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

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Manuscripts

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4 **Exercise improves sleep quality in older adults: a protocol for a systematic review**
5 **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.

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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 1985¹. In Canada, more than 40% of people have sleep disturbances². 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 delusions⁷, depression, anxiety, and dementia⁸ and often co-exist with major medical conditions, such as hypertension^{9 10}, diabetes¹¹, and cancer¹², 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 therapy¹⁵. Among these, pharmacological therapy is the most common treatment¹⁶. The use of sleep-inducing drugs can lead to negative effects such as drowsiness, gait disorders, and cognitive impairment¹⁷. 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 dependence²⁰. 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

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4 improve sleep quality²¹. However, due to the different forms of exercise, durations,
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6 frequencies, and cycles of the exercise interventions, the effects differ. Previous meta-
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8 analyses have drawn contradictory conclusions about the effects of exercise on sleep²²⁻
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10 ²⁴. However, these only studied the effects of a single or a few types of exercise on
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12 sleep, and the question of which type of exercise is most suitable for older adults was
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14 not investigated. It is also not clear how the duration, frequency, and intensity of
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16 exercise affects sleep quality in the elderly. Moreover, these studies did not explore
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18 differences in the effects of exercise on different types of sleep disturbances.
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20 Furthermore, additional studies have appeared since the publication of these meta-
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22 analyses and this new evidence from new evidence from other randomized trials should
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24 be considered. Our aim, therefore, is to synthesise the available evidence and conduct
25
26 a high-quality meta-analysis to compare the effects of different exercise patterns on
27
28 sleep quality in the elderly.

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30 We have asked five primary questions in this study:

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32 1. Which types of exercise intervention have been used in sleep intervention and how
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34 do these relate to the effectiveness of the intervention?
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36 2. What is the influence of exercise duration, frequency, and intensity on the effects
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38 of the exercise?
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40 3. Which exercise intervention is most appropriate for older adults with sleep
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42 disturbances?
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44 4. Does exercise affect the elderly in other ways?
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46 5. How does exercise affect different types of sleep disturbances?
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55 **METHODS AND ANALYSIS**

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4 This study follows the reporting guidelines of the Preferred Reporting Items for
5 Systematic Reviews and Meta-Analysis for Protocols 2015 (PRISMA-P). The research
6 method uses the guidelines described in the Cochrane Handbook for Systematic
7 Reviews of Diagnostic Test Accuracy. The protocol has been registered on the
8 International Platform of Registered Systematic Review and Meta-analysis Protocols
9 (INPLASY2020110032).
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15 16 **Eligibility criteria**

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19 Studies that meet all of the following criteria will be included in the meta-analysis.
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26 **Types of studies**

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

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

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4 be discussed and resolved by LY and ZW, and a third author (JY) if necessary. The
5 details of the study selection and identification process will be presented in a flowchart
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7 (Fig 1).
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10 11 12 13 14 Data collection and management 15

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

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4 and the Egger test to assess the likelihood of research bias in small studies. Asymmetry
5 in the funnel chart indicates bias with the more obvious the asymmetry, the greater the
6 degree of bias.
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10 11 12 13 14 Outcome measures

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17 RevMan 5.3.5 software (Cochrane, London, UK) will be used for the meta-analysis.
18 We will provide descriptive statistics on the available data from experimental studies
19 and demographic characteristics, as well as important variables (age, follow-up time,
20 outcome-related baseline risk factors, underlying diseases). Calculating the score or
21 score change after exercise intervention will standardize the mean difference (SMD)
22 and 95% confidence interval. SMD of 0.5 means that the average value of the exercise
23 group is more than half the standard deviation of the control group. $SMD \geq 0.8$ is
24 regarded as large, SMD is 0.5-0.79 is medium, SMD is 0.2-0.49 is small, $SMD < 0.2$ is
25 insignificant. A double tail $\alpha \leq 0.05$ will be considered statistically significant. Certain
26 secondary outcomes, for example, adverse events, belong to dichotomous variables. If
27 the data are available, the risk ratio (RR) or odds ratio (OR) with 95% CIs will be
28 calculated for these secondary outcomes.
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41 If the results are statistically significant, the 95% prediction interval (PI) will be
42 calculated. The PI can be used to approximate the therapeutic effect in the new study²⁵
43 ²⁶, and may be suitable for decision analysis²⁷. To improve the actual application effect,
44 the number-needed-to-treat (NNT) will be estimated. The NNT will be evaluated using
45 a control group risk of 30%. Cohen's U3 index will be calculated to estimate the
46 percentile gain in the intervention group²⁸.
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58 Data synthesis

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

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

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

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56 No patients or members of the public will be involved.
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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 adults²⁹ and has significant negative effects on physical and mental health. Despite this, relatively few people seek treatment or consult a healthcare provider². 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 diazepam (BZ), benzodiazepine receptor agonists (BZRAs), phytotherapeutic substances, and melatonin³⁰, 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

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4 will provide a comprehensive review of RCTs to examine the effects of various exercise
5 training programs on sleep quality in the elderly with sleep disturbances. The study will
6 determine the exercise patterns that have the least adverse reactions and are the most
7 effective for older adults as well as providing objective evidence for the diagnosis and
8 treatment of sleep disturbances.
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14 The study may also reveal additional effects of exercise training in the elderly. For
15 example, the root causes of sleep disturbances (such as depression and pain), the types
16 of insomnia (the time taken to fall asleep and the maintenance of sleep), and the
17 presence of underlying diseases (such as hypertension and diabetes) may influence the
18 effects of exercise in the elderly. It is hoped that this meta-analysis will provide
19 objective evidence for the custom design and individualisation of exercise plans for
20 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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7 **DECLARATION OF INTEREST**
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10 The authors declare no competing interests.
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17 **PATIENT CONSENT FOR PUBLICATION**
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20 Not required.
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33 **Figure 1.** Flow diagram of study selection.
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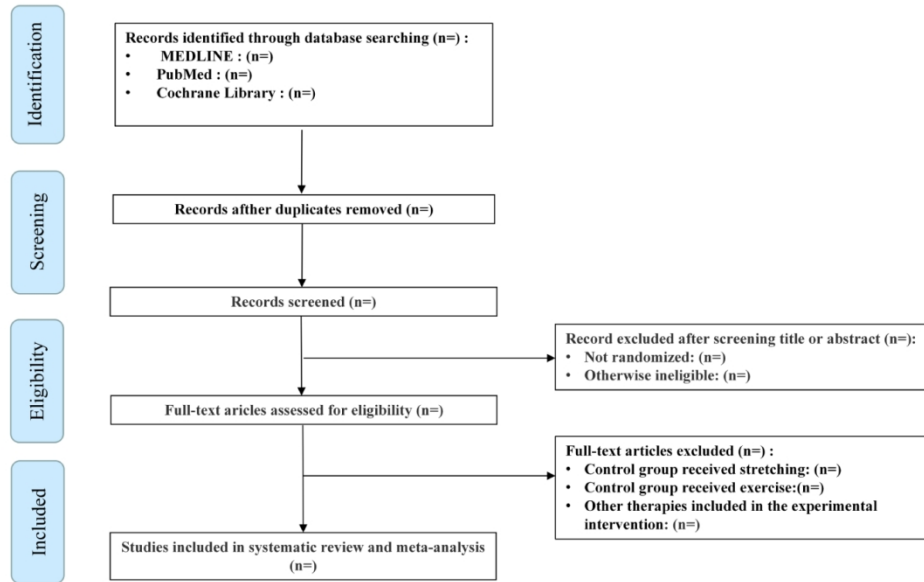


Figure 1. Flow diagram of study selection.

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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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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		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

1	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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7	Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	P.2
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12	Amendments			
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15		#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
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26	Sources	#5a	Indicate sources of financial or other support for the review	P.16
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29	Sponsor	#5b	Provide name for the review funder and / or sponsor	P.16
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32	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
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40	Rationale	#6	Describe the rationale for the review in the context of what is already known	P.4
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44	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
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51	Methods			
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54	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
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as criteria for eligibility for the review

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3	Information	#9	Describe all intended information sources (such as electronic	P.7
4	sources		databases, contact with study authors, trial registers or other	
5			grey literature sources) with planned dates of coverage	
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9	Search strategy	#10	Present draft of search strategy to be used for at least one	P.7
10			electronic database, including planned limits, such that it	
11			could be repeated	
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15	Study records -	#11a	Describe the mechanism(s) that will be used to manage	P.7
16	data management		records and data throughout the review	
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20	Study records -	#11b	State the process that will be used for selecting studies (such	P.8
21	selection process		as two independent reviewers) through each phase of the	
22			review (that is, screening, eligibility and inclusion in meta-	
23			analysis)	
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28	Study records -	#11c	Describe planned method of extracting data from reports	P.8
29	data collection		(such as piloting forms, done independently, in duplicate),	
30	process		any processes for obtaining and confirming data from	
31			investigators	
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35	Data items	#12	List and define all variables for which data will be sought	P.9
36			(such as PICO items, funding sources), any pre-planned data	
37			assumptions and simplifications	
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41	Outcomes and	#13	List and define all outcomes for which data will be sought,	P.8
42	prioritization		including prioritization of main and additional outcomes, with	
43			rationale	
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48	Risk of bias in	#14	Describe anticipated methods for assessing risk of bias of	P.9
49	individual studies		individual studies, including whether this will be done at the	
50			outcome or study level, or both; state how this information will	
51			be used in data synthesis	
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55	Data synthesis	#15a	Describe criteria under which study data will be quantitatively	P.8
56			synthesised	
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1	Data synthesis	#15b	If data are appropriate for quantitative synthesis, describe	P.9
2			planned summary measures, methods of handling data and	
3			methods of combining data from studies, including any	
4			planned exploration of consistency (such as I ² , Kendall's τ)	
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8	Data synthesis	#15c	Describe any proposed additional analyses (such as	P.9
9			sensitivity or subgroup analyses, meta-regression)	
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13	Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type	P.9
14			of summary planned	
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18	Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as	P.9
19			publication bias across studies, selective reporting within	
20			studies)	
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24	Confidence in	#17	Describe how the strength of the body of evidence will be	P.9
25	cumulative		assessed (such as GRADE)	
26	evidence			
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30 None The PRISMA-P checklist is distributed under the terms of the Creative Commons Attribution
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BMJ Open

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

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Manuscripts

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4 **Exercise improves sleep quality in older adults: a protocol for a systematic review**
5 **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.

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- 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.

For peer review only

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 sleep¹. It can be caused by variety of factors, often associated with physical diseases. The International Classification of Sleep disturbances (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 1985³. In Canada, more than 40% of people have sleep disturbances⁴. 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 delusions⁹, depression, anxiety, and dementia¹⁰ and often co-exist with major medical conditions, such as hypertension^{11,12}, diabetes¹³, and cancer¹⁴, 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 therapy¹⁷. Among these, pharmacological therapy is the most common treatment¹⁸. The use of sleep-inducing drugs can lead to negative effects such as drowsiness, gait disorders, and cognitive impairment¹⁹. 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 dependence²². It is, therefore, necessary to discover an effective non-drug treatment for insomnia.

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4 Age-related declines in physical activity and sleep are both important health
5 indicators for successful 'healthy ageing'. Exercise intervention began to receive
6 attention. Because comparing with traditional drug therapy, exercise is a low-cost
7 alternative therapeutic strategy with few adverse events. Present studies have shown an
8 association between exercise and sleep, mediated by a variety of psychological and
9 physiological pathways, and that moderate exercise can improve sleep quality²³. Due
10 to the different forms of exercise, durations, frequencies, and cycles of the exercise
11 interventions, the effects differ. Previous meta-analyses have drawn contradictory
12 conclusions about the effects of exercise on sleep²⁴⁻²⁸. And these only studied the effects
13 of a single or a few types of exercise on sleep. The question of which type of exercise
14 is most suitable for older adults was not investigated. It is also not clear how the
15 duration, frequency, and intensity of exercise affects sleep quality in the elderly.
16 Moreover, these studies did not explore differences in the effects of exercise on
17 different types of sleep disturbances. The etiology and clinical manifestations are
18 different for different sleep disturbances, so it is very necessary to develop personalized
19 exercise pattern for the elderly with sleep disturbances. Furthermore, additional studies
20 have appeared since the publication of these meta-analyses and this new evidence from
21 other randomized trials should be considered. Our aim, therefore, is to synthesis the
22 available evidence and conduct a high-quality meta-analysis to compare the effects of
23 different exercise patterns on sleep quality in the elderly.
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42 We have asked four primary questions in this study:

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

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

16 **Selection of studies**

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

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

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4 risk”, “bias uncertainty”, or “high bias risk”. Any disagreements in the abstracted data
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6 will be adjudicated by a third investigator (LDZ).
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10 Assessment of heterogeneity

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12 If the data is available, a heterogeneity analysis will be performed. The chi-square test
13 (test level: $\alpha = 0.1$) and I^2 will be used to test heterogeneity. If $P > 0.01$, there is no
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15 heterogeneity among the studies. If $P < 0.01$, there is heterogeneity among the studies.
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17 I^2 represents the level of heterogeneity between studies: if I^2 is between 0 and 40%, the
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19 heterogeneity is negligible, if I^2 is between 40 and 60%, there is moderate heterogeneity,
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21 if I^2 is between 60% and 75%, there is high heterogeneity, and if I^2 is between 75 and
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23 100%, this indicates very high heterogeneity.
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29 Assessment of reporting bias

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

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

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11 If the results are statistically significant, the 95% prediction interval (PI) will be
12 calculated. The PI can be used to approximate the therapeutic effect in the new study²⁹
13 ³⁰, and may be suitable for decision analysis³¹. To improve the actual application effect,
14 the number-needed-to-treat (NNT) will be estimated. The NNT will be evaluated using
15 a control group risk of 30%. Cohen's U3 index will be calculated to estimate the
16 percentile gain in the intervention group³².

27 28 Data synthesis

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

46 47 Subgroup analysis

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49 If sufficient RCTs are included, we will conduct a subgroup analysis when there is
50 significant heterogeneity in the study. We will conduct subgroup analyses of age,
51 gender, sports fields (indoor VS outdoor), sample size, research time (4 weeks, 8 weeks,
52 12 weeks, 16 weeks, and over 16 weeks), the existence of complications (hypertension,
53 diabetes, and cancer), the type of intervention, the type of sleep disturbance, and the
54 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 adults³³ and has significant negative effects on physical and mental health. Despite this, relatively few people seek treatment or consult a healthcare provider⁴. 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 diazepam (BZ), benzodiazepine receptor agonists (BZRAs),

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4 phytotherapeutic substances, and melatonin³⁴, may cause side-effects in patients with
5 long-term use. Therefore, exercise may be a useful alternative to improving sleep.
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8 Previous reviews and meta-analyses have attempted to investigate the effects of
9 exercise on insomnia. However, since most studies have only examined one or several
10 small-scale trials, they have not been able to find out which exercise patterns are most
11 effective for the elderly with sleep disturbances. This review and meta-analysis will
12 provide a comprehensive review of RCTs to examine the effects of various exercise
13 training programs on sleep quality in the elderly with sleep disturbances. The study will
14 determine the exercise patterns that have the least adverse reactions and are the most
15 effective for older adults as well as providing objective evidence for the diagnosis and
16 treatment of sleep disturbances.
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25 The study may also reveal additional effects of exercise training in the elderly. For
26 example, the root causes of sleep disturbances (such as depression and pain), the types
27 of sleep disturbances (such as insomnia disorders, sleep-related breathing disorders,
28 central disorders of hypersomnolence, circadian rhythm sleep-wake disorders), and the
29 presence of underlying diseases (such as hypertension and diabetes) may influence the
30 effects of exercise in the elderly. It is hoped that this meta-analysis will provide
31 objective evidence for customized exercise prescriptions for the elderly with sleep
32 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.

