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Treating patients with dyspepsia with acupuncture and homeopathy: a randomised pilot study of effectiveness and costs.

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 22/02/2008	**Condition category** Digestive System	

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
RS/08/04.98

Study information

Scientific Title

Study objectives
For patients with dyspepsia who are receiving orthodox general practice care, what is the effect on outcome and on NHS costs of adding treatment by a choice of acupuncture or homeopathy?

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)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Peptic ulcer disease

Interventions
Patients chose between acupuncture and homeopathy and were then randomised to this preference or to the control group of normal GP care:
1. Homeopathy versus placebo
2. Acupuncture versus placebo

Treatment and follow-up were for six months.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Clinical outcome will be measured by validated outcome questionnaires:
1. The 36-item short form health survey (SF-36)
2. Measure Yourself Outcome Profile (MYMOP)
3. The General Well-Being Index

Follow-up will be six-months.

NHS costs collected for each patient will be prescribing costs, referral costs, and number of general practitioner consultations. Complementary practitioner costs will be their fees and homeopathy prescriptions.

Secondary outcome measures
Not provided at time of registration

Overall study start date
21/11/1998

Completion date
12/06/2000

Eligibility

Key inclusion criteria
Sixty patients with dyspepsia presenting in one UK general practice.
Participants expressed their preference for homeopathy or acupuncture before being randomised to receive their choice or be in the control group receiving normal GP care.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
21/11/1998

Date of final enrolment
12/06/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Social Medicine
Bristol
United Kingdom
BS8 2PR

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
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+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	01/06/2003		Yes	No