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Exercise improves sleep quality in older adults: a protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction: Sleep disturbance is a common problem among the elderly and is associated with physical and mental health. Exercise has been reported as an alternative therapeutic strategy for people with sleep disturbances. However, this topic has not been systematically reviewed for older adults. This study was conducted to provide a protocol to systematically evaluate the effects of exercise on sleep quality in the elderly.

Methods and analysis: An electronic search of the PubMed, Embase, and Cochrane Library databases will be performed with no language restrictions, and data extraction will be performed by two independent reviewers. The reviewers will discuss and resolve any differences, and a third reviewer will be consulted in cases of uncertainty. Randomized controlled trials will be selected. The primary outcome will be an objective measurement of sleep quality (for example, polysomnography). The secondary outcomes will be self-reported sleep quality (using the Pittsburgh Sleep Quality Index scale), and adverse events (such as falls and fractures). RevMan 5.3.5 and Stata 16.0 software will be used for meta-analysis. If the heterogeneity tests show slight or no statistical heterogeneity, the fixed effects model will be used; in other cases, the random effect model will be used for data synthesis.

Ethics and dissemination: The protocol does not require ethical approval. The findings will be disseminated in peer-reviewed publications, journals, scientific conferences, and exchanges.

INPLASY registration number: INPLASY2020110032 (10.37766/inplasy2020.11.0032)

Strengths and limitations of this study:

- This protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols guidelines.
- Two independent reviewers will identify studies for inclusion and perform data extraction, and the third author will address any disagreements.
- This systematic review and meta-analysis will be conducted to evaluate the exercise intervention for sleep disturbances in older adults.
- By identifying the intervention effectiveness of exercise for sleep disturbances in the old, this study will provide an optimal exercise model suitable for the elderly with sleep disturbances.
- The principal limitation is that only studies published in English will be included.

INTRODUCTION

Sleep plays an important part in the maintenance and promotion of health, accounting for nearly one-third of human lives. The proportion of adults in the United States who have less than six hours of sleep a night has increased by 31% since 1985[1]. In Canada, more than 40% of people have sleep disturbances[2]. Qualitative and quantitative changes in sleep patterns occur with increasing age, and it is estimated that more than 50% of older adults have sleep disturbances[3 4]. Studies have shown that sleep disturbance is a potential risk factor for major health problems[5 6]. Sleep disturbances may be related to several mental and cognitive disorders including persistent delusions[7], depression, anxiety, and dementia[8] and often co-exist with major medical conditions, such as hypertension[9 10], diabetes[11], and cancer[12], which may increase pain and even increase the risk of mortality[13 14]. Therefore, sleep disturbance is an important therapeutic target for healthcare.

The American Psychiatric Association recommends three treatments for insomnia: pharmacological therapy, psychotherapy, and complementary and alternative therapy[15]. Among these, pharmacological therapy is the most common treatment[16]. The use of sleep-inducing drugs can lead to negative effects such as drowsiness, gait disorders, and cognitive impairment[17]. These drugs are frequently prescribed for women, older adults, and those in poor physical health. Older adults with an underlying disease may take a large number of other drugs in addition to medications for insomnia. Existing evidence suggests that the use of these drugs may increase the risk of falls and fractures in older adults[18 19], and long-term use of the drugs can cause withdrawal syndromes associated with its administration and dependence[20]. It is, therefore, necessary to discover an effective non-drug treatment for insomnia.

Exercise is a low-cost alternative therapeutic strategy with few adverse reactions. Present studies have shown an association between exercise and sleep, mediated by a variety of psychological and physiological pathways, and that moderate exercise can

improve sleep quality[21]. However, due to the different forms of exercise, durations, frequencies, and cycles of the exercise interventions, the effects differ. Previous meta-analyses have drawn contradictory conclusions about the effects of exercise on sleep[22-24]. However, these only studied the effects of a single or a few types of exercise on sleep, and the question of which type of exercise is most suitable for older adults was not investigated. It is also not clear how the duration, frequency, and intensity of exercise affects sleep quality in the elderly. Moreover, these studies did not explore differences in the effects of exercise on different types of sleep disturbances. Furthermore, additional studies have appeared since the publication of these meta-analyses and this new evidence from new evidence from other randomized trials should be considered. Our aim, therefore, is to synthesise the available evidence and conduct a high-quality meta-analysis to compare the effects of different exercise patterns on sleep quality in the elderly.

We have asked five primary questions in this study:

1. Which types of exercise intervention have been used in sleep intervention and how do these relate to the effectiveness of the intervention?
2. What is the influence of exercise duration, frequency, and intensity on the effects of the exercise?
3. Which exercise intervention is most appropriate for older adults with sleep disturbances?
4. Does exercise affect the elderly in other ways?
5. How does exercise affect different types of sleep disturbances?

METHODS AND ANALYSIS

This study follows the reporting guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis for Protocols 2015 (PRISMA-P). The research method uses the guidelines described in the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy. The protocol has been registered on the International Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY2020110032).

Eligibility criteria

Studies that meet all of the following criteria will be included in the meta-analysis.

Types of studies

Randomized controlled trials (RCTs) which compare different exercise methods on the sleep quality of the elderly (for example, Tai Chi, yoga, Qigong, gossip, walking, aerobic exercise, anti-resistance exercise, and a combination of aerobic and anti-resistance exercise) will be included. The study must include at least one self-report or observable measure of sleep. Other types of research, such as observational studies and animal trials, will be excluded. A flowchart of the study selection process is shown in Figure 1.

Types of participants

Participants will be included irrespective of country of origin, age, race, and gender. People over 60 years old diagnosed with sleep disturbances (according to the Pittsburgh Sleep Quality Index scale [PSQI] or other international measurement methods) will be included. People with persistent behavioural, cognitive, or mental disorders will be excluded.

Types of interventions

We will include interventions that meet the above criteria and include at least one controlled trial of an exercise intervention.. An intervention period of at least one month was chosen.

The eligible types of exercise will be the following:

- Tai Chi
- Qigong
- Yoga
- Bagua
- Working
- Aerobic exercise
- Resistance exercise
- Combination of aerobic exercise and resistance exercise

Types of outcome measures

Primary outcome: objective assessment of sleep quality (for example, polysomnography, sleep onset latency, sleep duration, sleep disturbance, habitual sleep efficiency, daytime dysfunction, and use of sleep medication).

Secondary outcome: subjective assessment of sleep quality (for example, the Pittsburgh Sleep Quality Index) and adverse events (for example, falls, fractures).

Information sources

Two investigators (LY and ZW) will search studies in PubMed, EMBASE, and the Cochrane Library using keywords for sleep disturbances (sleep disturbance/s, sleep quality, insomnia, sleep complaints) and for exercise (Tai Chi, Qigong, Yoga, Bagua, Working, Aerobic exercise, Resistance exercise, Combination of aerobic exercise and resistance exercise, exercise, physical activity, physical therapy). The retrieval words will be subject words plus free words, which are determined after repeated pre-checking, supplemented by manual retrieval. The study will limit the search results to articles published in Chinese or English. To prevent omissions, we will retrieve the references twice.

Data collection and analysis

Selection of studies

The Endnote X9.3.3 software will be used to manage records. A double-blind method will be used for literature screening by the two investigators (LY and ZW). First, for the preliminary screening, we will read the title and abstract of the article. After removing duplicates both manually and electronically, the overall accuracy of the search will be calculated by dividing the number of studies that meet the eligibility criteria by the total number of studies after the removal of duplicates. After the screening, LY and ZW will compare the extracted literature. Additionally, relevant articles cited in the included studies will be entered into the full-text screening. LY and ZW will independently screen the titles and abstracts of all the studies and will determine inclusion or exclusion according to the above criteria. All disagreements will

be discussed and resolved by LY and ZW, and a third author (JY) if necessary. The details of the study selection and identification process will be presented in a flowchart (Fig 1).

Data collection and management

After the study selection, the two independent investigators (LY and ZW) will collect all the essential data from each eligible study. If data information is lacking or unclear, the investigators will contact the original author by e-mail. The contents of the data extraction include (1) basic data (first author, publication year, country, sample size, age, and distribution mode of subjects); (2) participant characteristics (age, sex, race, country, basic illness, type of used drug, and type of sleep disturbance); (3) experimental characteristics (type of exercise, intervention measures, experimental cycle, duration, frequency, and control intervention mode); and (4) outcome indicators (objective measurement results, subjective measurement results, and adverse events). The outcome indicators we will consider include both objective and subjective measurement results. Objective measurement results include polysomnography, insomnia duration, sleep disturbances, habitual sleep efficiency, sleep latency, daytime dysfunction, and the use of sleeping pills. Subjective measurement results refer to the measurement of sleep quality using standardized instruments or scales, such as the PSQI. The PSQI consists of 19 questions generating 7 components, each with a score from 0 to 3. The seven scores are added together to generate a global PSQI score (ranging from 0 to 21). A score greater than 5 indicates clinical sleep disorder. The adverse events refer to falls, fractures, and death. In the event of a dispute over the included data, the two investigators will discuss and resolve the problem and, if necessary, the third researcher (JY) will join the discussion.

Statistical analysis

Study quality assessment

Two investigators (ZQ and JY) will conduct a quality assessment of each selected study according to the quality evaluation criteria of RCTs in Cochrane Collaboration's tool. This includes the random sequence allocation of participants and whether this was truly hidden from the investigators, blinding methods for subjects and researchers, the blinding method for outcome evaluation, the presence of incomplete outcome data, selective reporting, and other considerations. Each study will be evaluated as "low bias risk", "bias uncertainty", or "high bias risk". Any disagreements in the abstracted data will be adjudicated by a third investigator (LDZ).

Assessment of heterogeneity

If the data is available, a heterogeneity analysis will be performed. The chi-square test (test level: $\alpha = 0.1$) and I^2 will be used to test heterogeneity. If $P>0.01$, there is no heterogeneity among the studies. If $P<0.01$, there is heterogeneity among the studies. I^2 represents the level of heterogeneity between studies: if I^2 is between 0 and 40%, the heterogeneity is negligible, if I^2 is between 40 and 60%, there is moderate heterogeneity, if I^2 is between 60% and 75%, there is high heterogeneity, and if I^2 is between 75 and 100%, this indicates very high heterogeneity.

Assessment of reporting bias

The Stata 16 software package (StataCorp, College Station, TX, USA) will be used for the assessment of reporting bias. If there is sufficient data, we will use funnel charts

and the Egger test to assess the likelihood of research bias in small studies. Asymmetry in the funnel chart indicates bias with the more obvious the asymmetry, the greater the degree of bias.

Outcome measures

RevMan 5.3.5 software (Cochrane, London, UK) will be used for the meta-analysis. We will provide descriptive statistics on the available data from experimental studies and demographic characteristics, as well as important variables (age, follow-up time, outcome-related baseline risk factors, underlying diseases). Calculating the score or score change after exercise intervention will standardize the mean difference (SMD) and 95% confidence interval. SMD of 0.5 means that the average value of the exercise group is more than half the standard deviation of the control group. SMD $\geq$ 0.8 is regarded as large, SMD is 0.5-0.79 is medium, SMD is 0.2-0.49 is small, SMD<0.2 is insignificant. A double tail $\alpha \leq 0.05$ will be considered statistically significant. Certain secondary outcomes, for example, adverse events, belong to dichotomous variables. If the data are available, the risk ratio (RR) or odds ratio (OR) with 95% CIs will be calculated for these secondary outcomes.

If the results are statistically significant, the 95% prediction interval (PI) will be calculated. The PI can be used to approximate the therapeutic effect in the new study[25] [26], and may be suitable for decision analysis [27]. To improve the actual application effect, the number-needed-to-treat (NNT) will be estimated. The NNT will be evaluated using a control group risk of 30%. Cohen's U3 index will be calculated to estimate the percentile gain in the intervention group[28].

Data synthesis

Data synthesis will include the abstraction and pooling of results. Each study included from each meta-analysis will translate into an overall finding of similar results, such as overall sleep quality. RevMan 5.3.5 will be used for data synthesis and analysis. The random effect and fixed effect models will be used to complete the summary of the research. If no significant heterogeneity (I^2<50%), a fixed effect model will be used, otherwise, if $I^2 \geq 50\%$, a random effect model will be used. If the data cannot be merged due to essential heterogeneity, a descriptive analysis will be performed.

Subgroup analysis

If sufficient RCTs are included, we will conduct a subgroup analysis when there is significant heterogeneity in the study. We will conduct subgroup analyses of age, gender, area, sample size, research time, the existence of complications, the type of intervention, the type of sleep disturbance, and the type of drug used.

Sensitivity analysis

Sensitivity analysis is performed to investigate the effect of one study. We will conduct a sensitivity analysis based on sample size, method quality, statistical model, and lost data to evaluate the robustness of the main result indicators. After excluding low-quality research, the data will be merged and meta-analyzed again.

Patient and public involvement

No patients or members of the public will be involved.

Ethics and dissemination

We do not use data related to personal data, so this protocol does not require ethical approval. The findings will be disseminated in peer-reviewed publications, journals, scientific conferences, and exchanges.

Limitations

We acknowledge this protocol may suffer from limitations. We only search for studies written in Chinese and English and it is possible that the methodological quality of the eligible trials may be poor. Secondly, due to differences in exercise plans, there may be heterogeneity.

Discussion

Sleep disturbance is a common problem in older adults[29] and has significant negative effects on physical and mental health. Despite this, relatively few people seek treatment or consult a healthcare provider[2]. Although there are regional differences in the types of treatments used to manage sleep disturbance, pharmacological agents still are the most widely used therapeutic option. However, at present, the first-line drugs used in clinical practice, such as diazepines (BZ), benzodiazepine receptor agonists (BZRAs), phytotherapeutic substances, and melatonin[30], may cause side-effects in patients with long-term use. Therefore, exercise may be a useful alternative to improving sleep.

Previous reviews and meta-analyses have attempted to investigate the effects of exercise on insomnia. However, since most studies have only examined one or several small-scale trials, they have not been able to find out which exercise patterns are most effective in improving the sleep quality of the elderly. This review and meta-analysis

will provide a comprehensive review of RCTs to examine the effects of various exercise training programs on sleep quality in the elderly with sleep disturbances. The study will determine the exercise patterns that have the least adverse reactions and are the most effective for older adults as well as providing objective evidence for the diagnosis and treatment of sleep disturbances.