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4 **PATIENT CONSENT FOR PUBLICATION**
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7 Not required.
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15 **Figure 1.** Flow diagram of study selection.
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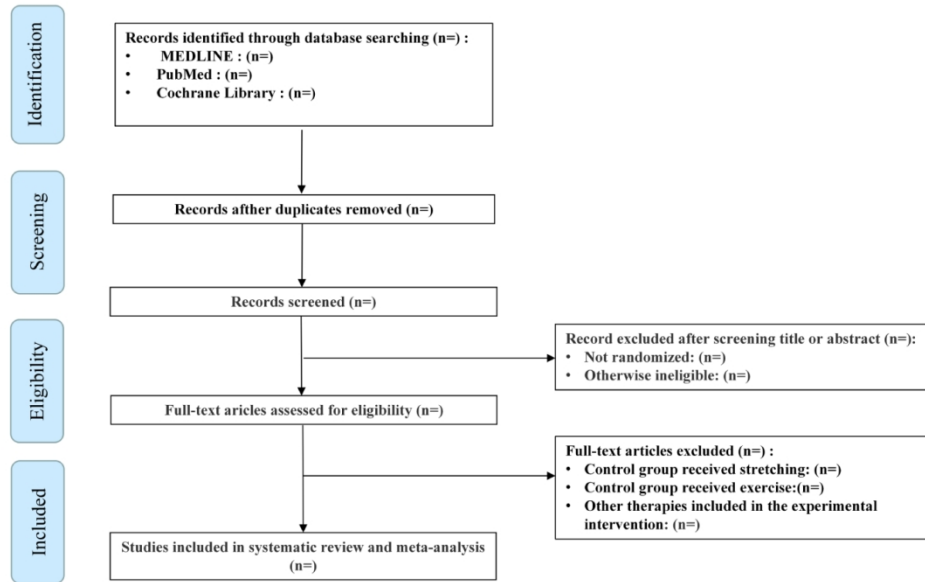


Figure 1. Flow diagram of study selection.

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.

Upload your completed checklist as an extra file when you submit to a journal.

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

1	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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7	Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	P.2
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12	Amendments			
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15		#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
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26	Sources	#5a	Indicate sources of financial or other support for the review	P.16
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29	Sponsor	#5b	Provide name for the review funder and / or sponsor	P.16
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32	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
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37	Introduction			
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40	Rationale	#6	Describe the rationale for the review in the context of what is already known	P.4
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44	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
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51	Methods			
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54	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
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as criteria for eligibility for the review

