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

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 27/02/2020	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
07/01/2002

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Not Specified

Target number of participants
60

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
England

United Kingdom

Study participating centre
St Mark's Academic Institute Level 5X
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Sponsor type
Government

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Funder(s)

Funder type
Hospital/treatment centre

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration