

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

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Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 27/02/2020	Condition category Digestive System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design

Interventional

Study design

Randomised controlled trial

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

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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