use Review Manager (version 5.3) to conduct a pairwise meta-analysis of direct evidence. For continuous outcomes, standardized mean differences with 95% confidence intervals will be used. The χ^2 test will be used to assess the heterogeneity across all included trials. A fixed-effects model will be used to synthesize the standardized mean difference if the p value is ≥0.1. Conversely, if the p value is <0.1, a random-effects model will be used.

Network meta-analysis

Considering the expected heterogeneity between studies, the effects of different art therapies will be compared by conducting a random-effects network meta-analysis within a Bayesian framework using Markov Chains Monte Carlo in R software (version 4.1.3). Brooks-Gelman-Rubin diagnosis and potential scale reduction factor will be used to ensure the convergence of the model.[25] Moreover, the surface under the cumulative ranking curve with its 95% confidence interval and rank-heat plot will be used to evaluate the hierarchy of each art therapy.[26 27]

Dealing with missing data

If there is a lack of some information, the missing data will be obtained by contacting the corresponding authors whenever possible. We will try to calculate the missing data based on availability factors if there is no reply. Sensitivity analysis will be used to examine the potential impact of missing data on the results of this study.

Assessment of publication bias

If more than nine studies are included in the analysis, funnel plots, Begg's rank correction and Egger's regression tests will be used to evaluate the presence of publication bias in Stata software (version 15.0).[28-30]

Assessment of inconsistency and subgroup analysis

Based on a loop-special method within each loop of the network,[31] the local inconsistency and global inconsistency will be measured in Stata software (version 15.0).[32]32 If there is heterogeneity or inconsistency, the sources of heterogeneity will be explored by network meta-regression. Subgroup analysis will be performed in accordance with age, gender, or duration of intervention.

Sensitivity analysis

We will perform a sensitivity analysis for primary outcomes to verify the robustness of the findings. In the sensitivity analysis, trials judged to be at high risk of bias, trials with missing data and trials with the smallest sample size will be excluded. Then, to examine whether the results change and whether the transitivity (consistency and model fit) is affected, the same methods used to conduct the network meta-analysis will be repeated.

Quality of evidence

We will also evaluate the quality of evidence conducing to primary outcomes based on the Grading of Recommendations Assessment, Development and Evaluation framework, in accordance with limitations of study, imprecision, heterogeneity, inconsistency, indirectness and publication bias.[33]

Patient and public involvement

Discussion

According to a cohort study, the prevalence of subjective cognitive decline is currently slightly high, ranging from 7.8% to 52.7% which is based on estimated based on age and gender standardization in the population.[34] This means that subjective cognitive decline is gradually becoming a health issue in elderly who requires special attention. Subjective cognitive decline is an important risk factor for mild cognitive impairment and Alzheimer's disease,[6] which may cause adverse effects on the quality of life of elderly and bring enormous burdens to caregivers and society, and obstruct the realization of healthy aging and active aging. The effects of pharmacological intervention are limited to some extent. Nonpharmacological interventions have become the preferred approach to treat and care for patients with cognitive impairment because of their simplicity, easy operation and high safety.[35]

At present, art therapies including music therapy, dance therapy, painting therapy, reading therapy, horticultural therapy, reminiscence therapy, calligraphy therapy and museum therapy have been applied to improve cognitive function in patients with subjective cognitive decline. To date, no network meta-analysis has been performed to evaluate the comparative efficacy of all available art therapies. Consequently, it is necessary to conduct a network meta-analysis to identify the effects of art therapies. To the best of our knowledge, this is the first network meta-analysis to analyze the effects of art therapies in elderly with subjective cognitive decline. Based on the comparative effectiveness evidence, this network meta-analysis is expected to provide a ranking of these art therapies for improving cognitive function in elderly with subjective cognitive

decline. The results could help patients and clinicians choose the best intervention. In addition, we hope that the results of this study could provide evidence for the recommendations of guidelines.

Ethics and dissemination

This study is based on published data, so ethical approval is not a requirement. We plan to publish the findings of this study in a peer-reviewed journal. This work is now in progress, and preparations has start on 28 June 2023. We are searching the relevant studies. The expected end time is 31 May 2024. The results will be reported based on the PRISMA-compliant guidelines.

Authors' contributions

Qian Liu designed this study with oversight by Xiuying Hu. Qian Liu drafted the protocol, and the draft was modified by Fang Wang and Li Liu. Qian Liu and Lixia Tan will search, select, and identify studies, and extract data independently, while Li Liu will be the third reviewer for study selection and data extraction. Qian Liu will be responsible for the methodology. All authors have approved the publication of this protocol.

Funding statement

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Competing interests statement

The authors have no conflicts of interest to disclose.

Patient and Public Involvement

This study is based on published data, so patients or the public were not involved in the design, conduct, reporting, and dissemination plans of our research.

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Figure legend

1 Figure 1. Study flow diagram

Supplementary Material 1: Search strategy

1. Cochrane Central Register of Controlled Trials

(subjective cognitive decline OR SCD) AND (art therapy OR music* OR singing OR danc* OR painting OR drawing OR collage OR clay OR theatre OR drama OR reading OR poetry OR woodwork OR garden* OR horticultural OR handwriting OR penmanship OR calligraphy OR ceramics OR pottery OR writing OR sculpture OR carving OR narrative OR reminiscence OR printmaking OR sewing OR knitting OR museum OR gallery) AND (randomized controlled trial OR RCT).

2. PubMed

("subjective cognitive decline" OR "SCD") AND ("art therapy" OR "music*" OR "singing" OR "danc*" OR "painting" OR "drawing" OR "collage" OR "clay" OR "theatre" OR "drama" OR "reading" OR "poetry" OR "woodwork" OR "garden*" OR "horticultural" OR "handwriting" OR "penmanship" OR "calligraphy" OR "ceramics" OR "pottery" OR "writing" OR "sculpture" OR "carving" OR "narrative" OR "reminiscence" OR "printmaking" OR "sewing" OR "knitting" OR "museum" OR "gallery") AND ("randomized controlled trial" OR "RCT").

3. Web of Science

(TS =subjective cognitive decline OR TS =SCD) AND (TS =art therapy OR TS =music* OR TS =singing OR TS =danc* OR TS =painting OR TS =drawing OR TS =collage OR TS =clay OR TS =theatre OR TS =drama OR TS =reading OR TS =poetry OR TS =woodwork OR TS =garden* OR TS =horticultural OR TS =handwriting OR TS =penmanship OR TS =calligraphy OR TS =ceramics OR TS =pottery OR TS =writing OR TS =sculpture OR TS =carving OR TS =narrative OR TS =reminiscence OR TS =printmaking OR TS =sewing OR TS =knitting OR TS =museum OR TS =gallery) AND (TS =randomized controlled trial OR TS =RCT).

4. Elsevier

(subjective cognitive decline OR SCD) AND (art therapy OR music* OR singing OR danc* OR painting OR drawing OR collage OR clay OR theatre OR drama OR reading OR poetry OR woodwork OR garden* OR horticultural OR handwriting OR penmanship OR calligraphy OR ceramics OR pottery OR writing OR sculpture OR carving OR narrative OR reminiscence OR printmaking OR sewing OR knitting OR museum OR gallery) AND (randomized controlled trial OR RCT).

5. China BioMedical Literature Database

(“主观认知能力下降” OR “主观认知下降”) AND (“音乐” OR “舞蹈” OR “绘画” OR “拼贴” OR “黏土” OR “戏剧” OR “诗歌” OR “阅读” OR “园艺” OR “书法” OR “陶艺 OR “写作” OR “雕塑” OR “叙事” OR “回忆” OR “缅怀”OR “版画” OR “缝纫” OR “针织” OR “博物馆” OR “画廊”) AND (“随机对照试验”)

6. China National Knowledge Infrastructure

(SU=主观认知能力下降 OR SU=主观认知下降) AND (SU=音乐 OR SU=舞蹈 OR SU=绘画 OR SU=拼贴 OR SU=黏土 OR SU=戏剧 OR SU=诗歌 OR SU=阅读 OR SU=园艺 OR SU=书法 OR SU=陶艺 OR SU=写作 OR SU=雕塑 OR SU=叙事 OR SU=回忆 OR SU=缅怀 OR SU=版画 OR SU=缝纫 OR SU=针织 OR SU=博物馆 OR SU= 画廊) AND (SU=随机对照试验)

7. VIP Database

(“主观认知能力下降” OR “主观认知下降”) AND (“音乐” OR “舞蹈” OR “绘画” OR “拼贴” OR “黏土” OR “戏剧” OR “诗歌” OR “阅读” OR “园艺” OR “书法” OR “陶艺 OR “写作” OR “雕塑” OR “叙事” OR “回忆” OR “缅怀”OR “版画” OR “缝纫” OR “针织” OR “博物馆” OR “画廊”) AND (“随机对照试验”)

8. Wanfang Database

(“主观认知能力下降” OR “主观认知下降”) AND (“音乐” OR “舞蹈” OR “绘画” OR “拼贴” OR “黏土” OR “戏剧” OR “诗歌” OR “阅读” OR “园艺” OR “书法”

OR “陶艺 OR “写作” OR “雕塑” OR “叙事” OR “回忆” OR “缅怀”OR “版画” OR “缝纫” OR “针织” OR “博物馆” OR “画廊”) AND (“随机对照试验”)

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	13-14
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Support:			
Sources	5a	Indicate sources of financial or other support for the review	14
Sponsor	5b	Provide name for the review funder and/or sponsor	14
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	14
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3-5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3-5
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6-7
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	8
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	8
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	8

Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	8
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	8-9
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	9
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	7
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	9-10
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	10
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	10
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	11
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	NA
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	11
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	12

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

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Art therapies improve cognitive function in elderly with subjective cognitive decline: a protocol for a network meta-analysis

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Title page

Title

Art therapies improve cognitive function in elderly with subjective cognitive decline: a protocol for a network meta-analysis

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Authors' contributions

Qian Liu designed this study with oversight by Xiuying Hu. Qian Liu drafted the protocol, and the draft was modified by Fang Wang and Li Liu. Qian Liu and Lixia Tan will search, select, and identify studies included, and extract data independently, while Li Liu will be the third reviewer for study selection and data extraction. Qian Liu will be responsible for methodology. All authors have approved the publication of this protocol.

Art therapies improve cognitive function in elderly with subjective cognitive decline: a protocol for a network meta-analysis

Abstract

Introduction: Subjective cognitive decline means a decline in the subjective perception of self-cognitive function, which is likely to evolve into mild cognitive impairment and dementia. The number of elderly with subjective cognitive decline has increased, bringing huge burdens and challenges to caregivers and society. With the increase in research on art therapies, some of them have gradually been proven to be effective for cognitive function. Therefore, this study aims to summarize the evidence and identify the best art therapy for elderly with subjective cognitive decline.

Methods and analysis: We will include published randomized controlled trials written in English and Chinese if the intervention is one of the art therapies and applied in people aged 60 and above with subjective cognitive decline. Eight electronic databases, including the Cochrane Central Register of Controlled Trials, PubMed, Web of Science, Elsevier, China BioMedical Literature Database, China National Knowledge Infrastructure, VIP Database, and Wanfang Database, will be searched from January 2013 to present. Art therapies will mainly include music therapy, reminiscence therapy, painting therapy, dance therapy, reading therapy, horticultural therapy, museum therapy, calligraphy therapy, and so on. The outcome will be cognitive function. Study selection, data extraction and quality assessment will

be performed by two reviewers. The risk of bias will be evaluated according to the Cochrane Collaboration's risk of bias tool, and the evidence quality will be assessed with the Grading of Recommendations Assessment, Development and Evaluation. Standard pairwise meta-analysis and Bayesian network meta-analysis will be conducted. The probabilities of each art therapy will be ranked based on the surface under the cumulative ranking curve.

Ethics and dissemination: Ethical approval is not required for reviewing published studies. To provide important evidence for clinicians and guideline developers, the findings of this study will be submitted to a peer-reviewed journal.

PROSPERO registration number: CRD42023443773.

Key words: subjective cognitive decline; elderly; art therapy; protocol; network meta-analysis

Strengths and limitations of this study

1. This network meta-analysis will integrate direct evidence with indirect evidence and allow the comparison of multiple art therapies in one model.

2. Network meta-analysis will promote precision of intervention and provide evidence for the decisions of intervention and the development of guidelines.

3. On account of the retrospective nature of this study, the findings may be influenced by the quantity and quality of the included studies.

Introduction

As a global public health problem that urgently needs to be addressed, dementia leads to the loss of reasoning, memory, language, and ultimately basic self-care skills, which places an enormous burden on families and the health-care system. The development of dementia, such as Alzheimer's disease, is insidious, with onset of clinical symptoms preceded years earlier by perceived and/or objective cognitive decline [1], which is also the early stage of mild cognitive impairment [2]. Subjective cognitive decline refers to the decline in the subjective perception of self-cognitive function compared with the previous normal state, mainly memory decline, but objective neuropsychological tests are not abnormal, and this decline is not related to other acute events [3]. Previous studies have suggested that subjective cognitive decline is a preclinical symptom of mild cognitive impairment and dementia [4-7]. The risk of developing dementia in the elderly with subjective cognitive decline was 2.48 times higher than that in the elderly without cognitive abnormalities, and the risk of developing mild cognitive impairment was 1.83 times higher than that in the elderly without cognitive abnormalities [7]. Moreover, the findings of a long-term observational study over 10 years indicate that subjective cognitive decline can occur 10 years before the diagnosis of Alzheimer's disease [8]. Therefore, the therapeutic window for addressing Alzheimer's disease can be moved forward, and subjective cognitive decline can be regarded as an important gateway for early prevention and treatment of Alzheimer's disease, which may help alleviate the major public health problem, although there are no approved treatments for Alzheimer's disease and even

mild cognitive impairment [9].

The efficacy of pharmacological interventions is limited. To avoid the side effects of antipsychotics, more attention is given to the application of nonpharmacological interventions [10]. Art therapy is an emerging nonpharmacological intervention with distinctive features that integrates psychology, art and medicine. Art therapy can take a variety of forms, such as music, singing, dancing, reading and poetry groups, museum/gallery art and collections, creative writing, life story narrative reminiscence, painting, printmaking, collage, pottery, sewing, knitting, woodwork and gardening [11]. As a kind of nonpharmacological intervention, art therapy has been widely proven to be beneficial in the care of patients with cognitive impairment and has been used in clinical practice in Europe and the United States [12]. It is helpful to reduce the mental and behavioral abnormalities of patients and slow down the progress of cognitive impairment, to achieve great effects in treatment and care. It is suggested that music listening can help to improve both subjective memory function and objective cognitive performance in adults with subjective cognitive decline [13]. Several randomized controlled trials have demonstrated that dance therapy can improve cognitive function, especially episodic memory and processing speed [14-16]. Moreover, painting therapy has been proven to improve cognitive function in patients with mild cognitive impairment [17]. A narrow review has summarized the positive effects of therapeutic gardens on the health, spanning physical, social, psychological and cognitive effects[18]. Additionally, spiritual reminiscence programs using expressive arts therapy are conducive to improving cognitive function [19].

