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Acupuncture for Irritable Bowel Syndrome (IBS)

Submission date 07/07/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2008	**Overall study status** Completed	
Last Edited 18/03/2016	**Condition category** Digestive System	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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.

Overall study start date
01/10/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
220

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
England

United Kingdom

Study participating centre
University of York
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Sponsor type
University/education

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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

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	exploratory results	01/03/2008		Yes	No
Protocol article	protocol	17/06/2010		Yes	No
Other publications	cost analysis	24/10/2012		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