Register a trial

Acknowledgment

Step 1: Titles & IDs

Step 2: Health condition

Step 3: Intervention/exposure

Step 4: Outcomes

Step 5: Eligibility

Step 6: Study design

Step 7: Recruitment

Step 8: Funding & Sponsors

Step 9: Ethics & Summary

Step 10: Contacts

Review & Submit

Request number

Current page

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Trial registered on ANZCTR

<table>
<thead>
<tr>
<th>Trial ID</th>
<th>ACTRN12617001106325</th>
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<tr>
<td>Ethics application status</td>
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<tr>
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<td>25/07/2017</td>
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<td>28/07/2017</td>
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Titles & IDs

<table>
<thead>
<tr>
<th>Public title</th>
<th>Self-administered acupressure for the management of allergic rhinitis</th>
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<tr>
<td>Scientific title</td>
<td>Effects of self-administered specific acupressure versus non-specific acupressure for the management of allergic rhinitis</td>
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<td>Secondary ID [1]</td>
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<td>Universal Trial Number (UTN)</td>
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<td>Trial acronym</td>
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Health condition

<table>
<thead>
<tr>
<th>Health condition(s) or problem(s) studied:</th>
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<tr>
<td>Allergic rhinitis</td>
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Condition category

<table>
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<tr>
<th>Alternative and Complementary Medicine</th>
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<tbody>
<tr>
<td>Inflammatory and Immune System</td>
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<tr>
<td>Respiratory</td>
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Condition code

<table>
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<tr>
<th>Other alternative and complementary medicine</th>
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<tbody>
<tr>
<td>Allergies</td>
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<tr>
<td>Other respiratory disorders / diseases</td>
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Intervention/exposure

<table>
<thead>
<tr>
<th>Study type</th>
<th>Interventional</th>
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</table>
| Description of intervention(s) / exposure | Participants will complete self-administered questionnaires for the severity of symptoms, quality of life and medication use during the 2-week run-in period. After randomisation at the first visit to the clinic laboratory during the treatment period, the registered acupuncturist will provide detailed instructions to each
participant in a 15-minute session on a one-on-one basis. Each participant will also receive an information sheet ("Location of 5 Acupoints for Self-administered Acupressure") showing the details of the location of acupuncture points and administration.

Participants in specific acupressure group will perform self-administered acupressure to five specific acupuncture points bilaterally, including Hegu (LI 4), Shangxing (GV 23), Zanzhu (BL 2), Yingxiang (LI 20) and Fengchi (GB 20). Participants will apply pressure to each acupuncture point for one minute, twice a day for four consecutive weeks. Participants will be asked to have a 10-minute one-on-one weekly visit for the four-week intervention period. The same acupuncturist will reinforce the participants’ self-administered acupressure skills in every visit during the treatment period and ensure their techniques are correct.

**Intervention code [1]**

Treatment: Other

**Comparator / control treatment**

Participants will complete self-administered questionnaires for the severity of symptoms, quality of life and medication use during the 2-week run-in period. After randomisation at the first visit to the clinic laboratory during the treatment period, the registered acupuncturist will provide detailed instructions to each participant in a 15-minute session on a one-on-one basis. Each participant will also receive an information sheet ("Location of 5 Acupoints for Self-administered Acupressure") showing the details of the location of acupuncture points and administration.

Participants in the control group will perform self-administered acupressure on five non-specific acupuncture points, including Extra-Luozhen, Baihui (GV 20), Hanyan (GB 4), Quanliao (SI 18) and Wangu (GB 12). Participants will apply pressure to each acupuncture point for one minute, twice a day for four consecutive weeks. Participants will be asked to have a 10-minute one-on-one weekly visit for the four-week intervention period. The same acupuncturist will reinforce the participants’ self-administered acupressure skills in every visit during the treatment period and ensure their techniques are correct.