With the increase in relevant research, art therapy has gradually been proven to be of great significance in alleviating cognitive decline. However, the advantages and disadvantages of the effects of different art therapies on elderly with subjective cognitive decline are still inconclusive at present, and studies directly comparing the differences in various art therapies are lacking. Network meta-analysis is capable of summarizing direct and indirect evidence, thus evaluating and comparing the relative efficacy of multiple treatments[20]. More importantly, network meta-analysis can provide the ranking of intervention options in accordance with their effectiveness. Therefore, this study aims to evaluate the effects of different art therapies on cognitive function in elderly with subjective cognitive decline through a network meta-analysis, providing important evidence for care decision-making.

Methods and analysis

This network meta-analysis protocol was registered on the PROSPERO platform (CRD42023443773). The timeline of this work is planned between 28 June 2023 and 31 May 2024. The results of this network meta-analysis will be reported following the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols [21].

Eligibility criteria

Type of participants

Elderly diagnosed with subjective cognitive decline will be included. Inclusion criteria will be (1) diagnosed as subjective cognitive declined according to the criteria published by the Subjective Cognitive Decline Initiative [22,23]; (2) aged 60 and above. The exclusion criteria will be (1) complicated with nervous system diseases

which may cause subjective cognitive decline, such as dementia, Parkinson's disease, stroke, cephalomeningitis, and craniocerebral trauma; (2) complicated with major diseases that may affect subjective cognitive function, such as severe metabolic diseases and severe cardiopulmonary diseases; (3) complicated with severe mental illnesses, such as schizophrenia, bipolar disorder, severe depression, and severe anxiety.

Type of studies

Only randomized controlled trials written in English or Chinese will be included. Cluster randomized controlled trials and cross-over randomized controlled trials will be excluded. Trials without a control group will be excluded. If the control group did not receive art therapy or usual care, the trial will also be excluded.

Type of intervention

Any art therapy that is combined with usual care and implemented in elderly with subjective cognitive decline will be included. However, multi-component interventions that two or more art interventions or art therapies combined with other types of treatment (in addition to usual care) are applied in a experimental group will be excluded. These art therapies may be aimed at improving cognitive function. The types of art therapies for elderly with subjective cognitive decline may include (1) music therapy, (2) dance therapy, (3) reading therapy, (4) painting therapy, (5) horticultural therapy, (6) reminiscence therapy, (7) calligraphy therapy, and (8) museum therapy.

Comparison

Comparator will be considered a usual care of subjective cognitive decline (such as guidance of drugs, diet, rehabilitation and complication prevention) or another art therapy combined with usual care.

Type of outcomes

The outcome will focus on cognitive function, which might be measured by a validated cognitive outcome measure, for example, subjective cognitive decline Questionnaire, the Mini-Mental State Examination, Montreal Cognitive Assessment, Addenbrooke's Cognitive Examination-III, Mini-Addenbrooke's Cognitive Examination, Memory Impairment Screen, Quick Screen for Mild Cognitive Impairment, Clock-Drawing Test, or Repeatable Battery for the Assessment of Neuropsychological Status. Subjective cognitive decline will be reported by using the original scores after intervention in the original study.

Data sources and search strategy

The search used a combination of Medical Subject Headings and free words for professional searches. The search items will include subjective cognitive decline or SCD, art therapy (music* or singing or danc* or painting or drawing or collage or clay or theatre or drama or reading or poetry or woodwork or garden* or horticultural or handwriting or penmanship or calligraphy or ceramics or pottery or writing or sculpture or carving or narrative or reminiscence or printmaking or sewing or knitting or museum or gallery) and randomized controlled trial. Searches will be undertaken in electronic databases to identify published studies, including the Cochrane Central Register of Controlled Trials, PubMed, Web of Science, Elsevier, China BioMedical

Literature Database, China National Knowledge Infrastructure, VIP Database, and Wanfang Database. A draft search strategy is summarized in Supplementary Material 1. The retrieval time will be from January 2013 to the present. In addition to the database search, the references of the included studies will be scanned to identify additional eligible studies.

Study selection

All investigators will receive appropriate training prior to study selection. All retrieved studies will be imported into NoteExpress software to download references. Duplicate studies will be removed. The titles and abstracts of selected studies will be screened independently by two reviewers to exclude studies that obviously do not meet the inclusion criteria. The preliminary results will be cross-checked. Then, the remaining full-text studies will be examined independently by the same two reviewers to determine eligibility. If there are disagreements, the third reviewer will be asked to evaluate the full text. Any discrepancies will be resolved through group discussions. We will record the excluded studies and reasons for exclusion. Figure 1 shows the process of study selection.

Data extraction

All researchers of this study will discuss and design a standard form for data extraction. Then, two reviewers will independently extract data in accordance with the standard form, including author (s), year of publication, sample size, characteristics of patients (gender and age), intervention (type, frequency and duration), and measurements of outcome. After completing data extraction, the results of two

reviewers will be crosschecked to ensure that there is no mistake. Team discussion will be used to resolve the disagreements.

Risk of bias assessment

The revised version of the Cochrane tool (RoB 2) will be used to assess the risk of bias for all included studies [24]. This tool will assess five domains, including (1) bias arising from the randomization process, (2) bias due to deviations from intended interventions, (3) bias due to missing outcome data, (4) bias in the measurement of the outcome and (5) bias in the selection of the reported result. The assessment of each domain will be rated as 'low risk of bias', 'some concerns' and 'high risk of bias'. The response options for an overall risk-of-bias judgment are the same as those for individual domains. If all domains are rated as 'low risk of bias', this trial will be judged to be at low risk of bias. If at least one domain is rated as 'some concerns' and no domain is rated as 'high risk of bias', this trial will be judged to be 'some concerns'. If at least one domain is rated as 'high risk of bias' or multiple domains are rated as 'some concerns' in a way that substantially lowers confidence in the result, this trial will be judged to be at high risk of bias. Two reviewers will independently evaluate the risk of bias for each study and then cross-check the results. Differences will be resolved through team discussion with the third reviewer.

Statistical analysis

Pairwise meta-analysis

We will use Review Manager (version 5.3) to conduct a pairwise meta-analysis of direct evidence. For continuous outcomes, standardized mean differences with 95%

confidence intervals will be used. The χ^2 test will be used to assess the heterogeneity across all included trials. A fixed-effects model will be used to synthesize the standardized mean difference if the p value is ≥0.1. Conversely, if the p value is <0.1, a random-effects model will be used.

Network meta-analysis

Considering the expected heterogeneity between studies, the effects of different art therapies will be compared by conducting a random-effects network meta-analysis within a Bayesian framework using Markov Chains Monte Carlo in R software (version 4.1.3). Brooks-Gelman-Rubin diagnosis and potential scale reduction factor will be used to ensure the convergence of the model [25]. Moreover, the surface under the cumulative ranking curve with its 95% confidence interval and rank-heat plot will be used to evaluate the hierarchy of each art therapy [26,27].

Dealing with missing data

If there is a lack of some information, the missing data will be obtained by contacting the corresponding authors whenever possible. We will try to calculate the missing data based on availability factors if there is no reply. Sensitivity analysis will be used to examine the potential impact of missing data on the results of this study.

Assessment of publication bias

If more than nine studies are included in the analysis, funnel plots, Begg's rank correction and Egger's regression tests will be used to evaluate the presence of publication bias in Stata software (version 15.0) [28-30].

Assessment of inconsistency and subgroup analysis

Based on a loop-special method within each loop of the network [31], the local inconsistency and global inconsistency will be measured in Stata software (version 15.0) [32].[32] If there is heterogeneity or inconsistency, the sources of heterogeneity will be explored by network meta-regression. Subgroup analysis will be performed in accordance with age, gender, or duration of intervention.

