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Acupuncture and the Acupoints Selections for Myopia: A Systematic Review and Meta-Analysis Protocol

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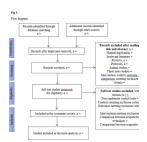
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Abstract

Myopia is a common worldwide disease and one of the leading factors of some severe visual impairments. Some systematic reviews have been conducted to summarize the efficacy of acupuncture for myopia. However, the heterogeneity of methods among acupuncture studies are high and there's no systematic review and meta-analysis that evaluate the effectiveness of traditional acupuncture on local, distal, and the combination of local and distal acupoints. The present study will use a systematic review and meta-analysis of randomized controlled trials, focusing on traditional needling techniques alone or in combination with other treatments, compared to active therapy controls. We will identify the most commonly used acupoints for myopia and, if more than two studies are available, conduct a meta-analysis and subgroup analysis to determine the most effective acupoints. We expect this study to provide more comprehensive evidence on the specific acupoint strategies in the traditional acupuncture that are most beneficial for myopia management.

Attachments



For Protocol 0410202...

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Objective

This study aimed to examine the therapeutic effect of traditional acupuncture on multi acupoints selection on myopia

Materials and Methods

2 Study Registration

The present systematic review will use Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) procedure and the Cochrane Handbook for Systematic Reviews of Interventions' guidelines with the help of RevMan 5.4.1 software for the overall and sub-group meta-analysis. This review is already registered in PROSPERO (CRD42021240408).

3 Types of Study

Inclusion Criteria

- 1) **Intervention**: Traditional acupuncture using needling techniques at selected local, distal, or combination of local and distal acupoints as the primary treatment, with or without other treatments and medications
- 2) Control: active treatment, such as massage, eye steam, other medications, or eye drops
- 3) **Participants**: patients diagnosed with myopia
- 4) **Study type**: randomized controlled trial, two arm/two groups studies.
- 5) **Outcomes**: The primary outcomes will be clinical efficacy (Risk Ratio), and the secondary outcomes will be visual acuity (standardized mean difference, SD change difference), diopter, ocular pressure, and subjective vision improvements (if available).

Exclusion Criteria

- 1) **Intervention**: non-needling traditional acupuncture techniques (acupressure), and the use of heating/moxibustion, electricity, or laser during needling, and acupuncture as adjunct treatment of other primary treatment,
- 2) **Control**: other types of acupuncture, other types of acupoints, and inactive controls such as eye health guidance or eye glasses,
- 3) **Types of study**: Non Randomized Controlled Trials or Pseudo RCTs, animal studies, three arms or three groups studies, case studies, comparison between acupoints studies, comparison between different acupuncture methods studies, protocols, reviews, literature reviews, meta-analyses, and qualitative studies.
- 6) **Outcomes**: those that are not clinical efficacy as the primary, or visual acuity, diopter and subjective visual acuity as the secondary
- 7) Participants: Non myopia patients

4 Search Method

Two reviewers (L.F. and G.Z.) will independently conduct electronic database searches for relevant studies published between 2014 and 2024 based on predefined search terms (see



attached PDF). This study will include four English-language electronic databases: PubMed, COCHRANE/CENTRAL, Medline/OVID, and Embase, as well as four Chinese biomedical databases: Wanfang Database, China Network Knowledge Infrastructure (CNKI), VIP, and SINOMED. We will also search for studies in additional sources such as ClinicalTrials.gov and clinicaltrialregister.gov. For a detailed search strategy, please refer to the attached PDF file.

5 **Data Extract Management**

The two reviewers will independently extract studies from databases based on the specific search strategy, then compile the studies' RIS files for extraction in EndNote 21 software. After electronically eliminating duplicates in EndNote, the reviewers will manually check for any remaining duplicates among English and Chinese language studies. The next step involves preliminary review of the relevant articles based on their titles and abstracts, tagging them according to the inclusion and exclusion criteria. The studies that inline with the inclusion and exclusion criteria will be read in full text for eligibility. Any disagreements will be resolved through discussion.

6 **Study Quality Assessment**

The characteristics of the eligible studies will be assessed based on the Cochrane risk-of-bias tool for randomized trials (RoB 2.0), namely: Randomization process, allocation concealment, blinding, attrition, selective outcome, and the overall bias. The classification of the risk of bias will be low risk, some concern, and high risk.

7 Data Analysis

The present study will use systematic review and meta-analysis for the synthesis of studies with the help of RevMan 5.4.1. Studies that meet the initial criteria based on titles and abstracts will be reviewed for further evaluation. 95% confidence intervals (CIs) will be used to measure the Risk Ratio of dichotomous data. The therapeutic effect on continuous data will be assessed using either the Mean Difference (MD) or Standardized Mean Difference (SMD). The meta-analysis data will be presented using tree plots.

1) Heterogeneity

We will use l^2 statistic and Q test (χ^2) to assess the heterogeneity based on the Cochrane Handbook for Systematic Reviews of Interventions recommendation. The fix effect model will be used when the heterogeneity of studies has no apparent heterogeneity or when the P-value in the chi-square (χ^2) test is >.10 or ℓ^2 is <50%. Otherwise, we will use a random-effects model when the heterogeneity across studies is significant, or the *P*-value in the chi-square (χ^2) test is <.10 or I^2 is >50%. If there will be more than 10 studies extracted, we will also perform sensitivity analysis by switching the fix and random effect model, or by using the tunnel plot after removing the small sample study (40 or less of total sample).

2) Sub Group Analyses

If there will be more than two studies extracted, after reading the full text of the eligible studies and performing the overall meta-analysis, we will sub group the multiacupoints selection based



on different acupoints categories (e.g. local, distal, combination) acupoints and compare the clinical efficacy and mean different of the sub group studies.

3) Synthesis of the studies

If there will be fewer than three studies extracted, we will only use systematic review. If there will be more than two studies extracted, we will use additional meta-analysis with Revman 5.4 software's help. We will select and synthesize studies for the meta-analysis using the 2020 flow diagram from PRISMA.

4) Dealing with Missing Continuous Data

When dealing with missing continuous data such as the standard deviation of change (SD change), we will contact the authors for clarification. If we will not receive any responses, we will estimate the SD change based on the Cochrane Handbook using correlation (Corr) formula. We will then use these correlations to calculate the SD change for each group in the other studies. If there are studies that use local Chinese visual acuity system, we will convert the number into the international standard decimal visual acuity, using Prof. Mao Tianrong's formula.

8 **Quality of Evidence**

We will evaluate the study quality based on the guidelines from the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. The levels for assessing the quality level will be from very low, low, moderate, to a high level based on risk of bias, inconsistency, indirectness, imprecision, publication bias, and overall certainty of evidence.