**Control group**

Placebo

**Outcomes**

**Primary outcome [1]**

Symptom scores assessed by 7-point scale questionnaire in the severity of symptoms

**Timepoint [1]**

Baseline, end of treatment (4 weeks) and end of follow-up period (8 weeks)

**Secondary outcome [1]**

Quality of life assessed by Rhinoconjuctivitis Quality of Life Questionnaire with Standardised Activities (RQLQs)

**Timepoint [1]**

Baseline, end of treatment (4 weeks) and end of follow-up period (8 weeks)

**Secondary outcome [2]**

Medication usage (name, dose and frequency of Western medication used for managing allergic rhinitis symptoms) recorded in the Medication use form

**Timepoint [2]**

Baseline, end of treatment (4 weeks) and end of follow-up period (8 weeks)

**Secondary outcome [3]**

Adverse events of self-administered acupressure recorded in adverse event form (eg. pain in the acupuncture point regions)

**Timepoint [3]**

During treatment period (4 weeks) and follow-up period (8 weeks)

**Secondary outcome [4]**

Participants’ opinion about self-administered acupressure by Participants’ Opinion of Self-administered Acupressure Credibility Expectancy Questionnaire (9-point scale)

**Timepoint [4]**

At the first week and the final week of the 4-week treatment period

**Eligibility**

**Key inclusion criteria**

- Aged 18 years old and above;
- A history of at least two years of typical symptoms of allergic rhinitis;
- Have a positive skin prick test to one or more of the allergens such as Seven-grass mix, Perennial Rye, Ragweed, House mite, Animal’s dander or Mould;
- Currently not involved in other clinical trials for the treatment of allergic rhinitis;
- Provide written consent for participant to sign;
- Have access to computer and internet; and
- Will not travel overseas or interstates for the 14 weeks of trial period.

**Minimum age**

18 Years

**Maximum age**

No limit

**Gender**

Both males and females

**Can healthy volunteers participate?**

No

**Key exclusion criteria**

- Current systemic corticosteroid therapy;
- Other current active respiratory disease such as asthma;
- Nasal polyposis;
- Other structural defects of the upper respiratory tract;
- History of asthma, HIV, Hepatitis B or C;
- Current pregnancy;
- Have used acupuncture/accupuncture for respiratory or allergic diseases within the last month;
- Chinese herbal medicine practitioner, acupuncturist, past or current Chinese medicine student;
- Travel overseas or interstates in the 14 weeks of trial period; or
- Do not understand English.
### Study design

**Purpose of the study**  
Treatment

**Allocation to intervention**  
Randomised controlled trial

**Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)**  
Each computer generated random number will be kept in a sealed opaque envelope until the participant is randomised prior to the first treatment.

**Methods used to generate the sequence in which subjects will be randomised (sequence generation)**  
Randomisation sequence will be computer generated by an independent researcher.

**Masking / blinding**  
Blinded (masking used)

**Who is / are masked / blinded?**  
The people receiving the treatment/s  
The people assessing the outcomes  
The people analysing the results/data

**Intervention assignment**  
Parallel

**Other design features**  
The grouping information will only be known to the registered acupuncturist who will provide instructions to the participants. This acupuncturist will not disclose the grouping information to the participants or other trial investigators.

**Phase**  
Not Applicable

**Type of endpoint(s)**  
Safety/efficacy

**Statistical methods / analysis**  
Data analysis will be conducted using the Statistical Package for Social Science (SPSS).

### Recruitment

**Recruitment status**  
Not yet recruiting

**Update**  
Recruiting

**Reason**  
The clinical trial has started to recruit participants since 1st August 2017.

**Date of first participant enrolment**

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**Date of last participant enrolment**

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**Date of last data collection**

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**Sample size**

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**Recruitment in Australia**

**Recruitment state(s)**  
VIC

**Funding & Sponsors**

**Funding source category [1]**  
University

**Name [1]**  
RMIT University

**Address [1]**  
School of Health and Biomedical Sciences  
RMIT University  
PO Box 71  
Bundoora VIC 3083

**Country [1]**  
Australia

**Primary sponsor type**  
University

---

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=373370&isClinicalTrial=False
Name: RMIT University
Address: School of Health and Biomedical Sciences
         RMIT University
         PO Box 71
         Bundoora VIC 3083
Country: Australia
Secondary sponsor category: None

Ethics approval
Ethics application status: Approved
Ethics committee name: RMIT University Human Research Ethics Committee
Ethics committee address: Research and Innovation office
          GPO Box 2476
          MELBOURNE VIC 3001
Ethics committee country: Australia
Date submitted for ethics approval: 02/06/2017
Approval date: 02/06/2017
Ethics approval number: 20742

Summary
Brief summary: This randomised controlled trial aims to investigate the efficacy and safety of self-administered acupressure for the management of allergic rhinitis. Acupressure is a subtype of acupuncture without needle insertion. It applies fingers to press points on the body. The study consists of 2-week run-in, 4-week treatment and 8-week follow-up period.

Contacts
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         RMIT University
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         Bundoora VIC 3083
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Contact person responsible for updating information
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Fax
Email

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