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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 07/09/2012	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Anne Kennedy

Contact details
National Primary Care Centre
5th Floor
Williamson Building
University of Manchester
Oxford Road
Manchester
United Kingdom
M13 9PL
akennedy@fs1.cpcr.man.ac.uk

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 quality 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?
Results article	results	01/10/2006		Yes	No