

A randomised controlled trial of a supervised exercise programme as a rehabilitation treatment for women receiving early stage breast cancer treatment

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
20/09/2005	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
20/01/2006	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
10/09/2012	Cancer	

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/exercise-therapy-for-women-having-treatment-for-early-stage-breast-cancer>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

CRUK grant C8305/A3902

Study information

Scientific Title

Study objectives

Exercise is an effective intervention during cancer treatment to decrease fatigue levels and improve quality of life and physical functioning

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)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Intervention: Group exercise class twice a week for 12 weeks

The control group will receive usual care from the healthcare team and will complete the questionnaires and walking test at baseline, week 12 and 6 months post intervention. At the end of the study period (9 months) they will be assisted by the senior researcher in constructing their own personalised exercise plan and invited to join the Glasgow GP exercise referral scheme.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Functional assessment of cancer therapy - general (FACT G) - measure of Quality of life

Key secondary outcome(s)

1. FACT - breast cancer specific
2. FACT - fatigue
3. FACT - endocrine symptoms
4. Beck Depression Inventory (BDI)

5. Positive and Negative Affects Scale (PANAS)
6. 12 minute walk test
7. Scottish physical activity questionnaire (SPAQ)

Completion date

31/12/2005

Eligibility

Key inclusion criteria

Any women undergoing treatment for early stage breast cancer.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Any woman with concurrent major health problems such as uncontrolled cardiac or hypertensive disease, respiratory disease, cognitive dysfunction or already exercising vigorously three times a week for 20 minutes or more.

Date of first enrolment

01/01/2004

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre**Dept Sport Culture and Art**

Glasgow

United Kingdom

G13 1PP

Sponsor information

Organisation

University of Strathclyde (UK)

ROR

<https://ror.org/00n3w3b69>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK - CRUK grant C8305/A3902

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	10/03/2007		Yes	No