

# Hypnotherapy for irritable bowel syndrome: streamlining provision

<b>Submission date</b> 30/09/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/01/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/07/2018	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Hypnotherapy has been shown to work as a treatment of irritable bowel syndrome (IBS). However, it has not been widely adopted by healthcare providers and this is probably because it is very time consuming and no set guidelines exist. It seems likely that hypnotherapy might be used more readily if it could be delivered over a shorter period of time and the technique better described so that therapists would find it easy to use the same methods.

This study aims to establish whether a short course of well described hypnotherapy works as well as conventional hypnotherapy where the sessions can be rather long and the content is dependent on the style of the therapist.

### Who can participate?

The trial will be open to men and women between the ages of 18 and 65 who have irritable bowel syndrome without any other illnesses that could interfere with treatment.

### What does the study involve?

A short course of six sessions of completely scripted hypnotherapy (like having a manual) will be compared with conventional hypnotherapy which involves twelve sessions of unscripted treatment.

### What are the possible benefits and risks of participating?

All patients will receive one or other of the forms of hypnotherapy and should, therefore, experience benefit from the treatment. However, if the patients receiving the short form of treatment are seen to not do so well, they will be offered further treatment sessions in order to try and improve them further. Hypnotherapy has no side effects and never makes irritable bowel worse.

### Where is the study run from?

Wythenshawe Hospital, Manchester (UK)

### When is the study starting and how long is it expected to run for?

March 2010 to March 2013.

Who is funding the study?  
National Institute for Health Research (UK).

Who is the main contact?  
Professor PJ Whorwell  
peter.whorwell@manchester.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Peter James Whorwell

**Contact details**  
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United Kingdom  
M23 9LT

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
RFPB PB-PG-0906-10134

## Study information

**Scientific Title**  
Hypnotherapy for irritable bowel syndrome: streamlining provision

**Study objectives**  
Abbreviated, highly structured hypnotherapy for irritable bowel syndrome (IBS) is as effective as conventional hypnotherapy for this condition

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
South Manchester Local Research Ethics Committee, 5 December 2007 ref: 07/Q1403/108

**Study design**

Randomised non-inferiority study comparing two forms of treatment

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**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**

Patients are randomly assigned to either the hypnotherapy group or conventional therapy group for treatment of IBS.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Combined global outcome score and symptom severity scores

**Secondary outcome measures**

1. Hospital Anxiety and Depression score
2. Quality of life score
3. Non colonic symptom score
4. EQ5D

**Overall study start date**

20/03/2010

**Completion date**

20/03/2013

**Eligibility**

**Key inclusion criteria**

1. Patients with refractory irritable bowel syndrome who are referred to the unit for hypnotherapy are eligible for this trial
2. Those with no other significant concomitant disease and agreeing to the study, having read the patient information details will be randomised to either of the treatment groups

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

300

**Key exclusion criteria**

Any significant concomitant disease that could interfere with the interpretation of the results

**Date of first enrolment**

20/03/2010

**Date of final enrolment**

20/03/2013

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

Education & Research Centre

Manchester

United Kingdom

M23 9LT

**Sponsor information****Organisation**

National Institute for Health Research (UK)

## Sponsor details

Research for Patient Benefit Programme  
Grange House  
15 Church Street  
Twickenham  
United Kingdom  
TW1 3NL

## Sponsor type

Government

## Website

<http://www.ccf.nihr.ac.uk/RfPB/Pages/home.aspx/>

## ROR

<https://ror.org/0187kwz08>

# Funder(s)

## Funder type

Government

## Funder Name

National Institute of Health Research (NIHR) (UK) - Research for Patient Benefit Programme ref: RfPB PB-PG-0906-10134

# 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="#">Abstract results</a>	results presented at DDW	01/04/2015		No	No