

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

Submission date 12/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 03/11/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/05/2012	Condition category Cancer	☐ 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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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

Primary study design

Interventional

Study design

Randomised controlled trial

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?
Results article	results	01/01/2010		Yes	No