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Hypnotherapy for irritable bowel syndrome: streamlining provision

Submission date 30/09/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 10/01/2012	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 05/07/2018	**Condition category** Digestive System	[_] 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised non-inferiority study comparing two forms of treatment

Study type(s)
Treatment

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(s)
Combined global outcome score and symptom severity scores

Key secondary outcome(s)
1. Hospital Anxiety and Depression score
2. Quality of life score
3. Non colonic symptom score
4. EQ5D

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Education & Research Centre
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
National Institute for Health Research (UK)

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

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?
Abstract results	results presented at DDW	01/04/2015		No	No