

INPLASY PROTOCOL

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**Review Stage at time of this
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Conflicts of interest:
None.

Methodological challenges when conducting randomized controlled trials in acupuncture: A systematic survey

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Review question / Objective: What are the challenges and solutions about the existing challenges in acupuncture randomized control trials reported in methodological studies?

Condition being studied: All conditions.

Information sources: We searched PubMed, EMBASE and four Chinese databases, including CNKI, VIP, CBM and Wanfang Data from their date of inception till Jun 25th, 2020.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 December 2020 and was last updated on 15 December 2020 (registration number INPLASY2020120080).

INTRODUCTION

Review question / Objective: What are the challenges and solutions about the existing challenges in acupuncture randomized control trials reported in methodological studies?

Condition being studied: All conditions.

METHODS

Participant or population: No restrict.

Intervention: We define acupuncture according to the World Health Organization definition as any type of interventions involving the penetration of the skin with needles or simulation of certain points with

other methods regardless of its theoretical basis excluding the forms combined with moxibustion or medication such as warm needling, acupoint injection or hydro-acupuncture.

Comparator: No restrict.

Study designs to be included: We define methodological studies as empirical studies, theoretical opinions or bibliometric studies on methodological aspects, including narrative opinion, literature analysis, surveys, interviews, systematic reviews, retrospective data analysis, clinical studies and other methodological studies based on real data or simulation data.

Eligibility criteria: We included methodological studies that aim to explore the acupuncture specific methodological features and challenges when designing and conducting randomized controlled trials in acupuncture. Methodological challenges cover both design aspects of participants, interventions, controls and outcomes, and the implementation aspects of informed consent, recruitment, adherence, randomization, blinding, dealing with missing data, statistical analysis, registration of protocol, operation, data management, reporting or dissemination of findings. No publication status or language restriction was applied.

Information sources: We searched PubMed, EMBASE and four Chinese databases, including CNKI, VIP, CBM and Wanfang Data from their date of inception till Jun 25th, 2020.

Main outcome(s): a. Opinions of challenge; b. Suggestions or attitudes of solutions, and barriers to implementing the solutions.

Quality assessment / Risk of bias analysis: The Critical Appraisal Skills Programme (2018), CASP Qualitative Checklist tool will be adopted to evaluate quality of qualitative studies. GRADE CERQual will be used to grade quality of evidence thesis of qualitative studies. For other studies, which no publicly accepted tool to evaluate risk of

bias, quality of the original studies would not be evaluated.

Strategy of data synthesis: Opinions will be induced based on evidence achieved from literature. To synthesize literature evidence, we adopted an integrated method of bibliometrics, qualitative evidence synthesis and evidence-based policy making methods. Following the Cochrane SURE Guides for Preparing and Using Evidence-Based Policy Briefs, we summarized and analyzed challenges and solutions by clarifying the problem, prioritising challenges for counter strategy development, deciding on and describing counter measure options, and identifying and addressing barriers to implementing the solutions. In our study, we used policy brief SURE frame to build our data abstraction form, develop data analyzing mind mapping and to build our theoretical frame, together with themes derived from qualitative evidence synthesis, to address our study aim; we used bibliometrics to quantitatively show the characteristics of the included studies and the challenges and solutions reported.

Subgroup analysis: Data will be analyzed according to different acupuncture types, complexity of interventions, specific health conditions, study geographic locations and author primary professional status, if data is available.

Sensibility analysis: Not involved.

Language: No Language limit.

Country(ies) involved: China, Canada, the United States.

Keywords: Acupuncture, randomized controlled trial, methodological, challenge, solutions.

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