

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	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 01/10/2012	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

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Additional identifiers

Protocol serial number

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

Study type(s)

Not Specified

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-C30, 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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Radiotherapy

Birmingham

United Kingdom

B15 2TH

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

University Hospital Birmingham NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration