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

Submission date 23/01/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/12/2014	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 02/06/2017	**Condition category** Signs and Symptoms	[_] Individual participant data [_] 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 heath 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
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

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
United Kingdom

England

Study participating centre
University of Bedfordshire
Luton
United Kingdom
LU1 3JU

Sponsor information

Organisation
University of Bedfordshire

ROR
https://ror.org/0400avk24

Funder(s)

Funder type
Research organisation

Funder Name
Research Centre for Applied Psychology (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration