Research to compare the effect of three different psychological treatments for the Irritable Bowel Syndrome.

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27823

Bron
NTR

Verkorte titel
IMAGINE

Aandoening

Irritable Bowel Syndrome
Keywords: IBS; Psychological treatment; Hypnotherapy; first and secondary line.

trefwoorden: Prikkelbare Darm Syndroom; Psychologische behandelmethode; behandeling met Hypnose; eerste- en tweede lijn.

Ondersteuning

Primaire sponsor: Performer: University Medical Center Utrecht, the Netherlands
Overige ondersteuning: Fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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), 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.

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.

Study population:

Primary care and secondary care patients (aged 18-65) with IBS, consulting their general practitioner, the medical specialist or gastroenterologist.

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).

Main study parameters/endpoints:

The primary efficacy parameter is the responder rate for IBS symptoms based on a weekly assessment of Adequate Relief (AR) score. Secondary efficacy parameters are changes in the IBS Symptom Severity Score (IBS-SSS) and Quality of Life (IBS-Qol), cognitions, psychological complaints, self-efficacy 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The patient will visit the therapist 7 times (intake + 6 sessions) during treatment, as well as being asked to fill in questionnaires. No adverse events of hypnotherapy in literature have been reported.

Doel van het onderzoek

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.

Onderzoeksopzet

Assessments:
1. Prior to start of treatment;

2. End of treatment (after 12 weeks);

3. 9 months after treatment (follow-up).

Onderzoeksproduct en/of interventie

Patients will be randomly allocated to:

1. 6 sessions of individual hypnotherapy (every 14 days);

2. 6 sessions of hypnotherapy in a group (6 patients)(every 14 days);

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

Contactpersonen

Publiek

Julius Center for Health Sciences and Primary care
Universiteitsweg 100
C.E. Flik
Utrecht 3584 CG
The Netherlands
+31 (0)88 7568355

Wetenschappelijk

Julius Center for Health Sciences and Primary care
Universiteitsweg 100
C.E. Flik
Utrecht 3584 CG
The Netherlands
+31 (0)88 7568355

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 and 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland
Status: Werving nog niet gestart

(Verwachte) startdatum:	01-05-2011
Aantal proefpersonen:	354
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-03-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39767
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2692
NTR-old	NTR2822
CCMO	NL30698.041.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39767

Resultaten

Samenvatting resultaten
N/A