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# A randomised controlled trial (RCT) of a Patient Self-Help Information Book in the Management of Irritable Bowel Syndrome (IBS)

**Submission date**
23/01/2004

**Recruitment status**
No longer recruiting

**Registration date**
23/01/2004

**Overall study status**
Completed

**Last Edited**
07/09/2012

**Condition category**
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
RHC11162

## Study information

## Scientific Title

## Study objectives
Use of a self-help guidebook will reduce or modify doctor-patient contacts and improve the health status and symptoms of patients with IBS. Patients randomised to the self-help group will gain additional benefits resulting in better symptom control, reduced anxiety and fewer doctor contacts.

## 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

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Irritable bowel syndrome

## Interventions
1. Provision of self-help guidebook
2. Provision of self-help guidebook plus invitation to attend one self-help group meeting
3. Treatment as usual, plus guidebook at the end of the study

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome(s)
To test the impact of two self-help interventions (a comprehensive self-help guidebook and a self-help group) on primary care consultation rates and global IBS symptom severity in patients with functional bowel disease

## Key secondary outcome(s))
To evaluate attendant changes in a range of other health outcomes, including use of secondary care, self-care, general health and quality of life.

## Completion date
31/05/2003

# Eligibility

### Key inclusion criteria
1. A working diagnosis of IBS as the reason for the consultation
2. At least one other visit with IBS symptoms in the preceding year
3. IBS diagnosed by GP (or hospital if patient has been seen by specialist) but not necessarily fulfilling 'Rome' criteria
4. Able to read and understand English

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Patients under the age of 18
2. Patients with significant learning difficulty or dementia who, in the opinion of the GP, would be unable to practice self-care

### Date of first enrolment
01/06/2000

### Date of final enrolment
31/05/2003

# Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**National Primary Care Centre**
Manchester
United Kingdom
M13 9PL

# Sponsor information

**Organisation**
NHS R&D Regional Programme Register - Department of Health (UK)

# Funder(s)

**Funder type**
Government

**Funder Name**
National Health Service (NHS) UK

# 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? |
|---|---|---|---|---|---|
| Results article | results | 01/10/2006 | | Yes | No |