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A trial for detecting and promoting physical activity for sedentary patients with breast cancer undergoing adjuvant chemotherapy

Submission date
20/02/2014

Recruitment status
No longer recruiting

Registration date
13/03/2014

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Breast cancer is one of the most common cancers diagnosed annually in Denmark. Improved cancer treatment has increased the number of survivors with an expected 5-year survival rate of 79%. Adjuvant chemotherapy is offered to approximately 90% of patients with breast cancer and is associated with moderate to severe side-effects. Furthermore, physical inactivity and significant reductions in aerobic capacity (the maximum amount of oxygen a body can use in an exercise session), as well as anxiety and depression, are well described among breast cancer patients undergoing adjuvant chemotherapy. During the last decade, the field of exercise oncology has given insight into the potential of physical activity to counter the symptoms and side-effects of treatment, increase quality of life and to promote healthy behavior. However, gaps in knowledge exist regarding optimal training intensity, setting and initiation. The purpose of this study is primarily for the participants to maintain or increase aerobic capacity during adjuvant chemotherapy, and secondly to meet the national recommendations for physical activity. Furthermore, the intervention intends to decrease treatment related side-effects and symptoms, increase vitality and well-being, and promote long-term lifestyle changes among sedentary patients with breast cancer undergoing adjuvant chemotherapy.

Who can participate?
Women undergoing adjuvant chemotherapy for breast cancer who have self-reported a physical activity level below the national recommended levels.

What does the study involve?
Participants will be randomly allocated to one of two study groups in order to test and compare the effect of two multimodal exercise interventions: 1) a supervised, hospital-based group exercise intervention of moderate to high intensity, or 2) an instructed, home-based individual pedometer intervention of low to moderate intensity. Both groups will receive health promotion counseling before the start of the study, and at 6, 12 and 39 weeks.

What are the possible benefits and risks of participating?
Possible benefits are a decrease in treatment-related side effects and an improved quality of life.

Where is the study run from?
The hospital exercise facilities are located at the Copenhagen University Hospital Rigshospitalet and are a part of Center for Integrated Rehabilitation (CIRE) affiliated to Copenhagen University, Faculty of Health Sciences.

When is the study starting and how long is it expected to run for?
Patients will be included from December 2013 until December 2015.

Who is funding the study?
The Novo Nordic Foundation, the Danish Cancer Society and Tryg Foundation (TrygFonden) , Denmark.

Who is the main contact?
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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 randomized controlled trial for detecting and promoting physical activity for sedentary patients with breast cancer undergoing adjuvant chemotherapy

Study objectives
1. That screening for physical inactivity and promoting physical activity by the treating oncologist /nurse, along with health promotion counseling performed by the research team, will motivate at least 50% of the potential participants to partake in the study.
2. That the hospital-based group exercise intervention will be more effective than the home-based individual pedometer intervention, after 12 and 39 weeks, in: maintaining or increasing aerobic capacity (Vo2-peak); increasing muscle strength and mass; reducing fatigue, anxiety and depression; increasing functional level, vitality, and general well-being; motivating participants to meet national recommendation levels for physical activity; facilitating relations to a network of other cancer patients.
3. That both interventions will be equally effective in: reducing perceptions of pain; affecting quality of life; affecting metabolic markers; motivating to smoking cessation; supporting completion of planned chemotherapy; retaining labor market attachment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the Capitol Region Copenhagen Denmark, 12/11/2013, ref.: H-3-2013-155. The Danish Data Protection Agency, 21/06/2011, J.nr. 2011-41-6349

Study design
Two-armed randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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 receiving adjuvant chemotherapy

Interventions
All study group participants are encouraged to meet the national recommendations for physical activity by their treating oncologist/nurse. Both groups receive individual motivational counseling to support behavioral change towards increased physical activity.

Intervention 1: A supervised 12-week hospital-based group physical training intervention of moderate to high-intensity equivalent to 40 MET / week. Includes various types of cardiovascular fitness activities, muscular strength training, relaxation and massage.

Intervention 2: A non-supervised 12-week home-based individual progressive pedometer intervention of low to moderate intensity.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Maximum oxygen uptake - VO2-peak (Measured baseline and at 6, 12 and 39 weeks).

Secondary outcome measures
1. Dual Energy X-ray Absorptiometry scan (baseline and 12, 39 weeks)
2. Muscular strength (baseline and at 6, 12 and 39 weeks)
3. Blood cholesterols (baseline, 12 and 39 weeks)
4. Blood pressure, pulse
5. Body mass index
6. Performance status (baseline and 6, 12 and 39 weeks)
7. Self-reported physical activity, Quality of Life (EORTC QLQ C-30)
8. General Wellbeing (SF 36)
9. Anxiety and Depression (HADs)
10. Motivational readiness
11. Decisional balance, Exercise self-efficacy, social support, (baseline and at 6, 12 and 39 weeks)
12. Labor market affiliation (baseline and at 12 and 39 weeks)
13. Cardiovascular comorbidity, disease free survival and recurrence.

The following two outcome measures were added to this record on 17/02/2015:

14. Bioimpedance spectroscopy
15. Subjective assessments of symptoms related to lymphedema using VAS

Overall study start date
15/12/2013

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Patients diagnosed with breast cancer (stage I - III) in adjuvant chemotherapy
2. WHO performance status of 0 or 1
3. Aged 18 + years who do not meet criteria for recommended physical activity levels of 150 min / week of moderate leisure time physical activity, and exercises at least 20 minutes of strenuous physical activity twice a week.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
154

Total final enrolment
153

Key exclusion criteria
1. Patients with myocardial infarction within the past three months
2. Symptomatic heart failure or contraindication for moderate to strenuous physical activity noted in the medical records.

Date of first enrolment
15/12/2013

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Denmark

Study participating centre
Copenhagen University Hospital Rigshospitalet Department 9701
Copenhagen
Denmark
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Sponsor information

Organisation
Novo Nordic Foundation (Novo Nordisk Fonden) (Denmark)

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Sponsor type
Industry

ROR
https://ror.org/04txyc737

Funder(s)

Funder type
Charity

Funder Name
The Novo Nordic Foundation (Denmark)

Funder Name
The Danish Cancer Society (Denmark)

Funder Name
Tryg Foundation (TrygFonden) (Denmark)

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	01/12/2019	17/12/2020	Yes	No