The study may also reveal additional effects of exercise training in the elderly. For example, the root causes of sleep disturbances (such as depression and pain), the types of insomnia (the time taken to fall asleep and the maintenance of sleep), and the presence of underlying diseases (such as hypertension and diabetes) may influence the effects of exercise in the elderly. It is hoped that this meta-analysis will provide objective evidence for the custom design and individualisation of exercise plans for older adults with sleep disturbances.

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AUTHORS' CONTRIBUTIONS

WZ, DL and WW conceived and designed the research; YL, YJ and DL wrote the first draft; JY, QZ YG, and ZW and WW reviewed and contributed to drafting, revising and finalising the manuscript. All authors have reviewed and approved the final version of the manuscript and have given their permission for publication.

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DECLARATION OF INTEREST

The authors declare no competing interests.

PATIENT CONSENT FOR PUBLICATION

Not required.

Figure 1. Flow diagram of study selection.

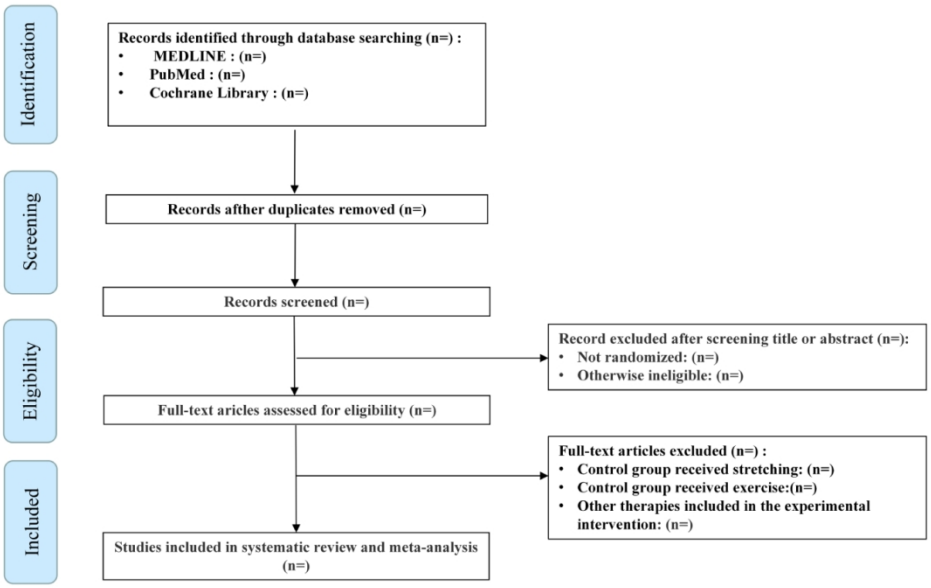

Figure 1. Flow diagram of study selection.

Flow diagram of study selection.

121x91mm (300 x 300 DPI)

Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

		Reporting Item	Page Number
Title			
Identification	#1a	Identify the report as a protocol of a systematic review	P.2
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	N/a
Registration			
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	P.2
Authors			

Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	P.1
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	P.2
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	N/a
Support			
Sources	#5a	Indicate sources of financial or other support for the review	P.16
Sponsor	#5b	Provide name for the review funder and / or sponsor	P.16
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	P.16
Introduction			
Rationale	#6	Describe the rationale for the review in the context of what is already known	P.4
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	P.6
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	P.6

		as criteria for eligibility for the review	
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	P.7
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	P.7
Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	P.7
Study records - 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)	P.8
Study records - 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	P.8
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	P.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	P.8
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	P.9
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	P.8

Data synthesis	#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 I2, Kendall's τ)	P.9
Data synthesis	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	P.9
Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	P.9
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	P.9
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	P.9

BMJ Open

Exercise improves sleep quality in older adults: a protocol for a systematic review and meta-analysis

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Exercise improves sleep quality in older adults: a protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction: Sleep disturbance is a common problem among the elderly and is associated with physical and mental health. Exercise has been reported as an alternative therapeutic strategy for people with sleep disturbances. However, this topic has not been systematically reviewed for older adults. This study was conducted to provide a protocol to systematically evaluate the effects of exercise on sleep quality in the elderly.

Methods and analysis: An electronic search of the PubMed, Embase, and Cochrane Library databases will be performed with no language restrictions, and data extraction will be performed by two independent reviewers. The reviewers will discuss and resolve any differences, and a third reviewer will be consulted in cases of uncertainty. Randomized controlled trials will be selected. The primary outcome will be an objective measurement of sleep quality (for example, polysomnography). The secondary outcomes will be self-reported sleep quality (using the Pittsburgh Sleep Quality Index scale), and adverse events (such as falls and fractures). RevMan 5.3.5 and Stata 16.0 software will be used for meta-analysis. If the heterogeneity tests show slight or no statistical heterogeneity, the fixed effects model will be used; in other cases, the random effect model will be used for data synthesis.

Ethics and dissemination: The protocol does not require ethical approval. The findings will be disseminated in peer-reviewed publications and journals.

INPLASY registration number: INPLASY2020110032 (10.37766/inplasy2020.11.0032)

Strengths and limitations of this study:

- This protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols guidelines.
- Two independent reviewers will identify studies for inclusion and perform data extraction, and the third author will address any disagreements.
- This systematic review and meta-analysis will be conducted to evaluate the exercise intervention for sleep disturbances in older adults.

- By identifying the intervention effectiveness of exercise for sleep disturbances in the old, this study will provide an optimal exercise model suitable for the elderly with sleep disturbances.
- The principal limitation is that only studies published in English will be included.

INTRODUCTION

Sleep plays an important part in the maintenance and promotion of health, accounting for nearly one-third of human lives. Sleep disorders can manifest as complaints of either insufficient sleep, abnormal movements during sleep, or excessive amount of perceived sleep[1]. It can be caused by variety of factors, often associated with physical diseases. The International Classification of Sleep disturbancess (ICSD-3)[2] identifying seven major categories that include insomnia disorders, sleep-related breathing disorders, central disorders of hypersomnolence, circadian rhythm sleep-wake disorders. The proportion of adults in the United States who have less than six hours of sleep a night has increased by 31% since 1985[3]. In Canada, more than 40% of people have sleep disturbances[4]. Qualitative and quantitative changes in sleep patterns occur with increasing age, and it is estimated that more than 50% of older adults have sleep disturbances[5 6]. Studies have shown that sleep disturbance is a potential risk factor for major health problems[7 8]. Sleep disturbances may be related to several mental and cognitive disorders including persistent delusions[9], depression, anxiety, and dementia[10] and often co-exist with major medical conditions, such as hypertension[11 12], diabetes[13], and cancer[14], which may increase pain and even increase the risk of mortality[15 16]. Therefore, sleep disturbance is an important therapeutic target for healthcare.

The American Psychiatric Association recommends three treatments for insomnia: pharmacological therapy, psychotherapy, and complementary and alternative therapy[17]. Among these, pharmacological therapy is the most common treatment[18]. The use of sleep-inducing drugs can lead to negative effects such as drowsiness, gait disorders, and cognitive impairment[19]. Older adults with an underlying disease may take a large number of other drugs in addition to medications for insomnia. Existing evidence suggests that the use of these drugs may increase the risk of falls and fractures in older adults[20 21], and long-term use of the drugs can cause withdrawal syndromes associated with its administration and dependence[22]. It is, therefore, necessary to discover an effective non-drug treatment for insomnia.

