

# Moxibustion for Allergic Rhinitis: Protocol for Evidence-based Clinical Practice Guideline

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## Study protocol

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# Abstract

## Introduction

Allergic rhinitis(AR) is a [widespread](#) non-infectious inflammatory [lesion](#) of the [schneiderian membrane](#). Moxibustion is a traditional Chinese treatment that can effectively treat AR. At present, there is a lack of guidelines to regulate the treatment of AR by moxibustion, so relevant clinical practice guideline (CPG) need to formulate.

## Methods and analysis

The guideline will base on the Institute of Medicine (IOM), the World Health Organization(WHO) guideline handbook, the Grade of Recommendations Assessment, Development and Evaluation (GRADE)the Appraisal of Guidelines for Research & Evaluation (AGREE), Reporting Items for practice Guideline in HealThcare (RIGHT). We will set up the Guideline working group to identify questions in the form of Population, Intervention, Comparison, Outcomes (PICO). Then we will [accomplish](#) evidence retrieval, synthesis and evaluation. Experts will [programme](#) recommendations through 2-3 rounds of the Delphi method. We will also consider patient preferences and complete peer reviews.

## Results

The study is not complete, so there are no results to report.

## Conclusions

The guideline will make moxibustion more standardized and effective in the treatment of AR.

## Registration number

IPGRP-2020CN012.

# Contributions To The Literature

- Clinical practice guidelines (CPGs) are systematic guidelines to assist clinicians and patients in the proper management of specific clinical situations.
- This study is the first clinical practice guideline for treating AR using moxibustion.
- This proposal for evidence-based CPG for the treatment of AR with moxibustion to ensure a scientific and transparent process of the guideline.

## Introduction

Allergic rhinitis(AR) is a common allergic disease, which is an inflammatory response mediated by immunoglobulin E (IgE) in the nasal mucosa after exposure to inhaled allergens. The main clinical

manifestations are stuffy nose, sneeze, rhinorrhea, itchy eyes, lacrimation, accompanied by anosmia. AR classify as seasonal and perennial, and the symptoms are intermittent or persistent.<sup>1,2</sup> The aetiology of AR is generally associated with genetic susceptibility and environmental factors.<sup>3</sup> In one study, the prevalence of allergic disease was as high as 75% in children of both parents and 50% in children of one parent.<sup>4</sup>

AR is a global disease that affects people of all ages, and the prevalence tends to increase.<sup>5,6</sup> In China, the prevalence of AR was 15.79% in children and 13.26% in adults.<sup>7</sup> In Europe, the incidence of AR was as high as 30%.<sup>8</sup> 10–40% of the world's population was affected by AR.<sup>9</sup> Although AR does not cause serious physical or functional impairment, it often accompanies with asthma and other comorbidities and complications.<sup>9,10</sup> A survey has found that allergic rhinitis increases the risk of panic attacks in young people.<sup>11</sup> AR can also affect the mental health of patients so that the quality of life of patients decline.<sup>12</sup> The research pointed out that AR in the quality of life, work efficiency, medical expenses and other aspects have brought a substantial burden.<sup>13</sup>

The therapeutic principle of AR, including allergen avoidance, pharmacotherapy, immunotherapy, surgical management.<sup>14</sup> Pharmacotherapy is the main treatment for AR, but these drugs(e.g. antihistamines, nasal corticosteroids) have limited effectiveness and often have adverse reactions, such as drowsiness, dry mouth, dizziness, fatigue.<sup>13</sup>

The American academy of otolaryngology in the CPG for AR recommends the use of acupuncture for AR patients who are interested in non-drug treatment.<sup>2</sup> Moxibustion is one of the acupuncture treatments. It is usually an external treatment of acupuncture points using burning mugwort.<sup>15</sup> Studies on the spectrum of diseases of moxibustion therapy have found that moxibustion can prevent and treat many diseases, including AR.<sup>16</sup> The mechanism of moxibustion in the treatment of AR may be related to the following: Moxibustion can activate transient receptor potential vanilloid(TRPV), promote the generation of growth factors and inflammatory regulatory factors; It can activate langerhans cell(LC) and increase toll-like receptor-3(TLR-3), toll-like receptor-4(TLR-4) and cluster of differentiation 40(CD40); It can also enhance the activity of heat shock protein(HSP); These substances are anti-inflammatory and regulate immunity.<sup>17–20</sup> In traditional Chinese medicine, AR is caused by deficiency of zang-fu organs, deficiency of vital qi, loose skin and feeling of external evil influences, mainly related to lung, spleen and kidney. Moxibustion has the function of warming Yang and strengthening the body.<sup>21</sup> Different treatment points have different effects. Treatment of AR common acupoints are yingxiang(LI 20), Feishu(BL 13), shen shu(BL 23), can XuanTong nasal orifices, benefit the lung and kidney function.<sup>22</sup> Studies have confirmed that moxibustion, as a safe, effective and simple traditional treatment, can improve the clinical symptoms of allergic rhinitis and reduce the recurrence rate compared with the current conventional western medicine treatment.<sup>23</sup>

