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A pilot study to investigate the effects on fitness and quality of life of an individualised exercise programme for breast cancer patients undergoing radiotherapy.

Submission date
30/09/2004

Registration date
30/09/2004

Last Edited
01/10/2012

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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

N0265134364

Study information

Scientific Title

Study objectives
1. Do fitness levels and perceptions of quality of life change during and following radiotherapy treatment for breast cancer?
2. Does an individualised exercise programme during radiotherapy treatment for cancer affect fitness levels?
3. Does perception of quality of life change during and following radiotherapy as a result of exercise intervention?

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)
Not Specified

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
Cancer: Breast

Interventions
The following activities will be in addition to the normal treatment programme, but will be conducted as an extension of out-patient appointments at the hospital during radiotherapy treatment, with 2 additional visits following completion of treatment.

10 participants will be randomly allocated to a control (n = 5) or intervention (n = 5) group.

Participants will complete the following assessments:

1. A modified step test of three minutes duration to provide an index of fitness. (The modified test allows variation of step height with a minimum of inches, which makes the test achievable by a wider range of individuals.) This will be completed immediately before the commencement of radiotherapy treatment, and at weekly intervals until follow-up appointment at 6 weeks from end of treatment (Buckley 1999)

2. A quality of life (QoL) questionnaire (The European Organisation for Research and Treatment of Cancer - EORTC QLQ-C3O, version3). This is a cancer specific multidimensional tool (EORTC 2001). The questionnaire will be completed before commencement, at completion and 3 weeks following completion of the radiotherapy programme.

3. Participants will also keep an activity diary during treatment and for a period of 3 weeks following completion of the radiotherapy course. This will include a daily rating of fatigue (visual analogue scale), and identification of the level of activity with completion of a grid of activities completed and time for activity. This will be a simple sheet taking less than 5 minutes for participants to complete.

4. The intervention group will also complete an individualised exercise programme, throughout this data collection period, with review and progression evaluated on a weekly basis for individuals.

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
01/11/2003

Completion date
01/11/2008

Eligibility

Key inclusion criteria
Female participants with breast cancer who are referred for a 3 week course of radiotherapy at the Queen Elizabeth Hospital, University Hospital Birmingham Trust will be invited to participate in the study when they are booked in. Inclusion criteria:
1. Participants will be recruited and randomised to control (n = 5) and intervention (n = 5) groups
2. Be able to complete the modified step test
3. Be able to understand instructions and complete an activity diary
4. Participants between the age of 50-70 years

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. Participants must be independent in self care and activities of daily living
2. Have no medical condition that prevents their participation in exercise (screening form and clearance for testing completed by Doctors at Clinic appointment)
3. Participants who will not be able to complete the requirements of assessments within the study
4. Participants having chemotherapy In addition to radiotherapy
5. Participants who have participated in the SEACRAB trial
6. Participants who are receiving radiotherapy for more than 3 weeks

Date of first enrolment
01/11/2003

Date of final enrolment
01/11/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Radiotherapy
Birmingham
United Kingdom
B15 2TH

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
University Hospital Birmingham 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