

# An investigation into the effectiveness of acupuncture in the treatment of psychosomatic symptoms and psychological distress - a double-blind randomised placebo controlled trial

<b>Submission date</b> 23/01/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/12/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/06/2017	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Somatic complaints are physical complaints that can't be explained medically. They are estimated to cost the NHS around £3.2 billion a year. Symptoms reported are both numerous and varied. They can include palpitations, chest pains, gastrointestinal problems (e.g. nausea, vomiting, diarrhoea), muscle and joint pains, headaches, feeling dizzy, loss of sex drive and problems with the menstrual cycle. Patients with somatic complaints often suffer from depression, anxiety or other mental health problems. They are often told that their symptoms are "all in their head", which can lead to a worsening of their symptoms and a detrimental effect on their everyday life. There is a big demand for rigorous investigation into more therapeutically intense treatments (or interventions) for somatic complaints to help alleviate pressure on the NHS. The aim of this study is to find out whether Traditional Chinese Acupuncture (TCA) can help alleviate symptoms in patients with somatic complaints.

### Who can participate?

Adults aged 18-65 that have medically unexplained physical symptoms

### What does the study involve?

Patients are randomly allocated into one of two groups. Those in group 1 are given 5 sessions of TCA. Those in group 2 are given a "placebo" acupuncture treatment. A special device is used to ensure that neither the practitioner or patient knows whether the needles are penetrating the skin. Patients are asked to report on their symptoms and fill in a general health questionnaire before they start their first acupuncture session, 5/6 weeks after they have had their 5 acupuncture sessions and then 2 months after their last acupuncture session. Patients in the placebo group are offered 5 free sessions of genuine acupuncture once the study is complete.

### What are the possible benefits and risks of participating?

For participants who have not had acupuncture before, this can be an exciting experience and an opportunity to try something new that may potentially improve symptoms not responsive to

other forms of treatment. The risks are low as acupuncture has been shown to be extremely safe when applied by a qualified practitioner. However, there is a small risk of local bruising/irritation to the site where the needles are applied.

Where is the study run from?

1. An acupuncture clinic based in Luton (UK)
2. Psychology department of the University of Bedfordshire (UK)

When is the study starting and how long is it expected to run for?  
May 2013 to May 2014

Who is funding the study?  
Research Centre for Applied Psychology (UK)

Who is the main contact?  
Ashley Bennett

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Ashley Bennett

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
Traditional chinese medicine (TCM), a solution to medically unexplained symptoms? A double-blind randomised control trial and the role of psychological attachment in TCM's therapeutic outcome

**Acronym**

N/A

**Study objectives**

Traditional Chinese acupuncture will show significantly greater reduction in unexplained symptoms when compared to a placebo.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

1. Research Centre for Applied Psychology ethics committee, 31/05/2013
2. University of Bedfordshire Research Ethics Committee, 06/09/2013, ref: UREC13

**Study design**

Single-centre randomised double-blind placebo-controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

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

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

Medically unexplained symptoms are closely related to somatisation which are a set of any symptoms that have no organic explanation

**Interventions**

This two arm trial has a treatment arm, in which participants will be given traditional Chinese acupuncture and the placebo arm whereby participants will be given placebo acupuncture using the park sham acupuncture device (or similar).

**Intervention Type**

Other

**Primary outcome measure**

1. Bradford somatic inventory (BSI) (Mumford et al., 1991)
2. General Health Questionnaire (GHQ-12) (Goldberg, 1978)

All measures are self-report and are taken at three time points: one at baseline (just before they have their first acupuncture session), 5/6 weeks later post-treatment (immediately after their last acupuncture session) and finally at follow-up, which is 2 months after their last appointment

### **Secondary outcome measures**

1. Client Therapist attachment (CATS) (Mallinckrodt et al., 1995)
2. General Attachment Questionnaire (Bartholomew & Horowitz, 1991)

All measures are self-report and are taken at three time points: one at baseline (just before they have their first acupuncture session), 5/6 weeks later post-treatment (immediately after their last acupuncture session) and finally at follow-up, which is 2 months after their last appointment

### **Overall study start date**

01/05/2013

### **Completion date**

01/05/2014

## **Eligibility**

### **Key inclusion criteria**

Patients who are deemed by independent assessor to have medically unexplained symptoms, between the ages of 18-65

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

65 Years

### **Sex**

Both

### **Target number of participants**

100

### **Key exclusion criteria**

1. Those who have had more than 5 treatments of acupuncture in the past 12 months will be excluded.
2. Those with complex and possibly terminal prognoses will be excluded (e.g., cancer patients)
3. Anyone who has undergone any major surgery in the preceding 6 months prior to the start of the trial
4. Anyone who has a severe psychiatric diagnosis

### **Date of first enrolment**

01/05/2013

**Date of final enrolment**

01/05/2014

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**University of Bedfordshire**

Luton

United Kingdom

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## **Sponsor information**

**Organisation**

University of Bedfordshire

**Sponsor details**

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**Sponsor type**

University/education

**Website**

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

**ROR**

<https://ror.org/0400avk24>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Research Centre for Applied Psychology (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