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

Submission date	Recruitment status	[ ] Prospectively registered
25/04/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/08/2009	Nervous System Diseases	

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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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