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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled single-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/03/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

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
England

United Kingdom

Study participating centre
Physiotherapy Department
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Physiotherapy Research Foundation (UK)

Sponsor details
14 Bedford Row
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Sponsor type
Charity

ROR
https://ror.org/04sn78z72

Funder(s)

Funder type
Charity

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration