Study Protocol Systematic Review

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Effects of core stability exercise for patients with neck pain

A protocol for systematic review and meta-analysis

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Abstract

Background: Neck pain is an important cause of disability. In spite of its high prevalence rate, treatment of the disorder is a challenging topic. Exercise therapy appears to be effective at decreasing pain and improving function for patients with NP in practice guidelines. Core stability exercise is becoming increasingly popular for NP. However, it is currently unknown whether core stability exercise produces more beneficial effects than general exercise in patients with NP. The aim of this study is to explore the therapeutic effect of core stability exercise for neck pain.

Methods: This review will only include randomized controlled trials (RCTs). Published articles from July 2009 to July 2019 will be identified using electronic searches. Search strategy will be performed in 3 English databases, 1 Chinese database, and the WHO International Clinical Trials Registry Platform. Two reviewers will screen, select studies, extract data, and assess quality independently. The methodological quality including the risk of bias of the included studies will be evaluated using a modified assessment form, which is based on Cochrane assessment tool and Physiotherapy Evidence Database scale. Review Manager Software (Revman5.3) will be used for heterogeneity assessment, generating funnel-plots, data synthesis, subgroup analysis, and sensitivity analysis. We will use GRADE system to evaluate the quality of our evidence.

Results: We will provide some more practical and targeted results investigating the effect of Core Stability Exercise (CSE) for Neck Pain (NP) in the current meta-analysis. Meanwhile, we will ascertain study progress of Core Stability Exercise for Neck Pain and find out defects or inadequacies of previous studies, so that future researchers could get beneficial guidance for more rigorous study.

Conclusion: The stronger evidence about Neck Pain's rehabilitative effect and safety will be provided for clinicians and policymakers.

Systematic review registration: PROSPERO CRD42017055711.

Ethics and dissemination: We do not apply for formal ethical approval from ethics committee because all of the study data in our review will be obtained in an anonymous way. Findings of this study are projected to be disseminated through peer-review publications.

Abbreviations: CI = confidence interval, CSE = Core Stability Exercise, NP = Neck Pain, RCT = randomized controlled trial.

Keywords: core stability exercise, meta-analysis, neck pain, patients, systematic review

1. Introduction

1.1. Description of the condition

Neck pain (NP) is a disagreeable sensation of different intensity, can be caused both by disease and injury to the structures in the neck, such as the muscles, ligaments and nerves.[1,2]

According to the International Association for the Study of Pain,[3] chronic pain in the neck or cervical column is a musculoskeletal disorder.[4] It is defined as persistent pain in the posterior cervical region, between the inion and the first thoracic vertebra, lasting 3 months or longer and is caused by a degenerative or inflammatory disorder of the joints often associated with nerve pain in the neck or cervical region, and possibly limiting movement resulting in disability and reduced quality of life. In order to improve patients' functional status and quality of life, it is important to understand which structures are capable of producing pain and disability. Over the past decade, numerous studies have shown an association between reduction in the strength and endurance capacity of the cervical muscles and

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Results of the current study will be disseminated through peer-reviewed publications.

The authors have no conflicts of interest to disclose.

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neck pain.[5–7] It has been found that certain muscles in the cervical spine tend to weaken in neck pain; the most common of these being the deep and anterior cervical flexors.[6–8] A study of patients with osteoarthritis showed more pronounced fatigue curves for anterior and posterior neck muscles than for the muscles of the control group.[9] Thus, in order to gain muscle strength, flexibility and endurance, to restore injured tissues, and to contribute to ability to sustain normal life activities, exercise is one of the most frequently used modalities in the rehabilitation of subjects with neck pain.[10]

