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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
22/06/2006		☐ Protocol		
Registration date 04/10/2006	Overall study status Completed	Statistical analysis plan		
		[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

#### Contact name

Dr Hugh MacPherson

#### Contact details

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#### Additional identifiers

Protocol serial number 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

#### Study type(s)

Treatment

#### 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(s)

IBS Symptom Severity and Global Impact Score

#### Key secondary outcome(s))

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

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### 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

United Kingdom

England

# Study participating centre Department of Health Sciences

York United Kingdom YO10 5DD

## Sponsor information

#### Organisation

University of York (UK)

#### **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**

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