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Cognitive behavioural therapy - irritable bowel syndrome feasibility study

Submission date 07/01/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/01/2014	**Overall study status** Completed	
Last Edited 14/11/2018	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Irritable Bowel Syndrome (IBS) is characterised by abnormal bowel function with symptoms such as diarrhoea, constipation, bloating and abdominal pain. IBS is more prevalent in women (14%) than men (6.6%). Patients with IBS frequently report a poor quality of life and demonstrate high levels of time off work. IBS is a significant burden on health care resources, with IBS patients consuming over 50% more resources than a matched group of people. Furthermore, IBS and its symptoms have a significant impact on daily activities and body image, and are a source of worry to patients.
50-90% of IBS patients have a co-existing psychological condition such as anxiety and depression. The presence of psychological conditions is associated with more persistent and severe symptoms, increased time off work and a greater need for specialist referral. Patients with IBS and psychological co-morbidities currently receive medical management aimed at bowel symptom control and the regulation of gastrointestinal motility. The provision of psychological interventions for treating anxiety and depression in patients with IBS within the NHS are rare. There is a growing body of evidence to support the use of Cognitive Behavioural Therapy (CBT) for improving the outcomes of patients with IBS. CBT is costly and therapists who offer IBS speciality clinics are rare. There is a need for further research regarding the use of psychological therapies for IBS which should focus on developing psychological interventions which address concerns relating to cost and treatment accessibility. This feasibility study will evaluate the proposed methods for the evaluation of a novel, nurse-delivered model of CBT as a treatment option for IBS and will also provide information for running a follow-on trial.

Who can participate?
Adult male and female patients diagnosed with Irritable Bowel Syndrome with and without associated anxiety and depression.

What does the study involve?
Participants are randomly allocated to one of four treatments:
1. High intensity cognitive behavioural therapy delivered by a psychotherapist
2. Guided self-help cognitive behavioural therapy delivered by a registered nurse
3. Self-help treatment delivered in the form of self-help materials without therapist support
4. Treatment as usual

What are the possible benefits and risks of participating?
Some participants who are allocated to the intervention groups of the study may experience an improvement in irritable bowel syndrome symptoms or may develop better ways of coping with their condition. It is anticipated that participants will not experience side effects from any treatment used within this study.

Where is the study run from?
This is a single-centre study taking place at the Queens Medical Centre Campus of Nottingham University Hospitals NHS Trust, Derby Road, Nottingham, NG7 2UH, UK.

When is the study starting and how long is it expected to run for?
The study will start recruitment in January 2014 for a period of about 20 months.

Who is funding the study?
The study is jointly funded by the University of Nottingham and the NIHR Nottingham Digestive Diseases Biomedical Research Unit, UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Sponsor Ref: 13127

Study information

Scientific Title
A mixed methods feasibility study to evaluate the use of low-intensity, nurse-delivered cognitive behavioural therapy in the treatment of irritable bowel syndrome

Study objectives
Nurse-delivered, low-intensity cognitive behavioural therapy may be a feasible method for the delivery of cognitive behavioural interventions used in the treatment of irritable bowel syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham 2 REC, 05/12/2013, REC ref: 13/EM/0428

Study design
Mixed methods feasibility randomised controlled trial with concurrent qualitative interviews

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Irritable Bowel Syndrome

Interventions
Participants in each of the study conditions will have measures taken at baseline and at 12 and 26 weeks post randomisation. Participants will be randomly allocated to one of four treatment conditions as described below.
1. High-intensity cognitive behavioural therapy consisting of 12 hours of weekly treatment sessions with a cognitive psychotherapist. Therapy will be delivered in accordance with the methods developed by Toner et al. (2000).
2. Low-intensity cognitive behavioural therapy delivered by a registered nurse consisting of a 1-hour initial assessment session and five 30-minute sessions of therapy. Participants will work through six treatment modules supported by self-help materials consisting of: psychoeducation, relaxation techniques, the cognitive model of stress, applying the cognitive model to IBS,

avoidance and exposure, diet and IBS. The six treatment modules used within this arm of the study are an adapted version of the treatment protocol originally developed by Hunt et al. (2009) at the University of Pennsylvania, USA.
3. Self-help. Participants will work through six modules of self-help materials consisting of: psychoeducation, relaxation techniques, the cognitive model of stress, applying the cognitive model to IBS, avoidance and exposure, diet and IBS. The six treatment modules used within this arm of the study are an adapted version of the treatment protocol originally developed by Hunt et al. (2009) at the University of Pennsylvania, USA. Participants in this treatment condition will not receive therapist support.
4. Treatment as usual control. Participants in this treatment condition will receive the usual care of their hospital gastroenterologist and general practitioner as indicated by current best practice guidance.

Hunt, M., Moshier, S. and Milonova, M. (2009) Brief cognitive-behavioral internet therapy for irritable bowel syndrome. Behaviour Research and Therapy 47(9): pp. 797-802.
Toner, B., Segal, Z., Emmott, S. and Myran, D. (2000) Cognitive-behavioral treatment of irritable bowel syndrome: The brain-gut connection. New York: Guilford Press.

Intervention Type
Behavioural

Primary outcome measure
Gastrointestinal Symptom Rating Scale for IBS (IBS-GSRS) measured at baseline, 12 weeks and 26 weeks post randomisation.

Secondary outcome measures
1. Irritable Bowel Syndrome Quality of Life Instrument (IBS-QOL)
2. Generalised Anxiety Disorder Assessment (GAD 7)
3. Patient Health Questionnaire (PHQ-9)

Measured at baseline, 12 weeks and 26 weeks post randomisation.

Overall study start date
30/01/2014

Completion date
30/10/2016

Eligibility

Key inclusion criteria
1. Adult male and female patients aged 18 years or older at the time of enrolment
2. Documented medical diagnosis of IBS with symptom onset at least six months prior to recruitment (in order to fulfil Rome criteria at screening)
3. Able to read, write and speak the English language
4. Able to provide written informed consent
5. Patients with and without concomitant antidepressant use
6. Not currently taking part in other research studies
7. Able to commit to weekly treatment sessions within the intervention arms of the study

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60 (randomised)

Key exclusion criteria
1. Already receiving psychological therapy or hypnotherapy
2. Existing diagnosis of bowel disease based on endoscopic or histologic criteria (i.e., Crohn's disease, ulcerative colitis, coeliac disease)
3. Presence or history of structural or surgical diseases of the GI tract (not including appendix or gall bladder surgery)
4. Evidence of alcohol or substance misuse
5. An established cause for bowel symptoms other than IBS (i.e., medication use)
6. The presence of suicidal ideation (current intent/plans/actions) or self-harm (current intent /plans/actions).
7. Significant psychiatric co-morbidity (schizophrenia, bipolar disorder, obsessive-compulsive disorder [OCD])

Date of first enrolment
30/01/2014

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NIHR Nottingham Biomedical Research Unit
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Research and Graduate Services
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Sponsor type
University/education

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http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/06/2014		Yes	No
HRA research summary			28/06/2023	No	No