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

Submission date 25/04/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/04/2003	**Overall study status** Completed	
Last Edited 21/08/2009	**Condition category** Digestive System	

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
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
Not provided at time of registration.

Completion date
31/12/2002

Eligibility

Key inclusion criteria
Patients with irritable bowel syndrome

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Department of General Practice
London
United Kingdom
SE11 6SP

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (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	20/08/2005		Yes	No
Other publications	HTA monograph	01/06/2006		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes