ISRCTN13039379 https://doi.org/10.1186/ISRCTN13039379

Healing therapy in a gastroenterology outpatients

Submission date	Recruitment status	[X] Prospectively registered
05/07/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/07/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/04/2016	Digestive System	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Pragmatic single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
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 measure
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.

Secondary outcome measures
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)

Overall study start date
19/07/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

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
England

United Kingdom

Study participating centre
Good Hope Hospital
Birmingham
United Kingdom
B75 7RR

Sponsor information

Organisation
Heart of England NHS Foundation Trust (UK)

Sponsor details
c/o June DelaRue
Research & Development Directorate

Birmingham Heartlands Hospital
Bordesley Green
Birmingham
England
United Kingdom
B9 5SS

Sponsor type
Hospital/treatment centre

Website
http://www.heartofengland.nhs.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

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