

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

Submission date 22/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/10/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/04/2009	Condition category Digestive System	<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
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
York
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YO10 5DD
smf3@york.ac.uk

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