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3	Information	#9	Describe all intended information sources (such as electronic	P.7
4	sources		databases, contact with study authors, trial registers or other	
5			grey literature sources) with planned dates of coverage	
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9	Search strategy	#10	Present draft of search strategy to be used for at least one	P.7
10			electronic database, including planned limits, such that it	
11			could be repeated	
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15	Study records -	#11a	Describe the mechanism(s) that will be used to manage	P.7
16	data management		records and data throughout the review	
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20	Study records -	#11b	State the process that will be used for selecting studies (such	P.8
21	selection process		as two independent reviewers) through each phase of the	
22			review (that is, screening, eligibility and inclusion in meta-	
23			analysis)	
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28	Study records -	#11c	Describe planned method of extracting data from reports	P.8
29	data collection		(such as piloting forms, done independently, in duplicate),	
30	process		any processes for obtaining and confirming data from	
31			investigators	
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35	Data items	#12	List and define all variables for which data will be sought	P.9
36			(such as PICO items, funding sources), any pre-planned data	
37			assumptions and simplifications	
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41	Outcomes and	#13	List and define all outcomes for which data will be sought,	P.8
42	prioritization		including prioritization of main and additional outcomes, with	
43			rationale	
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48	Risk of bias in	#14	Describe anticipated methods for assessing risk of bias of	P.9
49	individual studies		individual studies, including whether this will be done at the	
50			outcome or study level, or both; state how this information will	
51			be used in data synthesis	
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55	Data synthesis	#15a	Describe criteria under which study data will be quantitatively	P.8
56			synthesised	
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1	Data synthesis	#15b	If data are appropriate for quantitative synthesis, describe	P.9
2			planned summary measures, methods of handling data and	
3			methods of combining data from studies, including any	
4			planned exploration of consistency (such as I ² , Kendall's τ)	
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8	Data synthesis	#15c	Describe any proposed additional analyses (such as	P.9
9			sensitivity or subgroup analyses, meta-regression)	
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13	Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type	P.9
14			of summary planned	
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18	Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as	P.9
19			publication bias across studies, selective reporting within	
20			studies)	
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24	Confidence in	#17	Describe how the strength of the body of evidence will be	P.9
25	cumulative		assessed (such as GRADE)	
26	evidence			
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BMJ Open

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

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Primary Subject Heading:	Sports and exercise medicine
Secondary Subject Heading:	Geriatric medicine, Global health, Public health
Keywords:	GERIATRIC MEDICINE, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Old age psychiatry < PSYCHIATRY, SLEEP MEDICINE

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4 **Exercise improves sleep quality in older adults: a protocol for a systematic review**
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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 sleep¹. It can be caused by variety of factors, often associated with physical diseases. The International Classification of Sleep disturbances (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 1985³. In Canada, more than 40% of people have sleep disturbances⁴. 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 delusions⁹, depression, anxiety, and dementia¹⁰ and often co-exist with major medical conditions, such as hypertension^{11,12}, diabetes¹³, and cancer¹⁴, 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 therapy¹⁷. Among these, pharmacological therapy is the most common treatment¹⁸. The use of sleep-inducing drugs can lead to negative effects such as drowsiness, gait disorders, and cognitive impairment¹⁹. 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 dependence²². It is, therefore, necessary to discover an effective non-drug treatment for insomnia.

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4 Age-related declines in physical activity and sleep are both important health
5 indicators for successful 'healthy ageing'. Exercise intervention began to receive
6 attention. Previous studies showed²³ that regular exercise offers many health benefits,
7 including reduced risk of chronic disease, all-cause mortality, and premature death.
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9 Because comparing with traditional drug therapy, exercise is a low-cost alternative
10 therapeutic strategy with few adverse events. Present studies have shown an association
11 between exercise and sleep, mediated by a variety of psychological and physiological
12 pathways, and that moderate exercise can improve sleep quality²⁴. Due to the different
13 forms of exercise, durations, frequencies, and cycles of the exercise interventions, the
14 effects differ. Previous meta-analyses have drawn contradictory conclusions about the
15 effects of exercise on sleep²⁵⁻²⁹. And these only studied the effects of a single or a few
16 types of exercise on sleep. The question of which type of exercise is most suitable for
17 older adults was not investigated. It is also not clear how the duration, frequency, and
18 intensity of exercise affects sleep quality in the elderly. Moreover, these studies did not
19 explore differences in the effects of exercise on different types of sleep disturbances.
20 The etiology and clinical manifestations are different for different sleep disturbances,
21 so it is very necessary to develop personalized exercise pattern for the elderly with sleep
22 disturbances. Furthermore, additional studies have appeared since the publication of
23 these meta-analyses and this new evidence from other randomized trials should be
24 considered. Our aim, therefore, is to synthesis the available evidence and conduct a
25 high-quality meta-analysis to compare the effects of different exercise patterns on sleep
26 quality in the elderly.
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46 We have asked four primary questions in this study:

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

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

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21 Studies that meet all of the following criteria will be included in the meta-analysis.
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23 **Types of studies**

