

# Cognitive behavioural therapy versus antispasmodic therapy for irritable bowel syndrome in primary care

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| <b>Submission date</b><br>25/04/2003   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>25/04/2003 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>21/08/2009       | <b>Condition category</b><br>Digestive System     | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://gppc.kcl.ac.uk/report/study.asp?id=36>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

HTA 96/13/04

## **Study information**

**Scientific Title**

### **Study objectives**

Some patients with irritable bowel syndrome (IBS) do not benefit from explanation, reassurance and symptomatic management and develop a chronic illness with high health care costs. This study is designed to establish whether early intervention with CBT is advantageous over current treatment.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration.

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Digestive system diseases: Inflammatory bowel disease

### **Interventions**

Please note that, as of 15 January 2008, the start and end dates of this trial have been updated from 1 January 1999 and 31 December 2001 to 1 February 1999 and 31 December 2002, respectively.

Interventions:

The trial is divided into 4 stages:

Stage 1: Consecutive IBS patients presenting to their GP will be considered for the study.

Patients will receive standardised first line assessment including symptom explanation, advice and treatment in order to identify those who respond to 'usual measures'.

Stage 2: Those patients remaining symptomatic after two weeks will be given treatment with mebeverine hydrochloride, which is the most commonly used antispasmodic in the UK. We will interview patients at this stage to elicit their coping strategies.

Stage 3: After a further four weeks patients still symptomatic will be randomised to receive 6 sessions of cognitive behavioural therapy plus mebeverine hydrochloride (n=65) or continue on mebeverine hydrochloride alone (n=65).

Stage 4: Nine weeks after randomisation patients will be assessed for improvement with further assessments 3, 6 and 12 months after completing treatment.

## **Intervention Type**

Drug

## **Phase**

Not Specified

## **Drug/device/biological/vaccine name(s)**

Mebeverine

## **Primary outcome measure**

IBS Severity Scoring System (SSS), Hospital Anxiety and Depression Scale, Social Adjustment Scale, Illness Perception Questionnaire (IPQ) and a modified version of the Client Services Receipt Inventory (CSRI). The principle outcome will be the degree of improvement on the SSS. We will perform an economic analysis using the CSRI. An IBS specific coping questionnaire will be devised to identify successful coping in IBS and will be complemented by the IPQ and by qualitative interviews. A subsidiary outcome will be an evaluated and accredited training course equipping primary care nurses with skills in generic and IBS specific CBT.

## **Secondary outcome measures**

Not provided at time of registration.

## **Overall study start date**

01/02/1999

## **Completion date**

31/12/2002

# **Eligibility**

## **Key inclusion criteria**

Patients with irritable bowel syndrome

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Sex**

Both

**Target number of participants**

130

**Key exclusion criteria**

Not provided at time of registration.

**Date of first enrolment**

01/02/1999

**Date of final enrolment**

31/12/2002

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Department of General Practice**

London

United Kingdom

SE11 6SP

## **Sponsor information**

**Organisation**

Department of Health (UK)

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/en/index.htm>

**ROR**

<https://ror.org/03sbpja79>

## Funder(s)

**Funder type**

Government

**Funder Name**

NIHR Health Technology Assessment Programme - HTA (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="#">Results article</a>    | results       | 20/08/2005   |            | Yes            | No              |
| <a href="#">Other publications</a> | HTA monograph | 01/06/2006   |            | Yes            | No              |