Clinical practice guidelines (CPGs) are systematic guidelines to assist clinicians and patients in the proper management of specific clinical situations. Therefore, evidence-based guidelines are necessary for

both clinical workers and patients. However, as far as we knew, there are no guidelines for treating AR using moxibustion. In order to make moxibustion treatment of AR more standardized in the determination of moxibustion types, moxibustion acupoints, moxibustion quantity, etc., we plan to make a relevant guideline.

## Aims

To develop a proposal for evidence-based CPG for the treatment of AR with moxibustion to ensure a scientific and transparent process of the guideline. the guideline will provide the standards for moxibustion treating of AR.

## Methods

### Principle

We will base on the definition of the IOM and the WHO handbook for guideline development. We also adhere to the AGREE instrument, RIGHT checklist and GRADE system.<sup>24-27</sup>

### Study registration

This guideline was recorded on the International Practice Guidelines Registry Platform (<http://www.guidelines-registry.org/>), and the registration number is IPGRP-2020CN012.

### Development organization

The guideline was launched in February 2020 by the Acupuncture and Moxibustion Allergic Rhinitis Department, Affiliated Hospital of Jiangxi University of Traditional Chinese Medicine(TCM), Jiangxi University of TCM. The title of the guideline will be "Moxibustion for allergic rhinitis: Evidence based clinical practice guideline".

### Guideline Working Group

In March 2020, we will set up the Guideline Working Group, divided into the Guideline Development Group, the Guideline Steering Group and the Guideline Secretary Group. The guideline working group will compose of multidisciplinary experts, including not only clinicians and methodologists, but also the values and wishes of potentially conflicting interests and patients.

### Guideline Development Group

The Guideline Development Group will consist of the following: acupuncturists, TCM physicians, physical therapists, evidence-based medicine experts, nurse and economist. The Guideline Development Group will be responsible for the following : (1) to develop the scope of the guideline, and formulate clinical problems; (2) to assess the importance of outcomes; (3) to evaluate the quality of evidence; (4) to write a proposal; (5) to draft recommendations; and(6) to publish and popularise the guideline.

# Guideline Steering Group

The Guideline Steering Group will include several types of experts: acupuncturists, physiotherapists, evidence-based medicine experts, TCM physicians, economists. The Steering Group will be responsible for the following: (1) to ratify the scope of the guideline and the PICOs; (2) to supervise evidence retrieval, synthesis and evaluation; (3) to approve final recommendations; and(4) to confirm the issue of the guidelines.

## Guideline Secretary Group

The Guideline Secretary Group will comprise the following experts: 3 evidence-based medicine experts, acupuncturists and statistician. The Guideline Secretary Group will be allotted the following works: (1) to collect clinical problems; (2) to search the literature and accomplish the systematic reviews; (3) to investigate the patients' values and preferences; and(4) to coordinate the formulation of guidelines.

### Declaration of interest

Members of the Guideline Working Group will fill in a declaration of interest form to determine whether they have a conflict of interest.

### Guideline target users and population

Acupuncturists, physical therapists, nurses, editors and AR-related researchers become the guideline's target users. Patients with AR treated with moxibustion constitute the target population.

### Identifying questions and evaluating the importance of outcomes

After the Secretary Group has collected the clinical questions according to the scope of the guide, we will complete the PICOs. The Development Group will evaluate the importance of the outcomes. It will be assessed according to the approach recommended by the GRADE working group: a score of 7–9 indicates that the outcome is critical to the recommendation, 4–6 indicates important, 1–3 is not important.

