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

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

## Study design

Randomised controlled trial

## Primary study design

Interventional

## 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