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

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

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52 We will include RCTs which interventions that meet the above criteria and include at
53 least one exercise intervention. An intervention period of at least one month was chosen.
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55 The eligible types of exercise will be the following:
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- 58 ● Tai Chi
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- 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) from 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,

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4 insomnia duration, sleep disturbances, habitual sleep efficiency, sleep latency, daytime
5 dysfunction, and the use of sleeping pills. Pittsburgh sleep quality index (PSQI)³⁰ will
6 be employed as the primary outcome measurement. The PSQI consists of 19 questions
7 generating 7 components, each with a score from 0 to 3. The seven scores are added
8 together to generate a global PSQI score (ranging from 0 to 21). A score greater than 5
9 indicates clinical sleep disturbances. The adverse events refer to falls, fractures, and
10 death. Other standardized instruments or scales, such as the Self- Rating Scale of Sleep
11 (SRSS)³¹, Athens insomnia scale³² and the insomnia severity index³³ will be included.
12 The adverse events refer to muscle sprains and pains, myocardial infarction and stroke.
13 In the event of a dispute over the included data, the two investigators will discuss and
14 resolve the problem and, if necessary, the third researcher (JY) will join the discussion.
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27 **Statistical analysis**

28 Study quality assessment

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

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50 If the data is available, a heterogeneity analysis will be performed. The chi-square test
51 (test level: $\alpha = 0.1$) and I^2 will be used to test heterogeneity. If $P > 0.01$, there is no
52 heterogeneity among the studies. If $P < 0.01$, there is heterogeneity among the studies.
53 I^2 represents the level of heterogeneity between studies: if I^2 is between 0 and 40%, the
54 heterogeneity is negligible, if I^2 is between 40 and 60%, there is moderate heterogeneity,
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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 adults³⁸ and has significant negative effects on physical and mental health. Despite this, relatively few people seek treatment or consult a healthcare provider⁴. 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 diazepam (BZ), benzodiazepine receptor agonists (BZRAs), phytotherapeutic substances, and melatonin³⁹, 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

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4 presence of underlying diseases (such as hypertension and diabetes) may influence the
5 effects of exercise in the elderly. It is hoped that this meta-analysis will provide
6 objective evidence for customized exercise prescriptions for the elderly with sleep
7 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.

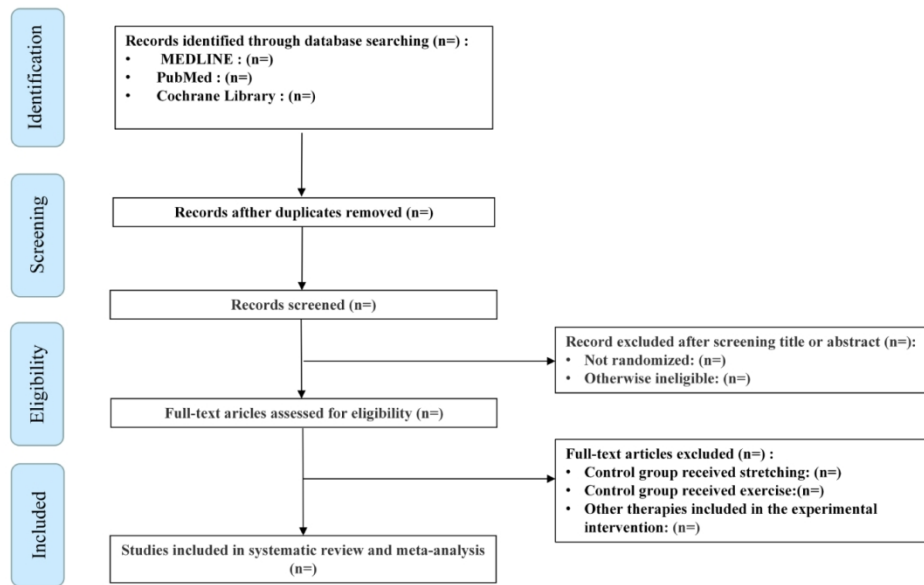


Figure 1. Flow diagram of study selection.

