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ACTIB: Assessing Cognitive behavioural Therapy in Irritable Bowel

Submission date
18/11/2013

Recruitment status
No longer recruiting

Registration date
18/11/2013

Overall study status
Completed

Last Edited
08/07/2021

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Irritable bowel syndrome (IBS) is a common chronic gastrointestinal (tummy) disorder that affects 10-22% of the UK population and costs the NHS over £200 million a year. Abdominal (tummy) pain, bloating and altered bowel habit (diarrhoea or constipation) affect quality of life, ability to enjoy social activities and time off work. Initial treatment relies on a positive diagnosis, reassurance, lifestyle advice and drug therapies. However, many patients suffer ongoing distressing symptoms. Guidelines recommend Cognitive Behavioural Therapy (CBT) for patients with IBS who continue to have symptoms after 12 months. CBT is a therapeutic approach which centres on the interaction of bodily symptoms, thoughts, emotions and what people do to cope with their symptoms. However, access to this therapy is limited due to the cost and availability of therapists and there is uncertainty regarding how effective it is in reducing symptoms in the long term and its cost-effectiveness. One way to make CBT available to larger numbers of patients is to provide a less intense form of the therapy on the internet. We have developed a CBT-based website which could be accessed by patients countrywide. The aim of this study is to assess the clinical and cost effectiveness of therapist-delivered CBT and web-based self-management in IBS compared to treatment as usual.

Who can participate?
Adults (aged 18 and over) with IBS that is resistant to treatment, i.e. those who have been offered first-line therapies (e.g. antispasmodics, anti-depressants or fibre-based medications) but still have continuing IBS symptoms for 12 months or more. If over 60, patients must have had a consultant review in the previous two years to confirm that their symptoms are related to IBS.

What does the study involve?
Participants will be randomly allocated to one of three groups: therapist-delivered CBT, a web-based self-management programme with therapist support, or treatment as usual. The therapist-delivered CBT group will receive six 1-hour telephone CBT sessions with trained therapists over 9 weeks. Therapists will provide information about IBS, and use behavioural and cognitive techniques aimed at improving bowel habits, addressing unhelpful thoughts, reducing heightened attention to symptoms and preventing relapse. Patients will complete tasks to reinforce the sessions. They will also have two booster 1-hour CBT telephone sessions at 4 and 8

months to provide further support to manage relapse. The web-based self-management group will have access to the interactive CBT-based self-management website developed based on input from patients involved in a previous study. Participants undertake eight sessions over 9 weeks at home, which include similar content to the therapist CBT, homework and weekly email reminders, and will have three 30-min telephone CBT sessions with a trained therapist over 9 weeks to support the website programme. They will also have two booster 30-minute CBT telephone sessions at 4 and 8 months to provide further support to manage relapse.

What are the possible benefits and risks of participating?
Previous studies suggest that IBS symptoms will be helped by the therapist or the self-management programme; however, we cannot guarantee this. This study will help us gain more knowledge regarding the website programme and the therapist treatment used in the study, the cost of each and whether we should offer either of these routinely to people with IBS. The blood test may cause a small amount of pain and bruising but this will be done in a usual clinical care setting andall usual precautions will be taken. All the blood test results that are outside of the normal range will be checked by a study clinician and then the research team will notify the patient and the GP (doctor) and will send the GP the result for them to follow up the patient. It may be that distressing issues arise during the CBT. If this does occur then the therapist will notify one of the Senior Psychologists for advice. The therapy will remain confidential unless there are any signs of potential risk to the participant or others in which case further action will be taken and the GP or appropriate authority will be contacted. The therapist will be trained in all these procedures prior to contact with participants.

Where is the study run from?
The study will be coordinated from the University of Southampton with collaboration from King's College Hospital, King's College London, and University Hospital Southampton.

When is the study starting and how long is it expected to run for?
Recruitment started in May 2013 and the study will run until February 2016.

Who is funding the study?
National Institute for Health Research, UK.

