Hypnotherapy for adolescents and adults with inflammatory bowel disease and symptoms compatible with irritable bowel syndrome.

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON43963

Source
ToetsingOnline

Brief title
HIPI: Hypnotherapy for IBD patients with IBS-like symptoms.

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, inflammatory bowel disease, ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw.

Intervention

Keyword: children & adults, hypnotherapy, inflammatory bowel disease, irritable bowel syndrome

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcomes are the effects of therapy on pain scores, 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, cortisol level in hair, faecal protease activity and microbiota and the ability of patient*s faecal supernatant to induce colonic hypersensitivity to distension in rats by colonic infusion.

Study description

Background summary

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.

Study objective

To study the effectiveness of gut-directed hypnotherapy in the treatment of

IBS-like symptoms in patients with inflammatory bowel disease.

Study design

Patients (aged > 11 years) with IBD in remission and in addition IBS-like symptoms will be randomly allocated to either 6 sessions of hypnotherapy or standard medical care and 6 sessions of supportive therapy.

Intervention

Patients in the hypnotherapy group will receive 6 sessions of 50 minutes therapy over a 3-months period. The hypnotherapy-protocol used is based on the Manchester protocol of gut-directed hypnotherapy and will consist of general relaxation, visualisations aiming at control of abdominal pain, gut and immune functions, and ego-strengthening suggestions. Patients in the standard medical care group will receive standard care for IBS consisting of explanation of the cause and origin of the IBS-like complaints by their treating physician and reassurance that the complaints are not related to inflammatory bowel disease, cancer or other life threatening diseases. If considered necessary pain medications, spasmolytic agents, proton-pump inhibitors will be prescribed. Moreover, patients in this group will receive 6 half-hour sessions of supportive therapy over a 3-month period. In these sessions, given by a physician, symptoms of the previous weeks will be discussed and if possible, contributory triggers, such as dietary products, emotional problems, and stressful events, will be explored.

Study burden and risks

There are no risks related to the rectal barostat. The burden is considered minimal. The introduction of the rectal balloon can be uncomfortable. The duration (around 2 hours) can also be considered uncomfortable. Most of these 2 hours, the patient will be lying on a bed comfortably. Controlled distension of the intra-rectal balloon will be done and the threshold for pain or discomfort will be determined, to evaluate the sensitivity of the colon. Previous comparable studies in patients with inflammatory bowel disease or irritable bowel syndrome, were well tolerated.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with inflammatory bowel disease and IBS-like symptoms, aged >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, faecal calprotectin levels either below 50, or between 50-200 in combination with a recent (up to 6 months) normal colonoscopy. IBS-like symptoms are defined as abdominal pain for at least two months, fulfilling the pediatric or adult Rome-III criteria for IBS.

Exclusion criteria

Exclusion criteria are a concomitant organic gastrointestinal disease, stenotic IBD, complicated IBD that had required surgery more than once, another coexisting 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-07-2012
Enrollment:	85
Type:	Actual

Ethics review

Approved WMO Date:	14-05-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-09-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-12-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-06-2013
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 22531
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL39964.018.12
OMON	NL-OMON22531