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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 01/04/2009	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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. Bloatedness
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