### Search for evidence

We will employ a broad electronic searching, including PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), WangFang Database(WF), Chinese Scientific Journal Database (VIP), Chinese Biomedical Literature Database (CBM), from establishment to March 31, 2020, and conduct normal searches according to the rules of each database. Evidence-based experts will help develop retrieval strategies. MeSH terms and free words to be searched will include: allergic rhinitis, anaphylactic rhinitis, AR, hay fever, pollinosis, nasal allergy, moxibustion, thunder fire needle, taiyi miraculous moxa roll. There will be no restrictions on publication language.

### Pre-test

To ensure that the selection criteria of the literature are consistent, the members will conduct predictive tests. We will summarize the screening results and discuss the inconsistencies. After this test, each member will explicitly include and exclude criteria.

### **Literature screening**

After the pre-test, we will formally select the literature. The major ranges will include systematic review, meta-analysis, and original studies. Members will exclude irrelevant literature by reading the title and abstract, and read the rest of the full text to select.

### **Systematic reviews**

Through the assessment of literature quality, high-quality systematic reviews will be used directly, if it is published more than two years will be updated. If the relevant system reviews are of low quality or absent, the Guideline Secretary Group will prepare a new system reviews.

### **Evidence evaluation**

The GRADE approach will be used to evaluate the quality of evidence. The level of evidence is classified as high, medium, low and very low. Five downgrading factors: risk of bias, inconsistency, accuracy, publication bias and indirection; Three escalation factors: large effect size, confounding factor bias and dose effect. The Guidelines Development group will be responsible for the assessment of evidence and the drafting of evidence summaries.

### **Patients' willingness**

We will conduct an investigation on the willingness of AR patients to treat AR with moxibustion. The researchers will ask relevant questions and record the results after letting the interviewees know the relevant medical vocabulary, background knowledge and analysis of advantages and disadvantages. Questions will include the effectiveness of moxibustion therapy for AR, adverse reactions, burdens, costs, potential benefits, etc. The findings will be summarized and analyzed for the reference of the experts in the guideline working group.

### **Developing recommendations**

The Guideline Development Group will draft recommendations through 2–3 rounds of the Delphi process based on the quality of evidence, patient willingness, economic analysis, and balance of advantages and disadvantages. The process will use the GRADE grid. There are five recommendation levels( strong recommendation, weak recommendation, unclear, weak no recommendation, strong no recommendation), and the results will be obtained by voting. The drafted recommendation will be approved by the Guideline Steering Group.

### **Peer review**

The guideline will be reviewed by external peer experts, we will discuss feedback and recommendations from peer experts, and some recommendations may be revised.

### **Publishing and updating of the guideline**

The reporting and publication of the guidelines will be conducted in a normative, systematic and transparent manner by the requirements of RIGHT. The guidelines will be published in one or two years. We plan to update it every 3–5 years.

### **Publicity and evaluation of the guideline**

After the publication of the guideline, Affiliated Hospital of Jiangxi University of TCM and Jiangxi University of TCM will conduct the dissemination and promotion of the guideline: (1) The guideline will be presented and disseminated at relevant academic conferences; (2) A nationwide study program will be organized for relevant personnel, such as acupuncturists, physiotherapists and nurses; and (3) Members of the guidelines will write papers related to the guidelines and publish them in the journal.

The application and dissemination of the guidelines will be investigated, and the impact of the guidelines on clinical decision making will be assessed.

## **Discussion**

This study is a proposal for CPG. This guideline will follow the latest definition of the IOM guidelines and will be a collaboration of multidisciplinary experts. The formulation of the guideline will help to standardize and popularize moxibustion for AR, and improve the effectiveness, safety and economy of moxibustion therapy for AR.

## **Abbreviations**

### **AR**

Allergic rhinitis

### **CPG**

Clinical practice guideline

### **IOM**

Institute of Medicine

### **WHO**

World Health Organization

### **GRADE**

Grade of Recommendations Assessment, Development and Evaluation

### **AGREE**

Appraisal of Guidelines for Research & Evaluation

### **RIGHT**

## PICO

Population, Intervention, Comparison, Outcomes

## Declarations

### Ethics approval and consent to participate

Not Applicable.

### Consent for publication

Not Applicable.

### Availability of data and materials

Not Applicable.

### Competing interests

The authors declare that they have no competing interests.

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### Authors' contributions

Jun Xiong and YF conceptualised the protocol and detailed the main content of the paper. Jie Xiang and HZ guided the implementation of the study. YJ, SH, FH, XZ, KL and LX collected and sorted out the relevant materials. All authors contributed to drafting the manuscript, and all have read and approved the final manuscript.

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