1.2. Description of intervention

In recent years, Core stability training has become a popular fitness trend that has begun to be applied in rehabilitation programs and in sports medicine.[11] Core exercises have a positive effect on reducing lower back pain,[12] improving upper extremities in breast cancer patients[13] and lower extremities in patients with total hip and knee arthroplasty,[14] as well as performance improvement for athletes.[15] Core exercises are taken seriously in rehabilitation, medical care, and sports.[16] On the other hand, neck stabilization exercises (NSE) were introduced as a rehabilitation program to limit pain, maximize function, and prevent further injury.[17,18] It is a method of exercise which, like its counterpart in the lumbar spine, is designed to improve the inborn mechanisms by which the cervical spine maintains a stable, injury-free state.[19] This is accomplished through a series of exercises that are relatively simple with respect to time and equipment, but are physiologically complex. Despite the popularity of stabilization training in the treatment of back and pelvic pain,[20,21] However, it is currently unclear whether core stability training produces more beneficial effects than conventional exercise for patients with NP.

1.3. Objective of this study

The objective of our study was to review all observational studies or clinical studies of patients with NP treated using various core stability exercises compared with other techniques to establish the efficacy of core stability exercises when used for this purpose.

2. Methods

This review protocol has been registered in the PROSPERO, which is the International Prospective Register of systematic reviews. Its registration number was CRD42017055711. Cochrane Handbook of Systematic Reviews of Interventions (Version 5.1.0, http://www.cochranehandbook.org) will guide this systematic review. The statement of preferred reporting items for systematic review and meta-analysis protocols[22] and preferred reporting items for systematic reviews and meta analyses (PRISMA)[23] will be used as guidelines for reporting present review protocol and the formal paper that follows. This protocol for systematic review and meta-analysis comes from published data and does not involve patients, so no ethical approval is required.

2.1. Inclusion criteria for study selection

2.1.1. Types of studies. Only randomized controlled trials (RCTs)will be included, whereas non-RCTs, quasi-RCTs, and any other types of studies will be excluded.

2.1.2. Types of participants. In our study, participants will be diagnosed as NP regardless of their age, sex, or race.

2.1.3. Types of interventions. We will include articles comparing treatment groups which received core stability exercise. The core stability exercise program can be described as enhancing the ability to ensure a stable neutral spine position.[11] Core stability exercises are usually performed on unstable equipment such as inflatable disks, low-density MATS, swing boards or Swiss balls and so on.[24]

2.1.4. Types of outcome assessments. In our study, primary outcomes will include pain score. Secondary outcomes will include neck function and disability, health-related quality of life, and adverse events.

2.1.5. Search strategy. To avoid losing any available literature that might meet our needs, we will systematically search the following electronic databases: PUBMED, The Cochrane Library, EMBASE, China Biology Medicine disc. All English and Chinese literature, published from July 1, 2009 to July 1, 2019, will seek to be unrestricted by race, gender or region. Our search will also include the WHO International Clinical Trial Registry Platform and its Registry Network for additional unpublished or ready to be published studies. In addition, the list of references to previous clinical studies and reviews will be served as the searching object. Search strategies will be established according to the Cochrane handbook. PUBMED's search strategy is shown in Table 1, and similar search strategies will be used for other electronic databases.

2.2. Data collection and analysis

2.2.1. Selection of studies. First of all, 2 review authors (XZ and LX) will independently examine the titles and abstracts of the search results and make a preliminary selection of possible articles. The Endnote X7 software will be used to record and manage them. Second, through continuous reading of the full text of the preliminary selective papers, 2 independent reviewers select eligible studies on the basis of our pre-determined inclusion criteria. Finally, the articles selected by two independent reviewers will be sorted out after the same contents are removed. If 2 articles are on behalf of duplicate publications of a study, only the 1 with the most complete data will be included. To resolve differences regarding inclusion or exclusion, 2 independent reviewers will first discuss with each other and then negotiate with another experienced reviewer YH. All eligible studies will be included in qualitative and/or quantitative analyses. Details of the entire selection process are shown in a PRISMA flow chart[25] (Fig. 1).

