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Homeopathy for Irritable Bowel Syndrome (HIBS)

Submission date 03/10/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 14/11/2011	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 17/07/2015	**Condition category** Digestive System	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Irritable Bowel Syndrome (IBS) is a common chronic disorder estimated to be present in about 10% of the population. IBS is characterised by abdominal pain or discomfort, bloating, nausea, vomiting, constipation, or diarrhoea. Patients' quality of life can be affected leading to tiredness, poor sleep and depression. The reasons for the symptoms in IBS are not well understood and treatment is aimed at controlling symptoms rather than curing them. Usual care for IBS generally includes advice on diet, exercise and reducing stress sometimes combined with medication. There are a number of different medicines used to help treat IBS: antispasmodic medicines, which help to reduce abdominal pain and cramping; laxatives, which help to treat the symptoms of constipation; antimotility medicines, which help to treat the symptoms of diarrhoea, and tricyclic antidepressants (TCAs), which were originally designed to treat depression, but also help to reduce the feeling of abdominal pain and cramping. It is not clear which treatments are acceptable, safe and work well. One promising treatment for IBS is homeopathic treatment. This is available on the NHS in some parts of the UK and is used worldwide but the treatment remains controversial in the UK. The aim of this study is to measure whether homeopathy is useful to treat patients with IBS.

Who can take part?
People who have been diagnosed with irritable bowl syndrome (IBS) or are taking medication associated with IBS e.g. mebeverine, loperamide or peppermint oil can take part in this trial.

What does the study involve?
Participants in the trial will be randomly allocated to usual care, supportive listening or homeopathic treatment on a 4:1:1 ratio (meaning that for every four participants allocated to usual care one participant will be allocated to supportive listening and one will be allocated to homeopathic treatment). All three groups will receive medical treatment as usual. Homeopathic treatment involves a consultation with a homeopath who will ask for a detailed description of symptoms the patient is experiencing. After the consultation a homeopathic remedy will be prescribed. Supportive listening is based on the theories and counselling techniques of Carl Rogers with the use of active listening skills (minimal encouraging, empathising reflecting and

summarising and paraphrasing) being used. Supportive listening will provide the patient with the opportunity to feel heard and with the opportunity to express themselves in a non judgemental environment.

What are the possible benefits and risks of participating?
Participants allocated to the homeopathic treatment will be offered up to five sessions with a homeopath and those allocated to the supportive listening treatment will be offered up to five sessions with a counsellor. A possible advantage to participants allocated to one of these treatments is an improvement in IBS, but this cannot be guaranteed. There are no known risks to participants.

Where is the study run from?
The study is taking place at Barnsley Hospital, UK and will start in January 2011. Approximately 6 GP practices and secondary care gastroenterology departments will be involved in the database search and mail out.

When is the study starting and how long is it expected to run for?
It is expected to run for two years, with participant recruitment taking place between January 2011 and January 2012.

Who is funding the study?
The study is funded by Barnsley Hospital Small Grants Fund, Friends of Barnsley Hospital and the Homeopathy Research Institute (UK).

Who is the main contact?
Dr Kapil Kapur
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Contact information

Type(s)
Scientific

Contact name
Dr Kapil Kapur

Contact details
Barnsley Hospital NHS Foundation Trust
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HIBS_ protocol_final_v3_ 19_07_11

Study information

Scientific Title
A randomised controlled trial to evaluate the clinical and cost effectiveness of two adjunctive treatments for patients with irritable bowel syndrome (IBS) compared to usual care alone: A - Homeopathic treatment (consultation + homeopathic medicine) and B - Supportive listening

Acronym
HIBS

Study objectives
This study is designed to test three different hypotheses.
1. Homeopathic consultation + a 'medication that may help' (homeopathic medicine) + usual care will improve the outcomes of patients with IBS in comparison to usual care alone
2. Homeopathic consultation + a 'medication that may help' (homeopathic medicine) + usual care will result in significantly more benefit than supportive listening + usual care
3. Supportive listening + usual care will improve the outcomes of patients with IBS in comparison to usual care alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds (East) Research Ethics Committee, 09/12/2010, ref: 10/H1306/73

Study design
Cohort multiple randomised controlled trial

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

Interventions
Three armed trial using the 'cohort multiple RCT' design (Relton 2010). The three arms will be:
1. Homeopathic treatment + usual care
2. Supportive listening + usual care
3. Usual care alone

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Irritable bowel syndrome symptom severity scale

Secondary outcome measures
1. Hospital Anxiety and Depression Scale (HADS)
2. EQ-5D

Overall study start date
14/01/2011

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Diagnosis of Irritable bowel syndrome (according to ROME III diagnostic criteria for IBS)
2. Aged 18 and over
3. Consent to fill in and return further postal questionnaires to the researchers
4. Score of more than 100 on the IBS Symptom Severity Score (Francis et al., 1997), this score if often taken as the cut off for symptomatic IBS
5. Fluent in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
198

Key exclusion criteria
1. Pregnant or breast feeding
2. Unstable medical or psychiatric illness
3. Currently receiving treatment from a homeopath or taking homeopathic medicines
4. Current diagnosis of haemophilia or cancer, or major gastrointestinal surgery in previous 6 months

Date of first enrolment
14/01/2011

Date of final enrolment
14/01/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barnsley Hospital NHS Foundation Trust
Barnsley
United Kingdom
S75 2EP

Sponsor information

Organisation
Barnsley Hospital NHS Foundation Trust (UK)

Sponsor details
c/o Mr Michael Bramall
Gawber Road
Barnsley
England
United Kingdom
S75 2EP

Sponsor type
Hospital/treatment centre

Website
http://www.barnsleyhospital.nhs.uk/

ROR
https://ror.org/00yx91b22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Barnsley Hospital - Small Grants Fund (UK)

Funder Name
Friends of Barnsley Hospital (UK)

Funder Name
Homeopathy Research Institute (UK)

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?
Protocol article	protocol	06/11/2012		Yes	No
Results article	results	01/07/2014		Yes	No