

# Homeopathy for Irritable Bowel Syndrome (HIBS)

<b>Submission date</b> 03/10/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/11/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/07/2015	<b>Condition category</b> Digestive System	<input type="checkbox"/> 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 bowel 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  
kapil.kapur@nhs.net

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Kapil Kapur

**Contact details**

Barnsley Hospital NHS Foundation Trust  
Gawber Road  
Barnsley  
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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 is 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?
<a href="#">Protocol article</a>	protocol	06/11/2012		Yes	No
<a href="#">Results article</a>	results	01/07/2014		Yes	No