

Acupuncture for migraine and headache in primary care: a pragmatic, randomised trial

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| Submission date 25/04/2003 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 25/04/2003 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 26/08/2009 | Condition category Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <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
HTA 96/40/15

Study information

Scientific Title

Study objectives

Acupuncture is widely if inconsistently used in primary care, particularly for the treatment of pain. Migraine and headache are common conditions which incur high health, economic and social costs. There is evidence from randomised trials which suggests that acupuncture is superior to placebo in the treatment and prophylaxis of headache and migraine. We aim to conduct a 'pragmatic' randomised trial comparing the policy of 'use acupuncture' to that of 'avoid acupuncture' in 400 headache and migraine patients recruited in primary care. The acupuncture treatment will be given by appropriately trained physiotherapists.

Such a trial design aims to reflect the real world of clinical practice so as to provide a test of service as it is provided and thus ease implementation of the results. The information provided by the trial, for example, on resource use and effect sizes, will be more applicable to the NHS than that from a placebo-controlled trial. The use of chartered physiotherapists ensures high standards of clinical competence: simpler integration of the service in the NHS: established channels for inter-disciplinary liaison and appropriate treatment, especially in cases where acupuncture might not be appropriate. Our overall question will be: what are the effects of an acupuncture service provided by physiotherapists in primary care on pain, well-being, days off work and resource use in patients with migraine or 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)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Headache and migraine

Interventions

1. Acupuncture
2. Standard care

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Pain, well being, days off work and resource use

Secondary outcome measures

Not provided at time of registration.

Overall study start date

01/10/1998

Completion date

31/05/2002

Eligibility

Key inclusion criteria

Headache and migraine patients in primary care

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

401

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/10/1998

Date of final enrolment

31/05/2002

Locations

Countries of recruitment

United Kingdom

United States of America

Study participating centre

Integrative Medicine

New York

United States of America

10021

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House

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Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/en/index.htm>

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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 | 27/03/2004 | | Yes | No |