PROTOCOL

Ayurvedic Interventions for Psoriasis: Protocol for a Systematic Review

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Abstract

Background: Psoriasis produces significant adverse effects on the psychological and social aspects of the patient, mainly because of its visibility. World Health Organization's (WHO) recent Global Report on Psoriasis states that there are many unmet research gaps in psoriasis with respect to treatment and ways to improve healthcare services. Clinical Research on psoriasis should focus on options that can be applicable globally, on a large-scale. Plenty of studies individually proving efficacy of various Ayurvedic treatment modalities in subjective and objective improvement of psoriasis are published. Systematic reviews of complementary and alternative medicine (CAM) on psoriasis are available, but these studies do not include Ayurvedic interventions.

Aim: Thorough review of published data of Ayurvedic interventions in the management of psoriasis to provide more precise estimates of safety and effectiveness of Ayurvedic interventions for psoriasis.

Objective: Outlining the protocol to conduct a Systematic Review of published studies examining the effects of Ayurvedic interventions on psoriasis.

Materials and methods: The preferred reporting items for systematic review and meta-analysis (PRISMA) protocols guidelines, The Cochrane Handbook for Systematic Reviews of Interventions, the consolidated standards of reporting trials guidelines, guidance on the conduct of narrative synthesis in systematic reviews provided the design to conduct and report the protocol, structure research question and search term selection and the data extraction form; though some adaptations may be made with regard to search terms, data synthesis, and evaluating the risk of bias.

Trial registration number: PROSPERO 2018 CRD42018097298.

Dissemination: The SR will be published in a peer-reviewed journal. The review will be updated to inform and guide healthcare practice and policy.

Keywords: Ayurveda, *Ekakushtha*, *Kitibha*, *Kushtha*, Protocol, Psoriasis, *Shaman*, *Shodhan*, Systematic Review.

Journal of Research in Ayurvedic Sciences (2019): 10.5005/jras-10064-0085

Introduction

Psoriasis is a chronic inflammatory skin disorder having characteristic lesions with several trigger factors like infection, stress, cold etc. The auto-immune reaction causes hyperkeratosis and increased blood flow resulting in the typical silvery scales with erythema, coin shaped to big palm sized plaques and bleeding (Auspitz's Sign). Significant adverse effects on the psychological and social aspects are produced in psoriasis patients mainly because of its visibility. Psoriasis is a common dermatological disorder in India. Its prevalence and epidemiological characteristics are similar to the presentation of disease in the West. It is twice more common in males compared to females. Occurrence of psoriasis is most commonly in the third or fourth decade of life of the patients.[1] Many effective agents used to treat severe psoriasis have the risk of significant morbidity including skin cancers, lymphoma, liver diseases, etc. The World Health Organization in its recent Global Report on Psoriasis has stated that there are many unmet research gaps in addressing various aspects of epidemiology, etiology, association with comorbidities, treatment, and ways to improve healthcare services for the disease. Therefore, the therapeutic research for psoriasis should focus on effective and safe options, which can be applicable globally, on a large-scale.[2]

Multiple studies in the form of case reports and prepost clinical trials with small sample size are found on searching for therapeutic efficacy of Ayurvedic interventions in psoriasis. They individually lead to prove the efficacy of various *Shodhan*, *Shaman*, and external application treatment modalities in subjective and objective improvement of psoriasis. However, studies presenting the data collected from large sample size are rare enough to state anything about efficacy and the line of treatment of the disease through Ayurveda. The Systematic reviews (SRs) of CAM on psoriasis are available, but these studies do not include Ayurvedic interventions.[3] The SR of oral Chinese herbal medicine vs placebo for psoriasis vulgaris is also available.[4] However, any SR of Ayurveda interventions for psoriasis is not found. In an effort to fill this gap, a review compiling and analyzing this information is needed. Thus, an SR protocol was developed. The authors are expected to adhere to this protocol to comprehensively review and synthesize published studies focusing on the effectiveness of Ayurvedic interventions for managing the disease and promoting quality of life (QOL) of the patients suffering from psoriasis. In view of the challenges of developing and conducting a SR on a topic with a paucity of

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How to cite this article: Mundada PS, Deshmukh S, Saketh Ram T, *et al.* Ayurvedic Interventions for Psoriasis: Protocol for a Systematic Review. J Res Ayurvedic Sci 2019;3(3):106–111.

Source of support: Central Council for Research in Ayurvedic Sciences

Conflict of interest: None

available research studies, adaptations from existing guidelines for SR protocols and SRs (i.e., PRISMA protocols, Cochrane Handbook for Systematic Reviews of Interventions, consolidated standards of reporting trials, guidance on the conduct of narrative synthesis in systematic reviews) may be necessary.

The aim of this SR protocol is to outline the step-by-step process to conduct an SR exploring the efficacy and safety of Ayurvedic interventions in the management of psoriasis to provide more precise estimates of effectiveness of Ayurvedic interventions for psoriasis.

Why it is Important to Perform this Review?

As compared to the number of trials testing efficacy of Ayurvedic medicines in the treatment of psoriasis, almost no SR assessing the effectiveness of Ayurvedic intervention for psoriasis has been conducted to date.

The efficacy and safety of Ayurvedic medicines and procedures used in psoriasis can be proved substantially by this SR. This can further allow appropriate recommendation of Ayurvedic treatment and establishing the line of treatment for this *anuktavyadhi*, meaning novel disease psoriasis. As this is the first SR on this topic, outlining the protocol ensures transparency for the completed review. Further, it illustrates how elements from several guidelines can be incorporated to answer the research question, i.e., what is the effect of Ayurvedic interventions in the management of psoriasis.

Materials and Methods

This review protocol is structured following the PRISMA protocols guidelines.[5] In addition, elements from the Cochrane Handbook for Systematic Reviews of Interventions, the consolidated standards of reporting trials, and the guidance on the conduct of narrative synthesis in systematic reviews will also be used as applicable.

Inclusion Criteria

Studies published in English, Hindi, and Marathi in peer-reviewed scientific journals will be reviewed. Clinical studies published on any date will be included. The types of participants, interventions, outcomes, and studies that will be considered for inclusion are described below.

Types of Participants

Studies with subjects diagnosed with any type of psoriasis of any type and both sexes will be included.

Types of Interventions

In this study, Ayurvedic interventions are defined as any Ayurvedic Shaman treatment (polyherbal, herbomineral, mineral–metallic preparations used internally or externally with the intent to cure or as add-on) or *Shodhan* procedures (biopurification procedures) or any other form of dietary interventions based on the principles of Ayurveda. No restrictions will be placed on where the interventions are delivered [e.g., out patient and in-patient departments (OPD/IPD), etc.]. Ayurvedic interventions including *Shodhan* or *Shodhan* and *Shaman* (internal and external medication) (with no limitations on dose, type, schedule, drug, dosage form) will be included.

Types of Outcome Measures

Studies that use objective or subjective outcome measures of improvement in the disease studied and measures of QOL as primary or secondary end points will be included. Health outcomes may include any participant-reported or objective assessment of signs and symptoms of the disease. The QOL outcomes may include any participant-reported assessment of functioning across physical, psychological/emotional, and social domains or dermatology or disease-specific QOL indices. Only experimental study designs will be included.

Types of Studies

Criteria for considering studies for this review are randomized controlled trial (RCT), non-RCT (NRCT), Quasi-RCT (QRCT; studies in which the group allocation was not purely random but rather determined by a factor such as a birth date, a hospital record number or an alternation), controlled clinical trial (CCT), randomized/nonrandomized placebo control trials, controlled before and after study, before and after comparison (prepost assessments), parallel arm comparative trials, and multiarm clinical trials. Dissertations and abstracts will be included if they contain sufficient details for critical evaluation.

Exclusion Criteria

Interventions having multiple or mixed interventions (e.g., Ayurvedic treatments concomitant with the conventional therapies for psoriasis management) will be excluded, as any observed effects as a result of the intervention could not be attributed solely to the Ayurvedic treatment. Cluster RCTs, case studies, case series, and qualitative studies will be excluded. Laboratory or nonhuman experiments, healthy volunteer studies of antipsoriatic drugs, studies including cases of psoriatic arthritis will also be excluded. Furthermore, those with insufficient details on the target population, intervention, comparison condition, or outcomes (if after study authors were contacted and it was determined that requested information was unavailable) will be made ineligible.

Data Sources and Search Strategy

Search Methods for Identifying the Studies[6]

- Electronic search will be conducted by using CAM databases such as HerbMed, Annotated Bibliography of Indian Medicine, Open-access databases.
- Scholarly exchange.
- Free medical journals database: Official publications (journals) of various Indian societies/associations, open-access and institutional repositories, with e-prints, main stream allopathic databases.
- PubMed and CAM on PubMed.
- Cochrane Library and Cochrane Central Register of Controlled Trials (CENTRAL).
- Indian databases, viz., National Institute of Science Communication and Information Resources (NISCAIR) and the NISCAIR project register, IndMED, Digital Helpline for Ayurveda Research Abstracts, AYUSH Research Portal.
- South Asian Database of CCTs.
- Shodhgnaga for dissertations available in public domain.

Searching Other Resources

Hand searching identifies studies in journals that may not have been indexed in any electronic database or may have been indexed in such a way that database searching is impractical.

- Ongoing studies will be sought in the clinical trial registry of India

- World Health Organizations International Clinical Trials Registry Platform
- Cochrane Complementary Medicine trial register
- Clinical trials.gov, all of which list ongoing trials.
- Bibliographic references of all of the included trials will be reviewed to identify other relevant studies.
- The postgraduate theses will be searched on the "Researches in Ayurveda" compilation of available MD/PhD thesis work done in Ayurvedic universities of India will be done by searching research in Ayurveda Online Directory of PG and PhD Titles by Prof MS Baghel and Dr Girish KJ.
- Conference proceedings/ reports/ compendia

Search Strategy

A search strategy is developed using an iterative process based on preliminary search. The strategy included a combination of medical subject headings terms and key words related to the

- Population (Ayurvedic and allopathic nomenclature of disease/ vernacular name/main characteristics of disease), e.g., psoriasis, kitibh, mandal, sidhma, Ekakushtha/Ekkushtha/ekkakushth, ekakushtha, kushtha, etc.
- Intervention, e.g., Ayurvedic therapy, Ayurvedic treatment, polyherbal, rasaushadhi, rasakalpa, mercurial, metallic, herbomineral, panchakarma, TM, CAM, shodhan, shaman, vaman, virechan, basti, raktamokshan, lepa, shirodhara, jalauka, siravedh, oil/tel, etc.
- Comparison condition (e.g., control groups, usual care)
- Outcomes (e.g., Kandu, Rukshata, Aswedanam, Mahvaastu, Krishnarunavarna, Matsyashakalopamam, Mandala, Bahalatva, Unnati, Srava; well-demarcated/circumscribed erythematous papules/plaques covered with dry, brittle, silvery grayish white micacious scales, Scaling, Auspitz sign, Koebnerphenomenon, Candle grease sign, PASI, DLQI, PGA, remission period, disease-free survival, QOL, immunomodulation, other clinical gradations of the disease per study).

(Ayurveda OR Ayurvedic therapy OR Ayurvedic treatment OR Herbal Ayurveda OR Polyherbal OR Panchakarma OR Rasaushadhi OR Rasakalpa OR Herbo-mineral OR Metallic Ayurveda OR Mercurial OR Plants OR Herbs OR Manjishth OR Haridra OR Curcumin OR Turmeric OR Nimba OR Guduchi Or Rasayana OR Triphala OR Gomutra OR Cow Urine OR Honey OR Madhu OR Traditional Medicine OR Alternative Medicine OR Complementary Medicine Ayurveda OR Massage OR Shirodhara OR Leech OR Vaman OR Virechan OR Basti OR Siravedh OR Lepa OR Tel OR Oil OR Jalauka OR Vati OR Guti OR Kwath OR Tikta OR Immuo-modulant OR Anti-inflammatory) AND (Psoriasis OR Kitibh OR Mandal OR Kushtha OR Ekkushtha OR Eka OR Ekka OR Sidhma OR Twak OR Twacha OR Rakta OR Auto-immune OR Inflammatory Skin) AND (Clinical trial) as title, abstract or keyword.

Following the completion of this searching process, the reference lists of all studies meeting the inclusion criteria and any relevant reviews identified during the electronic database search will be scanned to identify additional studies.

Study Selection

All studies identified in the database search will be exported to reference managing software to delete the duplicate records. Both authors will independently review the titles and abstracts of all references. Articles clearly not meeting the established inclusion/ exclusion criteria will be excluded. Following this, both authors will independently screen the full-text articles of abstracts identified to select the studies to be included. Then the reference lists of included studies and relevant reviews will be scanned to identify additional studies. Both authors will independently screen the full texts of these additional articles to determine inclusion/exclusion. Third-party arbitration (MSG) will be done to resolve any inconsistencies in the selection of studies for inclusion/exclusion. A PRISMA flow diagram[7,8] will be prepared to show the overall process of study selection and the number of citations reviewed at each stage of this review.

Data Collection

Two authors (PM and SD), after independently screening the titles and abstracts of the searched studies, will select the study appropriately. They will record their decisions on a standard eligibility form. The arbitrator (MSG) will decide on the study selection when a consensus cannot be reached. The details of selection process will be shown in PRISMA flow diagram.

Data Extraction and Data Management

Based on the recommendations provided in the Cochrane Handbook of Systematic Reviews of Interventions, a data extraction tool will be developed specifically for this review. Following information will be extracted from each included article: (1) sources of data, (2) study design and study period, (3) characteristics of the population (i.e., number of participants randomized, age, type(s) of psoriasis diagnosed), (4) intervention characteristics (i.e., Ayurvedic polyherbal, herbomineral, mineral–metallic preparations used internally or externally, with the intent of cure or as add-on and biopurification procedures), (5) outcome measures (i.e., response to treatment by evaluating improvement in subjective and/or objective criteria of assessment and health and/or QOL assessment; serious adverse events resulting in death, disability, or incapacity, complications, were life-threatening, led to hospitalization or prolong of hospitalization), and (6) outcomes (i.e., complete remission, partial remission of disease, health, and/or QOL, safety of Ayurvedic interventions).

In addition to extracting this standard data, additional information will be documented on the use of theoretical frameworks (i.e., whether the study was informed by theory). The use of intention-to-treat analysis will also be recorded since intention-to-treat analyzes generally provide an unbiased estimate of treatment effect (intention-to-treat is a well-regarded approach to the design, conduct, and analysis of a trial[9]). It is a key component in the Consolidated Standards of Reporting Trials guidelines.[10] Additionally, data on variables not considered to be health and/ or QOL outcomes (e.g., intervention acceptance, adverse events, adherence to the study protocol) will be extracted to provide a more comprehensive understanding of the state of the literature.

Assessment of Risk of Bias in the Included Studies

The risk of bias will independently be assessed in the eligible studies according to the criteria described in the Cochrane Handbook V.5.1.0.[11] Quality of the study will be classified as low, unclear, or high risk of bias. If necessary, the authors of eligible trials will be contacted for clarification. Any differences in opinion will be resolved by discussion or arbitration, involving a third author.

Measures of the Treatment Effect

For continuous data, mean difference (MD) will be used to measure the treatment effect at a 95% confidence interval (CI). Other forms of

data will be converted into mean differences. In the case of outcome variables with different scales, the standard mean difference with a 95% CI will be used. For dichotomous data, the treatment effects will be presented as a relative risk or risk difference with 95% CI. Based on these results, the associated numbers needed to treat will be calculated.

Unit of Analysis Issues

Data from parallel group studies will be included for meta-analysis. If there are crossover trials, the first phase of the data will be adopted for analysis.

Managing Missing Data

In cases where data about details of on study design, population, intervention, or outcomes are missing, the authors of the included studies will be contacted by e-mail or telephone to request additional information or clarification. After the first contact attempt, if no response is received, the study authors will be again contacted two more times approximately 3–4 weeks apart. Missing data from the original authors will be requested, whenever possible. If it is not possible to do this, only the available data will be analyzed.

