

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
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/04/2009	Condition category Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study hypothesis

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Condition

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 measure

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.

Secondary outcome measures

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

Overall study start date

05/01/1998

Overall study end date

06/01/2000

Eligibility

Participant 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

Age group

Adult

Sex

Both

Target number of participants

34

Participant exclusion criteria

Previous use of reflexology

Recruitment start date

05/01/1998

Recruitment end date

06/01/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Leeds

Leeds

United Kingdom

LS2 9LN

Sponsor information

Organisation

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

Sponsor details

The Department of Health

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Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)**Funder type**

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

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

Study outputs

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