2.2.2. Data and information extraction. We will make a detailed data and information extraction table (Table 2), which mainly includes the following items:

1. Published materials (first author's name, contact information, year, Country, and region);
2. Participants' characteristics (Source, Sample size, Sex ratio, Mean age, Race ratio, NP duration, Lesion side, NP type and severity, Use of painkillers for daily living or sleep disorders);
3. Intervention measures (CSE Styles, Frequency of each training, Time of each training, Total training time);
4. Comparison (Treatment modes and types, Frequencies, Time or dose per treatment, Course of treatment);
5. Outcomes and others (Scale tools, Evaluation time, Outcome details, Informed consent, Adverse events, Drop-out rates and causes, Costs and funding sources);

Table 1

Search strategy for PUBMED.

Number	Search items
#1	"Single-Blind Method"[Mesh] OR "Double-Blind Method"[Mesh] OR "Randomized Controlled Trials as Topic"[Mesh] OR "Randomized Controlled Trial" [Publication Type] OR "Intention to Treat Analysis"[Mesh] OR "Controlled Clinical Trials as Topic"[Mesh] OR "Clinical Trials as Topic"[Mesh] OR "Clinical Trial" [Publication Type] OR randomized controlled trial[Publication Type]
#2	"random*"[Text Word] OR allocation[Text Word] OR "random allocation"[Text Word] OR placebo[Text Word] OR single blind[Text Word] OR double blind[Text Word] OR "randomized controlled trial*"[Text Word] OR RCT[Text Word]
#3	#1 OR #2
#4	animals NOT humans
#5	#3 NOT #4
#6	#3 AND #5
#7	"Neck Pain"[Mesh] OR "Neck Pains"[Title/Abstract] OR "Pain, Neck"[Title/Abstract] OR "Pains, Neck"[Title/Abstract] OR "Neck Ache"[Title/Abstract] OR "Ache, Neck"[Title/Abstract] OR "Aches, Neck"[Title/Abstract] OR "Neck Aches"[Title/Abstract] OR "Cervicalgia"[Title/Abstract] OR "Cervicalgias"[Title/Abstract] OR "Cervicodynia"[Title/Abstract] OR "Cervicodynias"[Title/Abstract] OR "Neckache"[Title/Abstract] OR "Neckaches"[Title/Abstract] OR "Cervical Pain"[Title/Abstract] OR "Cervical Pains"[Title/Abstract] OR "Pain, Cervical"[Title/Abstract] OR "Pains, Cervical"[Title/Abstract] OR "Posterior Cervical Pain"[Title/Abstract] OR "Cervical Pain, Posterior"[Title/Abstract] OR "Cervical Pains, Posterior"[Title/Abstract] OR "Pain, Posterior Cervical"[Title/Abstract]) OR "Pains, Posterior Cervical"[Title/Abstract]) OR "Posterior Cervical Pains"[Title/Abstract] OR "Posterior Neck Pain"[Title/Abstract] OR "Neck Pain, Posterior"[Title/Abstract] OR "Neck Pains, Posterior"[Title/Abstract] OR "Pain, Posterior Neck"[Title/Abstract] OR "Pains, Posterior Neck"[Title/Abstract] OR "Posterior Neck Pains"[Title/Abstract] OR "Anterior Cervical Pain"[Title/Abstract] OR "Anterior Cervical Pains"[Title/Abstract] OR "Cervical Pain, Anterior"[Title/Abstract] OR "Cervical Pains, Anterior"[Title/Abstract] OR "Pain, Anterior Cervical"[Title/Abstract] OR "Pains, Anterior Cervical"[Title/Abstract] OR "Anterior Neck Pain"[Title/Abstract] OR "Anterior Neck Pains"[Title/Abstract] OR "Neck Pain, Anterior"[Title/Abstract] OR "Neck Pains, Anterior"[Title/Abstract] OR "Pain, Anterior Neck"[Title/Abstract] OR "Pains, Anterior Neck"[Title/Abstract]
#8	"Exercise"[Mesh] OR "Exercises"[Title/Abstract] OR "Physical Activity"[Title/Abstract] OR "Activities, Physical"[Title/Abstract] OR "Activitie, Physical"[Title/Abstract] OR "Physical Activities"[Title/Abstract] OR "Exercise, Physical"[Title/Abstract] OR "Exercises, Physical"[Title/Abstract] OR "Physical Exercise"[Title/Abstract] OR "Physical Exercises"[Title/Abstract] OR "Acute Exercise"[Title/Abstract] OR "Acute Exercises"[Title/Abstract] OR "Exercise, Acute"[Title/Abstract] OR "Exercises, Acute"[Title/Abstract] OR "Exercise, Isometric"[Title/Abstract] OR "Exercises, Isometric"[Title/Abstract] OR "Isometric Exercise"[Title/Abstract] OR "Isometric Exercises"[Title/Abstract] OR "Exercise, Aerobic"[Title/Abstract] OR "Aerobic Exercise"[Title/Abstract]) OR "Aerobic Exercises"[Title/Abstract] OR "Exercises, Aerobic"[Title/Abstract] OR "Exercise Training"[Title/Abstract] OR "Exercise Trainings"[Title/Abstract] OR "Training, Exercise"[Title/Abstract] OR "Trainings, Exercise"[Title/Abstract]
#9	#6 AND #7 AND #8

