ISRCTN87652313 https://doi.org/10.1186/ISRCTN87652313

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/11/2005	**Overall study status** Completed	
Last Edited 09/05/2012	**Condition category** Cancer	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

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

Overall study start date
01/04/2002

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

Age group
Adult

Sex
Female

Target number of participants
180

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
England

United Kingdom

Study participating centre
Institute of Rehabilitation
KIngston upon Hull
United Kingdom
HU3 2PG

Sponsor information

Organisation
NHS Research and Development National Cancer Programme (UK)

Sponsor details
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Sponsor type
Government

Website
http://www.exeter.ac.uk/shhs/canc

Funder(s)

Funder type
Government

Funder Name
NHS R&D National Cancer Programme

Funder Name
NCP/X229.

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	01/01/2010		Yes	No