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Psycho-vegetative self-regulation group intervention for refractory irritable bowel syndrome: RCT feasibility study with concurrent diary study

Submission date
28/05/2014

Recruitment status
No longer recruiting

Registration date
18/06/2014

Overall study status
Completed

Last Edited
31/01/2018

Condition category
Digestive System

[_] Prospectively registered
[_] 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 condition affecting the digestive system, with symptoms including stomach cramps, bloating, diarrhoea and constipation. It is a complex condition for which an exact cause is, as yet, unknown. More women suffer from IBS than men. IBS can affect people from all walks of life but with psychosocial variables (such as personality traits, life stress, psychological distress, psychiatric illness) that distinguish them from non-IBS suffers, and particularly so with those with severe symptoms. Furthermore, IBS is a source of worry to patients and causes them to avoid doing things that might trigger off their symptoms. Patients with IBS often report a poor quality of life. 25% of patients have a severe course of IBS, where the symptoms are more frequent, even persistent, very intense, associated with marked digestive problems, struggle with psychosocial problems (e.g. depression, stress etc.), and are heavy users of the healthcare system. Patients with severe symptoms also often suffer them long-term and find that their IBS does not respond particularly well conventional treatment (i.e. is refractory to treatment). Scientific efforts focus on improving our understanding of the cause and development of the condition with the aim to identify particular groups of people that can receive care catered to their particular needs. There is evidence to suggest that IBS can be treated with cognitive-behavioural therapy, psychodynamic-interpersonal psychotherapy, gut-directed hypnotherapy, relaxation training and stress management. Providing such care, however, is still rare and there is a need for further research regarding the development and implementation of specific psychotherapeutic treatments for refractory IBS which address concerns relating to treatment accessibility and improvement of patients quality of life and daily functioning. At the Department of General Internal Medicine and Psychosomatics at the University of Heidelberg, we run an IBS speciality clinic which are still rare. In this feasibility study we will develop, implement, and evaluate a manualised specific group intervention integrating approved psychotherapeutic elements as a treatment option for refractory IBS. In the diary study relevant psychosocial factors are recorded on a daily basis to understand their

associations with IBS symptom severity. This will help to deepen our insight into psycho-somatic interactions in IBS as a basis for specifically targeted treatment strategies. The project will also provide information for running a follow-on trial.

Who can participate?
Adult male and female patients from our IBS clinic diagnosed with irritable bowel syndrome and so far refractory to treatment.

What does the study involve?
Participants are randomly allocated to one of two groups. Group 1 will undergo a series of therapies including interactive psychoeducation, gut-directed hypnotherapy and stress management. They will also complete questionnaires and participate in the diary study. Group 2 is a wait-control group. They also participate in the diary study.

What are the possible benefits and risks of participating?
A substantial portion of the treated patients is expected to experience an improvement in IBS symptoms or quality of life. Adverse events (e.g. dizziness, panic attack) are rare, and patients will be monitored carefully for them by the group leaders to take appropriate action.

Where is the study run from?
The IBS clinic of the Department of General Internal Medicine and Psychosomatics, University of Heidelberg, Im Neuenheimer Feld 410, DE-69120 Heidelberg (Germany)

When is the study starting and how long is it expected to run for?
June 2014 to December 2014

Who is funding the study?
The study is funded jointly by the Department of General Internal Medicine and Psychosomatics at the University Hospital Heidelberg (Germany) and by the Postdoc Programme of the Medical Faculty of the University of Heidelberg (Germany)

Who is the main contact?
Dr Esther Stroe-Kunold
Esther.Stroe-Kunold@med.uni-heidelberg.de

Contact information

Type(s)
Scientific

Contact name
Dr Rainer Schaefert

Contact details
University Hospital Heidelberg,
Department of General Internal Medicine and Psychosomatics
Im Neuenheimer Feld 410
Heidelberg
Germany

D-69120
+49 / 62 21 / 56 - 38246
Rainer.Schaefert@med.uni-heidelberg.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A feasibility study in a randomised controlled wait-group design to evaluate a specific group intervention to improve psycho-vegetative self-regulation in the treatment of refractory irritable bowel syndrome; concurrent diary study of interactions between symptoms, psychosocial variables, biomedical parameters, and treatment conditions

Study objectives
A specific group intervention may be a feasible method to improve psycho-vegetative self-regulation in the treatment of refractory irritable bowel syndrome. Prospective longitudinal analyses of interactions between symptoms, psychosocial variables, biomedical parameters, and treatment conditions may allow to identify typical interaction patterns and respective IBS subtypes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the University of Heidelberg, 21/02/2014, refs: Group feasibility study: S-041 /2014, Diary study: S-037/2014

Study design
Specific group intervention feasibility randomised controlled trial with concurrent diary study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Treatment

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

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

Interventions
Intervention group: 12 weekly IBS specific outpatient group sessions. The main aim of the group intervention is to improve the patients psycho-vegetative self-regulation. The following intervention strategies are used:

1. Interactive psychoeducation to establish a biospychosocial symptom understanding; the main focus are brain-gut interactions
2. Gut-directed hypnotherapy following the Manchester protocol (Gonsalkorale 2006) for regulating the brain-gut interactions, i.e. control and normalization of gut function via the autonomous nervous system and other stress circuits
3. Becoming familiar with the brain in the gut and using somatic markers as a help for orientation (What do your gut feelings tell you?)
4. Improvement of stress management
5. Empowerment of healthy patterns of the patients functioning (resource activation)
6. Analysis of catastrophizing and avoidance behaviour, and developing directions of exposure and change

The group intervention emphazises an interpersonal approach of psychodynamically based therapy, and in a disorder-focused manner combines this with gut-directed hypnotherapy and cognitive behavioural elements. In the beginning phase of the group all patients formulate concrete and realistic treatment goals that later on are evaluated to individually adjust treatment strategies. A core focus lies on the interactive group process. The group leaders pay attention to establishing a stable group setting and a supporting group cohesion. They give the basic structure following the manual to enable and support an interactive group process.

