

INPLASY PROTOCOL

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Conflicts of interest:
None.

Effect of acupuncture and auricular acupressure on smoking cessation: protocol of a systematic review and Bayesian network meta-analysis

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ABSTRACT

Review question: A network meta-analysis will be conducted to evaluate the effect of nicotine replacement therapy, auricular acupressure alone, acupuncture, acupuncture combined with auricular acupressure, and sham acupoint therapy on smoking cessation, to find the best solution to reduce tobacco dependence. The main outcome indicator will be abstinence rate, including abstinence rate at the end of treatment and abstinence rate at the end of follow-up from 1 to 6 months. Sustained abstinence rate will be used as the preferable outcome. If the sustained abstinence outcome is not available, point abstinence rate will also be acceptable. The type of studies included in this study is randomized controlled trials.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 March 2020 and was last updated on 01 April 2020 (registration number INPLASY202040002).

INTRODUCTION

Objectives / Review question: A network meta-analysis will be conducted to evaluate the effect of nicotine replacement therapy, auricular acupressure alone,

acupuncture, acupuncture combined with auricular acupressure, and sham acupoint therapy on smoking cessation, to find the best solution to reduce tobacco dependence. The main outcome indicator will be abstinence rate, including

abstinence rate at the end of treatment and abstinence rate at the end of follow-up from 1 to 6 months. Sustained abstinence rate will be used as the preferable outcome. If the sustained abstinence outcome is not available, point abstinence rate will also be acceptable. The type of studies included in this study is randomized controlled trials.

Condition being studied: The health hazards of smoking are well known. Tobacco kills more than 8 million people each year globally, of which more than 7 million are directly from tobacco use, and about 1.2 million from non-smokers exposed to secondhand smoke. In adults, second-hand smoke can cause serious cardiovascular and respiratory diseases, including coronary heart disease and lung cancer. For infants, secondhand smoke increases the risk of sudden infant death. In pregnant women, secondhand smoke can lead to pregnancy complications and low birth weight. Smoking has become a major health and social problem that countries around the world must pay great attention to. And quitting smoking is the only proven way to reduce the harm of smoking. For all smokers, quitting has immediate and long-term health benefits. In addition, quitting smoking can reduce the risk of many childhood illnesses associated with secondhand smoke and can bring health benefits.

METHODS

Participant or population: Inclusion criteria: 1) The tobacco smokers who wished to stop smoking 2) Smokers receiving acupuncture, ear acupuncture and body acupuncture, auricular acupressure alone, or acupuncture combined with auricular acupressure. Exclusion criteria: 1) Quitters who receive any combination of two or more therapies other than auricular acupressure combined with acupuncture 2) Any acupuncture with electric or laser stimulation.

Intervention: The eligible interventions include acupuncture, ear acupuncture and body acupuncture, auricular acupressure

alone, or acupuncture combined with auricular acupressure, excluding any combination of two or more therapies other than auricular acupressure combined with acupuncture, and any acupuncture with electric or laser stimulation.

Comparator: Control interventions include sham acupuncture, sham auricular acupressure, nicotine replacement therapy or auricular acupressure alone, excluding any two or more combination therapies other than auricular acupressure plus acupuncture, and any acupuncture with electric or laser stimulation as the intervention.

Study designs to be included: The review includes randomized controlled trials.

Eligibility criteria: Type of studies: We will include only randomized controlled trials (RCTs) with acupuncture, nicotine replacement therapy, auricular acupressure, and other interventions. Participants: 1) The tobacco smokers who wish to stop smoking 2) Smokers receiving acupuncture, ear acupuncture and body acupuncture, auricular acupressure alone, or acupuncture combined with auricular acupressure. Interventions: The eligible interventions include acupuncture, ear acupuncture and body acupuncture, auricular acupressure alone, or acupuncture combined with auricular acupressure. Comparators: The control interventions will be included sham acupuncture, sham auricular acupressure, nicotine replacement therapy or auricular acupressure alone. Outcomes: Our eligibility criteria will include all outcomes that reported in the included study.

Information sources: A literature search for randomized controlled trials (RCTs) will be performed in five electronic databases from inception to December 2019, including one Chinese and four English databases: Chinese Biomedical Database (SinoMed), PubMed, the Cochrane Library, EMBASE, and Web of Science. In order to find more relevant papers, we will conduct forward and backward citation screening through the citation and bibliography of systematic

review. Search word for smoking cessation, nicotine replacement, acupuncture and auricular acupressure. Multiple synonyms for each word will be incorporated into the search.

Main outcome(s): The main outcome measures will be abstinence rate, including abstinence rate at the end of treatment and abstinence rate at the end of follow-up from 1 to 6 months. Sustained abstinence rate will be used as the preferable outcome. If the sustained abstinence outcome is not available, point abstinence rate will also be acceptable. Abstinence rates can be measured by the expiration test for carbon monoxide content or cotinine in the urine or cigarette withdrawal symptom scores or self-developed criteria.

Data management: Data will be entered into a systematic coding form that included first author, year of publication, detailed questions on interventions, methods, and outcomes. When multiple treatment durations were reported, data for each time period will be recorded.

Quality assessment / Risk of bias analysis: The methodological quality of each included study will be assessed using the Cochrane Collaboration quality assessment tool by two independent reviewers. The assessment tool includes the following criteria: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of the results assessment, incomplete data of the results, selective reporting, and other sources of bias. Disagreement will be decided by discussion with a third investigator.

Search strategy: WinBUGS will be used for the bayesian network meta-analysis, and Stata 14 will be used to draw the network diagram, while RevMan 5.3.5 used to assess the risk of literature bias. The odds ratio (OR) for dichotomous data, weighted mean difference (WMD) for continuous data, and 95% credible intervals (CI) will be used to estimate the network-analysis. The consistency model analysis of the main outcome indexes and the probability

ranking of the best treatment measures will be carried out, and the node model analysis of the network graph with closed rings will be carried out to evaluate the consistency. Potential Scale Reduction Factors (PSRF) will be used to evaluate the model convergence. The closer PSRF will be to 1, the better the model convergence is. A two-tailed value of $P \leq 0.05$ will be considered to indicate statistical significance.

Subgroup analysis: None

Sensibility analysis: Sensitivity analysis was conducted by excluding the study that the quality was rated as 'high risk'.

Language: English and Chinese.

Countries involved: China.

Keywords: acupuncture; auricular acupressure; nicotine replacement; smoking cessation; tobacco control.

Contributions of each author:

Author 1 - Planning and design research, develop the search strategies and write the manuscript;

Author 2 - Develop the search strategies and write the manuscript;

Author 3 - Develop the search strategies;

Author 4 - Develop the search strategies;

Author 5 - Test the feasibility of the study and provide methodological advice;

Author 6 - Test the feasibility of the study, provide methodological advice and polish and revise the manuscript;

Author 7 - Planning and design research, provide methodological advice and polished and revise the manuscript.