ISRCTN95527771 https://doi.org/10.1186/ISRCTN95527771

A pilot study for a randomised controlled trial to determine if reflexology can help improve neurological damage caused by taxane chemotherapy drugs

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/11/2015	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Rebecca J Pitt

Contact details
St Chad's Outpatients and Chemotherapy Department
City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0064131831

Study information

Scientific Title
A pilot study for a randomised controlled trial to determine if reflexology can help improve neurological damage caused by taxane chemotherapy drugs

Study objectives
Does reflexology help to improve the neurotoxicity (tingling and numbness) in the hands and feet experienced by some patients following cytotoxic chemotherapy with Paclitaxel and Docetaxel?
Can the benefits of using reflexology in this setting be proven by the use of nerve conduction studies? (i.e. will there be a statistical difference over time in the reflexology group compared to the control group?).
Does the use of reflexology in this context help patients to feel better in themselves? (Quality of Life questionnaire will be used for this).

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
Neurotoxicity after chemotherapy

Interventions
Single centre, patient volunteers, prospective, controlled, therapeutic, observational, randomised, questionnaire study.

Reflexology vs no reflexology

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2003

Completion date
01/06/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Total of 40 patients required for reflexology and control groups, 20 for each arm of the study.

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2003

Date of final enrolment
01/06/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
City Hospital
Birmingham
United Kingdom
B18 7QH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Sandwell and West Birmingham Hospitals NHS Trust (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