Age-related declines in physical activity and sleep are both important health indicators for successful 'healthy ageing'. Exercise intervention began to receive attention. Because comparing with traditional drug therapy, exercise is a low-cost alternative therapeutic strategy with few adverse events. Present studies have shown an association between exercise and sleep, mediated by a variety of psychological and physiological pathways, and that moderate exercise can improve sleep quality[23]. Due to the different forms of exercise, durations, frequencies, and cycles of the exercise interventions, the effects differ. Previous meta-analyses have drawn contradictory conclusions about the effects of exercise on sleep[24-28]. And these only studied the effects of a single or a few types of exercise on sleep. The question of which type of exercise is most suitable for older adults was not investigated. It is also not clear how the duration, frequency, and intensity of exercise affects sleep quality in the elderly. Moreover, these studies did not explore differences in the effects of exercise on different types of sleep disturbances. The etiology and clinical manifestations are different for different sleep disturbances, so it is very necessary to develop personalized exercise pattern for the elderly with sleep disturbances. Furthermore, additional studies have appeared since the publication of these meta-analyses and this new evidence from other randomized trials should be considered. Our aim, therefore, is to synthesis the available evidence and conduct a high-quality meta-analysis to compare the effects of different exercise patterns on sleep quality in the elderly.

We have asked four primary questions in this study:

1. Which type of exercise intervention is most effective for older adults with sleep disturbances?
2. How does the exercise duration, frequency, and intensity mediate/moderate the exercise-sleep relationship?
3. Does exercise affect the elderly in other ways (mental health, physical health, cognitive function)?
4. For different sleep disturbances, which type of exercise intervention is most effective?

METHODS AND ANALYSIS

This study follows the reporting guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis for Protocols 2015 (PRISMA-P). The research method uses the guidelines described in the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy. The protocol has been registered on the International Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY2020110032).

Eligibility criteria

Studies that meet all of the following criteria will be included in the meta-analysis.

Types of studies

Randomized controlled trials (RCTs) which compare different exercise methods on the sleep quality of the elderly (for example, Tai Chi, yoga, Qigong, Bagua, aerobic exercise, anti-resistance exercise, and a combination of aerobic and anti-resistance exercise) will be included. The study must include at least one self-report or observable measure of sleep. Other types of research, such as observational studies and animal trials, will be excluded. A flowchart of the study selection process is shown in Figure 1.

Types of participants

Participants will be included irrespective of country of origin, age, race, and gender. People over 60 years old diagnosed with sleep disturbances (according to the ICSD-3) will be included. People with persistent behavioural, cognitive, or mental disorders (such as dementia, Parkinson's disease, Alzheimer's disease, schizophrenia, depression, etc) will be excluded.

Types of interventions

We will include RCTs which interventions that meet the above criteria and include at least one exercise intervention. An intervention period of at least one month was chosen. The eligible types of exercise will be the following:

- Tai Chi
- Qigong
- Yoga
- Bagua
- Aerobic exercise (Walking, brisk walking, jogging, race walking, skating, long-distance swimming, cycling, ball game, etc)
- Resistance exercise (Push-ups, dumbbells, barbells, etc)
- Combination of aerobic exercise and resistance exercise
- Combination of aerobic exercise and resistance exercise (Tai Chi, Qigong, Yoga, Bagua)

Types of outcome measures

Primary outcome: objective assessment of sleep quality (for example, polysomnography, sleep onset latency, sleep duration, sleep disturbance, habitual sleep efficiency, daytime dysfunction, and use of sleep medication).

Secondary outcome: subjective assessment of sleep quality (for example, the Pittsburgh Sleep Quality Index) and adverse events (for example, muscle sprains and pains, time taken from other duties, money spent on exercise equipment, myocardial infarction, stroke).

Information sources

Two investigators (LY and ZW) will search studies in PubMed, EMBASE, and the Cochrane Library using keywords for sleep disturbances (sleep disturbance/s, sleep quality, insomnia, sleep complaints, sleep disorder) and for exercise (Tai Chi, Qigong, Yoga, Bagua, Aerobic exercise, Resistance exercise, Combination of aerobic exercise

and resistance exercise, exercise, physical activity, physical therapy) form their inception up to July 2021. The retrieval words will be subject words plus free words, which are determined after repeated pre-checking, supplemented by manual retrieval. The study will limit the search results to articles published in Chinese or English. To prevent omissions, we will retrieve the references twice.

Data collection and analysis

Selection of studies

The Endnote X9.3.3 software will be used to manage records. A double-blind method will be used for literature screening by the two investigators (LY and ZW). First, for the preliminary screening, we will read the title and abstract of the article. After removing duplicates both manually and electronically, the overall accuracy of the search will be calculated by dividing the number of studies that meet the eligibility criteria by the total number of studies after the removal of duplicates. After the screening, LY and ZW will compare the extracted literature. Additionally, relevant articles cited in the included studies will be entered into the full-text screening. LY and ZW will independently screen the titles and abstracts of all the studies and will determine inclusion or exclusion according to the above criteria. All disagreements will be discussed and resolved by LY and ZW, and a third author (JY) if necessary. The details of the study selection and identification process will be presented in a flowchart (Fig 1).

Data collection and management

After the study selection, the two independent investigators (LY and ZW) will collect all the essential data from each eligible study. If data information is lacking or unclear, the investigators will contact the original author by e-mail. The contents of the data extraction include (1) basic data (first author, publication year, country, sample size, age, and distribution mode of subjects); (2) participant characteristics (age, sex, race,

country, basic illness, type of used drug, and type of sleep disturbance); (3) experimental characteristics (type of exercise, intervention measures, experimental cycle, duration, frequency, and control intervention mode); and (4) outcome indicators (objective measurement results, subjective measurement results, and adverse events). The outcome indicators we will consider include both objective and subjective measurement results. Objective measurement results include polysomnography, insomnia duration, sleep disturbances, habitual sleep efficiency, sleep latency, daytime dysfunction, and the use of sleeping pills. Pittsburgh sleep quality index (PSQI) will be employed as the primary outcome measurement. The PSQI consists of 19 questions generating 7 components, each with a score from 0 to 3. The seven scores are added together to generate a global PSQI score (ranging from 0 to 21). A score greater than 5 indicates clinical sleep disturbances. The adverse events refer to falls, fractures, and death. Other standardized instruments or scales, such as the Self- Rating Scale of Sleep (SRSS), Athens insomnia scale and the insomnia severity index will be included. The adverse events refer to muscle sprains and pains, time taken from other duties, money spent on exercise equipment, myocardial infarction and stroke. In the event of a dispute over the included data, the two investigators will discuss and resolve the problem and, if necessary, the third researcher (JY) will join the discussion.

Statistical analysis

Study quality assessment

Two investigators (ZQ and JY) will conduct a quality assessment of each selected study according to the quality evaluation criteria of RCTs in Cochrane Collaboration's tool. This includes the random sequence allocation of participants and whether this was truly hidden from the investigators, blinding methods for subjects and researchers, the blinding method for outcome evaluation, the presence of incomplete outcome data, selective reporting, and other considerations. Each study will be evaluated as "low bias

risk", "bias uncertainty", or "high bias risk". Any disagreements in the abstracted data will be adjudicated by a third investigator (LDZ).

