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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/01/2004		[_] Protocol		
Registration date	Overall study status	[] Statistical analysis plan		
23/01/2004	Completed	[X] Results		
Last Edited 07/09/2012	Condition category Digestive System	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Secondary study design Randomised controlled trial

Study setting(s) GP practice

Study type(s) Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

To evaluate attendant changes in a range of other health outcomes, including use of secondary care, self-care, general health and guality of life.

Overall study start date

01/06/2000

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

Age group

Adult

Sex

Both

Target number of participants 420

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 England

United Kingdom

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)

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website http://www.doh.gov.uk

Funder(s)

Funder type Government

Funder Name National Health Service (NHS) 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?
<u>Results article</u>	results	01/10/2006		Yes	No