

Acupuncture for Irritable Bowel Syndrome (IBS)

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| Submission date 07/07/2008 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 12/09/2008 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 18/03/2016 | Condition category Digestive System | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

<http://www.nres.npsa.nhs.uk/researchsummaries/?entryid29=19031&q=0%c2%ac08%2fH1311%2f66%c2%ac>

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

PB-PG-0407-13241

Study information

Scientific Title

Acupuncture for Irritable Bowel Syndrome (IBS): a randomised controlled trial to evaluate effectiveness and cost-effectiveness

Acronym

Acupuncture for IBS

Study objectives

The aim is to establish rigorous evidence on the clinical effectiveness and cost effectiveness of acupuncture plus usual general practitioner (GP) care when compared to usual GP care alone for patients with irritable bowel syndrome (IBS) in primary care. The null hypothesis is that there is no difference between outcome in groups in our primary clinical outcome measure, the IBS Symptom Severity Score, at three months.

Our related aim with the cost-effectiveness analysis is to determine at twelve months what the cost per quality assisted life years (QALY) gained is, and whether this is at a level that might be thought acceptable if it were to be considered by the National Institute for Clinical Excellence.

Our secondary aim is to explore patient experiences of acupuncture, and this will include addressing areas of acceptability and safety directly with patients. In addition, we will also explore the potential influence of patient preferences, beliefs and expectations on patient outcome. We will do this by measuring these using accepted scales prior to randomisation, and assessing whether they modify the outcomes at three months.

Ethics approval required

Old ethics approval format

Ethics approval(s)

York Research Ethics Committee, Learning and Research Centre, 06/06/2008, ref: 08/H1311/66

Study design

Two-armed multicentre open pragmatic randomised trial design. The qualitative aspect of this study is designed using a phenomenological approach.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Irritable bowel syndrome (IBS)

Interventions

Patients will be randomised to 10 sessions of acupuncture plus usual GP care or to usual GP care alone.

Acupuncture will be provided by professional acupuncturists who are registered with the British Acupuncture Council, and have at least three years experience. The acupuncture will be provided at independent clinics, and comprise up to 10 treatment sessions over a three month period. Acupuncturists will follow a treatment protocol adapted from one that has been devised previously and tested by acupuncturists taking part in the pilot trial of acupuncture for IBS.

All patients will remain under the care of their general practitioner and will continue to receive their usual NHS treatment. Both groups will be able seek care elsewhere according to need.

Patients in both arms will be seen for 3 months, on an average of once a week for approximately one hour per session.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. IBS Symptom Severity Score (IBS SSS) at 3 months
2. Cost-effectiveness study: European quality of life questionnaire (EQ-5D) at 12 months
3. Medication use at baseline, 3 months, 6 months, 9 months and 12 months
4. Health services used at baseline, 3 months, 6 months, 9 months and 12 months
5. Days lost from work at baseline, 3 months, 6 months, 9 months and 12 months

Key secondary outcome(s)

Secondary outcomes at 3, 6, 9, and 12 months:

1. IBS Non-Colonic Symptom Score (which includes lethargy and tiredness, "wind", backache, and other symptoms)
2. The 12-item short form (SF-12) to evaluate patients' general well-being
3. The Hospital Anxiety and Depression Scale (HADS)
4. Information associated with hospitalisations; open text questions will be used to gather qualitative data on patient experiences of acupuncture, including adverse events at three months
5. Safety and treatment processes, gained from logs completed by the acupuncturists
6. Acceptability, assessed through patient reports on satisfaction and willingness to try acupuncture again, as well as the uptake of acupuncture
7. For the qualitative analysis, we will use in-depth interviews with flexible topic guides to collect data. Additionally, interview participants will be allowed to illustrate their explanation how acupuncture works. Researchers will record detailed field notes to track the development of emerging themes.

Completion date

30/09/2011

Eligibility

Key inclusion criteria

1. Aged 18 or older, either sex
2. A diagnosis of IBS from GP or being given medication to treat IBS symptoms (such as antispasmodics or bulking agents)
3. Have had a primary care consultation within the last two years regarding IBS or its symptoms
4. Screened for IBS symptoms according to the Rome III diagnostic criteria

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Doesn't speak English
2. Score less than 100 on the IBS Symptom Severity Score (SSS)
3. Have a current diagnosis of haemophilia or cancer
4. Have had major gastrointestinal surgery in the previous six months
5. Receiving acupuncture at the time

Date of first enrolment

01/10/2008

Date of final enrolment

30/09/2011

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

University of York

York

United Kingdom

YO10 5DD

Sponsor information**Organisation**

University of York (UK)

ROR

<https://ror.org/04m01e293>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

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 | exploratory results | 01/03/2008 | | Yes | No |
| Results article | results | 24/10/2012 | | Yes | No |
| Results article | substudy results | 01/09/2014 | | Yes | No |
| Results article | results | 01/03/2017 | | Yes | No |
| Protocol article | protocol | 17/06/2010 | | Yes | No |
| Other publications | cost analysis | 24/10/2012 | | Yes | No |