Sensitivity analysis

We will perform a sensitivity analysis for primary outcomes to verify the robustness of the findings. In the sensitivity analysis, trials judged to be at high risk of bias, trials with missing data and trials with the smallest sample size will be excluded. Then, to examine whether the results change and whether the transitivity (consistency and model fit) is affected, the same methods used to conduct the network meta-analysis will be repeated.

Quality of evidence

We will also evaluate the quality of evidence conducing to primary outcomes based on the Grading of Recommendations Assessment, Development and Evaluation framework, in accordance with limitations of study, imprecision, heterogeneity, inconsistency, indirectness and publication bias [33].

Patient and Public Involvement

This study is based on published data, so patients or the public were not involved in the design, conduct, reporting, and dissemination plans of our research.

Discussion

According to a cohort study, the prevalence of subjective cognitive decline is

currently slightly high, ranging from 7.8% to 52.7% which is based on estimated based on age and gender standardization in the population [34]. This means that subjective cognitive decline is gradually becoming a health issue in elderly who requires special attention. Subjective cognitive decline is an important risk factor for mild cognitive impairment and Alzheimer's disease [6], which may cause adverse effects on the quality of life of elderly and bring enormous burdens to caregivers and society, and obstruct the realization of healthy aging and active aging. The effects of pharmacological intervention are limited to some extent. Nonpharmacological interventions have become the preferred approach to treat and care for patients with cognitive impairment because of their simplicity, easy operation and high safety [35].

At present, art therapies such as music therapy, dance therapy, painting therapy, reading therapy, horticultural therapy, reminiscence therapy, calligraphy therapy and museum therapy have been applied to improve cognitive function in patients with subjective cognitive decline. Music, as an artistic manifestation, offers a profound impact on the emotional, cognitive, and physiological aspects of personal experiences [36]. Some studies have shown that music therapy has a positive impact on individuals with decreased cognitive function, helping improve objective and subjective cognitive functions, such as subjective memory function [37]. Reminiscence therapy is also one of the common methods used to improve cognitive function in the elderly, which helps stimulate autobiographical memory and simultaneously improve mental health [38]. Horticultural therapy can promote active contact and interaction between human and natural elements, thereby improving the

cognitive function and mental health of the elderly [39]. In addition, some scholars believe that horticultural therapy may improve cognition function through metabolic biomarkers such as tryptophan, kynurenine, and serotonin [40]. From the current research results, it can be seen that arious art therapies have a positive effect on improving cognitive function through different means. However, to date, no network meta-analysis has been performed to evaluate the comparative efficacy of all available art therapies. Consequently, it is necessary to conduct a network meta-analysis to identify the effects of art therapies. To the best of our knowledge, this is the first network meta-analysis to analyze the effects of art therapies in elderly with subjective cognitive decline. Based on the comparative effectiveness evidence, this network meta-analysis is expected to find the best art therapy for improving cognitive function in elderly with subjective cognitive decline. The results could help patients and clinicians choose the best intervention. In addition, we hope that the results of this study could provide evidence for the recommendations of guidelines.

Ethics and dissemination

This study is based on published data, so ethical approval is not a requirement. We plan to publish the findings of this study in a peer-reviewed journal. This work is now in progress, and preparations has start on 28 June 2023. We are searching the relevant studies. The expected end time is 31 May 2024. The results will be reported based on the PRISMA-compliant guidelines.

Authors' contributions

Qian Liu designed this study with oversight by Xiuying Hu. Qian Liu drafted the protocol, and the draft was modified by Fang Wang and Li Liu. Qian Liu and Lixia Tan will search, select, and identify studies, and extract data independently, while Li Liu will be the third reviewer for study selection and data extraction. Qian Liu will be responsible for the methodology. All authors have approved the publication of this protocol.

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Competing interests statement

The authors have no conflicts of interest to disclose.

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Figure legend

Figure 1. Study flow diagram

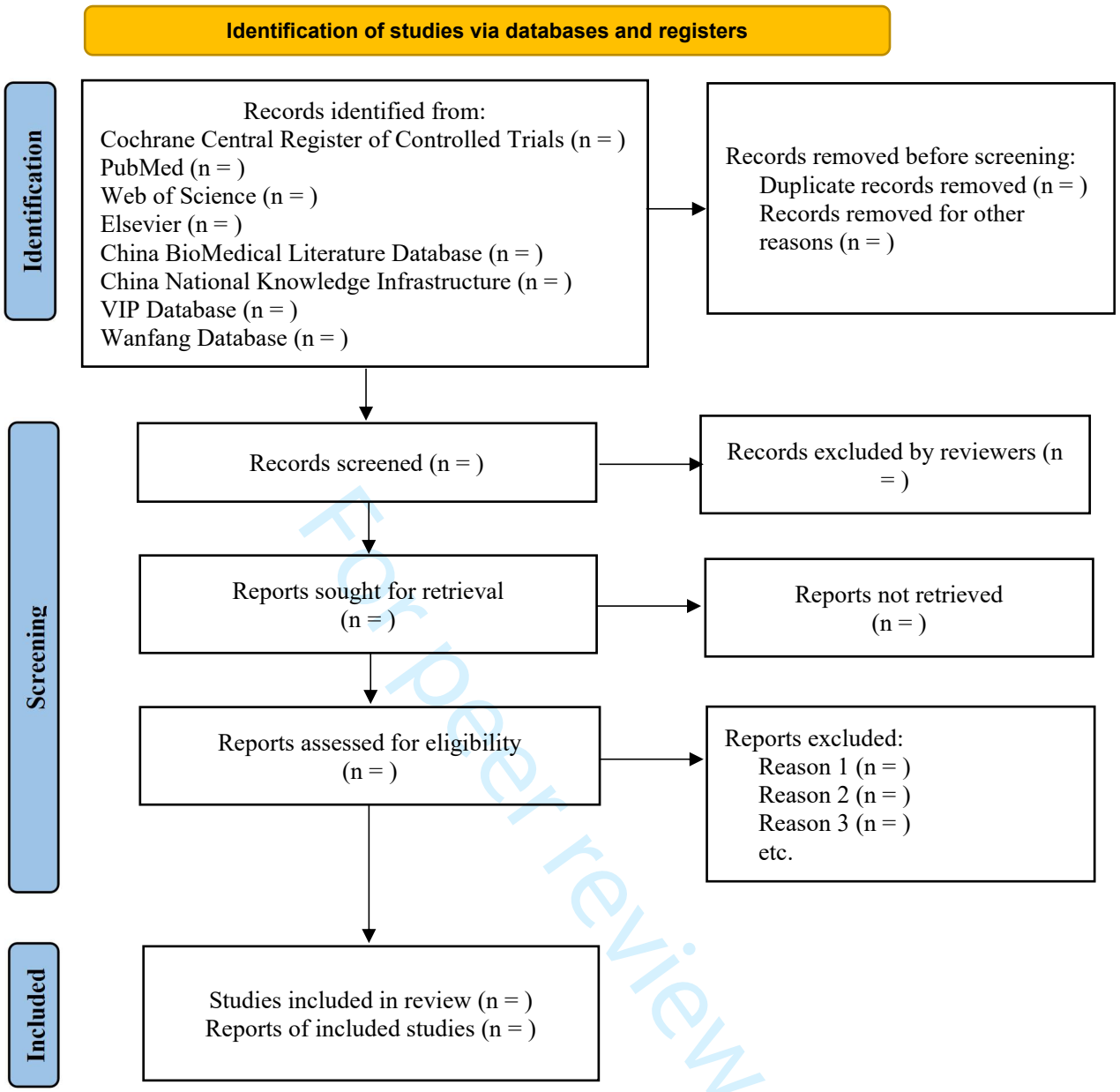

Fig. 1 The processes of study selection

Supplementary Material 1: Search strategy

1. Cochrane Central Register of Controlled Trials

(subjective cognitive decline OR SCD) AND (art therapy OR music* OR singing OR danc* OR painting OR drawing OR collage OR clay OR theatre OR drama OR reading OR poetry OR woodwork OR garden* OR horticultural OR handwriting OR penmanship OR calligraphy OR ceramics OR pottery OR writing OR sculpture OR carving OR narrative OR reminiscence OR printmaking OR sewing OR knitting OR museum OR gallery) AND (randomized controlled trial OR RCT).

