

A randomised controlled trial of acupuncture for the treatment of hyperventilation syndrome

Submission date 29/12/2005	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 03/02/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 10/05/2016	Condition category Signs and Symptoms	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Miss Denise Gibson

Contact details
Physiotherapy Department
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD
-
deniseg902@aol.com

Additional identifiers

Protocol serial number
PRF/04/3

Study information

Scientific Title
A randomised controlled trial of acupuncture for the treatment of hyperventilation syndrome

Study objectives

Continual and subtle hyperventilation can lead to a chronic condition which has been termed hyperventilation syndrome. Patients with hyperventilation syndrome are known to breathe at lower levels of arterial carbon dioxide and only small changes in this level can produce symptoms that can mimic serious disease e.g. chest pain, breathlessness, headaches, paraesthesia.

The aim of this study is to evaluate whether the use of acupuncture complements conventional physiotherapy treatment for hyperventilation syndrome. It is hypothesised that acupuncture, as an adjunct to conventional treatment for hyperventilation syndrome, will be beneficial, in terms of reducing anxiety and symptoms of hyperventilation.

Please note that, as of 14/10/2008, the anticipated end date of this trial has been extended from 31/12/2006 to 31/03/2009. The extension is due to delays in recruitment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Southampton and Southwest Hampshire Research Ethics Committee, 03/05/2006, ref: 06/Q1704/28

Primary study design

Interventional

Study design

Randomised controlled single-blind trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hyperventilation syndrome

Interventions

Current interventions as of 14/10/2008:

Physiotherapy in the form of breathing retraining:

Participants will be taught relaxed diaphragmatic breathing and encouraged to reduce their breath rate to 6 - 8 breaths per minute. They will also be taught a contact-relaxation technique. They will then be advised to carry out these techniques at home at least 3 times per day.

Acupuncture:

A western approach to acupuncture therapy will be used. Participants will receive either real acupuncture or placebo acupuncture using the Streitberger needle. Needles will be placed on 8 points of the body and a draining technique will be used i.e. once inserted, the needles will be left for a period of 30 minutes. Each participant in the acupuncture group will receive twice weekly treatments for 4 weeks (therefore 8 acupuncture treatments in total).

Previous interventions:

Physiotherapy in the form of breathing retraining:

Participants will be taught relaxed diaphragmatic breathing and encouraged to reduce their

breath rate to 6 - 8 breaths per minute. They will also be taught a contact-relaxation technique. They will then be advised to carry out these techniques at home daily.

Acupuncture:

A western approach to acupuncture therapy will be used. Participants will receive either real acupuncture or placebo acupuncture using the Streitberger needle. Needles will be placed on 8 points of the body and a draining technique will be used i.e. once inserted, the needles will be left for a period of 30 minutes.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Hospital Anxiety and Depression scale. This is a validated questionnaire which is used to identify anxiety and depression in non-psychiatric hospital clinics.

Added as of 14/10/2008:

All primary and secondary outcomes are measured at 1) baseline 2) pre-treatment (after a 4-week wait period to ensure participant's condition is stable) and 3) post-treatment on the 9th session.

Key secondary outcome(s)

1. Nijmegen Questionnaire - this is a validated screening tool which has been shown to have 95% effectiveness in discriminating hyperventilators from normals
2. Measure Yourself Medical Outcome Profile (MYMOP2) - this is a validated quality of life measure, which is individualised and problem specific and also includes general wellbeing
3. Objective measures of cardiorespiratory performance will also be taken e.g. respiratory rate and pattern, resting end tidal carbon dioxide, pulse oximetry, pulse rate and blood pressure
4. Borkovec and Nau credibility rating - this will be used to assess the success of blinding

Added as of 14/10/2008:

All primary and secondary outcomes are measured at 1) baseline 2) pre-treatment (after a 4-week wait period to ensure participant's condition is stable) and 3) post-treatment on the 9th session.

Completion date

31/03/2009

Eligibility

Key inclusion criteria

Any patient newly diagnosed with hyperventilation syndrome by the respiratory physicians at Southampton General Hospital.

Added as of 14/10/2008:

Both males and females, over 18 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Any person for whom acupuncture would be contraindicated e.g. in pregnancy, pacemaker wearers
2. Any person who is receiving conventional or alternative treatment for the condition
3. People who are allergic to sticking plaster
4. People who are unable to attend for the required treatment sessions

Date of first enrolment

01/03/2006

Date of final enrolment

31/03/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Physiotherapy Department

Southampton

United Kingdom

SO16 6YD

Sponsor information

Organisation

Physiotherapy Research Foundation (UK)

ROR

<https://ror.org/04sn78z72>

Funder(s)

Funder type

Charity

Funder Name

Physiotherapy Research Foundation (UK) (ref: PRF/04/3)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration