Register a trial

Request number 373370

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Trial registered on ANZCTR

Trial ID	ACTRN12617001106325
Ethics application status	Approved
Date submitted	25/07/2017
Date registered	28/07/2017
Type of registration	Prospectively registered

Titles & IDs

Public title	Self-administered acupressure for the management of allergic rhinitis
Scientific title	Effects of self-administered specific acupressure versus non-specific acupressure for the management of allergic rhinitis
Secondary ID [1]	Nil
Universal Trial Number (UTN)	U1111-1199-8020
Trial acronym	ARCT
Linked study record	

Health condition

Health condition(s) or problem(s) studied:

Allergic rhinitis

Condition category	Condition code
Alternative and Complementary Medicine	Other alternative and complementary medicine
Inflammatory and Immune System	Allergies
Respiratory	Other respiratory disorders / diseases

Intervention/exposure

Study type	Interventional
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/acupressure 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

Anticipated	31/07/2017	**Actual**	
		Update	1/11/2017
		Reason	The first participant came in for interview.

Date of last participant enrolment

Anticipated	**Actual**

Date of last data collection

Anticipated	**Actual**

Sample size

Target	110	**Accrual to date**		**Final**
		Update	15	
		Reason	15 participants enrolled in the pilot study,	

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

Name	RMIT University
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Country	Australia
Secondary sponsor category [1]	None
Name [1]	
Address [1]	
Country [1]	

Ethics approval

Ethics application status	Approved
Ethics committee name [1]	RMIT University Human Research Ethics Committee
Ethics committee address [1]	Research and Innovation office GPO Box 2476 MELBOURNE VIC 3001
Ethics committee country [1]	Australia
Date submitted for ethics approval [1]	
Approval date [1]	02/06/2017
Ethics approval number [1]	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.
Trial website	
Trial related presentations / publications	
Public notes	
Private notes	

Contacts

Principal investigator

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