

Healing therapy in a gastroenterology outpatients

Submission date 05/07/2010	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 16/07/2010	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 11/04/2016	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

Contact name
Dr Sukhdev Singh

Contact details
Gastroenterology
Good Hope Hospital
Rectory Road
Sutton Coldfield
Birmingham
United Kingdom
B75 7RR

Additional identifiers

Protocol serial number
DSS01

Study information

Scientific Title
A randomised controlled trial of healing therapy in a gastroenterology outpatient setting

Study objectives

Principal question:

Does healing therapy in addition to usual management impact on symptoms in individuals with irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD), compared to normal management alone?

Secondary question:

Does healing therapy in addition to usual management impact on an individual's quality of life, compared to usual management alone?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Black Country Research Ethics Committee, 11/06/2010, ref: 10/H1202/36

Primary study design

Interventional

Study design

Pragmatic single-centre randomised controlled trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Irritable bowel syndrome (IBS), inflammatory bowel disease (IBD), ulcerative colitis and Crohn's disease

Interventions

Obtaining consent and allocation of patients to study arms (1 interview at start of trial lasting 30 minutes):

1. Intervention: healing therapy, patient to attend 5 weekly 30 minute sessions (held in consecutive weeks)
2. Control: waiting list will undergo therapy sessions after 12 weeks

After this questionnaire data (1 baseline; 3 follow-up questionnaires completed each lasting 15 minutes) and qualitative semi-structured interviews (potentially 2 interviews, depending on selection, each lasting 1 hour) will take place.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Change in Measure Yourself Medical Outcome Profile (MYMOP) score at week 6 and 12. This well validated individualised patient-centred instrument developed by researchers working in the study of alternative and complementary therapies.

Key secondary outcome(s)

Current secondary outcome measures as of 20/09/2012:

1. Change in disease specific quality of life scores at week 6 and 12. Appropriate disease specific tools will be used for patients with IBS (Irritable Bowel Syndrome Quality of Life Instrument [IBS-QOL]) and IBD (Inflammatory Bowel Disease Questionnaire [IBDQ]) and change in arm assessed for each disease type separately.
2. Change in disease specific symptom scores at weeks 6 and 12 will also be compared using the Birmingham IBS symptom questionnaire and modified version of the Simple Clinical Colitis Activity Index (SCCAI) and modified version of the Harvey-Bradshaw Index.

Previous secondary outcome measures until 20/09/2012:

2. Change in disease specific symptom scores at weeks 6 and 12 will also be compared using the Birmingham IBS symptom questionnaire and modified version of the Simple Clinical Colitis Activity Index (SCCAI)

Completion date

01/07/2012

Eligibility

Key inclusion criteria

Current inclusion criteria as of 20/09/2012:

1. Over 18 years of age, either sex
2. Attending clinic with a clinician diagnosis of IBS (confirmed by ROME II criteria) or with a clinician diagnosis of ulcerative colitis or Crohn's disease

Previous inclusion criteria until 20/09/2012:

2. Attending clinic with a clinician diagnosis of IBS (confirmed by ROME II criteria) or with a clinician diagnosis of ulcerative colitis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Already receiving healing, Reiki or other similar complementary treatments elsewhere (or having done so in the previous 12 months)
2. Unable to give fully informed consent due to learning disability, mental illness or other reason
3. Pregnant

Date of first enrolment

19/07/2010

Date of final enrolment

01/07/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Good Hope Hospital

Birmingham

United Kingdom

B75 7RR

Sponsor information

Organisation

Heart of England NHS Foundation Trust (UK)

Funder(s)

Funder type

Government

Funder Name

Big Lottery Fund (UK) (ref: C811A1336)

Alternative Name(s)

BIG

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration