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Classical ACupuncture Treatment for people with Unexplained Symptoms

Submission date	Recruitment status	[ ] Prospectively registered
05/10/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/08/2011	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Nicky Britten

Contact details
Institute of Health Service Research
Peninsula Medical School
University of Exeter
St Luke's Campus
Exeter
United Kingdom
EX1 2LU

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
EX1 2LU

Sponsor information

Organisation

Peninsula Medical School (UK)

Sponsor details
Institute of Health Service Research
St Luke's Campus
Exeter
England
United Kingdom
EX1 2LU
+44 (0)1392 264859
charlotte.paterson@pms.ac.uk

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?
Results article	results	01/06/2011		Yes	No

Results article	results	01/06/2011	Yes	No