Can physical activity enhance emotion, memory, attention and concentration in breast cancer patients receiving chemotherapy?

Submission date	Recruitment status	Prospectively registered
23/10/2012	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
31/10/2012	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
23/04/2019	Cancer	

Plain English summary of protocol

http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-at-physical-activity-during-chemotherapy-for-breast-cancer

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

11/EM/0437

Study information

Scientific Title

Physical activity intervention for emotional & cognitive functioning in breast cancer patients receiving chemotherapy

Study objectives

- 1. Women who complete the physical activity intervention will report higher emotional well-being and show less impairment on memory, attention and concentration tasks in comparison to women in the non-intervention group.
- 2. Within the intervention group, emotional well-being will mediate between physical activity level and level of impairment in memory, attention and concentration.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES committee East Midlands - Northampton, 02/02/2012, ref: 11/EM/0437

Study design

Interventional study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Quality of life

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

Breast cancer patients

Interventions

The study will involve 26 breast cancer patients committing to a 12-week home-based, moderate intensity walking intervention. Patients in this group will be provided with guidance, encouragement and motivation to incorporate 30 mins of moderate intensity walking five times a week around their treatment schedules. The control comparison will receive usual care only.

Intervention Type

Behavioural

Primary outcome measure

Measures of emotional distress and cognitive functioning.

Secondary outcome measures

Self-esteem, fatigue, intention to exercise, executive function, memory, attention, visual-spatial skills and motor function.

Overall study start date

01/06/2012

Completion date

01/10/2013

Eligibility

Key inclusion criteria

- 1. Age 18-75 female breast cancer patients
- 2. Those who do not exceed recommended guidelines of 30 mins of moderate intensity exercise five times a week.
- 3. Those whose breast cancer is a primary diagnosis
- 4. Those who have no previous history of cancer
- 5. Those who are able to speak and read standard English

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Female

Target number of participants

52

Total final enrolment

50

Key exclusion criteria

- 1. Males
- 2. Those who exceed the recommended guidelines of 30 minutes exercise five times a week

- 3. Those whose breast cancer is a secondary diagnosis
- 4. Those who have previous history of cancer
- 5. Those who cannot speak and read Standard English

Date of first enrolment

01/06/2012

Date of final enrolment

01/10/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Loughbrough University

Loughborough United Kingdom LE11 3TU

Sponsor information

Organisation

Loughborough University (UK)

Sponsor details

c/o Peter Townsend Research Office Room 2.01 Rutland Building Loughborough England United Kingdom LE11 3TU

Sponsor type

University/education

Website

http://www.lboro.ac.uk/

ROR

Funder(s)

Funder type

University/education

Funder Name

School of Sport, Exercise and Health Science at Loughborough University (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Results article	psychosocial wellbeing and physical activity results	01/03/2016		Yes	No
Results article	cognitive decline results	28/11/2018	23/04 /2019	Yes	No