Assessment of heterogeneity

If the data is available, a heterogeneity analysis will be performed. The chi-square test (test level: $\alpha = 0.1$) and I^2 will be used to test heterogeneity. If $P>0.01$, there is no heterogeneity among the studies. If $P<0.01$, there is heterogeneity among the studies. I^2 represents the level of heterogeneity between studies: if I^2 is between 0 and 40%, the heterogeneity is negligible, if I^2 is between 40 and 60%, there is moderate heterogeneity, if I^2 is between 60% and 75%, there is high heterogeneity, and if I^2 is between 75 and 100%, this indicates very high heterogeneity.

Assessment of reporting bias

The Stata 16 software package (Stata Corp, College Station, TX, USA) will be used for the assessment of reporting bias. If there is sufficient data, we will use funnel charts and the Egger test to assess the likelihood of research bias in small studies. Asymmetry in the funnel chart indicates bias with the more obvious the asymmetry, the greater the degree of bias.

Outcome measures

RevMan 5.3.5 software (Cochrane, London, UK) will be used for the meta-analysis. We will provide descriptive statistics on the available data from experimental studies and demographic characteristics, as well as important variables (age, follow-up time, outcome-related baseline risk factors, underlying diseases). Calculating the score or score change after exercise intervention will standardize the mean difference (SMD) and 95% confidence interval. SMD of 0.5 means that the average value of the exercise group is more than half the standard deviation of the control group. SMD $\geq$ 0.8 is

regarded as large, SMD is 0.5-0.79 is medium, SMD is 0.2-0.49 is small, SMD<0.2 is insignificant. A double tail $\alpha \leq 0.05$ will be considered statistically significant. Certain secondary outcomes, for example, adverse events, belong to dichotomous variables. If the data are available, the risk ratio (RR) or odds ratio (OR) with 95% CIs will be calculated for these secondary outcomes.

If the results are statistically significant, the 95% prediction interval (PI) will be calculated. The PI can be used to approximate the therapeutic effect in the new study[29] [30], and may be suitable for decision analysis [31]. To improve the actual application effect, the number-needed-to-treat (NNT) will be estimated. The NNT will be evaluated using a control group risk of 30%. Cohen's U3 index will be calculated to estimate the percentile gain in the intervention group[32].

Data synthesis

Data synthesis will include the abstraction and pooling of results. Each study included from each meta-analysis will translate into an overall finding of similar results, such as overall sleep quality. RevMan 5.3.5 will be used for data synthesis and analysis. The random effect and fixed effect models will be used to complete the summary of the research. If no significant heterogeneity (I^2<50%), a fixed effect model will be used, otherwise, if $I^2 \geq 50\%$, a random effect model will be used. If the data cannot be merged due to essential heterogeneity, a descriptive analysis will be performed.

Subgroup analysis

If sufficient RCTs are included, we will conduct a subgroup analysis when there is significant heterogeneity in the study. We will conduct subgroup analyses of age, gender, sports fields (indoor VS outdoor), sample size, research time (4 weeks, 8 weeks, 12 weeks, 16 weeks, and over 16 weeks), the existence of complications (hypertension, diabetes, and cancer), the type of intervention, the type of sleep disturbance, and the type of drug used.

Sensitivity analysis

Sensitivity analysis is performed to investigate the effect of one study. We will conduct a sensitivity analysis based on sample size, method quality, statistical model, and lost data to evaluate the robustness of the main result indicators. After excluding low-quality research, the data will be merged and meta-analyzed again.

Patient and public involvement

No patients or members of the public will be involved.

Ethics and dissemination

We do not use data related to personal data, so this protocol does not require ethical approval. The findings will be disseminated in peer-reviewed publications and journals.

Limitations

We acknowledge this protocol may suffer from limitations. We only search for studies written in Chinese and English and it is possible that the methodological quality of the eligible trials may be poor. Secondly, due to differences in exercise plans, there may be heterogeneity.

Discussion

Sleep disturbance is a common problem in older adults[33] and has significant negative effects on physical and mental health. Despite this, relatively few people seek treatment or consult a healthcare provider[4]. Although there are regional differences in the types of treatments used to manage sleep disturbance, pharmacological agents still are the most widely used therapeutic option. However, at present, the first-line drugs used in clinical practice, such as diazepines (BZ), benzodiazepine receptor agonists (BZRAs),

phytotherapeutic substances, and melatonin[34], may cause side-effects in patients with long-term use. Therefore, exercise may be a useful alternative to improving sleep.

Previous reviews and meta-analyses have attempted to investigate the effects of exercise on insomnia. However, since most studies have only examined one or several small-scale trials, they have not been able to find out which exercise patterns are most effective for the elderly with sleep disturbances. This review and meta-analysis will provide a comprehensive review of RCTs to examine the effects of various exercise training programs on sleep quality in the elderly with sleep disturbances. The study will determine the exercise patterns that have the least adverse reactions and are the most effective for older adults as well as providing objective evidence for the diagnosis and treatment of sleep disturbances.

The study may also reveal additional effects of exercise training in the elderly. For example, the root causes of sleep disturbances (such as depression and pain), the types of sleep disturbances (such as insomnia disorders, sleep-related breathing disorders, central disorders of hypersomnolence, circadian rhythm sleep-wake disorders), and the presence of underlying diseases (such as hypertension and diabetes) may influence the effects of exercise in the elderly. It is hoped that this meta-analysis will provide objective evidence for customized exercise prescriptions for the elderly with sleep disorders.

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AUTHORS' CONTRIBUTIONS

WZ, DL and WW conceived and designed the research; YL, YJ and DL wrote the first draft; JY, QZ YG, and ZW and WW reviewed and contributed to drafting, revising and finalising the manuscript. All authors have reviewed and approved the final version of the manuscript and have given their permission for publication.

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DECLARATION OF INTEREST

The authors declare no competing interests.

PATIENT CONSENT FOR PUBLICATION

Not required.

Figure 1. Flow diagram of study selection.

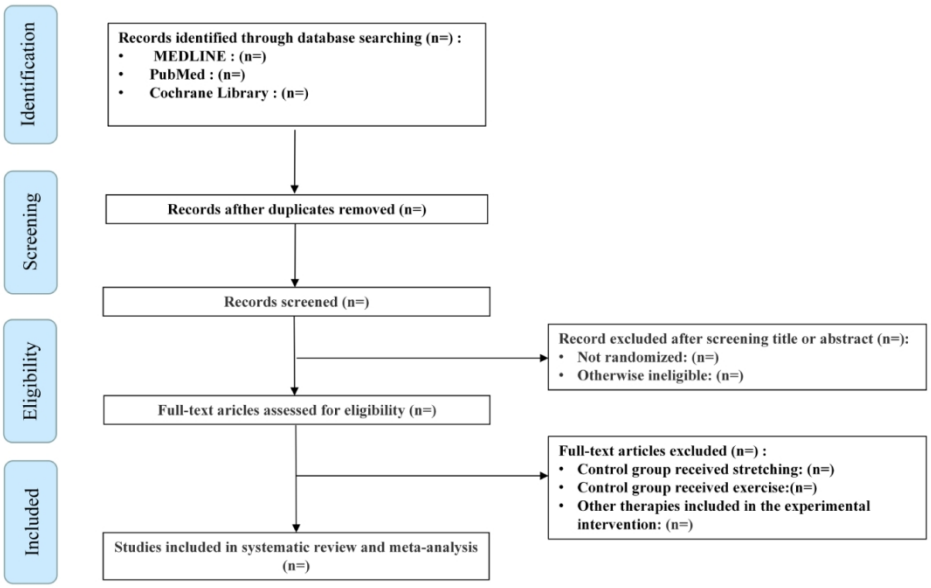

Figure 1. Flow diagram of study selection.