Who is the main contact?
Dr Gilly O'Reilly
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
15428

Study information

Scientific Title
ACTIB: (Assessing Cognitive behavioural Therapy in Irritable Bowel): a randomised controlled trial of clinical and cost effectiveness of therapist-delivered cognitive behavioural therapy and web-based self-management in irritable bowel syndrome

Acronym
ACTIB

Study objectives
IBS affects 10-22% of the UK population, with NHS costs over £200 million a year. Abdominal pain, bloating and altered bowel habit affect quality of life, social functioning and time off work. Current GP treatment relies on positive diagnosis, reassurance, lifestyle advice and drug therapies, but many suffer ongoing symptoms.

CBT and self-management can be helpful, but poor NHS availability restricts its use. Further evidence on the clinical and cost-effectiveness of CBT for IBS and low intensity alternatives will help in service planning and provision in the NHS.

This trial will assess the clinical and cost-effectiveness of CBT for IBS in a well-designed rigorous study with a long-term outcome. This will enable clinicians, patients and health service planners to make informed decisions regarding the management of IBS with CBT.

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=15428

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Berkshire, 31/05/2013 (conditions met 11/06/2013), ref: 13/SC/0206

Study design
Randomised interventional trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England, Oral and Gastrointestinal; Subtopic: Not Assigned, Oral and Gastrointestinal (all Subtopics); Disease: All Diseases, Gastrointestinal

Interventions
495 participants with refractory IBS will be randomised to a high-intensity therapist-delivered CBT (TCBT) + treatment as usual (TAU), or a lower intensity web-based CBT programme (LIBT) + TAU, or TAU alone.

TCBT will consist of six 60-minute CBT sessions with a therapist over the telephone completed over 9 weeks at home and two 'booster' one-hour follow-up phone calls at 4 and 8 months (8 hours therapist contact time).

LIBT will consist of access to a previously developed and piloted web-based CBT self-management programme (Regul8) and three 30-minute therapist telephone sessions completed over 9 weeks at home and two 'booster' 30-minute follow-up phone calls at 4 and 8 months (2.5 hours contact time).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measures as of 05/12/2013:
1. IBS Symptom Severity Score (IBS SSS)
2. Work and Social Adjustment Scale (WASAS)
Timepoint(s): 3, 6 and 12 months

Previous primary outcome measures:
1. The Subjects Global Assessment of Relief (SGA of Relief)
2. IBS Symptom Severity Score (IBS SSS)
Timepoint(s): 3, 6 and 12 months

Key secondary outcome(s))
No secondary outcome measures

Completion date
29/02/2016

Eligibility

Key inclusion criteria
1. Adults (male and female, 18 years and over) with refractory IBS (clinically significant symptoms defined by a IBS-SSS i.e. >75)
2. Fulfilling ROME III criteria and who have been offered first-line therapies (e.g. anti-spasmodics, anti-depressants or fibre-based medications) but still have continuing IBS symptoms for 12 months or more

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
558

Key exclusion criteria
Current exclusion criteria as of 05/12/2013:
1. Unexplained rectal bleeding or weight loss
2. Diagnosis of inflammatory bowel disease, coeliac disease, peptic ulcer disease or colorectal carcinoma
3. Unable to participate in CBT due to speech or language difficulties
4. No access to an internet computer to be able to undertake the low intensity CBT, previous access to the MIBS website, received CBT for IBS in the last two years

Previous exclusion criteria:
1. Unexplained rectal bleeding or weight loss
2. Diagnosis of inflammatory bowel disease, coeliac disease, peptic ulcer disease or colorectal carcinoma
3. Unable to participate in CBT due to speech or language difficulties
4. No access to an internet computer to be able to undertake the low intensity CBT or previous participation in the MIBS study

Date of first enrolment
01/05/2014

Date of final enrolment
29/02/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Aldermoor Health Centre
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Coordinating Centre (UK); Grant Codes: 11/69/02

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	qualitative study results	01/09/2018		Yes	No
Results article	RCT results	01/04/2019	11/04/2019	Yes	No
Results article	results	01/11/2019	09/09/2019	Yes	No
Results article	results	01/09/2019	27/09/2019	Yes	No
Results article	cost effectiveness results	06/07/2021	08/07/2021	Yes	No
Protocol article	protocol	15/07/2015		Yes	No

Abstract results	results abstract	01/04/2019	02/05/2019	No	No
HRA research summary			28/06/2023	No	No