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

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| **Submission date**<br>23/01/2004 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>23/01/2004 | **Overall study status**<br>Completed | |
| **Last Edited**<br>01/04/2009 | **Condition category**<br>Digestive System | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### 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

### 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 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. Bloatedness
3. Overall health
4. Personal well being
5. Tiredness
6. Anxiety

### Overall study start date
05/01/1998

### 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

### Age group
Adult

### Sex

Both

**Target number of participants**
34

**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**
England

United Kingdom

**Study participating centre**
**University of Leeds**
Leeds
United Kingdom
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# Sponsor information

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

**Sponsor details**
The Department of Health
Richmond House
79 Whitehall
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+44 (0)20 7307 2622
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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 |