Hypnotherapy for IBD patients with IBS-like symptoms.

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Gut-directed hypnotherapy leads to a substantial reduction in IBS-like symptoms in patients with IBD.

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

Samenvatting

ID

NL-OMON22531

Bron
Nationaal Trial Register

Verkorte titel
HIPI

Aandoening

Inflammatory bowel disease
Inflammatoire darmziekte
Irritable bowel syndrome
Prikkelbare darmsyndroom

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)
Overige ondersteuning: Zon-Mw, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of patients with >50% reduction in IBS-SSS pain score.

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND:

30-50% of patients with inflammatory bowel disease (IBD) in remission have irritable bowel syndrome(IBS)-like symptoms for which treatment options are limited. Often these complaints result in additional health care use. Gut-directed hypnotherapy has been effective in the treatment of patients with IBS only.

AIM:

To study the effectiveness of gut-directed hypnotherapy in the treatment of IBS-like symptoms in patients with inflammatory bowel disease.

METHODS:

Patients (age >11 years) with IBD in remission and in addition IBS-like symptoms will be will be recruited in the Netherlands and randomly allocated to either 6 sessions of hypnotherapy or standard medical care and 6 sessions of supportive therapy. The primary outcome will be the number of patients with >50% reduction in the pain component of the IBS severity scoring system (IBS-SSS) score. Based on results in studies on the effectiveness of hypnotherapy in IBS patients it is estimated that 75% of the patients will have a >50% reduction 6 months after treatment versus only 40% of the control group. With an estimated drop-out rate of 10%, 80 patients are needed to detect a 35% reduction with a statistical power of 80%, and a twosided alpha of 5%. Secondary outcomes are the effects of therapy on total IBS-SSS score, adequate relief, health related quality of life, IBD disease activity, health utility index, depression, anxiety and somatisation, abdominal pain related cognitions, absence of school or work, use of health care resources and additional costs, use of IBD medication, colonic sensitivity to distension, faecal protease activity and microbiota and the ability of patient’s faecal supernatant to induce colonic hypersensitivity to distension in rats by colonic infusion.

Doel van het onderzoek

Gut-directed hypnotherapy leads to a substantial reduction in IBS-like symptoms in patients with IBD.

Onderzoeksopzet

Primary outcome: At 6 months follow-up.

Onderzoeksproduct en/of interventie

Either 6 sessions of gut-directed hypnotherapy, or 6 sessions of standard medical treatment with supportive therapy.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with inflammatory bowel disease and IBS-like symptoms, age >11 years will be recruited. Patients have to be in remission of their inflammatory bowel disease as defined as no signs of inflammatory bowel disease, low inflammatory markers in laboratory tests and no disease activity on imaging studies of the intestine. IBS-like symptoms are defined as

abdominal pain for at least two months, fulfilling the pediatric or adult Rome-III criteria for IBS.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are a concomitant organic gastrointestinal disease, stenotic IBD, complicated IBD that had required surgery more than once, another coexisiting complicated disease (e.g. malignancy, unstable cardiovascular, hepatic or renal disease), treatment by another health care professional for abdominal symptoms, mental retardation, insufficient knowledge of the Dutch language and previous hypnotherapy treatment.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2012
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-05-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43963
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3261
NTR-old	NTR3414
CCMO	NL39964.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON43963

Resultaten

Samenvatting resultaten
N/A