2. PubMed

("subjective cognitive decline" OR "SCD") AND ("art therapy" OR "music*" OR "singing" OR "danc*" OR "painting" OR "drawing" OR "collage" OR "clay" OR "theatre" OR "drama" OR "reading" OR "poetry" OR "woodwork" OR "garden*" OR "horticultural" OR "handwriting" OR "penmanship" OR "calligraphy" OR "ceramics" OR "pottery" OR "writing" OR "sculpture" OR "carving" OR "narrative" OR "reminiscence" OR "printmaking" OR "sewing" OR "knitting" OR "museum" OR "gallery") AND ("randomized controlled trial" OR "RCT").

3. Web of Science

(TS =subjective cognitive decline OR TS =SCD) AND (TS =art therapy OR TS =music* OR TS =singing OR TS =danc* OR TS =painting OR TS =drawing OR TS =collage OR TS =clay OR TS =theatre OR TS =drama OR TS =reading OR TS =poetry OR TS =woodwork OR TS =garden* OR TS =horticultural OR TS =handwriting OR TS =penmanship OR TS =calligraphy OR TS =ceramics OR TS =pottery OR TS =writing OR TS =sculpture OR TS =carving OR TS =narrative OR TS =reminiscence OR TS =printmaking OR TS =sewing OR TS =knitting OR TS =museum OR TS =gallery) AND (TS =randomized controlled trial OR TS =RCT).

4. Elsevier

(subjective cognitive decline OR SCD) AND (art therapy OR music* OR singing OR danc* OR painting OR drawing OR collage OR clay OR theatre OR drama OR reading OR poetry OR woodwork OR garden* OR horticultural OR handwriting OR penmanship OR calligraphy OR ceramics OR pottery OR writing OR sculpture OR carving OR narrative OR reminiscence OR printmaking OR sewing OR knitting OR museum OR gallery) AND (randomized controlled trial OR RCT).

5. China BioMedical Literature Database

(“主观认知能力下降” OR “主观认知下降”) AND (“音乐” OR “舞蹈” OR “绘画” OR “拼贴” OR “黏土” OR “戏剧” OR “诗歌” OR “阅读” OR “园艺” OR “书法” OR “陶艺 OR “写作” OR “雕塑” OR “叙事” OR “回忆” OR “缅怀”OR “版画” OR “缝纫” OR “针织” OR “博物馆” OR “画廊”) AND (“随机对照试验”)

6. China National Knowledge Infrastructure

(SU=主观认知能力下降 OR SU=主观认知下降) AND (SU=音乐 OR SU=舞蹈 OR SU=绘画 OR SU=拼贴 OR SU=黏土 OR SU=戏剧 OR SU=诗歌 OR SU=阅读 OR SU=园艺 OR SU=书法 OR SU=陶艺 OR SU=写作 OR SU=雕塑 OR SU=叙事 OR SU=回忆 OR SU=缅怀 OR SU=版画 OR SU=缝纫 OR SU=针织 OR SU=博物馆 OR SU= 画廊) AND (SU=随机对照试验)

7. VIP Database

(“主观认知能力下降” OR “主观认知下降”) AND (“音乐” OR “舞蹈” OR “绘画” OR “拼贴” OR “黏土” OR “戏剧” OR “诗歌” OR “阅读” OR “园艺” OR “书法” OR “陶艺 OR “写作” OR “雕塑” OR “叙事” OR “回忆” OR “缅怀”OR “版画” OR “缝纫” OR “针织” OR “博物馆” OR “画廊”) AND (“随机对照试验”)

8. Wanfang Database

(“主观认知能力下降” OR “主观认知下降”) AND (“音乐” OR “舞蹈” OR “绘画” OR “拼贴” OR “黏土” OR “戏剧” OR “诗歌” OR “阅读” OR “园艺” OR “书法”

OR “陶艺 OR “写作” OR “雕塑” OR “叙事” OR “回忆” OR “缅怀”OR “版画” OR “缝纫” OR “针织” OR “博物馆” OR “画廊”) AND (“随机对照试验”)

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	13-14
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Support:			
Sources	5a	Indicate sources of financial or other support for the review	14
Sponsor	5b	Provide name for the review funder and/or sponsor	14
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	14
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3-5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3-5
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6-7
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	8
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	8
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	8

Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	8
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	8-9
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	9
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	7
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	9-10
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	10
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	10
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	11
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	NA
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	11
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	12

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Art therapies and cognitive function in elderly with subjective cognitive decline: a protocol for a network meta-analysis

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Title page

Title

Art therapies and cognitive function in elderly with subjective cognitive decline: a protocol for a network meta-analysis

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Authors' contributions

Qian Liu designed this study with oversight by Xiuying Hu. Qian Liu drafted the protocol, and the draft was modified by Fang Wang and Li Liu. Qian Liu and Lixia Tan will search, select, and identify studies included, and extract data independently, while Li Liu will be the third reviewer for study selection and data extraction. Qian Liu will be responsible for methodology. All authors have approved the publication of this protocol.

Art therapies and cognitive function in elderly with subjective cognitive decline: a protocol for a network meta-analysis

Abstract

Introduction: Subjective cognitive decline means a decline in the subjective perception of self-cognitive function, which is likely to evolve into mild cognitive impairment and dementia. The number of elderly with subjective cognitive decline has increased, bringing huge burdens and challenges to caregivers and society. With the increase in research on art therapies, some of them have gradually been proven to be effective for cognitive function. Therefore, this study aims to summarize the evidence and identify the best art therapy for elderly with subjective cognitive decline.

Methods and analysis: We will include published randomized controlled trials written in English and Chinese if the intervention is one of the art therapies and applied in people aged 60 and above with subjective cognitive decline. Eight electronic databases, including the Cochrane Central Register of Controlled Trials, PubMed, Web of Science, Elsevier, China BioMedical Literature Database, China National Knowledge Infrastructure, VIP Database, and Wanfang Database, will be searched from January 2013 to December 2023. Art therapies will mainly include music therapy, reminiscence therapy, painting therapy, dance therapy, reading therapy, horticultural therapy, museum therapy, calligraphy therapy, and so on. The outcome will be cognitive function. Study selection, data extraction and quality assessment will

be performed by two reviewers. The risk of bias will be evaluated according to the Cochrane Collaboration's risk of bias tool, and the evidence quality will be assessed with the Grading of Recommendations Assessment, Development and Evaluation. Standard pairwise meta-analysis and Bayesian network meta-analysis will be conducted. The probabilities of each art therapy will be ranked based on the surface under the cumulative ranking curve.

Ethics and dissemination: Ethical approval is not required for reviewing published studies. To provide important evidence for clinicians and guideline developers, the findings of this study will be submitted to a peer-reviewed journal.

PROSPERO registration number: CRD42023443773.

Key words: subjective cognitive decline; elderly; art therapy; protocol; network meta-analysis

Strengths and limitations of this study

1. This network meta-analysis will integrate direct evidence with indirect evidence and allow the comparison of multiple art therapies in one model.

2. Network meta-analysis will promote precision of intervention and provide evidence for the decisions of intervention and the development of guidelines.

3. On account of the retrospective nature of this study, the findings may be influenced by the quantity and quality of the included studies.

