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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

Study website
http://gppc.kcl.ac.uk/report/study.asp?id=36

Contact information

Type(s)
Scientific

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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
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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?
Results article	results	20/08/2005		Yes	No
Other publications	HTA monograph	01/06/2006		Yes	No