

A randomised controlled trial of a course of reflexology on irritable bowel syndrome (IBS) in a primary care setting

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 01/04/2009	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Philip Tovey

Contact details
University of Leeds
Centre for Research in Primary Care
30-32 Hyde Terrace
Leeds
United Kingdom
LS2 9LN
+44 (0)113 233 4838
p.a.tovey@leeds.ac.uk

Additional identifiers

Protocol serial number
PCC1012R; RSU440900

Study information

Scientific Title

Study objectives

The aim of this study is to provide the first systematic evidence on the potential of reflexology to improve symptoms for patients with irritable bowel syndrome (IBS). As a result the study provides evidence on:

1. The overall effectiveness of reflexology
2. Its impact on a range of physical and psychological symptoms
3. Potential cost-effectiveness
4. The extent to which benefits are dependent on the nature of touch

It contributes to more informed decision making for professionals and service users.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from Local Ethics Committee

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Inflammatory bowel disease

Interventions

1. Experimental reflexology group
2. Control group

The reflexology experimental group were given six 30 minute treatment sessions over an eight week period conducted as closely as possible in line with 'normal practice'. The length of the sessions and the total number of those sessions was agreed with the lead reflexologist. The treatment consisted of an initial 'whole foot' massage followed by localised attention to the areas of the foot considered - within reflexology theory - to be related to IBS. The indistinguishable control group was given the same number of contact sessions as the experimental group and those sessions were carried out in exactly the same way, following the same procedures, with the single exception that a non-reflexology foot massage was given. According to reflexology theory this should have no curative effect as no stimulation of healing has occurred.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

The study was designed to test the effectiveness of reflexology on the core defining symptoms of IBS and wider physical and psychological outcomes. The principal outcome measure was abdominal pain.

Key secondary outcome(s)

1. Constipation/diarrhoea
2. Bloating
3. Overall health
4. Personal well being
5. Tiredness
6. Anxiety

Completion date

06/01/2000

Eligibility**Key inclusion criteria**

Inclusion criteria were tightly defined:

1. Patients currently under the care of a primary care physician following referral to a Gastroenterologist
2. The diagnosis of IBS in line with the Rome Criteria
3. Exclusion of other causes of symptoms

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Previous use of reflexology

Date of first enrolment

05/01/1998

Date of final enrolment

06/01/2000

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

University of Leeds

Leeds

United Kingdom

LS2 9LN

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2002		Yes	No