Introduction

As a global public health problem that urgently needs to be addressed, dementia leads to the loss of reasoning, memory, language, and ultimately basic self-care skills, which places an enormous burden on families and the health-care system. The development of dementia, such as Alzheimer's disease, is insidious, with onset of clinical symptoms preceded years earlier by perceived and/or objective cognitive decline [1], which is also the early stage of mild cognitive impairment [2]. Subjective cognitive decline refers to the decline in the subjective perception of self-cognitive function compared with the previous normal state, mainly memory decline, but objective neuropsychological tests are not abnormal, and this decline is not related to other acute events [3]. Previous studies have suggested that subjective cognitive decline is a preclinical symptom of mild cognitive impairment and dementia [4-7]. The risk of developing dementia in the elderly with subjective cognitive decline was 2.48 times higher than that in the elderly without cognitive abnormalities, and the risk of developing mild cognitive impairment was 1.83 times higher than that in the elderly without cognitive abnormalities [7]. Moreover, the findings of a long-term observational study over 10 years indicate that subjective cognitive decline can occur 10 years before the diagnosis of Alzheimer's disease [8]. Therefore, the therapeutic window for addressing Alzheimer's disease can be moved forward, and subjective cognitive decline can be regarded as an important gateway for early prevention and treatment of Alzheimer's disease, which may help alleviate the major public health problem, although there are no approved treatments for Alzheimer's disease and even

mild cognitive impairment [9].

The efficacy of pharmacological interventions is limited. To avoid the side effects of antipsychotics, more attention is given to the application of nonpharmacological interventions [10]. Art therapy is an emerging nonpharmacological intervention with distinctive features that integrates psychology, art and medicine. Art therapy can take a variety of forms, such as music, singing, dancing, reading and poetry groups, museum/gallery art and collections, creative writing, life story narrative reminiscence, painting, printmaking, collage, pottery, sewing, knitting, woodwork and gardening [11]. As a kind of nonpharmacological intervention, art therapy has been widely proven to be beneficial in the care of patients with cognitive impairment and has been used in clinical practice in Europe and the United States [12]. It is helpful to reduce the mental and behavioral abnormalities of patients and slow down the progress of cognitive impairment, to achieve great effects in treatment and care. It is suggested that music listening can help to improve both subjective memory function and objective cognitive performance in adults with subjective cognitive decline [13]. Several randomized controlled trials have demonstrated that dance therapy can improve cognitive function, especially episodic memory and processing speed [14-16]. Moreover, painting therapy has been proven to improve cognitive function in patients with mild cognitive impairment [17]. A narrow review has summarized the positive effects of therapeutic gardens on the health, spanning physical, social, psychological and cognitive effects [18]. Additionally, spiritual reminiscence programs using expressive arts therapy are conducive to improving cognitive function [19].

With the increase in relevant research, art therapy has gradually been proven to be of great significance in alleviating cognitive decline. However, the advantages and disadvantages of the effects of different art therapies on elderly with subjective cognitive decline are still inconclusive at present, and studies directly comparing the differences in various art therapies are lacking. Network meta-analysis is capable of summarizing direct and indirect evidence, thus evaluating and comparing the relative efficacy of multiple treatments [20]. More importantly, network meta-analysis can provide the ranking of intervention options in accordance with their effectiveness. Therefore, this study will evaluate the effects of different art therapies on cognitive function in elderly (aged 60 and above) with subjective cognitive decline through a network meta-analysis, with the aim of identifying the most effective art therapy for this patient group. These findings may provide important evidence for care decision-making in elderly with subjective cognitive decline.

Methods and analysis

This network meta-analysis protocol was registered on the PROSPERO platform (CRD42023443773). The timeline of this work is planned between 28 June 2023 and 31 May 2024. The results of this network meta-analysis will be reported following the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols [21].

Eligibility criteria

Type of participants

Elderly diagnosed with subjective cognitive decline will be included. Inclusion criteria will be (1) diagnosed as subjective cognitive declined according to the criteria

published by the Subjective Cognitive Decline Initiative [22,23]; (2) aged 60 and above. The exclusion criteria will be (1) complicated with nervous system diseases which may cause subjective cognitive decline, such as dementia, Parkinson's disease, stroke, cephalomeningitis, and craniocerebral trauma; (2) complicated with major diseases that may affect subjective cognitive function, such as severe metabolic diseases and severe cardiopulmonary diseases; (3) complicated with severe mental illnesses, such as schizophrenia, bipolar disorder, severe depression, and severe anxiety.

Type of studies

Only randomized controlled trials written in English or Chinese will be included. Cluster randomized controlled trials and cross-over randomized controlled trials will be excluded. Trials without a control group will be excluded. If the control group did not receive art therapy or usual care, the trial will also be excluded.

Type of intervention

Any art therapy that is combined with usual care and implemented in elderly with subjective cognitive decline will be included. However, multi-component interventions that two or more art interventions or art therapies combined with other types of treatment (in addition to usual care) are applied in a experimental group will be excluded. These art therapies may be aimed at improving cognitive function. The types of art therapies for elderly with subjective cognitive decline may include (1) music therapy, (2) dance therapy, (3) reading therapy, (4) painting therapy, (5) horticultural therapy, (6) reminiscence therapy, (7) calligraphy therapy, and (8)

museum therapy.

Comparison

Comparator will be considered a usual care of subjective cognitive decline (such as guidance of drugs, diet, rehabilitation and complication prevention) or another art therapy combined with usual care.

Type of outcomes

The outcome will focus on cognitive function, which might be measured by a validated cognitive outcome measure, for example, subjective cognitive decline Questionnaire, the Mini-Mental State Examination, Montreal Cognitive Assessment, Addenbrooke's Cognitive Examination-III, Mini-Addenbrooke's Cognitive Examination, Memory Impairment Screen, Quick Screen for Mild Cognitive Impairment, Clock-Drawing Test, or Repeatable Battery for the Assessment of Neuropsychological Status. Subjective cognitive decline will be reported by using the original scores after intervention in the original study.

Data sources and search strategy

The search used a combination of Medical Subject Headings and free words for professional searches. The search items will include subjective cognitive decline or SCD, art therapy (music* or singing or danc* or painting or drawing or collage or clay or theatre or drama or reading or poetry or woodwork or garden* or horticultural or handwriting or penmanship or calligraphy or ceramics or pottery or writing or sculpture or carving or narrative or reminiscence or printmaking or sewing or knitting or museum or gallery) and randomized controlled trial. Searches will be undertaken in

electronic databases to identify published studies, including the Cochrane Central Register of Controlled Trials, PubMed, Web of Science, Elsevier, China BioMedical Literature Database, China National Knowledge Infrastructure, VIP Database, and Wanfang Database. A draft search strategy is summarized in Supplementary Material 1. The retrieval time will be from January 2013 to December 2023. In addition to the database search, the references of the included studies will be scanned to identify additional eligible studies.

Study selection

All investigators will receive appropriate training prior to study selection. All retrieved studies will be imported into NoteExpress software to download references. Duplicate studies will be removed. The titles and abstracts of selected studies will be screened independently by two reviewers to exclude studies that obviously do not meet the inclusion criteria. The preliminary results will be cross-checked. Then, the remaining full-text studies will be examined independently by the same two reviewers to determine eligibility. If there are disagreements, the third reviewer will be asked to evaluate the full text. Any discrepancies will be resolved through group discussions. We will record the excluded studies and reasons for exclusion. Figure 1 shows the process of study selection.

Data extraction

All researchers of this study will discuss and design a standard form for data extraction. Then, two reviewers will independently extract data in accordance with the standard form, including author (s), year of publication, sample size, characteristics of

patients (gender and age), intervention (type, frequency and duration), and measurements of outcome. After completing data extraction, the results of two reviewers will be crosschecked to ensure that there is no mistake. Team discussion will be used to resolve the disagreements.

