# INPLASY PROTOCOL

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**None declared.**

# Traditional Chinese medicine for smoking cessation: a systematic review and meta-analysis of randomization controlled trials

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**Review question / Objective:** **To summarize all TCM modalities to figure out possible therapies and to evaluate the effectiveness of TCM compared with conventional treatment for short-term and long-term abstinence and the safety of TCM.**
**Eligibility criteria:** **Inclusion criteria: 1.Study design: Randomized controlled trials (RCTs). 2.Participants: Smokers with no restrictions on age, occupation, or gender. 3.Interventions: TCM therapies such as herbal preparations and non-drug therapies. 4.Comparators: There is no restriction on the comparators. Exclusion criteria: Duplicates or phased publications will be included as one study and extracted all needed information; 2) Abstracts that failed to access the full text would be excluded; 3) Protocols that were unable to provide the data would be excluded; 4) Publications that reported the total abstinence without classification will be regarded as the continued abstinence of the most extended follow-up period.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 September 2021 and was last updated on 01 September 2021 (registration number INPLASY202190001).

## INTRODUCTION

**Review question / Objective:** **To summarize all TCM modalities to figure out possible therapies and to evaluate the effectiveness of TCM compared with conventional treatment for short-term and long-term abstinence and the safety of TCM.**

**Condition being studied:** **The harm of smoking is one of the most severe public health problems in today's world, resulting**

in a global annual death toll of 6 million. Smoking will not only lead to serious respiratory diseases but also trigger cardio-cerebrovascular diseases, diabetes, male sexual dysfunction, and so on. Therefore, smoking cessation is the most effective and economical intervention in health improvement and saving lives. Because of the features of overall adjustment, traditional Chinese medicine (TCM) therapy has special advantages in smoking cessation. There is a growing number of studies and applications of TCM treatment. Based on TCM theory, tobacco can do harm to the lung and other viscera. So, TCM treatments attempted to stimulate the related acupuncture points to cure. Many TCM practitioners have tried to test the effectiveness of TCM for smoking cessation as well as their related symptoms with acupuncture, acupoint application, material medica, etc. These studies showed that although the TCM therapies are effective, they lack significant advantages based on high quality evidence. Current literature and systematic reviews have not involved or included all kinds of TCM modalities and enough comparison. For example, there is a lack of comparison between the short-term and long-term efficacy of TCM interventions for smoking cessation, as well as the comparison between the effectiveness of acupoints stimulation and herbal medicine. There is not sufficient evidence to rule out an effect of acupuncture, acupressure, and laser stimulation on smoking cessation, with a lack of studies on acupuncture and related interventions for smoking cessation with large sample sizes and low risk of bias. We should consider their possible mechanism of action in relation to justifying further research. Currently, the number of randomized controlled trials (RCTs) on smoking cessation carried out in schools, hospitals, communities, research institutes, and other institutions is increasing year by year. However, when designing TCM smoking cessation RCTs, the methodological quality evaluation is absent and urgently needed. Therefore, we aim to conduct a systematic review and meta-analysis of RCTs on all possible TCM modalities for smoking cessation.

## METHODS

**Search strategy:** The main searching terms will be as follows: [Chinese medicine, integrated traditional Chinese and western medicine, Chinese herbs, herb, Chinese patent medicine, decoction, acupuncture and moxibustion, acupuncture, electroacupuncture, auricular acupuncture, laser needle, akupotomye, rolling acupuncture, scalp acupuncture, body acupuncture, abdomen acupuncture, nose acupuncture, wrist ankle acupuncture, needle-embedding therapy, catgut embedding, Semen Vaccariae embedding, auricular, auricular point sticking, auricular-plaster acupressure, ear pressure therapy, acupressure, acupoint injection, plaster on acupuncture points, intergrated acupuncture and herb, acupoint massage, moxibustion, tuina, massage, cupping, scraping, compress, hot compress, plaster therapy, tea, qi gong, Tai Chi, dietotherapy.] [Smoking cessation, tobacco withdrawal symptoms, tobacco withdrawal syndrome, nicotine, nicotine dependence, nicotine withdrawal.] [Random].

