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Acupuncture for episodic tension-type headache: a subject blind multi-centre randomised controlled trial (RCT)

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
15/01/2010

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

C/CM/09/7.96/W

Study information

Scientific Title

Study objectives
To compare the efficacy of acupuncture with sham acupuncture for episodic tension-type headache.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Tension-type headache

Interventions
Participants received 6 weekly treatments with either standardised, brief needle acupuncture to between 4 and 8 relevant points, or sham acupuncture to non-tender points with a novel cocktail-stick placebo. Two follow-up treatments were given, 1 and 2 months later.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

1. Number of headaches
2. Intensity measured by Visual Analogue Scale (VAS)
3. Duration of headaches
4. Number of analgesics taken
Recorded by a daily headache diary

Secondary outcome measures
Not provided at time of registration

Overall study start date
03/03/1997

Completion date
03/06/1999

Eligibility

Key inclusion criteria
Participants were recruited during consultation with GP, from disease registers or from notices in GP premises or local media.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50 (added 15/01/1; see publication)

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
03/03/1997

Date of final enrolment
03/06/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Complementary Medicine
Exeter
United Kingdom
EX2 4NT

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive South West (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	01/09/2000		Yes	No