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A study to evaluate the effect of a home-based exercise programme to manage cancer-related fatigue and improve quality of life for women recently diagnosed with gynaecological cancer

Submission date
25/03/2008

Recruitment status
No longer recruiting

Registration date
25/07/2008

Overall study status
Completed

Last Edited
12/10/2017

Condition category
Cancer

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised, single blind, controlled trial to evaluate the safety and efficacy of a home-based exercise programme to manage cancer-related fatigue for women recently diagnosed with gynaecological cancer

Acronym
FATIGUE study

Study objectives
Recently diagnosed gynaecological cancer patients who participate in a home-based exercise programme will experience significantly less cancer-related fatigue than the contact control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Provisional ethics approval received from Office for Research Ethics Committee in Northern Ireland (ORECNI) on 20/02/2008. Currently waiting on final approval.

Study design
Randomised outcome assessor blinded controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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
Gynaecological cancer

Interventions
1. Exercise group (usual care plus home-based exercise programme):
Participants randomised to this group will be facilitated to participate in a moderate home-

based exercise programme during the course of the trial. The programme includes a progressive home-based walking programme and strengthening and toning exercises.

Programme structure:
1.1. Initial 1-1 consultation: (exercise counselling and programme explanation and provision of educational booklet, exercise diary and pedometer). Upon initial contact, a 1-1 consultation will take place, whereby the programme will be explained including appropriate exercise parameters and relevant safety issues. Exercise counselling strategies to promote behavioural change will be employed and structured on the trans-theoretical model (TTM) and based on guidelines for conducting PA consultations with the general population.
1.2. Exercise frequency: the recommended exercise frequency is outlined for participants within the booklet under weekly exercise goals. This encourages participants to walk for at least 10 minutes on at least two days of the week for the first week, and the goals progressively increase over the 12 weeks to 30 minutes of walking on at least five days per week. The strengthening and toning programme also includes exercise goals based on strength training principles.
1.3. Weekly telephone contact between physiotherapist and participants: each participant will receive weekly telephone calls for ten weeks from the investigator during the twelve week intervention. Participants will report on their physical activity (PA) as recorded in their exercise diary and will receive feedback. Relevant health problems will be identified and benefits and barriers to PA will be discussed. Participants will be encouraged to increase the frequency and duration of walking over the twelve weeks at a safe and appropriate manner. For participants who have not managed to progress their PA small achievable goals to increase PA will be discussed.
1.4. Interim fitness test: an interim fitness test will be conducted at six weeks post-baseline
1.5. Programme completion and final consultation: after the twelve week programme, participants will return for a final consultation. This session will focus on relapse prevention and improving long term maintenance of PA. This includes identifying situations that may have a negative effect on exercise participation and ways to overcome this. Baseline strategies will also be repeated including looking at benefits, costs and barriers to being physically active. Future short and long term exercise goals will be agreed and set for the next three months.
1.6. Monthly calls at 4th, 5th and 6th month post-baseline: participants will receive monthly calls for three months to monitor activity levels. During these calls previously set goals and experienced benefits and costs of becoming more active will be discussed.

2. Control group (usual care plus telephone contact):
The control participants will not be provided with a structured intervention to change their activity levels during the 12 weeks. They will receive a weekly phone call from the investigator for 12 weeks, during the call a symptom questionnaire will be administered. The goal of the call will be to match the frequency of the contact with the exercise group, but there will be no attempt made to match the duration of the telephone contact between groups.

Participants will be informed that post-intervention, a physiotherapist will be available to assess their current activity levels and suggest ways of increasing physical activity. They will also receive the educational booklet, the exercise diary and a pedometer. This will take place after the six-month follow up.

Intervention Type
Behavioural

Primary outcome measure

Fatigue: the Multi-dimensional Fatigue Symptom Inventory-Short Form (MFSI-SF) and Functional Assessment of Cancer Therapy - Fatigue Subscale (FACT-F). Outcome measures will be taken at four timepoints including, baseline, 6 weeks, 12 weeks and 3 months post-intervention.

Secondary outcome measures
1. Quality of life: Functional Assessment of Cancer Therapy - General (FACT-G)
2. Cardiorespiratory fitness: 12-minute walk test
3. Physical activity questionnaire: Seven- Day Physical Activity Recall (7-Day PAR)
4. Stage of motivational readiness for PA
5. Self-efficacy to exercise: Self-Efficacy Scale
6. Decisional balance for PA
7. Processes of change for PA
8. Mood: Positive And Negative Affects Scale (PANAS)
9. Sleep hygiene: Pittsburgh Sleep Disturbance Scale
10. Depression: Beck Depression Inventory
11. Functional assessment: timed sit to stand

Outcome measures will be taken at four timepoints including, baseline, 6 weeks, 12 weeks and 3 months post-intervention.

Overall study start date
07/04/2008

Completion date
01/05/2009

Eligibility

Key inclusion criteria
1. Women aged 18 years old or over
2. Recently diagnosed with stages 0 - III gynaecological cancer
3. Completed surgery and are currently receiving radiotherapy or chemotherapy or have completed anti-cancer treatment and are less than one year post anti-cancer treatment
4. Reporting mild, moderate or severe fatigue based on a numeric rating scale (where 0 = no fatigue and 10 = worst fatigue you can imagine)
5. Currently sedentary (exercising less than once a week for 20 minutes at a vigorous intensity or less than two times per week for 30 minutes at moderate intensity or less than 20 minutes three times per week, for the past six months)
6. Ambulatory and without use of a walking aid
7. Willing to be randomised

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
60

Key exclusion criteria
1. Have any medical or current psychiatric illness that could make compliance with the study protocol difficult or dangerous (e.g., unstable cardiovascular disease, hypertension, diabetes, respiratory disease, severe mental illness, cognitive dysfunction or orthopaedic problems that would limit exercise training)
2. Previously diagnosed with a fatigue-related co-morbid medical condition (fibromyalgia, chronic fatigue syndrome, multiple sclerosis (MS), myalgic encephalopathy (ME), lupus or arthritis)
3. History of cancer, i.e., not treatment naive
4. Participating in other intervention trials

Date of first enrolment
07/04/2008

Date of final enrolment
01/05/2009

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name
Department for Employment and Learning, Northern Ireland

Alternative Name(s)
Department for Employment and Learning, DEL, NI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
Ulster Cancer Foundation (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	results	01/09/2011		Yes	No