Risk of bias assessment

The revised version of the Cochrane tool (RoB 2) will be used to assess the risk of bias for all included studies [24]. This tool will assess five domains, including (1) bias arising from the randomization process, (2) bias due to deviations from intended interventions, (3) bias due to missing outcome data, (4) bias in the measurement of the outcome and (5) bias in the selection of the reported result. The assessment of each domain will be rated as 'low risk of bias', 'some concerns' and 'high risk of bias'. The response options for an overall risk-of-bias judgment are the same as those for individual domains. If all domains are rated as 'low risk of bias', this trial will be judged to be at low risk of bias. If at least one domain is rated as 'some concerns' and no domain is rated as 'high risk of bias', this trial will be judged to be 'some concerns'. If at least one domain is rated as 'high risk of bias' or multiple domains are rated as 'some concerns' in a way that substantially lowers confidence in the result, this trial will be judged to be at high risk of bias. Two reviewers will independently evaluate the risk of bias for each study and then cross-check the results. Differences will be resolved through team discussion with the third reviewer.

Statistical analysis

Pairwise meta-analysis

We will use Review Manager (version 5.3) to conduct a pairwise meta-analysis of direct evidence. For continuous outcomes, standardized mean differences with 95% confidence intervals will be used. The χ^2 test will be used to assess the heterogeneity across all included trials. A fixed-effects model will be used to synthesize the standardized mean difference if the p value is ≥0.1. Conversely, if the p value is <0.1, a random-effects model will be used.

Network meta-analysis

Considering the expected heterogeneity between studies, the effects of different art therapies will be compared by conducting a random-effects network meta-analysis within a Bayesian framework using Markov Chains Monte Carlo in R software (version 4.1.3). Brooks-Gelman-Rubin diagnosis and potential scale reduction factor will be used to ensure the convergence of the model [25]. Moreover, the surface under the cumulative ranking curve with its 95% confidence interval and rank-heat plot will be used to evaluate the hierarchy of each art therapy [26,27].

Dealing with missing data

If there is a lack of some information, the missing data will be obtained by contacting the corresponding authors whenever possible. We will try to calculate the missing data based on availability factors if there is no reply. Sensitivity analysis will be used to examine the potential impact of missing data on the results of this study.

Assessment of publication bias

If more than nine studies are included in the analysis, funnel plots, Begg's rank correction and Egger's regression tests will be used to evaluate the presence of

publication bias in Stata software (version 15.0) [28-30].

Assessment of inconsistency and subgroup analysis

Based on a loop-special method within each loop of the network [31], the local inconsistency and global inconsistency will be measured in Stata software (version 15.0) [32].[32] If there is heterogeneity or inconsistency, the sources of heterogeneity will be explored by network meta-regression. Subgroup analysis will be performed in accordance with age, gender, or duration of intervention.

Sensitivity analysis

We will perform a sensitivity analysis for primary outcomes to verify the robustness of the findings. In the sensitivity analysis, trials judged to be at high risk of bias, trials with missing data and trials with the smallest sample size will be excluded. Then, to examine whether the results change and whether the transitivity (consistency and model fit) is affected, the same methods used to conduct the network meta-analysis will be repeated.

Quality of evidence

We will also evaluate the quality of evidence conducing to primary outcomes based on the Grading of Recommendations Assessment, Development and Evaluation framework, in accordance with limitations of study, imprecision, heterogeneity, inconsistency, indirectness and publication bias [33].

Patient and Public Involvement

This study is based on published data, so patients or the public were not involved in the design, conduct, reporting, and dissemination plans of our research.

Discussion

According to a cohort study, the prevalence of subjective cognitive decline is currently slightly high, ranging from 7.8% to 52.7% which is based on estimated based on age and gender standardization in the population [34]. This means that subjective cognitive decline is gradually becoming a health issue in elderly who requires special attention. Subjective cognitive decline is an important risk factor for mild cognitive impairment and Alzheimer's disease [6], which may cause adverse effects on the quality of life of elderly and bring enormous burdens to caregivers and society, and obstruct the realization of healthy aging and active aging. The effects of pharmacological intervention are limited to some extent. Nonpharmacological interventions have become the preferred approach to treat and care for patients with cognitive impairment because of their simplicity, easy operation and high safety [35].

At present, art therapies such as music therapy, dance therapy, painting therapy, reading therapy, horticultural therapy, reminiscence therapy, calligraphy therapy and museum therapy have been applied to improve cognitive function in patients with subjective cognitive decline. Music, as an artistic manifestation, offers a profound impact on the emotional, cognitive, and physiological aspects of personal experiences [36]. Some studies have shown that music therapy has a positive impact on individuals with decreased cognitive function, helping improve objective and subjective cognitive functions, such as subjective memory function [37]. Reminiscence therapy is also one of the common methods used to improve cognitive function in the elderly, which helps stimulate autobiographical memory and

simultaneously improve mental health [38]. Horticultural therapy can promote active contact and interaction between human and natural elements, thereby improving the cognitive function and mental health of the elderly [39]. In addition, some scholars believe that horticultural therapy may improve cognition function through metabolic biomarkers such as tryptophan, kynurenine, and serotonin [40]. From the current research results, it can be seen that arious art therapies have a positive effect on improving cognitive function through different means. However, to date, no network meta-analysis has been performed to evaluate the comparative efficacy of all available art therapies. Consequently, it is necessary to conduct a network meta-analysis to identify the effects of art therapies. To the best of our knowledge, this is the first network meta-analysis to analyze the effects of art therapies in elderly with subjective cognitive decline. Based on the comparative effectiveness evidence, this network meta-analysis is expected to find the best art therapy for improving cognitive function in elderly with subjective cognitive decline. The results could help patients and clinicians choose the best intervention. In addition, we hope that the results of this study could provide evidence for the recommendations of guidelines.

Ethics and dissemination

This study is based on published data, so ethical approval is not a requirement. We plan to publish the findings of this study in a peer-reviewed journal. This work is now in progress, and preparations has start on 28 June 2023. We are searching the relevant studies. The expected end time is 31 May 2024. The results will be reported based on the PRISMA-compliant guidelines.

Authors' contributions

Qian Liu designed this study with oversight by Xiuying Hu. Qian Liu drafted the protocol, and the draft was modified by Fang Wang and Li Liu. Qian Liu and Lixia Tan will search, select, and identify studies, and extract data independently, while Li Liu will be the third reviewer for study selection and data extraction. Qian Liu will be responsible for the methodology. All authors have approved the publication of this protocol.

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Competing interests statement

The authors have no conflicts of interest to disclose.

