INPLASY PROTOCOL

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None declared.

Non-traditional acupuncture therapies for smoking cessation: a protocol of a systematic review of randomized controlled trials

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Review question / Objective: **A systematic review and meta-analysis will be conducted to evaluate the effects of non-traditional acupuncture (NTA) therapies on smoking cessation and withdrawal symptoms. The study population are smokers at any age who wished to quit smoking. Randomized controlled trials (RCTs) comparing NTA with medications, behavioral counseling, sham acupuncture or no treatment will be included. The primary outcome is smoking cessation.**
Information sources: **We comprehensively search RCTs from PubMed, the Cochrane Library, EMBASE, Scopus, Web of Science, China National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), Sino-Med and Wanfang database from their inception to January 2021. There is no language limit. Additionally, relevant references from systematic reviews were also obtained.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 February 2021 and was last updated on 18 February 2021 (registration number INPLASY202120054).

INTRODUCTION

Review question / Objective: **A systematic review and meta-analysis will be conducted to evaluate the effects of non-traditional acupuncture (NTA) therapies on smoking cessation and withdrawal symptoms. The study population are smokers at any age who wished to quit smoking. Randomized controlled trials (RCTs) comparing NTA with medications, behavioral counseling, sham acupuncture or no treatment will be**

included. The primary outcome is smoking cessation.

Condition being studied: Acupuncture as an alternative and complementary therapy has been applied in smoking cessation for nearly 50 years. Clinical and experimental studies have found that acupuncture was effective for withdrawal syndrome through promoting the release of endogenous opioids or suppressing the craving for cigarettes. With the development of acupuncture techniques, various acupuncture techniques have been used for smoking cessation. Non-traditional acupuncture (NTA) therapies differ from traditional acupuncture. Traditional acupuncture generally using filiform needles inserted through the skin at acupoints of the body. NTA generally refers to acupressure, transcutaneous acupoint electrical stimulation (TAES), laser therapy, intradermal needle, acupoint catgut embedding or acupoint injection, which are usually also called acupuncture or acupuncture related therapies. NTA have been widely used for nicotine dependence in several trials worldwide due to convenience and acceptability. The majority of systematic reviews aimed to evaluate the effectiveness of traditional acupuncture for abstinence, only one latest Cochrane systematic review focused on the effectiveness of both traditional acupuncture and partly NTA therapies on cessation. So far, we have not found any systematic reviews that comprehensively and individually evaluate NTA for smoking cessation.

METHODS

Search strategy: An example of a search strategy for PubMed: (((((((acupuncture [Title/Abstract]) OR (acupressure[Title/Abstract])) OR (transcutaneous OR [Title/Abstract])) OR(electric stimulation[Title/Abstract])) OR (auricular therapy[Title/Abstract])) OR (laser therapy[Title/Abstract])) OR (acupoint catgut embedding[Title/Abstract])) AND (smoking cessation[Title/Abstract])).

Participant or population: Smokers at any age who had no serious diseases or pregnancy and wished to quit smoking.

Intervention: Non-traditional acupuncture (NTA) is used alone or in combination with medications or counselling. NTA refers to acupressure, transcutaneous or electric acupoint stimulation (TAES), laser therapy, intradermal needle, acupoint catgut embedding or acupoint injection.

Comparator: Medications (NRT, bupropion or varenicline), behavioral counseling, sham acupuncture or non-specific acupoint stimulation, no treatment.

Study designs to be included: Parallel group randomized controlled trials (RCTs) in regardless of blinding will be included.

