

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Gastrointestinal inflammatory conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON34040

### Source

ToetsingOnline

### Brief title

HIPI: Hypnotherapy for IBD Patients with IBS like symptoms

### Condition

- Gastrointestinal inflammatory conditions

### Synonym

Crohns 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, inflammatory bowel disease hypnotherapy, irritable bowel syndrome

## Outcome measures

### Primary outcome

The primary outcome will be the number of patients with > 50% reduction in intensity and frequency of abdominal pain.

### Secondary outcome

Secondary outcomes include the change in pain scores during follow-up, IBD disease activity score, quality of life scores, depression and anxiety scores, use of additional medication, health utility, societal costs, school absence and absence of work, measured after treatment and at 3 and 6 months follow-up.

## 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 (age > 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 the 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

None

## Contacts

### Public

Academisch Medisch Centrum

Meibergdreef 9  
1105 AZ Amsterdam  
NL

### Scientific

Academisch Medisch Centrum

Meibergdreef 9  
1105 AZ Amsterdam  
NL

## 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, 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 and adult Rome-III criteria for IBS

### Exclusion criteria

Exclusion criteria are a concomitant organic gastrointestinal 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 phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Primary purpose: Treatment

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-03-2012  
Enrollment: 80  
Type: Anticipated

## Ethics review

Approved WMO  
Application type: First submission  
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

No registrations found.

### In other registers

Register	ID
CCMO	NL33724.018.10