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Acupuncture for irritable bowel syndrome: a pilot for a randomised controlled trial

Submission date	Recruitment status	[_] Prospectively registered
22/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/10/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/04/2009	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
N/A

Study information

Scientific Title

Study objectives
That a randomised controlled trial is feasible and the design can be optimised on the basis of the pilot.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Solihull Local Research Ethics Committee approved on the 28th June 2006 (ref: 06/Q2706/3)

Study design
Randomised controlled trial pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Irritable bowel syndrome

Interventions
Group one: acupuncture plus usual General Practitioner (GP) care
Group two: usual GP care alone

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
IBS Symptom Severity and Global Impact Score

Secondary outcome measures

1. Quality of life
2. Anxiety and depression
3. Euro-QOL (EQ-5D) instrument
4. Medication and service use

Overall study start date
22/06/2006

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. Consulted in primary care in the previous two years
2. Diagnosed with Irritable Bowel Syndrome (IBS) which meets the Rome II criteria
3. Aged over 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Not currently having acupuncture
2. No haemophilia
3. Not diagnosed with cancer
4. No major abdominal surgery in the previous six months
5. Sufficient English to complete documentation

Date of first enrolment
22/06/2006

Date of final enrolment
30/06/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Health Sciences
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York (UK)

Sponsor details
Research Support Office
Heslington
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England
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Sponsor type
University/education

Website
http://www.york.ac.uk/research

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
University/education

Funder Name
University of York (UK) - Innovation and Research Priming Fund Award

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	01/03/2008		Yes	No