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The effect of a 10 week exercise intervention on cancer related fatigue in cancer survivor's with documented fatigue compared to a 10 week health education programme

Submission date
24/05/2017

Recruitment status
No longer recruiting

Registration date
08/06/2017

Overall study status
Completed

Last Edited
14/10/2022

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cancer related fatigue (CRF) is a debilitating side effect reported among cancer survivors, often lasting years following treatment, causing them to experience low energy and tiredness. There is some evidence of a small to moderate effect of exercise training on fatigue, however these studies have typically been undertaken in mixed populations, including those with and without documented fatigue. In addition, there is often a lack of a proper comparison condition to provide a matched degree of group support and investigator attention. The aim of overall purpose of this study is to develop and evaluate a sustainable semi-supervised exercise training programme to reduce cancer-related fatigue in survivors with fatigue and compare changes to those of a health education comparison group.

Who can participate?
Adults aged 18 and older who are either breast, colorectal or prostate cancer survivors with ongoing fatigue.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undertake two one hour sessions of exercise weekly for five weeks and then one session of exercise for the next five weeks. The exercise bouts are both gentle and short to begin with participants are assisted in gradually increasing exercise intensity and duration as the ten weeks progress. The programme combines both group-based and home-based exercise. Participants are free to bring an exercise buddy with them to all classes. Those in the second group meet once per week for ten weeks for one hour sessions that focus on strategies other than exercise to manage fatigue, such as food and nutrition, cognitive behaviour therapy (a type of talking therapy) and sleep management. After this, those in the education group receive the exercise programme as well. Participants fill out questionnaires before and after the 10 week programme period to assess fatigue, fear of exercise, quality of sleep and quality of life. Their fitness and the stiffness of their arteries (measure of their heart health) are also measured. Blood and saliva samples are

taken to measure markers that are believed to influence fatigue. Participants are followed up again six months after the programmes are finished to assess their quality of life, fatigue, exercise, physical fitness, arterial stiffness and markers in the blood.

What are the possible benefits and risks of participating?
Participants may benefit from the health education they receive free of charge, and from receiving a copy of their personal results including changes in your fatigue and fitness profile upon request. Participants may benefit from being part of a network of individuals with similar health issues and they may find the peer support beneficial. There are risks involved with exercising, such as risks of heart problems, loss of sensation in feet, hot flushes, suppressed immune systems and lymphedema (swelling in the arms and legs). Participants may also experience extra fatigue on exercise days. Participants may experience discomfort while providing blood samples.

Where is the study run from?
1. University Hospital Waterford (Ireland)
2. Solas Cancer Support Centre (Ireland)
3. Solas Cancer Support Centre West Waterford (Ireland)

When is the study starting and how long is it expected to run for?
September 2014 to March 2018

Who is funding the study?
Waterford Institute of Technology (Ireland)

Who is the main contact?
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Additional identifiers

Protocol serial number
1725

Study information

Scientific Title
Evaluation of a Sustainable Intervention using Exercise - for Cancer Fatigue (ESIE-CF Trial)

Acronym
ESIE-CF Trial

Study objectives

Research questions:
1. Does exercise/health education promote positive changes in fatigue, physical fitness, sleep, cognitive functioning and quality of life in cancer survivors following a 10 week exercise/health education program?
2. Are there greater positive changes in fatigue, physical fitness, sleep, cognitive functioning and quality of life in cancer survivors who participate in an exercise intervention compared to those in a health education intervention?
3. Is exercise more effective than health education in reducing cancer related fatigue in fatigued post treatment cancer survivors?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Waterford Institute of Technology, The Health Service Executive South East and University Hospital Waterford, 10/06/2015

Study design
Interventional non randomised multi-centre cross over study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cancer related fatigue in post treatment cancer survivors

Interventions
This study is a quasi-experimental multi centre trial. A repeated measures design is being used comparing a ten week semi-supervised progressive exercise intervention to a non-exercise health education comparison condition, with crossover from the comparison (health education) to the exercise arm of the study at the end of the comparison period. Those who express interest are either sent or given an information letter. After providing written informed consent, participants obtain medical clearance from their general practitioner and complete baseline assessments. Participants are allocated to either the non-exercise health education or the progressive arm consecutively.

Arm 1: Exercisers meet twice per week (p/w) for the first five weeks reducing to once p/w for the remaining five weeks to enable sustainability of exercise on intervention completion. Classes are one-hour sessions and can include brisk walking, indoor circuits, flexibility and mobility. The classes include progressive aerobic exercise (both in volume and intensity) starting with low-moderate intensity. Exercise principally group based and supervised though allowing for individual differences in fitness and energy levels. Some home-based, potentially buddied activity included as intervention progresses. They include a combination of walking and indoor exercise classes as primary exercise mode. Walking sessions can include some interval work towards end of intervention to increase intensity intermittently as needed to ensure progression

Arm 2: The health education group meet once per week for ten weeks. One-hour sessions focus on strategies other than exercise to manage fatigue, such as food and nutrition, cognitive behaviour therapy and sleep management. Meetings emphasis positive health focus and peer support. The cognitive behaviour therapy includes structured briefing/induction session, study booklet particularly emphasizing exercise, cancer and fatigue, evidence, benefits, barriers, misconceptions, goal setting and review, session reviews (in diaries),monitoring and recording of intensity and volume (diaries),ongoing fitness and functional assessments (e.g. six min walk), one-to-one and group exercise counselling/motivational interviewing centered on fatigue, phone support in the case of non-attendance, study materials needed for self-monitoring and the identification of primary exercise buddy who can attend all sessions with study participant. Participants in this group have the option to crossover to the first group.

Participants are assessed for their fatigue using the FACT-F scale at baseline, week four, week eight, post intervention and at six month follow up. Blood and saliva samples are taken to measure markers that are believed to influence fatigue. Participants are only included in the study if they have a score of < 45. All other assessments take place at baseline, post intervention and at the six month follow up. Sustainability is measured at 6 months.

Intervention Type
Behavioural

Primary outcome(s)
Fatigue is measured using the FACT-F measured at baseline, week four, week eight, post intervention and at six month follow up.

Key secondary outcome(s))
1. Quality of life is measured using Quality of life (EORTC) questionnaire at baseline, post intervention, and at six month follow up
2. Fear of Physical Activity among breast cancer survivors is measured using Fear of Physical Activity and Exercise in Survivors of Breast Cancer questionnaire at baseline, post intervention, and at six month follow up
3. Sleep difficulties are measured using Insomnia Severity Index at post intervention, and at six month follow up
4. Self-efficacy in general health management is measured using the Perceived Health Competency questionnaire at baseline, post intervention, and at six month follow up
5. Fitness is measured using the six minute walk/run test, handgrip dynamometer, sit to stand test, sit & reach test and the one legged balance test at baseline, post intervention, and at six month follow up
6. Vascular function is measured using the arterial stiffness via pulse wave velocity at baseline, post intervention, and at six month follow up
7. Body weight, height and blood pressure are measured at baseline, post intervention, and at six month follow up
8. Physical activity levels are measured using the International Physical Activity Questionnaire (IPAQ) at baseline, post intervention, and at six month follow up
9. Salivary cortisol are measured using saliva samples at baseline and post intervention
10. Cytokines are measured using blood samples at baseline, post intervention, and at six month follow up

Completion date
01/12/2017

Eligibility

Key inclusion criteria
1. Women and men
2. Aged 18 or older
3. Breast, colorectal and prostate cancer survivors
4. At least 6 weeks but not more than 10 years following the completion of surgery, radiotherapy and chemotherapy (to allow for stabilisation of fatigue following treatment) but not excluding those on ongoing hormonal therapy
5. Ongoing fatigue (FACT-F score <45) (the lower the score the higher the fatigue)
6. Currently undertaking less than 90 min or more of moderate intensity exercise weekly

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
37

Key exclusion criteria
1. Inability to travel for testing and to group exercise/health education sites
2. GP unwilling to provide medical clearance for moderate intensity exercise
3. Orthopaedic limitations that render participant unable to participate in a class-based moderate intensity exercise programme
4. Currently undertaking 90 min or more of moderate intensity exercise weekly

Date of first enrolment
26/06/2015

Date of final enrolment
26/01/2017

Locations

Countries of recruitment
Ireland

Study participating centre
University Hospital Waterford
Dunmore Road
Waterford
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Study participating centre
Solas Cancer Support Centre
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Study participating centre
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Ireland
-

Sponsor information

Organisation
Waterford Institute of Technology

Funder(s)

Funder type
University/education

Funder Name
Waterford Institute of Technology

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository https://www.researchgate.net/project/Evaluation-of-a-Sustainable-Intervention-using-Exercise-for-Cancer-Fatigue-ESIE-CF-Trial. They will also be will be included in the subsequent results publication and will be available upon request from [patricia.sheehan@postgrad.wit.ie]

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/02/2020	14/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes