

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

Submission date 14/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/06/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/11/2018	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised placebo-controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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 alternative healers, use of medicines and loss of labour productiveness

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

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 aggressive) 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)

ROR

<https://ror.org/0575yy874>

Funder(s)

Funder type

University/education

Funder Name

University Medical Center Utrecht (The Netherlands)

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