# Healing therapy in a gastroenterology outpatients

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered	
05/07/2010		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	<ul><li>Record updated in last year</li></ul>	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Sukhdev Singh

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

 ${\bf Clinical Trials. gov\ number}$ 

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