Assessment of Heterogeneity

If a meta-analysis is possible, then I^2 statistic may be used to quantify the inconsistencies among the included studies. An I^2 value of >50% will be considered indicative of substantial heterogeneity. If heterogeneity is observed, a subgroup analysis will be done to explore its possible causes.[12]

Assessment of Reporting Biases

Funnel plots will be prepared to assess the reporting biases if sufficient studies are available (at least 10 trials).[13] However, funnel plot asymmetry is not the same as publication bias; therefore, different possible reasons for the asymmetry will be tried to distinguish, such as small-study effects, poor methodological quality, and the true heterogeneity of the included studies.[13,14]

Data Synthesis

Heterogeneity of studies initially will be assessed according to the content, rather than by performing statistical tests of homogeneity as it is expected that the studies included in this review would vary widely. Given that the main purpose of the SR is to comprehensively review and synthesize published studies focusing on the effectiveness of Ayurvedic interventions for treating psoriasis, all data extracted from the articles will be presented narratively in text and summary tables if it is expected that studies will be too heterogeneous to allow for a quantitative summary.[15] To ensure the quality of the narrative synthesis, the guidance on the conduct of narrative synthesis in systematic reviews will be followed as appropriate to accurately report the review search results and analysis summary.[15] Specifically, the included studies will be carefully reviewed and the limitations of each (i.e., quality assessment) will be described. Additionally, the entire data extraction and synthesis process will be carefully detailed, and objective third-party review (SR) will be utilized.

Data synthesis for comparable trials with comparable outcomes will be performed using Review Manager (RevMan), V.5.2.6. Data Synthesis.

Subgroup Analysis and Investigation of Heterogeneity

If the data are available, a predefined subgroup analysis will be conducted to assess the heterogeneity of different studies, including the following:

- Type of psoriasis;
- Site of the body affected;
- Duration or chronicity of psoriasis;
- Duration of conventional or other than Ayurvedic treatment;
- Type of Ayurvedic intervention;
- Type of control;
- Age-group

Sensitivity Analysis

Sensitivity analysis will principally be performed as follows:

- Sample size (e.g., more or less than 40 participants in each group);
- Low risk of bias (e.g., allocation concealment or the blinding of participants/assessors).

Outcome Measures

Primary

- Response to treatment (improvement in subjective and/or objective criteria of assessment)

Secondary

- Serious adverse events (resulting in death, disability or incapacity, complications, life-threatening, led to hospitalization or prolongation of hospitalization)
- Reported improvement in the patient's health-related QOL

Discussion

Several clinical trials and published studies reveal the efficacy of different types of Ayurvedic interventions (internal and external) but no SR is available regarding the same till date. Too much of work on the same problem or haphazardly reaching a conclusion where the results do not match the aim of the clinical trial creates confusion, and SR may help to end such confusion or at least let us know where there is either enough evidence or lacuna in the present system of clinical trial.[16] Recent SRs were undertaken to investigate the benefits of CAM, Chinese traditional medicines, and herbal medicines for treating psoriasis, but none have focused on Ayurvedic interventions to treat psoriasis. Thus, this protocol adds to the field of management of psoriasis through Ayurveda. A key strength of this review protocol is the use of multiple gold standard guidelines. By incorporating different elements from each guideline, a solid framework and structure is created by which the research question can be answered.

There were some challenges in preparing and finalizing this review protocol, like in formulating the inclusion/exclusion criteria. In general, given the complexity and types of the disease and the numerous iterations of Ayurvedic interventions, careful consideration will be given to ensure the best evidence to be identified to answer the research question. Identifying pertinent literature will be difficult, given the paucity of results obtained in preliminary tests of the search strategy. A flexible approach

to search terms and key words will be necessary to ensure more studies to be identified for review. In light of variety of assessment criteria, outcome measures (mostly subjective) and self-developed scales to assess the improvement, synthesis, and interpretation of data are assumed to be a challenge. Per an editorial of a peer-reviewed journal, there is a need to re-strategize clinical trials or to properly review them,[16] and there may be lack of well-designed clinical studies including Ayurvedic interventions. Thus, a narrative approach to data synthesis may be selected if the data obtained are too heterogeneous to allow for a quantitative summary.

Psoriasis and its Ayurvedic interventions is a relatively new topic of research in Ayurveda. Generally, new topics pose inherent challenges for SR protocol development. As the literature in this area grows, so will the opportunities to refine protocols, rerun search, and update findings. However, until then, protocols should be disseminated to ensure transparency of completed reviews and aid other researchers in developing their review protocols.[17]

Approval of institutional ethics committee has been received for this study.

Results

After the review is completed, it will be sent for publication in a peer-reviewed journal. It will also be disseminated electronically and in print. The review will be updated, and a GRADE evaluation of the quality of evidence will be conducted to provide summaries of the future state of the evidence for the efficacy of interventions utilizing Ayurvedic interventions for psoriasis. The review may guide healthcare practices and policies regarding the administration of Ayurvedic interventions to treat psoriasis.

Contributors

The protocol was drafted by all authors. It was revised and the final version approved by all authors. Further, all the authors approved the order of authorship.

Acknowledgments

The authors would like to thank Director General and Deputy Director General, CCRAS, for the inspiration and support to initiate the study.

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हिन्दी सारांश

सोराइसिस पर आयुर्वेदिक उपचारों की कार्यकारिता एवं सुरक्षितता के सिस्टेमेटिक रिव्यू का प्रोटोकॉल

पल्लवी एस. मुंदड़ा, सायली देशमुख, टी साकेत राम, मनोहर एस. गुंडेटी

रोगी के मानसिक एवं सामजिक स्वास्थ्य पर भी असर डालनेवाले 'सोरायसिस' इस चर्मरोग के उपचार में अभी भी समाधानकारक विधियों अथवा औषधियों की उपलब्धता नहीं है ऐसा विश्व स्वास्थ्य संघटन की ग्लोबल रिपोर्ट में पाया गया है| आयुर्वेद द्वारा इस रोग का उपचार किये जाने से सम्बंधित कई एकल संशोधन आलेख पाए जाते हैं परन्तु, आयुर्वेदिक उपचारों की कार्यकारिता का मूल्यमापन कर सोरायसिस के चिकित्सा सूत्र की स्थापना अभी तक नहीं की जा सकी है| अतः इस विषय में सिस्टेमेटिक रिव्यू तथा आगे चलकर संभवतः मेटा एनालिसिस करके यह देखा जा सकता है कि, क्या आयुर्वेदिक उपचार (विधियां तथा औषधियां) सोरायसिस के इलाज में कारगर एवं सुरक्षित हैं? इसी उद्देश्य से सोराइसिस पर आयुर्वेदिक उपचारों की कार्यकारिता एवं सुरक्षितता के सिस्टेमेटिक रिव्यू हेतु एक प्रोटोकॉल की संरचना की गई|

यह प्रोटोकॉल, सिस्टेमेटिक रिव्यू एवं ट्रायल के रिपोर्टिंग हेतु वर्त्तमान में प्रचलित विविध दिशानिर्देशों के आधार पर लिखा गया है | इन्हीं के आधार पर कुछ बदलाव के साथ अनुसंधान प्रश्न, शोध हेतु पारिभाषिक शब्द, डेटा एक्सट्रैक्शन फॉर्म, आदि भी तैयार किये गए हैं | विभिन्न इलेक्ट्रॉनिक डेटाबेस से योग्य संशोधन आलेखों को तथा हैण्ड सर्चिंग कर अप्रकाशित अनुसंधान डेटा संकलित कर इसका परीक्षण किया जाएगा | कम से कम दो संशोधक इस कार्य को स्वतन्त्र रूप से करेंगे | डेटा सिंथेसिस के उपरांत यदि डेटा में एकरूपता एवं योग्यता पायी गई तो मेटा एनालिसिस भी किया जाएगा | इस प्रोटोकॉल को प्रोस्पेरो में रजिस्टर किया गया है जिसका रजिस्ट्रेशन आई डी है- **PROSPERO 2018 CRD42018097298**| इस सिस्टेमेटिक रिव्यू को पियर रिव्यूड जर्नल में प्रकाशित किया जाएगा |

अब तक इस प्रकार का अनुसंधान इस विषयमें कभी नहीं हुआ है, अतः इस विषय में प्रोटोकॉल का प्रकाशन भी एक महत्वपूर्ण कदम हो सकता है | साथ ही इस प्रोटोकॉल के आधार पर ही सिस्टेमेटिक रिव्यू को सफलता से करते हुए उचित निष्कर्ष तक पहुँचा जा सकेगा |