Waiting-control group: Enhanced medical care (EMC) based on the recommendations of our IBS clinic. After 3 months also the control patients get the group intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Portion of recruitable patients
2. Drop-out rates in intervention and control condition
3. Questionnaire completion rates
4. General evaluation of feasibility of randomisation and group intervention in speciality clinical care
5. Time series of IBS symptom severity, and of postulated psychosocial influences on the IBS symptoms: Somatization, catastrophizing, anxiety, depression, coping, stress.

Secondary outcome measures
IBS physical symptom experience:
1. Irritable bowel symptom severity scale (IBS-SSS)
2. Bristol stool scale (BSS)

Psychosocial factors:
1. Patient Health Questionnaire: somatic symptom severity (PHQ-15), depressive symptom scale (PHQ-9), generalised anxiety (GAD-7)
2. Illness anxiety (WI-7)
3. Perceived Stress Questionnaire PSQ-D (subscale demands)
4. Coping Strategies Questionnaire (CSQ)
5. Short Scale for Measuring General Self-efficacy Beliefs (Allgemeine Selbstwirksamkeit Kurzskala, ASKU)
6. Functional Digestive Diseases Quality of Life Questionnaire (FDDQOL) (subscale daily activities)
7. Experience of Close Relationships-Revised, German Version (ECR-RD12)
8. Evaluation of social systems (EVOS)

Group process:
1. Group questionnaire, German version (GQ-D)

Biomedical markers:
1. Stress circuits:
1a. HPA axis: ACTH, Cortisol
1b.Epigenetic programming of stress responses: Methylation of Cytosin-phosphatidyl-Guanin (CpG) islands within the promoter region of the neuron-specific glucocorticoid receptor gene NR3C1, and of the corticotrophin releasing factor (CRF) gene
2. Serotonergic system: Serotonin; Typing of functional SNPs (Single Nucleotide Polymorphism) in HTR3- and HTR4-genes, and in the serotonin transporter (SERT) gene SLC6A4 at baseline
3. Inflammatory processes: Calprotectin

Patient-Reported Outcomes (PRO):
1. Adequate relief (AR)
2. Subjective global assessment (SGA) measured on a 7-point Likert scale

Measures are assessed at baseline, 3 months and 6 months post randomisation.

Overall study start date
16/06/2014

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Adult male and female patients aged 18 years or older at the time of enrolment
2. At least one contact to the IBS clinic at Heidelberg University for making the diagnosis
3. Documented medical diagnosis of IBS according to Rome III criteria
4. IBS symptoms refractory to previous IBS therapies (IBS medication, antidepressants, or psychotherapies)

4a. Without adequate relief (AR)
4b.Subjective global assessment (SGA) at best moderately relieved on a 7-point Likert scale
5. Entry criteria:
5a.Abdominal Pain Intensity: Weekly average of worst abdominal pain in past 24 hours score of >3.0 on a 0 to 10 point scale and/ or
5b. IBS-D (with diarrhea): Stool Consistency: At least 2 days per week with at least one stool that has a consistency of Type 6 or Type 7 on the Bristol Stool Scale (BSS) and/ or
5c. IBS-C (with constipation): Stool Frequency <3 complete spontaneous bowel movements (CSBMs) per week
5d. IBS-M (mixed): At least 25% of stools are hard or lumpy and at least 25% are loose (mushy) or watery
5e. IBS-U (unsubtyped): Insufficient abnormality of stool consistency to meet criteria for IBS-D, IBS-C, or IBS-M.
6. Able to read, write and speak the German language
7. Written informed consent
8. Residing within 45-min reachability from Heidelberg
9. Set of problems suited for group intervention (e.g. patient is able to commit to weekly group sessions)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24 for the group intervention (12 patients randomised to intervention group, 12 patients to wait control group)

Key exclusion criteria
1. Newly started psychotherapy or antidepressant medication (psychotherapies for at least three months or antidepressants for at least one month were allowed for admission to the study if IBS was refractory to these interventions)
2. Evidence of alcohol or substance misuse
3. Severe psychiatric co-morbidity (e.g. bipolar disorder, schizophrenia, dementia)
4. Presence of suicidal ideation (current intent/ plans/ actions)
5. Severe organic disease (operationalized by a Karnofsky index <70%)
6. Inability to complete the questionnaires
7. Ongoing litigation due to disability pension or compensation for personal suffering
8. Patients with lactose intolerance and fructose malabsorption were not excluded if they had no adequate relief after an appropriate exclusion diet for more than 3 weeks

Date of first enrolment
16/06/2014

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Heidelberg
Heidelberg
Germany
D-69120

Sponsor information

Organisation
Postdoc Programme of the Medical Faculty of the University of Heidelberg (Germany)

Sponsor details
Im Neuenheimer Feld 672
Heidelberg
Germany
D-69120

Sponsor type
University/education

Website
http://www.medizinische-fakultaet-hd.uni-heidelberg.de/Forschungsdekanat.104169.0.html

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
University/education

Funder Name
Universität Heidelberg

Alternative Name(s)
University of Heidelberg, Ruprecht-Karls-Universität Heidelberg

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Germany

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	01/02/2018		Yes	No