Eligibility criteria: Parallel group RCTs in regardless of blinding will be included. The study population comprise of smokers at any age who had no serious diseases or pregnancy and wished to quit smoking. The study interventions are NTA therapies used alone or in combination with NRT or counselling, NTA therapies refer to acupressure, transcutaneous or electric acupoint stimulation (TAES), laser therapy, intradermal needle, acupoint catgut embedding or acupoint injection. Interventions of traditionally inserted filiform needles on the body for smoking cessation will be excluded, as well as non-acupoint interventions. The controls are medications (NRT, bupropion or varenicline), behavioral counseling, sham acupuncture or non-specific acupoint stimulation, and no treatment. The primary outcome is smoking cessation; the secondary outcomes are nicotine withdrawal symptoms (NWS), daily cigarettes consumption, the Fagerström test for nicotine dependence (FTND), the level of exhaled carbon monoxide (CO), relapse rate, craving for cigarettes and adverse events. Trials that fail to report at least one required outcome will be excluded.

Information sources: We comprehensively search RCTs from PubMed, the Cochrane

Library, EMBASE, Scopus, Web of Science, China National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), Sino-Med and Wanfang database from their inception to January 2021. There is no language limit. Additionally, relevant references from systematic reviews were also obtained.

Main outcome(s): The primary outcome is smoking cessation measured by self-reported or biochemically verified abstinence rate.

Additional outcome(s): The secondary outcomes include nicotine withdrawal symptoms, daily cigarettes consumption, nicotine dependence, the level of exhaled carbon monoxide (CO), relapse rate, craving for cigarettes and adverse events.

Data management: After removing duplicates, two authors (ZYY and HDL) will independently screen studies by title and abstract, uncertainty will be determined for eligibility through full texts. Reasons for excluding trials will be recorded at the full-text screening stage, any discrepancies will be resolved by discussion or third party adjudication (JPL). In the data extraction process, data will be extracted by two authors (ZYY and HDL) independently using a pre-defined electronic data extraction form which include basic information of study design (study ID, setting, sample size, funding), participants characteristics, details of NTA therapies and controls, outcomes in different measuring time, follow ups, dropouts and adverse events.

Quality assessment / Risk of bias analysis: The methodological quality of each included trial will be evaluated independently by two authors (ZYY and HDL), Cochrane Risk of Bias tool (ROB) will be employed to assess the risk of bias in each RCT based on its seven domains (the adequacy of sequence generation, allocation concealment, blindness of participants, blindness of outcome assessors, incomplete outcome data, selective reporting, and other bias). Grading of Recommendations Assessment, Development and Evaluation (GRADE) will be employed to evaluate the certainty of the body of evidence based on risk of bias, directness, precision, consistencies, and publication bias.

Strategy of data synthesis: For dichotomous data, data will be presented as risk ratio (RR) with 95% confidence interval (CI); for continuous data, mean difference (MD) with 95% CI will be estimated. Meta-analysis will be performed by Cochrane Review Manger 5.3 software when the trials have similarities in study design and clinical characteristics, otherwise, data will be synthesized qualitatively. The I2 statistic will be utilized to test the statistical heterogeneity, the heterogeneity is considered as substantial when I2 statistic value is greater than 50%, and random effects model will be used in this case, otherwise the fixed effects model will be applied in meta-analysis. To explain heterogeneity, subgroup analysis will be predefined by follow-up time and the course of treatment. Sensitivity analysis will be conducted to explore the influence of the randomization concealment (clear or not) and blindness (blinded or not). Funnel plots will be generated to detect possible publication bias if 10 or more trials are included in a meta-analysis.

Subgroup analysis: To explain heterogeneity, subgroup analysis will be predefined by the comparisons (active control and inactive control). Active control refers to medications and/or behavioral counseling, inactive control refers to sham acupuncture, non-specific acupoint stimulation, or no treatment.

Sensitivity analysis: Sensitivity analysis will be conducted to explore the influence of the randomization concealment (clear or not) and blindness (blinded or not).

Language: There is no language limit.

Country(ies) involved: China and UK.

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Keywords: acupuncture; acupressure; smoking cessation; randomized controlled trials; systematic review.

Contributions of each author:

Author 1 - Ying-ying Zhang - conceived the review and will carry out the study.
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Author 3 - Hui-di Lan - participated in the study design.
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