6. Study design (Randomized, blinded).

The above information or data will be obtained through reading the full text and contact the original investigator for confirmation. Data and information management will use Microsoft Excel 2013.

2.2.3. Dealing with missing data. The missing data may influence research results to some extent and even lead to different research conclusions. Therefore, in the process of data extraction, we will contact the author of the article or the original researcher to determine whether there is any missing data in each included study. If there is missing data, we will further examine and record how they are processed in the statistical analysis, and evaluate whether their methods are reasonable. If the processing method is unlikely to significantly distort the statistical results, we will combine their data. Otherwise, we will have to stop synthesizing these data to reduce bias. For a small number of research results lacking standard deviation, we will try to get from the original researchers. If the attempts fail, we will attempt to fix them by borrowing the standard deviations of the most similar studies. Importantly, we will analyze and report on the potential impact of missing or incomplete data in the summary results.

2.2.4. Appraisal of study quality. In view of the specificity of CSE interventions, we developed a revised assessment form based on the Cochrane tool bias risk and physiotherapy evidence database (PEDro) scale to assess methodological quality of eligible studies. The revised evaluation form mainly includes the following 11 items: item 1= clear inclusion criteria; Item 2 = prior sample size estimation; Item 3 = similar baseline; Item 4 = randomization; Item 5 = hidden order of assignment; Item 6 = CSE isolated intervention; Item 7 = blind jurors; Item 8 = pre-posttest design; Item 9 = cross-domain comparisons; Item 10= retention rate over 85%; Item 11= management of missing data (if missing data exists); Item 12 = selective reporting. Each item will be graded as Y = yes (clearly described in the article and verified by communication), or N=no (absent or unclear). The Y value of the project identification is 1, and the N value of the project identification is 0. According to the total score, each study was divided into three quality levels: high (10–12 points), medium (6–9 points) and low (0–5 points). The details of the qualitative assessment are shown in Figure 2.

Prior to the appraisal of the above methodology project, two independent reviewers (XZ and LX) communicate and verify with the original author in advance to avoid misjudgment. As the primary basis for evaluating the quality and classification of research, all responses or explanations of the original authors are recorded in detail. Any differences will be resolved through discussion and negotiation with a third experienced reviewer YH.

2.2.5. Assessment of reporting bias. If there are no <10 studies available for quantitative analysis, we will generate funnel plots to assess reported bias. For continuous variables, the Egger test will also be adopted to check the asymmetry of funnel plots. However, even if the test does not provide evidence of funnel plot asymmetry, reporting bias (including publication bias) cannot be excluded due to the relatively low testing capacity. Asymmetric funnel plots are generally considered to have publication bias, which is a type of reporting bias, but it also implies that there may be other causes, such as differences in methodological quality or true heterogeneity of intervention effects. We will analyze the possible reasons and give a reasonable explanation for the asymmetric funnel plot.

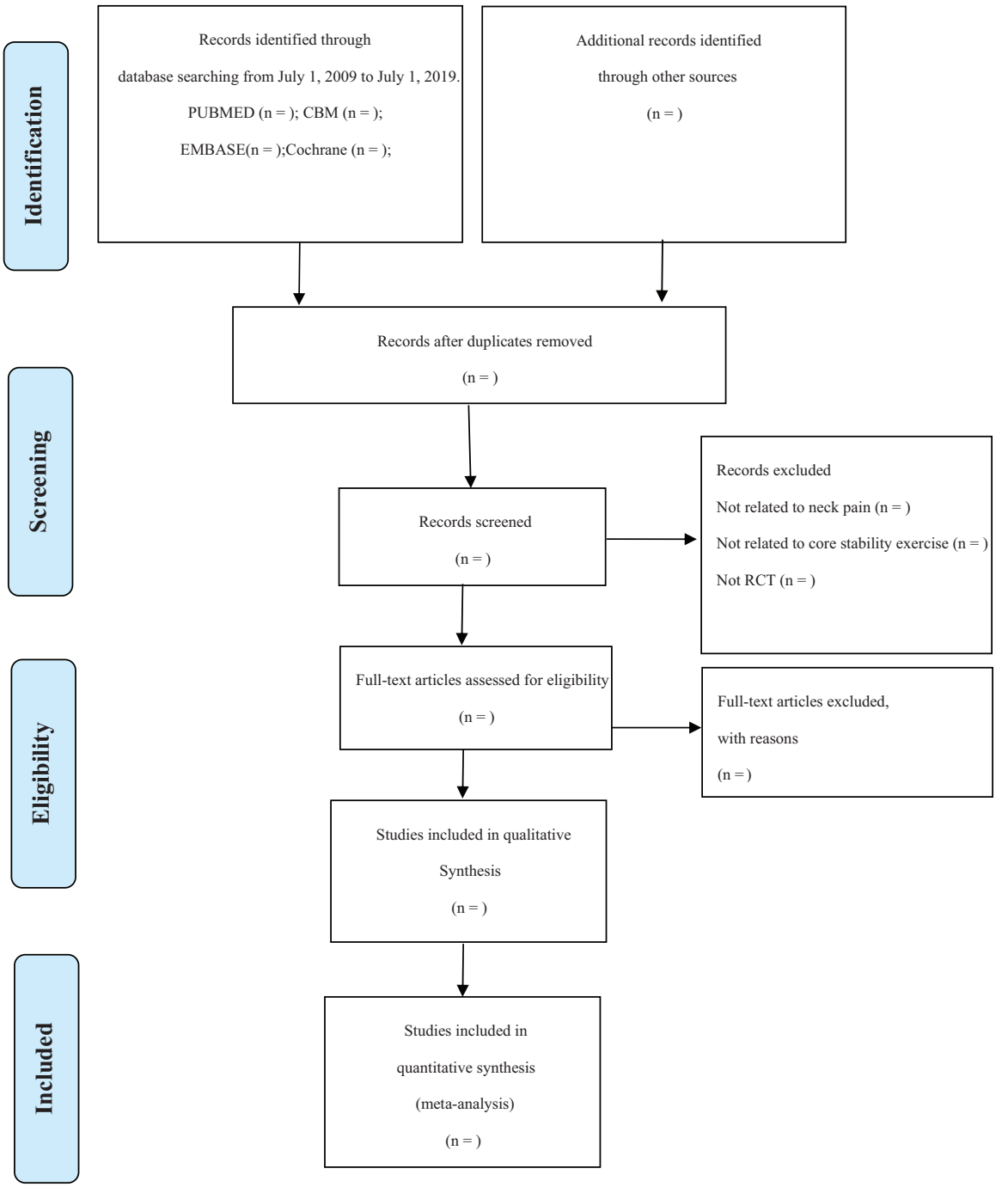

Figure 1. Flow diagram of study selection. CBM = Chinese BioMedicial Literature Database, RCT = randomized controlled trial.

2.2.6. Assessment of heterogeneity. Heterogeneity evaluation included 2 heterogeneity tests, x^2 test (significance level:0.1) and I^2 test. The former checks for heterogeneity, while the latter reflects the degree of heterogeneity through a specific value (typically 25% or less = low, 25% to 75% = medium, 75% or more = high). When high heterogeneity occurs, we will analyze its possible sources.

2.2.7. Measure of treatment effect. For dichotomous variables such as adverse events, we will calculate the risk ratio or odds ratio with 95% confidence interval (CI). For continuous variables, we will calculate the mean difference from 95% CI or the standard mean difference.

2.2.8. Data synthesis. Quantitative synthesis will be carried out after qualitative analysis. Qualified studies with complete and no missing data will be quantitatively synthesized. It will also include studies of incomplete data for quantitative synthesis where data can be retrieved or reasonably repaired. Only qualitative analysis can be carried out for the research that has been existed with

Table 2

Data and information extraction schedule.

Subject	Contents
Publication	Name of first author, Contact details, Year, Country, and region
Participants	Source, Sample size, Average age, Sex ratio, NP duration, NP types and severity, Compliances of mental disorders or sleep disorders, Neck dysfunction, Usage of drug for NP
Interventions	CSE styles, Training frequencies and training time of every time, Total training time
Comparison	Treatment ways and types, Frequencies, Treatment time or dose of every time, Course of treatment
Outcomes	Scale instruments, Assessment time, Details of results (e.g. means and standard deviations)
Study design	Randomization realization, Blinding implementation
Others	Informed consent, Drop-out rate and reasons, Adverse events, Costs and funding sources

CSE = core stability exercise, NP = neck pain.

Item	*Contents*	*Identification*	*Total Scores*	*Quality*
1	explicit inclusion criteria	*Y or N*	*0 ~ 5 or 6 ~ 9 or 10 ~ 12*	*High or Moderate or Low*
2	prior sample size estimation	*Y or N*		
3	similar baseline	*Y or N*		
4	randomization	*Y or N*		
5	allocation sequence concealment	*Y or N*		
6	isolated Tai Chi intervention	*Y or N*		
7	blinding of assessors	*Y or N*		
8	pre-posttest design	*Y or N*		
9	cross-group comparison	*Y or N*		
10	more than 85% retention	*Y or N*		
11	missing data management	*Y or N*		
12	selective reporting	*Y or N*		

Y = yes (explicitly described in article and verified by communication); *N* = no (absent or unclear). *Y* scores 1, *N* scores 0. Three quality level: high (total scores 10-12), moderate (total scores 6-9), low (total scores 0-5).

Figure 2. Modified assessment form. Y = yes (explicitly described in article and verified by communication); N = no (absent or unclear). Y scores 1, N scores 0. Three quality level: high (total scores 10-12), moderate (total scores 6–9), low (total scores 0–5).

incomplete data and/or unreasonable methods for processing missing data. Quantitative data synthesis will be carried out by Review Manager software (Revman5.3, available from the Cochrane Web site http://tech.cochrane.org/Revman). If the I^2 value is no $> 50\%$, indicating relatively small heterogeneity, the fixed effect model should be used to obtain the comprehensive results. Otherwise, the random effect model will be used.

2.2.9. Subgroup analysis. Considering the possibility of high heterogeneity, we will conduct a subgroup analysis project to get an objective conclusion. First, data of participants in different recovery periods (within 1 month, 2–6 months, and 6 months or more) will be analyzed. Second, data of different comparative designs, such as CSE and blank control, CSE and conventional rehabilitation therapy (CRT), combined application of CSE and CRT, will be analyzed. Third, if possible, analyze the data separately for different CSE styles, training times, and frequencies. In addition, heterogeneity may be higher due to factors such as quality of test methodology, age, lesion site or nature, severity, ability to live daily or sleep disorders. These factors need to be considered in subgroup analysis.

2.2.10. Sensitivity analysis. After data synthesis, we plan to conduct sensitivity analysis by excluding combined studies one by one to observe whether there is significant change in the comprehensive results. Significant changes are reflected in studies that are sufficient to affect the overall synthesis results, so it is necessary to reevaluate them and make a careful decision whether

to merge or not. We must give a reasonable reason before we make a decision. If there is no significant change, we can assume that our overall results are firm.

2.2.11. Quality of evidence. An internationally recognized scoring system will be used to assess the quality of our evidence. We will use GRADEpro3.6 software to qualitatively evaluate the level of evidence. Considering the fact that only RCT is accepted, we will downgrade the quality of the evidence model, which involves the following five factors: risk of bias, inconsistency, indirectness, inaccuracy, and publication bias. The level of evidence will be high, medium, low and very low.

3. Discussion

As the saying goes: "Exercise is the medicine". Stability training exercises such as yoga, pilates, sling, bobath balls, etc, are often recommended for neck pain and low back pain. However, few high-quality studies could provide strong evidence about their efficacy and safety. Investigators have made some systematic reviews or meta-analyses to get comprehensive evidence in recent years. A meta-analysis demonstrated that compared to general exercise, core stability exercise is more effective in decreasing pain and may improve physical function in patients with chronic LBP in the short term.[16,26] Another meta-analysis showed that there was inconclusive evidence for the effectiveness of non-invasive management of cervicobrachial pain. Effects of non-invasive management on function and disability were mixed. Future studies should identify which sub-groups of cervicobrachial pain respond to specific interventions.[27] A meta-analysis of manual therapy and exercise showed that combining different forms of manual therapy with exercise is better than manual therapy, nevertheless, future RCTs should be more rigorous in their investigation by not mixing categories of patients as well as intervention types.[28] Therefore, this paper conducted a meta-analysis on the treatment of neck pain with core stability exercise, providing more reliable evidence for future studies. It is noteworthy that this study lacks subgroup analysis according to the types of different core stability exercises, which may lead to relative broad conclusions. To the best of our knowledge, there has been no one meta-analysis specially analyzing CSE's effect for NP. We hope to provide more practical and targeted results investigating the effect of CSE for NP in the current systematic review and meta-analysis.

As is known, the key to achieve a reliable meta-analysis result lies in incorporating sufficient data from high-quality original literature and perform rigorous methodological quality assessment. Allowing for the particularity of CSE, we make a modified assessment form which incorporates the advantages of Cochrane assessment tool and PEDro scale, making our qualitative evaluation more reasonable and practical. And also, it is sensible that our quality assessment will not only include reading original articles to know methodological execution but also making verification with original authors to reduce the possibility of misjudgment.

The strengths of our study mainly include that comprehensive searching for Chinese and English databases, rigorous evaluation of quality, and sensible subgroup analysis design, all of which will make our analysis result more convictive. One limitation of this review is that we will only search Chinese and English databases, possibly missing some articles published using other language. Another limitation is that the large heterogeneity may emerge, leading to adverse effect on the final conclusion.

Author contributions

Conceptualization: Yikang He, Zengbin Zheng, Liang Xu.
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Funding acquisition: Ming Ma, Wudong Sun.
Investigation: Xianghu Zhao, Ming Ma, Liang Xu.
Methodology: Xianghu Zhao, Ming Ma, Liang Xu.
Software: Zengbin Zheng, Liang Xu.
Supervision: Ming Ma.
Writing – original draft: Xianghu Zhao, Yikang He, Zengbin Zheng.
Writing – review & editing: Ming Ma, Wudong Sun.

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