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Research to compare the effect of three different psychological treatments for irritable bowel syndrome

Submission date 14/04/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/06/2011	**Overall study status** Completed	
Last Edited 27/11/2018	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL30698.041.10

Study information

Scientific Title
Individual or group hypnotherapy in the treatment of irritable bowel syndrome in primary and secondary care

Acronym
IMAGINE

Study objectives
1. At the end of therapy, patients in the hypnotherapy condition will report more adequate relief than in the educational supportive therapy condition (placebo treatment)
2. Hypnotherapy offered in a group format, is as effective as individual hypnotherapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of the University Hospital Utrecht, 23/02/2011, METC-Protocol No. 10-201/O

Study design
Randomised placebo-controlled trial

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
Gastroenterology

Interventions
Patients will be randomly allocated to one of the following:
1. Six sessions of individual hypnotherapy (every 14 days)
2. Six sessions of hypnotherapy in a group consisting of 6 patients (every 14 days)

3. Six sessions of educational-supportive therapy (every 14 days) in a group consisting of 6 patients

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Responder rate for IBS symptoms based on a weekly assessment of Adequate Relief (AR) score.

Secondary outcome measures
1. Changes in the IBS Symptom Severity Score (IBS-SSS) and Quality of life (IBS-Qol)
2. Cognitions, self-efficacy, psychological complaints and direct and indirect costs of the disease, measured as the costs of visits to doctors and alernative healers, use of medicines and loss of labour productiveness

Overall study start date
01/05/2011

Completion date
01/05/2013

Eligibility

Key inclusion criteria
1. Patients aged 18-65 years
2. In primary and secondary care
3. Diagnosed with IBS (Rome III criteria)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
354

Key exclusion criteria

1. Patients unable to understand the content of the sessions, because of insufficient command of the Dutch language
2. Patients unable to fill in the questionnaires
3. Patients unable (for example: too agressive) or unwilling to function in a group
4. Patients in whom a psychiatric condition needs attention first (for example severe depression or psychosis)
5. Patients who have IBS in addition to other chronic bowel diseases, as far as they are already diagnosed, such as ulcerative colitis, Crohn's disease or coeliac disease
6. Patients who have undergone major surgery to the lower gastrointestinal tract, such as partial or total colectomy, small bowel resection or partial or total gastrectomy

Date of first enrolment
01/05/2011

Date of final enrolment
01/05/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Julius Center, Health Sciences and Primary Care
Utrecht
Netherlands
3584 CG

Sponsor information

Organisation
University Medical Center Utercht (Netherlands)

Sponsor details
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Sponsor type

University/education

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
University/education

Funder Name
University Medical Center Utrecht (The Netherlands)

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	1. results	20/12/2011		Yes	No
Results article	results	01/01/2019		Yes	No