

# Hypnotherapy in inflammatory bowel disease. A randomised, placebo-controlled trial

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 27/02/2020	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Alastair Forbes

**Contact details**  
St Mark's Academic Institute Level 5X  
North West London Hospitals NHS Trust  
St Mark's Hospital  
Watford Road  
Harrow  
United Kingdom  
HA1 3UJ

## Additional identifiers

**Protocol serial number**  
N0515107957

## Study information

**Scientific Title**  
Hypnotherapy in inflammatory bowel disease. A randomised, placebo-controlled trial

**Study objectives**

Patients with chronic inflammatory bowel disease have an impaired quality of life compared to healthy controls. The most prevalent problems are not only disease related symptoms (e.g. diarrhoea and abdominal pain), but also worries about subsequent exacerbations, surgery, cancer, social restrictions and sexual dysfunction. These symptoms are often in considerable disparity to apparent disease activity. Hypnosis is an altered state of consciousness, trying to focus the mind's inner unconscious resources to activate or inhibit a psychological or a physiological response. Hypnotherapy has been used successfully as an aid to treat many conditions of medical and psychological origin. In gastroenterology, hypnotherapy has been shown by previous studies to be highly effective in the treatment of refractory irritable bowel syndrome and has also been tried in organic disorders. To our knowledge, hypnotherapy has not been formally assessed in patients with inflammatory bowel disease. We hypothesise that hypnotherapy has the ability to improve quality of life in symptomatic patients with inflammatory bowel disease when offered as an adjunct to conventional therapy. We propose to study the efficacy of individual hypnotherapy in the symptomatic treatment of patients with inflammatory bowel disease. It will be a randomised, placebo-controlled trial comparing individual hypnotherapy, 'gastroenterological input' therapy and placebo.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Not Specified

### **Health condition(s) or problem(s) studied**

Digestive System: Inflammatory bowel disease

### **Interventions**

We plan to recruit sixty patients who will be randomised into one of the four arms of our study. There will be a complex stratification given the many parameters that may effect quality of life issues. This will include age, sex, disease type (Crohn's or ulcerative colitis), use of immunosuppressants, and presence/absence of stoma. The first group (n=15) will have 6 "gastroenterological input" sessions (one session per week) conducted by a Gastroenterology Registrar at St Mark's Hospital. These sessions will consist of a 20 minute consultation with each individual on different issues concerning the patient's gastroenterological problems. The rationale of this control group is to permit the assessment of the possible superiority of hypnotherapy over informal psychological therapy. The third and fourth (placebo) group (n=30) will receive no treatment during the first 6 week-period of the study, however they will then be randomised into either the hypnotherapy or "gastroenterological input" therapy which will both be administered for the subsequent six weeks. The primary end-point of the study will be a change in the patient's quality of life assessment by the disease specific inflammatory bowel disease questionnaire (IBDQ). Secondary end-points will include improvements in the EuroQol quality of life index, and (depending on the underlying inflammatory bowel disease) either the

modified Crohn's disease activity index (mCDAI) or the ulcerative colitis scoring system Crohn's disease (unless clinically indicated) The IBDQ and EuroQol will be administered at weeks 0, 6, 12 and 18. The mCDAI or UCSS will be assessed at weeks 0,6,12 and 18, with the exception of sigmoidoscopy (needed for the UCSS) which will only be performed twice or three times in patients with ulcerative colitis at 0 and 6 weeks, or at 0, 6 and 12 weeks in those in the delayed are) and not at all in patients with Crohn's disease (unless clinically indicated).

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

The primary end-point of the study will be a change in the patients' perception of their overall status as assessed by the disease specific inflammatory bowel disease questionnaire (IBDQ). The secondary end-point of the study will be the improvement of the inflammatory bowel disease activity indices: modified Crohn's disease activity index (CDAI) and ulcerative colitis scoring system (UCSS). Hypnotherapy is a psychological treatment of uncertain mechanism of action. We would expect it to target mainly quality of life problems and functional symptoms related to inflammatory bowel disease rather than the inflammatory process itself. Nevertheless, there is evidence in favour of the concept that brain-gut interaction can modify inflammatory intestinal responses as well

**Key secondary outcome(s))**

Not provided at time of registration

**Completion date**

31/03/2005

**Eligibility****Key inclusion criteria**

Total number 60, hypnotherapy group 15, gastrointestinal input group 15 delayed treated (placebo) group 30 (delayed hypnotherapy 15, delayed gastroenterological input therapy 15. The age range will be 18-80 years.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

80 years

**Sex**

Not Specified

**Key exclusion criteria**

Does not match inclusion criteria

**Date of first enrolment**

07/01/2002

**Date of final enrolment**

31/03/2005

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

St Mark's Academic Institute Level 5X

Harrow

United Kingdom

HA1 3UJ

**Sponsor information**

**Organisation**

Department of Health

**Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

North West London Hospitals NHS Trust (UK) NHS R&D Support Funding

# Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration