INPLASY PROTOCOL

To cite: Zhong et al. Effectiveness and Safety of Acupuncture for Psoriasis Vulgaris: A protocol of Systematic Review and Meta-analysis. Inplasy protocol 202210042. doi: 10.37766/inplasy2022.1.0042

Received: 09 January 2022

Published: 09 January 2022

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Support: **2021MS541.**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None declared.

Effectiveness and Safety of Acupuncture for Psoriasis Vulgaris: A protocol of Systematic Review and Meta-analysis

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Review question / Objective: **Our study aims to evaluate the efficacy and safety of acupuncture for psoriasis vulgaris.**
Condition being studied: **Psoriasis vulgaris (PV) refers to a common chronic, immune-mediated inflammatory skin disease with red papules or plaques covered with silvery-white scales as the main lesion manifestation, which is most prevalent on the extensor surfaces of the extremities and caudal sacral region. It tends to break out in autumn and winter and relapse in summer. According to the International Federation of Psoriasis Associations (IFPA), 3% of the global population, about 125 million people, are afflicted by psoriasis and the proportion of PV patients exceeds 97% of the total psoriasis patients. Psoriasis vulgaris affects the physical, psychological, and even social activities of patients, for example, PV patients tend to experience depression, distress, and anxiety from occupation and daily life. Furthermore, its high medical costs have emerged as a serious global health burden. A multitude of clinical trials revealed that acupuncture or acupuncture-related therapy could exert promising and facilitating effects on PV treatment, such as PASI scores improvement, fewer side effects, the extension of recurrence time, and reduction of recurrence rate. Besides, it could facilitate the treatment of psoriasis in an effective and convenient way. Some studies have shown that acupuncture treatment could modulate the immune response to psoriasis: for example, by reducing levels of IL-8, TNF-α.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 January 2022 and was last updated on 09 January 2022 (registration number INPLASY202210042).

INTRODUCTION

Review question / Objective: **Our study aims to evaluate the efficacy and safety of acupuncture for psoriasis vulgaris.**

Rationale: **Acupuncture, one of the complementary alternative modalities, has been utilized in the health care system to treat PV and even achieve promising**

effects on PV, such as itching relief, local lesion reduction, fewer side effects and drug resistance. Although extensive research has been carried out on the benefits of acupuncture on PV, no single study exists which systematically evaluates the efficacy of acupuncture PV. Therefore, our study aims to evaluate the efficacy and safety of acupuncture for PV.

Condition being studied: Psoriasis vulgaris (PV) refers to a common chronic, immune-mediated inflammatory skin disease with red papules or plaques covered with silvery-white scales as the main lesion manifestation, which is most prevalent on the extensor surfaces of the extremities and caudal sacral region. It tends to break out in autumn and winter and relapse in summer. According to the International Federation of Psoriasis Associations (IFPA), 3% of the global population, about 125 million people, are afflicted by psoriasis and the proportion of PV patients exceeds 97% of the total psoriasis patients. Psoriasis vulgaris affects the physical, psychological, and even social activities of patients, for example, PV patients tend to experience depression, distress, and anxiety from occupation and daily life. Furthermore, its high medical costs have emerged as a serious global health burden. A multitude of clinical trials revealed that acupuncture or acupuncture-related therapy could exert promising and facilitating effects on PV treatment, such as PASI scores improvement, fewer side effects, the extension of recurrence time, and reduction of recurrence rate. Besides, it could facilitate the treatment of psoriasis in an effective and convenient way. Some studies have shown that acupuncture treatment could modulate the immune response to psoriasis: for example, by reducing levels of IL-8, TNF-α.

METHODS

Search strategy: The following databases will be searched to collate documents relating to acupuncture for PV: Web of Science, PubMed, EMBASE, Ovid, The Cochrane Library, China Science and Technology Journal (VIP), Wanfang database, Chinese Biological Medical (CBM), and China National, Knowledge Infrastructure (CNKI). Gray literature will be obtained from GreyNet, Clinical Trails, Chinese Cochrane Center and Chinese Clinical Trial Registry. Literature is limited to those published prior to January 1, 2022, whose study type is clinical randomized controlled trials (RCTs) only and the language is restricted to English and Chinese. The search terms involve psoriasis vulgaris, acupuncture and clinical randomized controlled trials. Search strategy will be adjusted according to the characteristics of databases. The management of all references will be performed by Endnote 20.0.

Participant or population: Patients diagnosed with PV (diagnosed by licensed clinicians or conforming to any recognized diagnostic criteria), regardless of their ethnicity, country, age, and course of the disease.

Intervention: The treatment group underwent acupuncture solely or combined with other treatments, such as fire acupuncture, electroacupuncture, moxibustion, or Narrow Bound Ultra Violet B Light, regardless of acupoint selection, treatment frequency, or course. The control group adopted conventional Western medicine treatment, placebo, sham, or no treatment.

Comparator: The control group adopted conventional treatment, medication, such as corticosteroids, salicylic acid and Vitamin D analogues, placebo, sham acupuncture, or no treatment.

Study designs to be included: Only randomized control trials (RCTs) studies will be included.

Eligibility criteria: (1)Type of participants: Patients diagnosed with PV (diagnosed by licensed clinicians or conforming to any recognized diagnostic criteria), regardless of their ethnicity, country, age, and course of the disease. (2)Types of study: Randomized controlled trials (RCTs) of

acupuncture therapy for the treatment of PV, which were published in English or Chinese before 1st January 2022. (3) Type of interventions: The treatment group underwent acupuncture solely or combined with other treatments, such as fire acupuncture, electroacupuncture, moxibustion, or Narrow Bound Ultra Violet B Light, regardless of acupoint selection, treatment frequency, or course. The control group adopted conventional Western medicine treatment, placebo, sham, or no treatment.(4) Type of comparator: The control group adopted conventional treatment, medication, such as corticosteroids, salicylic acid and Vitamin D analogues, placebo, sham acupuncture, or no treatment.(5)Type of studies: Only randomized control trials (RCTs) studies will be included.

Information sources: Published studies will be obtained from Web of Science, PubMed, EMBASE, Ovid, The Cochrane Library, China Science and Technology Journal (VIP), Wanfang database, Chinese Biological Medical (CBM), and China National, Knowledge Infrastructure (CNKI). Gray literature will be obtained from GreyNet, Clinical Trails, Chinese Cochrane Center and Chinese Clinical Trial Registry.

Main outcome(s): The effective rate will be our primary outcome.

Additional outcome(s): Additional outcomes are changes of Psoriasis Area Severity Index (PASI) score, Dermatology Life Quality Index (DLQI), the improvement rate of symptoms (itching, pain, and cracking of the affected skin), the recurrence rate and the adverse reactions.

Data management: Two authors (Yanmei Zhong, Haizhen Lu) will independently read the titles and abstracts to include studies meeting our criteria. Any disagreement will be addressed through discussion until consensus is reached, or a third author (Lu Liu) will be consulted to make the final decision. We will complete our literature selection process according to the PRISMA 2009 flowchart. Then, two authors will independently extract the following necessary information: author, title, publication year, country, gender, age, sample size, study type, intervention measurement and duration of treatment.

Quality assessment / Risk of bias analysis: The risk of bias tool of the Cochrane Handbook 5.1.0. will be utilized by two authors independently to evaluate the quality of included trials, which involves the following indicators: the allocation sequence random, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, and other bias. And the risk of bias was rated as “low”, “unclear” or “high”.

Strategy of data synthesis: The statistical analysis will be achieved by RevMan 5.4.1. and STATA 12.0. The heterogeneity test will be carried out by I2 statics; I2 exceeding 50% indicates significant heterogeneity. The random-effects model will be applied when 12 is more than 50%, while when 12 is less than 50%, the fixed-effects model will be used. Risk ratio (RR) with 95% confidence interval (CI) will be used to determine dichotomous data, and weighted mean differences (95% CI) or standardized mean differences (95% CI)will be used to analyze the continuous data. As for publication bias, if the number of included studies is over ten, we will construct a funnel plot by Egger’s test and assess whether it is symmetrical.

Subgroup analysis: When the heterogeneity test results are substantial (I2>50%), RevMan 5.4.1. will perform subgroup analysis of age, gender, interventions, acupoints selection and treatment intervals.

Sensitivity analysis: If the heterogeneity test of outcome is substantial (I2>50%), the sensitivity analysis will be conducted for identifying the source of homogeneity.

Language: Language is restricted to English and Chinese.

Country(ies) involved: China.

Keywords: psoriasis vulgaris; acupuncture; meta-analysis.

Contributions of each author:

Author 1 - Yanmei Zhong - Author 1 was responsible for conceptualization of the manuscript, methodology of the study, project administration and writing the manuscript.
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