

# Classical ACupuncture Treatment for people with Unexplained Symptoms

<b>Submission date</b> 05/10/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/04/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/08/2011	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

**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**

1

# Study information

## Scientific Title

## Acronym

CACTUS study

## Study objectives

1. In patients who attend frequently in primary care with medically unexplained physical symptoms that have persisted for more than three months, does the addition of five-element acupuncture to usual General Practitioner (GP) care, compared to usual care alone, improve self-reported health, increase health-improving behaviours, and reduce conventional medication and general practice consultation rates?
2. How do these patients experience the process and effects of acupuncture, how do they integrate it with conventional medical care and self-care, and how does it affect their use of other health care resources?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Lewisham Research Ethics Committee (REC) on 05/12/2007 (ref: 07/H0810/54)

## Study design

A pragmatic randomised trial of usual care versus acupuncture plus usual care, with a nested qualitative study involving interviews with patients.

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

GP practice

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Medically unexplained physical symptoms

## Interventions

Both groups will receive usual care. The intervention group will also receive up to twelve sessions of classical five-element acupuncture over a six month period. The control group will

receive the same acupuncture intervention after a six month period. The two groups will be followed up for two years.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

The primary quantitative outcome will be change in health status, from baseline to end of six months treatment, as measured by the Measure Yourself Medical Outcome Profile (MYMOP) questionnaire. MYMOP is a brief individualised questionnaire that measures change in two symptoms, one activity of daily living and general wellbeing, all measured on a seven point scale, and combined to give a single MYMOP profile score.

## **Secondary outcome measures**

1. Change in health status and wellbeing as measured by:
  - 1.1. General Wellbeing Questionnaire (GW-B12), which has three dimensions of energy, negative wellbeing (includes anxiety and depression), and positive wellbeing
  - 1.2. Patient Enablement Instrument
  - 1.3. Medication Change Questionnaire, a detailed measure of medication in a weekly diary format
  - 1.4. EuroQol-5D, a brief generic outcome questionnaire
2. Health resource use:
  - 2.1. GP consultation rates from practice computers
  - 2.2. Other health resource use by self-report
3. Change in health-improving behaviours and self-care: primarily by qualitative methods

Secondary outcomes measured at 3, 6, 12 and 24 months after randomisation.

## **Overall study start date**

01/01/2008

## **Completion date**

31/10/2009

# **Eligibility**

## **Key inclusion criteria**

Fulfill the Peveler criteria for medically unexplained symptoms:

1. Present to GP consultation with:
  - 1.1. The presentation of a physical symptom
  - 1.2. The symptom had existed for at least three months
  - 1.3. It had caused clinically significant distress or impairment
  - 1.4. It could not be explained by physical disease. The definition of this point will be clarified by adding that of Burton (2003), as physical symptoms for which no clear or consistent organic pathology can be demonstrated
2. Have a GP consultation rate of eight or more in the previous 12 months
3. Over 18 years, male and female

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

100

**Key exclusion criteria**

1. Under 18 years of age
2. Insufficient cognitive ability to complete the self-report questionnaires
3. Insufficient mobility and/or available transport to attend surgery for acupuncture treatment
4. Pregnant
5. A co-existent life-threatening condition, psychotic illness, severe substance abuse
6. Acupuncture treatment in the previous six months

**Date of first enrolment**

01/01/2008

**Date of final enrolment**

31/10/2009

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

Institute of Health Service Research

Exeter

United Kingdom

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**Sponsor information****Organisation**

Peninsula Medical School (UK)

### **Sponsor details**

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### **Sponsor type**

Hospital/treatment centre

### **Website**

<http://www.pms.ac.uk/pms/>

### **ROR**

<https://ror.org/04dtfyh05>

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

King's Fund (UK) - research grant (<http://www.kingsfund.org.uk/>)

## **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

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2011		Yes	No

[Results article](#)

results

01/06/2011

Yes

No