Flow diagram of study selection.

121x91mm (300 x 300 DPI)

Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

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		Reporting Item	Page Number
Title			
Identification	#1a	Identify the report as a protocol of a systematic review	P.2
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	N/a
Registration			
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	P.2
Authors			

Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	P.1
Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	P.2
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	N/a
Support			
Sources	#5a	Indicate sources of financial or other support for the review	P.16
Sponsor	#5b	Provide name for the review funder and / or sponsor	P.16
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	P.16
Introduction			
Rationale	#6	Describe the rationale for the review in the context of what is already known	P.4
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	P.6
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	P.6

		as criteria for eligibility for the review	
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	P.7
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	P.7
Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	P.7
Study records - 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)	P.8
Study records - 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	P.8
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	P.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	P.8
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	P.9
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	P.8

Data synthesis	#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 I2, Kendall's τ)	P.9
Data synthesis	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	P.9
Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	P.9
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	P.9
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	P.9

BMJ Open

Exercise improves sleep quality in older adults: a protocol for a systematic review and meta-analysis

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Exercise improves sleep quality in older adults: a protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction: Sleep disturbance is a common problem among the elderly and is associated with physical and mental health. Exercise has been reported as an alternative therapeutic strategy for people with sleep disturbances. However, this topic has not been systematically reviewed for older adults. This study was conducted to provide a protocol to systematically evaluate the effects of exercise on sleep quality in the elderly.

Methods and analysis: An electronic search of the PubMed, Embase, and Cochrane Library databases will be performed with no language restrictions, and data extraction will be performed by two independent reviewers. The reviewers will discuss and resolve any differences, and a third reviewer will be consulted in cases of uncertainty. Randomized controlled trials will be selected. The primary outcome will be an objective measurement of sleep quality (for example, polysomnography). The secondary outcomes will be self-reported sleep quality (using the Pittsburgh Sleep Quality Index scale), and adverse events (such as falls and fractures). RevMan 5.3.5 and Stata 16.0 software will be used for meta-analysis. If the heterogeneity tests show slight or no statistical heterogeneity, the fixed effects model will be used; in other cases, the random effect model will be used for data synthesis.

Ethics and dissemination: The protocol does not require ethical approval. The findings will be disseminated in peer-reviewed publications and journals.

PROSPERO registration number: CRD42021287980

Strengths and limitations of this study:

- This study will provide an optimal exercise model suitable for the elderly with sleep disturbances by identifying the intervention effectiveness of exercise for sleep disturbances in the old.
- This protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols guidelines.
- Two independent reviewers will identify studies for inclusion and perform data extraction, and the third author will address any disagreements.
- There will be have language restriction in the selection of the studies.

INTRODUCTION

Sleep plays an important part in the maintenance and promotion of health, accounting for nearly one-third of human lives. Sleep disorders can manifest as complaints of either insufficient sleep, abnormal movements during sleep, or excessive amount of perceived sleep[1]. It can be caused by variety of factors, often associated with physical diseases. The International Classification of Sleep disturbancess (ICSD-3)[2] identifying seven major categories that include insomnia disorders, sleep-related breathing disorders, central disorders of hypersomnolence, circadian rhythm sleep-wake disorders. The proportion of adults in the United States who have less than six hours of sleep a night has increased by 31% since 1985[3]. In Canada, more than 40% of people have sleep disturbances[4]. Qualitative and quantitative changes in sleep patterns occur with increasing age, and it is estimated that more than 50% of older adults have sleep disturbances[5 6]. Studies have shown that sleep disturbance is a potential risk factor for major health problems[7 8]. Sleep disturbances may be related to several mental and cognitive disorders including persistent delusions[9], depression, anxiety, and dementia[10] and often co-exist with major medical conditions, such as hypertension[11 12], diabetes[13], and cancer[14], which may increase pain and even increase the risk of mortality[15 16]. Therefore, sleep disturbance is an important therapeutic target for healthcare.

The American Psychiatric Association recommends three treatments for insomnia: pharmacological therapy, psychotherapy, and complementary and alternative therapy[17]. Among these, pharmacological therapy is the most common treatment[18]. The use of sleep-inducing drugs can lead to negative effects such as drowsiness, gait disorders, and cognitive impairment[19]. Older adults with an underlying disease may take a large number of other drugs in addition to medications for insomnia. Existing evidence suggests that the use of these drugs may increase the risk of falls and fractures in older adults[20 21], and long-term use of the drugs can cause withdrawal syndromes associated with its administration and dependence[22]. It is, therefore, necessary to discover an effective non-drug treatment for insomnia.

Age-related declines in physical activity and sleep are both important health indicators for successful 'healthy ageing'. Exercise intervention began to receive attention. Previous studies showed[23] that regular exercise offers many health benefits, including reduced risk of chronic disease, all-cause mortality, and premature death. Because comparing with traditional drug therapy, exercise is a low-cost alternative therapeutic strategy with few adverse events. Present studies have shown an association between exercise and sleep, mediated by a variety of psychological and physiological pathways, and that moderate exercise can improve sleep quality[24]. Due to the different forms of exercise, durations, frequencies, and cycles of the exercise interventions, the effects differ. Previous meta-analyses have drawn contradictory conclusions about the effects of exercise on sleep[25-29]. And these only studied the effects of a single or a few types of exercise on sleep. The question of which type of exercise is most suitable for older adults was not investigated. It is also not clear how the duration, frequency, and intensity of exercise affects sleep quality in the elderly. Moreover, these studies did not explore differences in the effects of exercise on different types of sleep disturbances. The etiology and clinical manifestations are different for different sleep disturbances, so it is very necessary to develop personalized exercise pattern for the elderly with sleep disturbances. Furthermore, additional studies have appeared since the publication of these meta-analyses and this new evidence from other randomized trials should be considered. Our aim, therefore, is to synthesis the available evidence and conduct a high-quality meta-analysis to compare the effects of different exercise patterns on sleep quality in the elderly.

We have asked four primary questions in this study:

1. Which type of exercise intervention is most effective for older adults with sleep disturbances?
2. How does the exercise duration, frequency, and intensity mediate/moderate the exercise-sleep relationship?
3. Does exercise affect the elderly in other ways (mental health, physical health, cognitive function)?

4. For different sleep disturbances, which type of exercise intervention is most effective?

METHODS AND ANALYSIS

This study follows the reporting guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis for Protocols 2015 (PRISMA-P). The research method uses the guidelines described in the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy.

Eligibility criteria

Studies that meet all of the following criteria will be included in the meta-analysis.

Types of studies

Randomized controlled trials (RCTs) which compare different exercise methods on the sleep quality of the elderly (for example, Tai Chi, yoga, Qigong, Bagua, aerobic exercise, resistance exercise, and a combination of aerobic and resistance exercise) will be included. The study must include at least one self-report or observable measure of sleep. Other types of research, such as observational studies and animal trials, will be excluded. A flowchart of the study selection process is shown in Figure 1.

