Acupuncture combined with herbal medicine versus herbal medicine alone for plaque psoriasis: a systematic review protocol

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Background: Psoriasis is a condition with a multifactorial etiopathogenesis worldwide, and plaque psoriasis, which is characterized by redness, thickness, and scaling, is the most common kind. Individuals living with psoriasis show low levels of life quality, and having fewer or less extensive lesions may improve spiritual and mental health. Therefore, our objective is to explore the effectiveness of acupuncture combined with herbal medicine for plaque psoriasis and to compare acupuncture combined with herbal medicine with herbal medicine alone.

Methods: Databases including PubMed, MEDLINE, the Cochrane Library, Excerpta Medica (EMBASE), the Chinese Biomedical Literature Database (CBM), the China National Knowledge Infrastructure Database (CNKI), the Wanfang database and the Chinese Scientific Journal Database (VIP database) will be searched from inception to March 2018. We will employ hand searches, and grey literature will also be obtained. Only randomized controlled trials evaluating acupuncture combined with herbal medicine to treat plaque psoriasis in adults will be assessed. The Psoriasis Area and Severity Index score (PASI score), the itching index, the life quality scores, and the anxiety index will be the outcome measures. Two independent reviewers will select the articles included, assess the risk of bias and extract data according to the inclusion criteria. A third reviewer will resolve disagreements. The purpose of this study will be to identify the effect of acupuncture combined with herbal medicine on the lesions (PASI score), symptoms (itching index, life quality scores) and mental status (anxiety index) of the patients.

Discussion: The meta-analysis will retrospectively examine current evidence regarding the effectiveness of the practice of acupuncture combined with herbal medicine to treat plaque psoriasis. This study may reveal, for the first time, an adjuvant therapy for psoriasis.

Trial registration: As the study is a systematic review protocol, trial registration will not be necessary. An article containing the results will be published in a peer-reviewed journal and disseminated through scientific conferences.

Keywords: Acupuncture; herbal medicine; meta-analysis; protocol; psoriasis

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Introduction

Psoriasis is a common inflammatory and refractory disease with a prevalence of 2–4% (1). Overall, 90% of psoriasis cases are the plaque psoriasis type (2), which is characterized by redness, thickness, and scaling, leading to social isolation and stigmatization (3,4) and negatively affecting the quality of daily life (5-12). Physicians use topical vitamin D analogues and corticosteroids to treat lesions according to clinical guidelines; however, these treatments are imperfect due to side effects and limited effects (13,14). Although no evidence-based guidelines exist, many plaque psoriasis patients pursue herbal medicine and acupuncture, which have been effectively and safely used in traditional Chinese medicine (TCM) for a long time (13,14). In traditional Chinese medicine, plaque psoriasis is believed to be a type of intractable disease owing to blood stagnation, and both herbal medicine and acupuncture can invigorate the circulation of blood, relieve stasis, and reduce toxins for many plaque psoriasis patients. Several clinical trials used acupuncture combined with herbal medicine to treat psoriasis. Although there are systematic reviews about acupuncture for psoriasis, no study so far has authenticated the effect of acupuncture combined with herbal medicine and compared the effect of acupuncture combined with herbal medicine and herbal medicine alone, and the effectiveness of acupuncture combined with herbal medicine is still controversial. Therefore, the purpose of the meta-analysis is to offer a retrospective investigation of the current evidence regarding the effectiveness of the practice of acupuncture combined with herbal medicine to treat plaque psoriasis and to identify complementary therapeutic approaches in psoriasis to guide clinical treatment. The Psoriasis Area and Severity Index (PASI) score, the itching index, life quality and the extent of anxiety of psoriasis patients will be investigated, which can aid comparisons of the effectiveness of acupuncture combined with herbal medicine and herbal medicine alone to treat lesions, relieve itch, promote life quality and relieve anxiety.

Objectives

To perform a meta-analysis to explore the effectiveness of acupuncture combined with herbal medicine on the healing of plaque psoriasis irrespective of age (>18 years old), sexual orientation, and educational background.

Methods/design

The meta-analysis will be guided by the Cochrane Handbook (V.5.1.0) and the use of software (RevMan 5.3). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement will guide the meta-analysis (when possible), and the PRISMA-P checklist is shown in *Table 1* (15). As the systematic review is based on published data, an ethical statement will not be required. The results will benefit the amelioration of the therapeutic tactics for plaque psoriasis.

Eligible criteria

Types of studies

All randomized controlled trials (RCTs) will be included. Quasi-RCTs, commentaries, case reports and animal studies will not be included.

Types of patients

Participants with plaque psoriasis will be included, whereas patients with psoriatic arthritis, pustulosis of the palms and soles and erythrodermic psoriasis will not be included.

Patients affected by plaque psoriasis will be included, with no restrictions. We will contact the authors of the RCTs when necessary for missing data.

Types of interventions

All trials that assessed acupuncture combined with herbal medicine for plaque psoriasis will be included. Their possible effects after the intervention will be assessed.

Types of comparisons

If the patients were treated with herbal medicine in the control group, the studies will be included.

Types of outcome measures

The principal outcome will be the PASI score. The itching index measured by the itching evaluation scale, the life quality scores, and the anxiety index will be the secondary outcomes.

These outcome measures can help compare the effectiveness of acupuncture combined with herbal medicine and herbal medicine alone in the treatment of psoriasis and in regard to PASI score reduction, itch relief, life quality promotion and anxiety relief.