**Participant or population:** Smokers with no restrictions on age, occupation, or gender.

**Intervention:** TCM therapy was used as the interventions, including herbal preparations, and non-drug therapies such as invasive and non-invasive acupoints stimulation (acupuncture by hands, auricular acupuncture, auricular point sticking, etc.).

**Comparator:** There is no restriction on the comparators, Blank control, placebo, waiting list, positive drugs (varenicline, bupropion hydrochloride), conventional therapy (nicotine replacement therapy, psychological intervention), or other TCM therapy will be included. Meta-analysis will be conducted based on comparisons of TCM with placebo, blank and positive drugs.

**Study designs to be included:** Randomized controlled trials.

**Eligibility criteria:** Inclusion criteria: 1.Study design: Randomized controlled trials (RCTs). 2.Participants: Smokers with no restrictions on age, occupation, or gender. 3.Interventions: TCM therapies such as herbal preparations and non-drug therapies. 4.Comparators: There is no restriction on the comparators.Exclusion criteria: Duplicates or phased publications will be included as one study and extracted all needed information; 2) Abstracts that failed to access the full text would be excluded; 3) Protocols that were unable to provide the data would be excluded; 4) Publications that reported the total abstinence without classification will be regarded as the continued abstinence of the most extended follow-up period.

**Information sources:** China National Knowledge Infrastructure (CNKI), Wanfang database, Chongqing Vip database, Sinomed, PubMed, the Cochrane Central Register of Controlled Trials (CENTRAL) were searched. Journal articles, dissertations, and conference papers will be retrieved from their inceptions to now.

**Main outcome(s):** Abstinence rate confirmed by laboratory indices (carbon monoxide breath teat or urine Cotinine teat). The definition of the outcome indices of abstinence in this review was made by John R. Hughes. 1.Continuous abstinence: maintaining smoking cessation between the cessation date and the follow-up date. 2.Prolonged abstinence: sustained cessation after an initial grace period or between the two follow-up visits (which were of equal length). 3.Point prevalence abstinence: the rate of abstinence before follow-up visits. 4.Repeated point prevalence: the rate of abstinence between two times or more smoking permitted follow-up visits. Observation time points of point prevalence abstinence were at one day, seven days, one month, and six months. Observation time points of continuous abstinence were at seven days or less, seven days to one month, one month to six months, six months to one year and more.

**Additional outcome(s):** Secondary outcomes include nicotine withdrawal symptoms (records extracted from literal or verbal expressions, data extracted from nicotine withdrawal symptom (NWS), Fagerstrom Test for Nicotine Dependence (FTND), and relapse rate. The safety outcome refers to adverse events resulted from trial participation (other adverse events besides withdrawal symptoms reported in the trials would be extracted).

**Quality assessment / Risk of bias analysis:** Two authors will independently assess the methodological quality of the included studies using the Cochrane risk of bias tool (Cochrane ROB Tool). The random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias of included trials were assessed by "Low risk", "High risk", or "Unclear". Any disagreements were resolved by discussion with a third author. In this review, the funding of the study and the conflict of interest will be assessed as the "other bias".

**Strategy of data synthesis:** Revman 5.4.0 will be used for data pooling and analysis. For continuous data, we will use mean difference (MD) with 95% confidence intervals (CI), and for dichotomous data, we used relative risk (RR) with 95% CI. Subgroup analysis will be performed if the data are available. Publication bias will be evaluated when there are more than ten trials included in a meta-analysis. As recommended by the Cochrane Handbook for Systematic Reviews of Interventions, we used I-square ($I^2$) to test the statistical heterogeneity. When the $I^2$ value is greater than 75%, it will be considered that the heterogeneity is substantial. The fixed effect model will be applied when included trials are considered having low heterogeneity ($I^2$<30%). The random effects model will be used for data pooling with high heterogeneity (usually when $I^2$> 75%).

**Subgroup analysis:** Subgroups will be divided according to the different interventions such as acupoints stimulation or Chinese herbal preparations. We will define that there is a statistical difference when $P < 0.05$.

**Sensitivity analysis:** Sensitivity analyses will be performed if there are enough trials for determining the robustness of the conclusions.

**Language:** The language will be limited to Chinese and English.

**Country(ies) involved:** China.

**Keywords:** Smoking cessation; Traditional Chinese medicine; Randomization controlled trials; Systematic review; Acupoints stimulation; Abstinence symptoms.

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