Types of participants

Participants will be included irrespective of country of origin, age, race, and gender. People over 60 years old diagnosed with sleep disturbances (according to the ICSD-3) will be included. Samples of clinical populations such as individuals with a diagnosis of dementia or Parkinson's disease will be excluded.

Types of interventions

We will include RCTs which interventions that meet the above criteria and include at least one exercise intervention. An intervention period of at least one month was chosen. The eligible types of exercise will be the following:

- Tai Chi

- Qigong
- Yoga
- Bagua
- Aerobic exercise (Walking, brisk walking, jogging, race walking, skating, long-distance swimming, cycling, ball game, etc)
- Resistance exercise (Push-ups, dumbbells, barbells, etc)
- Combination of aerobic exercise and resistance exercise
- Combination of aerobic exercise and resistance exercise (Tai Chi, Qigong, Yoga, Bagua)

Types of outcome measures

Primary outcome: objective assessment of sleep quality (for example, polysomnography, sleep onset latency, sleep duration, sleep disturbance, habitual sleep efficiency, daytime dysfunction, and use of sleep medication).

Secondary outcome: subjective assessment of sleep quality (for example, the Pittsburgh Sleep Quality Index) and adverse events (for example, muscle sprains and pains, myocardial infarction, stroke).

Information sources

Two investigators (LY and ZW) will search studies in PubMed, EMBASE, and the Cochrane Library using keywords for sleep disturbances (sleep disturbance/s, sleep quality, insomnia, sleep complaints, sleep disorder) and for exercise (Tai Chi, Qigong, Yoga, Bagua, Aerobic exercise, Resistance exercise, Combination of aerobic exercise and resistance exercise, exercise, physical activity, physical therapy) form their inception up to December 2021(see supplemental file 1. Results of the literature retrieval in PubMed). The retrieval words will be subject words plus free words, which are determined after repeated pre-checking, supplemented by manual retrieval. The study will limit the search results to articles published in Chinese and English. To prevent omissions, we will retrieve the references twice.

Data collection and analysis

Selection of studies

The Endnote X9.3.3 software will be used to manage records. A double-blind method will be used for literature screening by the two investigators (LY and ZW). First, for the preliminary screening, we will read the title and abstract of the article. After removing duplicates both manually and electronically, the overall accuracy of the search will be calculated by dividing the number of studies that meet the eligibility criteria by the total number of studies after the removal of duplicates. After the screening, LY and ZW will compare the extracted literature. Additionally, relevant articles cited in the included studies will be entered into the full-text screening. LY and ZW will independently screen the titles and abstracts of all the studies and will determine inclusion or exclusion according to the above criteria. All disagreements will be discussed and resolved by LY and ZW, and a third author (JY) if necessary. The details of the study selection and identification process will be presented in a flowchart (Fig 1).

Data collection and management

After the study selection, the two independent investigators (LY and ZW) will collect all the essential data from each eligible study. If data information is lacking or unclear, the investigators will contact the original author by e-mail. The contents of the data extraction include (1) basic data (first author, publication year, country, sample size, age, and distribution mode of subjects); (2) participant characteristics (age, sex, race, country, basic illness, type of used drug, and type of sleep disturbance); (3) experimental characteristics (type of exercise, intervention measures, experimental cycle, duration, frequency, and control intervention mode); and (4) outcome indicators (objective measurement results, subjective measurement results, and adverse events). The outcome indicators we will consider include both objective and subjective measurement results. Objective measurement results include polysomnography,

insomnia duration, sleep disturbances, habitual sleep efficiency, sleep latency, daytime dysfunction, and the use of sleeping pills. Pittsburgh sleep quality index (PSQI)[30] will be employed as the primary outcome measurement. The PSQI consists of 19 questions generating 7 components, each with a score from 0 to 3. The seven scores are added together to generate a global PSQI score (ranging from 0 to 21). A score greater than 5 indicates clinical sleep disturbances. The adverse events refer to falls, fractures, and death. Other standardized instruments or scales, such as the Self- Rating Scale of Sleep (SRSS)[31], Athens insomnia scale[32] and the insomnia severity index[33] will be included. The adverse events refer to muscle sprains and pains, myocardial infarction and stroke. In the event of a dispute over the included data, the two investigators will discuss and resolve the problem and, if necessary, the third researcher (JY) will join the discussion.

Statistical analysis

Study quality assessment

Two investigators (ZQ and JY) will conduct a quality assessment of each selected study according to the quality evaluation criteria of RCTs in Cochrane Collaboration's tool. This includes the random sequence allocation of participants and whether this was truly hidden from the investigators, blinding methods for subjects and researchers, the blinding method for outcome evaluation, the presence of incomplete outcome data, selective reporting, and other considerations. Each study will be evaluated as "low bias risk", "bias uncertainty", or "high bias risk". Any disagreements in the abstracted data will be adjudicated by a third investigator (LDZ).

Assessment of heterogeneity

If the data is available, a heterogeneity analysis will be performed. The chi-square test (test level: $\alpha = 0.1$) and I^2 will be used to test heterogeneity. If $P>0.01$, there is no heterogeneity among the studies. If $P<0.01$, there is heterogeneity among the studies. I^2 represents the level of heterogeneity between studies: if I^2 is between 0 and 40%, the heterogeneity is negligible, if I^2 is between 40 and 60%, there is moderate heterogeneity,

if I^2 is between 60% and 75%, there is high heterogeneity, and if I^2 is between 75 and 100%, this indicates very high heterogeneity.

Assessment of reporting bias

The Stata 16 software package (Stata Corp, College Station, TX, USA) will be used for the assessment of reporting bias. If there is sufficient data, we will use funnel charts and the Egger test to assess the likelihood of research bias in small studies. Asymmetry in the funnel chart indicates bias with the more obvious the asymmetry, the greater the degree of bias.

Outcome measures

RevMan 5.3.5 software (Cochrane, London, UK) will be used for the meta-analysis. We will provide descriptive statistics on the available data from experimental studies and demographic characteristics, as well as important variables (age, follow-up time, outcome-related baseline risk factors, underlying diseases). Calculating the score or score change after exercise intervention will standardize the mean difference (SMD) and 95% confidence interval. SMD of 0.5 means that the average value of the exercise group is more than half the standard deviation of the control group. SMD $\geq$ 0.8 is regarded as large, SMD is 0.5-0.79 is medium, SMD is 0.2-0.49 is small, SMD<0.2 is insignificant. A double tail $\alpha \leq 0.05$ will be considered statistically significant. Certain secondary outcomes, for example, adverse events, belong to dichotomous variables. If the data are available, the risk ratio (RR) or odds ratio (OR) with 95% CIs will be calculated for these secondary outcomes.

If the results are statistically significant, the 95% prediction interval (PI) will be calculated. The PI can be used to approximate the therapeutic effect in the new study[34 35], and may be suitable for decision analysis [36]. To improve the actual application effect, the number-needed-to-treat (NNT) will be estimated. The NNT will be evaluated using a control group risk of 30%. Cohen's U3 index will be calculated to estimate the percentile gain in the intervention group[37].

Data synthesis

Data synthesis will include the abstraction and pooling of results. Each study included from each meta-analysis will translate into an overall finding of similar results, such as overall sleep quality. RevMan 5.3.5 will be used for data synthesis and analysis. The random effect and fixed effect models will be used to complete the summary of the research. If no significant heterogeneity (I^2<50%), a fixed effect model will be used, otherwise, if $I^2 \geq 50\%$, a random effect model will be used. If the data cannot be merged due to essential heterogeneity, a descriptive analysis will be performed.

Subgroup analysis

If sufficient RCTs are included, we will conduct a subgroup analysis when there is significant heterogeneity in the study. We will conduct subgroup analyses of age, gender, sports fields (indoor VS outdoor), sample size, research time (4 weeks, 8 weeks, 12 weeks, 16 weeks, and over 16 weeks), the existence of complications (hypertension, diabetes, and cancer), the type of intervention, the type of sleep disturbance, and the type of drug used.

Sensitivity analysis

Sensitivity analysis is performed to investigate the effect of one study. We will conduct a sensitivity analysis based on sample size, method quality, statistical model, and lost data to evaluate the robustness of the main result indicators. After excluding low-quality research, the data will be merged and meta-analyzed again.

Patient and public involvement

No patients or members of the public will be involved.

Ethics and dissemination

We do not use data related to personal data, so this protocol does not require ethical approval. The findings will be disseminated in peer-reviewed publications and journals.

Limitations

We acknowledge this protocol may suffer from limitations. We only search for studies written in Chinese and English and it is possible that the methodological quality of the eligible trials may be poor. Secondly, due to differences in exercise plans, there may be heterogeneity.

Discussion

Sleep disturbance is a common problem in older adults[38] and has significant negative effects on physical and mental health. Despite this, relatively few people seek treatment or consult a healthcare provider[4]. Although there are regional differences in the types of treatments used to manage sleep disturbance, pharmacological agents still are the most widely used therapeutic option. However, at present, the first-line drugs used in clinical practice, such as diazepines (BZ), benzodiazepine receptor agonists (BZRAs), phytotherapeutic substances, and melatonin[39], may cause side-effects in patients with long-term use. Therefore, exercise may be a useful alternative to improving sleep.

Previous reviews and meta-analyses have attempted to investigate the effects of exercise on insomnia. However, since most studies have only examined one or several small-scale trials, they have not been able to find out which exercise patterns are most effective for the elderly with sleep disturbances. This review and meta-analysis will provide a comprehensive review of RCTs to examine the effects of various exercise training programs on sleep quality in the elderly with sleep disturbances. The study will determine the exercise patterns that have the least adverse reactions and are the most effective for older adults as well as providing objective evidence for the diagnosis and treatment of sleep disturbances.

The study may also reveal additional effects of exercise training in the elderly. For example, the root causes of sleep disturbances (such as depression and pain), the types of sleep disturbances (such as insomnia disorders, sleep-related breathing disorders, central disorders of hypersomnolence, circadian rhythm sleep-wake disorders), and the

presence of underlying diseases (such as hypertension and diabetes) may influence the effects of exercise in the elderly. It is hoped that this meta-analysis will provide objective evidence for customized exercise prescriptions for the elderly with sleep disorders.

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AUTHORS' CONTRIBUTIONS

WZ, DL and WW conceived and designed the research; YL, YJ and DL wrote the first draft; JY, QZ YG, and ZW and WW reviewed and contributed to drafting, revising and finalising the manuscript. All authors have reviewed and approved the final version of the manuscript and have given their permission for publication.

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DECLARATION OF INTEREST

The authors declare no competing interests.

PATIENT CONSENT FOR PUBLICATION

Not required.

Figure 1. Flow diagram of study selection.

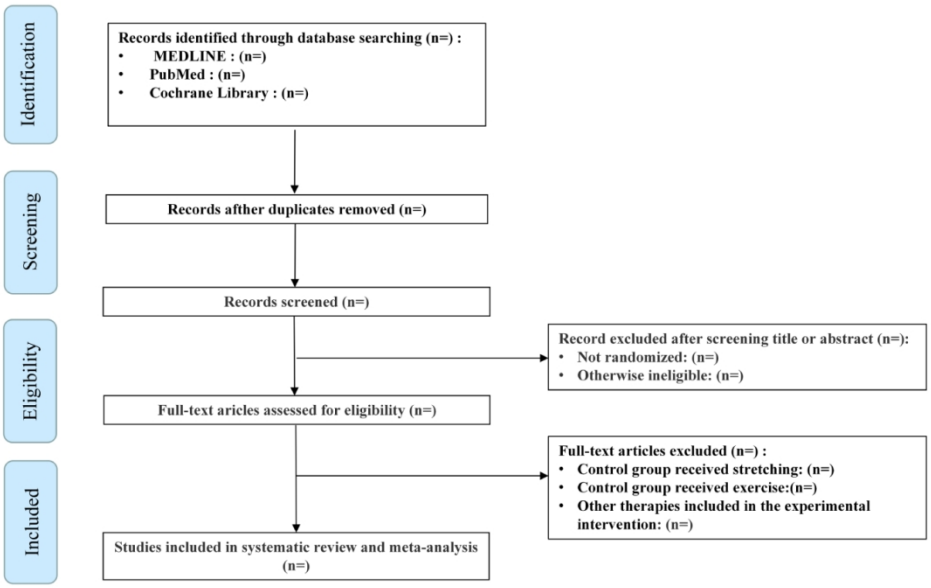

Figure 1. Flow diagram of study selection.

Flow diagram of study selection.

121x91mm (300 x 300 DPI)

Supplementary file 1. Results of the literature retrieval in PubMed.

#1	'Randomized Controlled Trials' OR 'Random allocation' OR 'Controlled Clinical Trials' OR 'Control groups' OR 'Clinical trials' OR 'Clinical Trials Data Monitoring Committees' OR 'Double- blind method' OR 'Single- blind method'
#2	'Exercise' OR 'Exercise Therapy' OR 'Exercise' OR 'Physical Activity' OR 'Aerobic Exercise' OR 'Train' OR 'High-Intensity Interval Training' OR 'Resistance exercise' OR 'Endurance training' OR 'Tai Chi' OR 'Qigong' OR 'Yoga' OR 'Bagua'
#3	'Sleep disturbance' OR 'Sleep quality' OR 'Insomnia' OR 'Sleep complaints' OR 'Sleep disorder'
#4	#1 and #2 and #3
#5	Search (#4 NOT animal[mh])

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Based on the PRISMA-P guidelines.

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		Reporting Item	Page Number
Title			
Identification	#1a	Identify the report as a protocol of a systematic review	P.2
Update	#1b	If the protocol is for an update of a previous systematic review, identify as such	N/a
Registration			
	#2	If registered, provide the name of the registry (such as PROSPERO) and registration number	P.2
Authors			

Contact	#3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	P.1
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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	N/a
Support			
Sources	#5a	Indicate sources of financial or other support for the review	P.16
Sponsor	#5b	Provide name for the review funder and / or sponsor	P.16
Role of sponsor or funder	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing the protocol	P.16
Introduction			
Rationale	#6	Describe the rationale for the review in the context of what is already known	P.4
Objectives	#7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	P.6
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	P.6

		as criteria for eligibility for the review	
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	P.7
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	P.7
Study records - data management	#11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	P.7
Study records - 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)	P.8
Study records - 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	P.8
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	P.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	P.8
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	P.9
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	P.8

Data synthesis	#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 I2, Kendall's τ)	P.9
Data synthesis	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	P.9
Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	P.9
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	P.9
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	P.9