Table 1 PRISMA-P checklist

Section and topic	Item No.	Checklist item	Reported on page #
Administrative information			
Title			
Identification	1a	Identify the report as a protocol of a systematic review	P4
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	It is not an update of a previous systematic review
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	No registration
Authors			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	P1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	P15
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	We plan to document important protocol amendments
Support			
Sources	5a	Indicate sources of financial or other support for the review	P15
Sponsor	5b	Provide name for the review funder and/or sponsor	P15
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	P15
Introduction			
Rationale	6	Describe the rationale for the review in the context of what is already known	P4
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	P5
Methods			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	P8
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	P9
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	P10
Study records			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	P10
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	P10
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	P9

Table 1 (*continued*)

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Section and topic	Item No.	Checklist item	Reported on page #
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	P10
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	P12
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	P11
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	P11
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	P11
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	P12
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	P12
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	P11
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	P12

The Hamilton Anxiety Scale (HAMA), which assesses the extent of patient anxiety, contains 14 items. The maximum score is 56, representing the greatest degree of anxiety. The Dermatology Life Quality Index (DLQI) Scale, which evaluates the life quality of patients with plaque psoriasis, contains 10 items. The maximum score, representing the worst quality of life, is 30.

Search strategy for the identification of relevant studies

The MEDLINE (via Ovid SP), PubMed, Excerpta Medica (EMBASE), the Cochrane Library, the Chinese Biomedical Literature Database (CBM), the China National Knowledge Infrastructure Database (CNKI), the Wanfang database and the Chinese Scientific Journal Database (VIP database) will be searched from their inception to March 2018. The first three aforementioned databases are the most holonomic databases for RCTs (15). The CBM, CNKI, Wanfang and VIP databases contain studies published in the Chinese language. We will search the Cochrane library for RCTs in the references of published systematic reviews and meta-analyses to avoid overlooking potential trials. We will search CENTRAL for eligible clinical trials.

Manual searches for relevant articles will be applied. All published and unpublished studies, conferences or presentations will be searched without restriction in the English and Chinese languages. We will search correlative websites such as Google Scholar, Opengrey, the recent Cochrane Systematic Review and that of the WHO for grey literature. Relevant search terms will be developed from Medical Subject Headings (MeSH). The principles of Boolean logic will be followed. The search strategy will be conducted according to the most recent Cochrane Systematic Review and Cochrane Handbook for Systematic Reviews of Interventions (15,16). The PubMed full search strategy will be included in a table (i.e., "acupuncture (Title/Abstract) AND psoriasis (Title/Abstract)"), and that strategy will also be applied to the other databases.

Screening and selection of the RCTs

Duplicates will be excluded. Two researchers will screen the titles and abstracts of all the searched eligible RCTs according to the previously described inclusion criteria independently. The full text will be downloaded and evaluated according to the inclusion criteria. A third researcher will resolve disagreements. We will record the reasons when RCTs are excluded. The process will be

presented as a flow process chart, following the PRISMA flow diagram (17).

Data extraction

The data extraction will be carried out independently by two researchers to include the following: (I) RCT details: title, authors, publishing year, country and study design; (II) patient demographics: number of participants, age, sex, type and criteria for the classification of psoriasis; (III) methods: details of randomization process, treatment duration, dropouts, interventions; and (IV) information to assess the quality of the studies. We will contact the authors for missing data when necessary. In cases of disagreement, the third author will decide by consensus.

All included studies will be exported into Endnote for administration. Two researchers will extract and verify data independently, and any disagreements will be resolved by the authors.

Quality assessment

The quality of the included trials will be independently evaluated by two reviewers, and disagreements will be resolved by a third researcher. The assessment will be in accordance with the 7 correlative items in the 'risk of bias' tool of the Cochrane Handbook for Systematic Review of Interventions (18). The symmetry of funnel plots will be employed if possible to assess the risk of publication bias.

Data synthesis

If adequate data of relevant outcome measures are obtainable and the trials are homogeneous, meta-analyses will be carried out, and forest plots will be presented. The random effects model of DerSimonian-Laird will be employed (19). Dichotomous outcomes will be evaluated using relative risks, while continuous outcomes will be evaluated using mean differences. A P value of <0.05 will indicate statistical significance. We will assess heterogeneity applying the I^2 statistic, with a value of I^2>50% indicating substantial heterogeneity. Subgroup analysis will be conducted to explore the possible reasons for heterogeneity when feasible. We will assess publication bias using funnel plots and Egger's test (provided we have at least ten studies included in the meta-analysis) (20). Data will be summarized and synthesized using RevMan V.5.3 to perform a meta-analysis and to generate a pooled estimate of the effect of acupuncture.

Discussion

The meta-analysis will aim to supply correlative proof of the effectiveness of acupuncture combined with herbal medicine to control plaque psoriasis and will define the effects of the interventions.

Strengths (i.e., the inclusion of unpublished data, low heterogeneity of studies, and regression analysis) and limitations (unblinded methods, small sample sizes, bias) will be discussed, and the review aims to determine gaps for future research.

Assessing the quality of the trials will help identify grey regions of the research. Analysis of the effect of acupuncture combined with herbal medicine could help develop curative approaches to prevent plaque psoriasis lesions and to determine and suggest areas for future studies.

Due to the language barrier, the review will only include the published literature in the English and Chinese languages, which may be another limitation of this study, for which publication bias may exist.

Presenting and reporting of results

The meta-analysis will be reported in accordance with PRISMA (21) and the meta-analyses of observational studies (MOOSE) (22). A flow chart will be presented for the process of the screening and selection of the RCTs.

We will give reasons for excluding trials. Extracted information will be shown in tables. Summary statistics of quantitative data will be complemented with narrative syntheses. Forest plots will be presented if possible. The evaluation of risk of bias will be presented in figures.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest

to declare.

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