INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy of acupuncture for melasma: a protocol of systematic review and meta-analysis

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Review question / Objective: **How effective is acupuncture in treating melasma compared to conventional treatment?**
Condition being studied: **Melasma is a common acquired hyperpigmentation of the skin. The clinical manifestations are light brown or dark brown patches symmetrically distributed on the cheeks, forehead and mandibular with different shades and unclear borders. Melasma particularly affects women during menstruation, especially in thirties and forties Asian women. The incidence of Asian women of childbearing age is as high as 30%. Current treatments for melasma include topical drugs, chemical peeling agents, laser and light treatments, and systemic drugs. Despite the strong demand for treatment, the treatment of melasma is still very challenging, the results are inconsistent, and the recurrence rate is almost constant.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 November 2021 and was last updated on 27 November 2021 (registration number INPLASY2021110097).

INTRODUCTION

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METHODS

Participant or population: Participants will include patients diagnosed with melasma based on medical history and typical clinical manifestations: there are no restrictions on the age, gender or race of the subject.

Intervention: We will include all randomized controlled trials in which the treatment group uses acupuncture alone. Acupuncture treatment is defined as acupuncture at acupoints on the meridian, including manual acupuncture or electroacupuncture, but not other acupuncture therapies, such as ear acupuncture, scalp acupuncture, dry acupuncture, and acupressure therapy.

Comparator: The control group uses only conventional treatment. Conventional treatments include topical medications, chemical stripping agents, laser and light therapy, systemic medications, and other necessary treatments.

Study designs to be included: We will include all randomized controlled trials (RCTs) of acupuncture for the treatment of melasma without any blinding or publication language restrictions. We will also exclude cohort studies, case reports, and duplicate publications.

Eligibility criteria: Article screening and data extraction will be independently evaluated by two reviewers trained in methodology according to the established selection criteria. Any disagreements between the two reviewers will be resolved by reaching a consensus with the other authors (the third reviewer).

Information sources: We will search PubMed, EMBASE, the Cochrane Central Register of Controlled Trials, China National Knowledge Infrastructure (CNKI), Wan Fang Database, VIP database, Chinese Biomedical Literature Service System (SinoMed), Chinese Biomedicine (CBM) database and TCM Literature Analysis and Retrieval Database from inception to July 1, 2021 to identify any eligible study. We include all randomized controlled trials (RCTs) without any limitation of blinding or publication language, exclude cohort studies and case reports.

Main outcome(s): The main outcomes include Melasma Area and Severity Index (MASI), quantification is carried out according to the area, color depth and color uniformity of melasma. Pigmentation area assessment: forehead (F), right cheek (MR), left cheek (ML) and lower jaw (C) are divided into four areas, with weights of 30%, 30%, 30% and 10%, respectively. The color depth (D) and uniformity (H) scores are counted as 0-4 points: 0 means nothing, 1 means slight, 2 means moderate, 3 means obvious, and 4 means maximum. MASI = forehead [0.3A (D + H)] + right cheek [0.3A (D + H)] + left cheek [0.3A (D + H)] + lower jaw [0.1A (D + H)]. The maximum is 48 points, the minimum is 0.

Additional outcome(s): Secondary results include scanning reflectance spectrophotometer detection technology (colorimetric method), VISIA image analysis, non-invasive physiological function test, Reflectance Confocal Microscopy (RCM), dermoscopic observation and evaluation of the improvement of the number and shape of blood vessels in the skin lesions before and after treatment of melasma, Physician's Global Assessment (PGA), patient satisfaction evaluation, safety indicators and the number of adverse events.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the risk of bias using the Cochrane Risk of Bias Tool of Randomized Trials. They will compare their own assessments and

discuss any differences of opinion between them. If they fail to do so, they will be arbitrated by a third-party reviewer. Area to be evaluated: Is there enough sequence generation (selection bias)? Is the allocation sufficiently masked (selection bias)? During the course of the research, is there sufficient knowledge about the interventions allocated? Participants and personnel (performance bias), result assessor (detection bias); are incomplete result data adequately resolved (attrition bias)? Is there no hint of selective result reporting (reporting bias) in the research report? Is this study apparently free of other issues that might put it at risk of bias? Based on the relevant information extracted from each qualified study, the risk of bias in each area will be divided into high risk, low risk, and unclear risk of bias.

Strategy of data synthesis: If there is no heterogeneity, use a fixed-effects model to synthesize the data; if there is significant heterogeneity, use a random-effects model for analysis. We will provide a narrative synthesis of the outcomes and results of the studies if a meta- analysis is not possible.

Subgroup analysis: If a sufficient number of randomized controlled trials are included in the review, we plan to conduct subgroup analysis to explore the source of heterogeneity. The subgroup analysis will be based on the type of acupuncture (manual acupuncture or electro-acupuncture) and the test time of the secondary results (3 or 7 days after the intervention).If more than 10 articles are included, we will use funnel plot and Egger test to assess publication bias.

Sensitivity analysis: We plan to use the "leave-one-out" methods to conduct sensitivity analyses for the main outcomes to confirm the reliability of our findings.

Country(ies) involved: China.

Keywords: Acupuncture; melasma; protocol; systematic review and meta-analysis; randomized controlled trials.

Contributions of each author:

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