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Figure legend

Figure 1. Study flow diagram

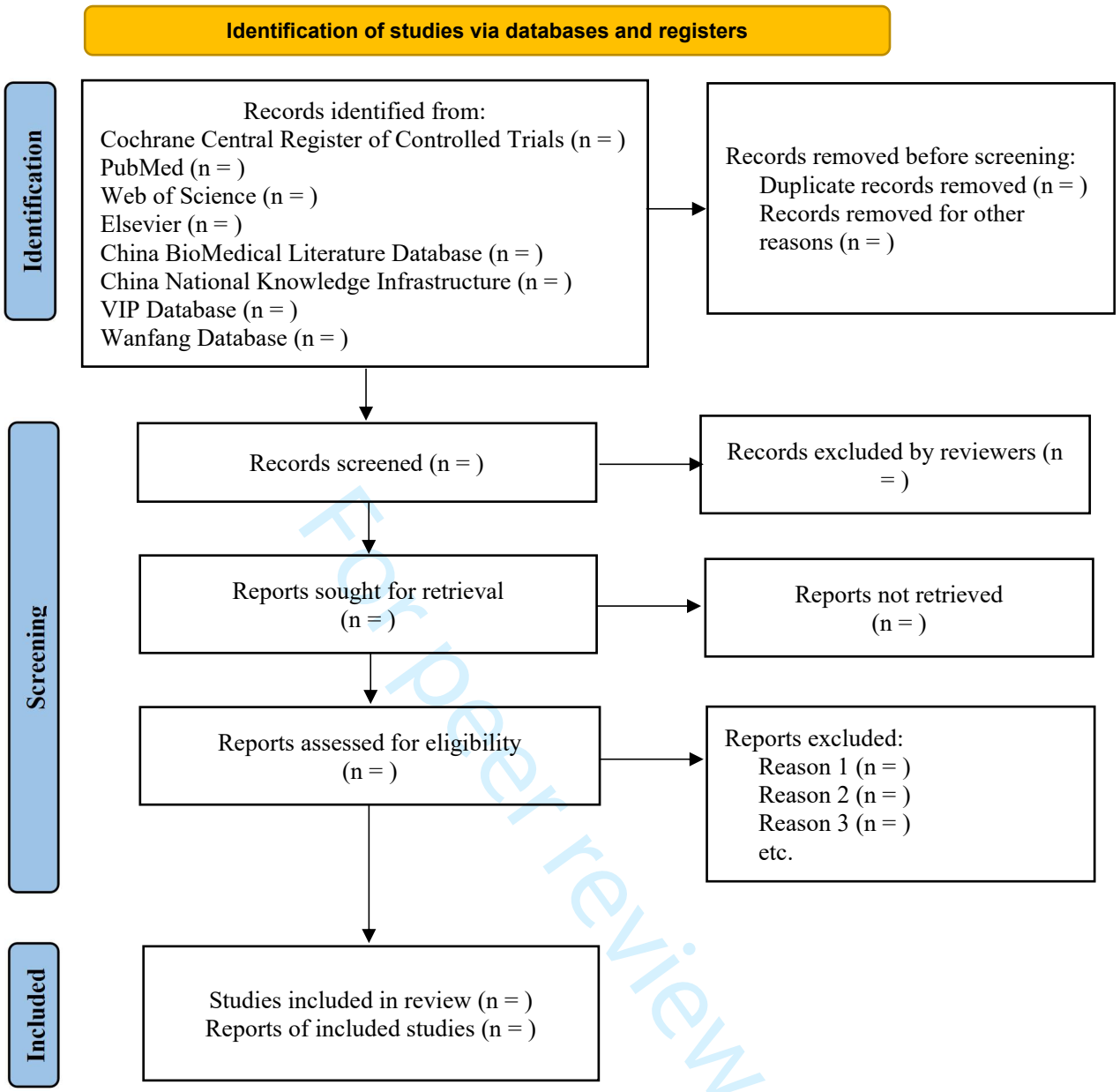

Fig. 1 The processes of study selection

Supplementary Material 1: Search strategy

1. Cochrane Central Register of Controlled Trials

(subjective cognitive decline OR SCD) AND (art therapy OR music* OR singing OR danc* OR painting OR drawing OR collage OR clay OR theatre OR drama OR reading OR poetry OR woodwork OR garden* OR horticultural OR handwriting OR penmanship OR calligraphy OR ceramics OR pottery OR writing OR sculpture OR carving OR narrative OR reminiscence OR printmaking OR sewing OR knitting OR museum OR gallery) AND (randomized controlled trial OR RCT).

2. PubMed

("subjective cognitive decline" OR "SCD") AND ("art therapy" OR "music*" OR "singing" OR "danc*" OR "painting" OR "drawing" OR "collage" OR "clay" OR "theatre" OR "drama" OR "reading" OR "poetry" OR "woodwork" OR "garden*" OR "horticultural" OR "handwriting" OR "penmanship" OR "calligraphy" OR "ceramics" OR "pottery" OR "writing" OR "sculpture" OR "carving" OR "narrative" OR "reminiscence" OR "printmaking" OR "sewing" OR "knitting" OR "museum" OR "gallery") AND ("randomized controlled trial" OR "RCT").

3. Web of Science

(TS =subjective cognitive decline OR TS =SCD) AND (TS =art therapy OR TS =music* OR TS =singing OR TS =danc* OR TS =painting OR TS =drawing OR TS =collage OR TS =clay OR TS =theatre OR TS =drama OR TS =reading OR TS =poetry OR TS =woodwork OR TS =garden* OR TS =horticultural OR TS =handwriting OR TS =penmanship OR TS =calligraphy OR TS =ceramics OR TS =pottery OR TS =writing OR TS =sculpture OR TS =carving OR TS =narrative OR TS =reminiscence OR TS =printmaking OR TS =sewing OR TS =knitting OR TS =museum OR TS =gallery) AND (TS =randomized controlled trial OR TS =RCT).

4. Elsevier

(subjective cognitive decline OR SCD) AND (art therapy OR music* OR singing OR danc* OR painting OR drawing OR collage OR clay OR theatre OR drama OR reading OR poetry OR woodwork OR garden* OR horticultural OR handwriting OR penmanship OR calligraphy OR ceramics OR pottery OR writing OR sculpture OR carving OR narrative OR reminiscence OR printmaking OR sewing OR knitting OR museum OR gallery) AND (randomized controlled trial OR RCT).

5. China BioMedical Literature Database

(“主观认知能力下降” OR “主观认知下降”) AND (“音乐” OR “舞蹈” OR “绘画” OR “拼贴” OR “黏土” OR “戏剧” OR “诗歌” OR “阅读” OR “园艺” OR “书法” OR “陶艺 OR “写作” OR “雕塑” OR “叙事” OR “回忆” OR “缅怀”OR “版画” OR “缝纫” OR “针织” OR “博物馆” OR “画廊”) AND (“随机对照试验”)

6. China National Knowledge Infrastructure

(SU=主观认知能力下降 OR SU=主观认知下降) AND (SU=音乐 OR SU=舞蹈 OR SU=绘画 OR SU=拼贴 OR SU=黏土 OR SU=戏剧 OR SU=诗歌 OR SU=阅读 OR SU=园艺 OR SU=书法 OR SU=陶艺 OR SU=写作 OR SU=雕塑 OR SU=叙事 OR SU=回忆 OR SU=缅怀 OR SU=版画 OR SU=缝纫 OR SU=针织 OR SU=博物馆 OR SU= 画廊) AND (SU=随机对照试验)

7. VIP Database

(“主观认知能力下降” OR “主观认知下降”) AND (“音乐” OR “舞蹈” OR “绘画” OR “拼贴” OR “黏土” OR “戏剧” OR “诗歌” OR “阅读” OR “园艺” OR “书法” OR “陶艺 OR “写作” OR “雕塑” OR “叙事” OR “回忆” OR “缅怀”OR “版画” OR “缝纫” OR “针织” OR “博物馆” OR “画廊”) AND (“随机对照试验”)

8. Wanfang Database

(“主观认知能力下降” OR “主观认知下降”) AND (“音乐” OR “舞蹈” OR “绘画” OR “拼贴” OR “黏土” OR “戏剧” OR “诗歌” OR “阅读” OR “园艺” OR “书法”

OR “陶艺 OR “写作” OR “雕塑” OR “叙事” OR “回忆” OR “缅怀”OR “版画” OR “缝纫” OR “针织” OR “博物馆” OR “画廊”) AND (“随机对照试验”)

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Page
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	13-14
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	NA
Support:			
Sources	5a	Indicate sources of financial or other support for the review	14
Sponsor	5b	Provide name for the review funder and/or sponsor	14
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	14
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3-5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3-5
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6-7
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	8
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	8
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	8

Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	8
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	8-9
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	9
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	7
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	9-10
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	10
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	10
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	11
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	NA
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	11
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	12

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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