

# A randomised controlled trial of the effects of reflexology on mood, coping and quality of life in women with early breast cancer

<b>Submission date</b> 12/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 03/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/05/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

NCP2/X229

## Study information

### Scientific Title

**Study objectives**

1. Reflexology will be superior to a comparator contact intervention (massage) and treatment as usual (self-initiated support) in terms of its effect on quality of life
2. Reflexology will be acceptable to patients with early breast cancer as manifest by high levels of patient satisfaction and a high uptake of reflexology sessions
3. Reflexology will enhance perceived self control of health

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Early breast cancer.

**Interventions**

Intervention 1: self-initiated support in the Oncology Health Centres (treatment as usual)

Intervention 2: self-initiated support in the Oncology Health Centres plus scalp massage (comparator physical and social contact intervention)

Intervention 3: self-initiated support in the Oncology Health Centres plus reflexology (a standard foot reflexology routine)

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

The primary outcome measures will be patient acceptability (number of sessions of reflexology actually attended) and scores on the Clinical Trials Index derived from the Functional Assessment of Cancer Therapy: Breast Version (FACT-B) at week 18.

**Key secondary outcome(s)**

1. Mood Rating Scale (MRS)
2. Patient Satisfaction Questionnaire (PSQ)
3. FACT-B at week 24

**Completion date**

31/12/2005

## Eligibility

### Key inclusion criteria

Newly diagnosed early breast cancer (T1, T2 <3 cm, N0, N1a, M0).

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

Female

### Key exclusion criteria

1. Unable to complete the study questionnaires
2. Unwilling to give written informed consent

### Date of first enrolment

01/04/2002

### Date of final enrolment

31/12/2005

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

Institute of Rehabilitation

Kingston upon Hull

United Kingdom

HU3 2PG

## Sponsor information

### Organisation

## Funder(s)

### Funder type

Government

### Funder Name

NHS R&D National Cancer Programme

### Funder Name

NCP/X229.

## 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?
<a href="#">Results article</a>	results	01/01/2010		Yes	No