Individual or Group Hypnotherapy in the treatment of Irritable Bowel Syndrome in primary and secondary care.

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This study has two main objectives:1. To assess the efficacy of hypnotherapy on symptoms and quality of life in IBS patients;2. To compare the efficacy of individual hypnotherapy with a group application of hypnotherapy in IBS treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON39767

Source
ToetsingOnline

Brief title
Imagine

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Irritable Bowel Syndrome; unexplained abdominal symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: first and secondary line, Hypnotherapy, IBS, Psychological treatment

Outcome measures

Primary outcome

The primary efficacy parameter is the responder rate for IBS symptoms based on a weekly assessment of Adequate Relief (AR) score.

Secondary outcome

Secondary efficacy parameters are changes in the IBS Symptom Severity Score (IBS-SSS) and Quality of Life (IBS-Qol), 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.

Study description

Background summary

Rationale: Irritable Bowel Syndrome (IBS) is a common gastro-intestinal disorder in primary and secondary care. IBS is a chronic functional gastro-intestinal disorder, characterized by recurrent periods of abdominal pain, discomfort, altered bowel habits and/or symptoms of bloating and distension. In general the efficacy of drug therapies is weak. Several reviews have been written on the effectiveness of psychological therapeutic interventions for these complaints. According to the Clinical practice guideline from the National Institute for Health and Clinical Excellence(NICE) (1), Hypnotherapy as well as Cognitive Behaviour Therapy and short Psychodynamic Therapy are useful options for patients with refractory IBS in secondary care and for this group of patients the therapies are cost-effective. Hypnotherapy may be considered a promising intervention for IBS, but the evidence is still too limited. Further research is recommended, with special focus on the potential of this intervention as a first line therapy option, with long term follow-up(1).

Study objective

This study has two main objectives:
1. To assess the efficacy of hypnotherapy on symptoms and quality of life in IBS patients;
2. To compare the efficacy of individual hypnotherapy with a group application of hypnotherapy in IBS treatment.

Study design

We propose a randomised placebo-controlled trial to evaluate the effects of individual - and group hypnotherapy in the treatment of IBS patients in primary and secondary care. To this end, we assess the efficacy of hypnotherapy compared to control therapy and compare the efficacy of group-hypnotherapy to individual hypnotherapy. Follow-up for all patients is 9 months post treatment. In the study period of two years a total of 354 IBS patients will be included in primary and secondary care.

Intervention

Patients will be randomly allocated to 6 sessions of individual hypnotherapy, 6 sessions of group-hypnotherapy or 6 sessions of educational-supportive therapy in a group (placebo).

Study burden and risks

The patient will visit the therapist 7 times (intake + 6 sessions) during treatment, to practice at home (hypnotherapy) or do home-work assignments (EOT-group) as well as being asked to fill in questionnaires, three times. No adverse events of hypnotherapy in literature have been reported (2).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients aged 18-65 years in primary and secondary care , who are diagnosed with IBS (Rome III criteria)

Exclusion criteria

Patients unable to understand the content of the sessions, because of insufficient command of the Dutch language.
Patients unable to fill in the questionnaires.
Patients unable (for example: too aggressive) or unwilling to function in a group.
Patients in whom a` psychiatric condition needs attention first (for example severe depression or psychosis).
Patients who have IBS and other chronic bowel diseases, as far as they are already diagnosed, such as ulcerative colitis, Crohn*s disease or coeliac disease.
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.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2011
Enrollment:	354
Type:	Actual

Ethics review

Approved WMO Date:	15-02-2011
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	22-08-2011
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-07-2013
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-03-2014
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27823
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL30698.041.10
OMON	NL-OMON27823