Flow diagram of study selection.

121x91mm (300 x 300 DPI)

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

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7 #1 'Randomized Controlled Trials' OR 'Random allocation' OR 'Controlled
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9 Clinical Trials' OR 'Control groups' OR 'Clinical trials' OR 'Clinical Trials
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11 Data Monitoring Committees' OR 'Double- blind method' OR 'Single- blind
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13 method'
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17 #2 'Exercise' OR 'Exercise Therapy' OR 'Exercise' OR 'Physical Activity' OR
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19 'Aerobic Exercise' OR 'Train' OR 'High-Intensity Interval Training' OR
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21 'Resistance exercise' OR 'Endurance training' OR 'Tai Chi' OR 'Qigong' OR
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23 'Yoga' OR 'Bagua'
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27 #3 'Sleep disturbance' OR 'Sleep quality' OR 'Insomnia' OR 'Sleep complaints'
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29 OR 'Sleep disorder'
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32 #4 #1 and #2 and #3
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35 #5 Search (#4 NOT animal[mh])
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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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		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

1	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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7	Contribution	#3b	Describe contributions of protocol authors and identify the guarantor of the review	P.2
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12	Amendments			
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15		#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
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23	Support			
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26	Sources	#5a	Indicate sources of financial or other support for the review	P.16
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29	Sponsor	#5b	Provide name for the review funder and / or sponsor	P.16
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32	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
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37	Introduction			
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40	Rationale	#6	Describe the rationale for the review in the context of what is already known	P.4
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44	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
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51	Methods			
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54	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
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as criteria for eligibility for the review

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3	Information	#9	Describe all intended information sources (such as electronic	P.7
4	sources		databases, contact with study authors, trial registers or other	
5			grey literature sources) with planned dates of coverage	
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9	Search strategy	#10	Present draft of search strategy to be used for at least one	P.7
10			electronic database, including planned limits, such that it	
11			could be repeated	
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15	Study records -	#11a	Describe the mechanism(s) that will be used to manage	P.7
16	data management		records and data throughout the review	
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20	Study records -	#11b	State the process that will be used for selecting studies (such	P.8
21	selection process		as two independent reviewers) through each phase of the	
22			review (that is, screening, eligibility and inclusion in meta-	
23			analysis)	
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28	Study records -	#11c	Describe planned method of extracting data from reports	P.8
29	data collection		(such as piloting forms, done independently, in duplicate),	
30	process		any processes for obtaining and confirming data from	
31			investigators	
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35	Data items	#12	List and define all variables for which data will be sought	P.9
36			(such as PICO items, funding sources), any pre-planned data	
37			assumptions and simplifications	
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41	Outcomes and	#13	List and define all outcomes for which data will be sought,	P.8
42	prioritization		including prioritization of main and additional outcomes, with	
43			rationale	
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48	Risk of bias in	#14	Describe anticipated methods for assessing risk of bias of	P.9
49	individual studies		individual studies, including whether this will be done at the	
50			outcome or study level, or both; state how this information will	
51			be used in data synthesis	
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55	Data synthesis	#15a	Describe criteria under which study data will be quantitatively	P.8
56			synthesised	
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1	Data synthesis	#15b	If data are appropriate for quantitative synthesis, describe	P.9
2			planned summary measures, methods of handling data and	
3			methods of combining data from studies, including any	
4			planned exploration of consistency (such as I ² , Kendall's τ)	
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8	Data synthesis	#15c	Describe any proposed additional analyses (such as	P.9
9			sensitivity or subgroup analyses, meta-regression)	
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13	Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type	P.9
14			of summary planned	
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18	Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as	P.9
19			publication bias across studies, selective reporting within	
20			studies)	
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24	Confidence in	#17	Describe how the strength of the body of evidence will be	P.9
25	cumulative		assessed (such as GRADE)	
26	evidence			
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30 None The PRISMA-P checklist is distributed under the terms of the Creative Commons Attribution
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