

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

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

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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/01/2004

Completion date

31/12/2005

Eligibility

Key inclusion criteria

Any women undergoing treatment for early stage breast cancer.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

182

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

Scotland

United Kingdom

Study participating centre

Dept Sport Culture and Art

Glasgow

United Kingdom

G13 1PP

Sponsor information

Organisation

University of Strathclyde (UK)

Sponsor details

Lynda Frew

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Sponsor type

University/education

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ROR

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

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK - CRUK grant C8305/A3902

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 | 10/03/2007 | | Yes | No |